

North Macedonia

This document is a compilation of all questions, justifications, and sources used to determine the 2021 Global Health Security Index scores for North Macedonia. For a category and indicator-level summary, please see the Country Profile for North Macedonia.

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Category 1: Preventing the emergence or release of pathogens with potential for international concern

1.1 ANTIMICROBIAL RESISTANCE (AMR)

1.1.1 AMR surveillance, detection, and reporting

1.1.1a

Is there a national AMR plan for the surveillance, detection, and reporting of priority AMR pathogens?

Yes, there is evidence of an AMR plan, and it covers surveillance, detection, and reporting = 2, Yes, there is evidence of an AMR plan, but there is insufficient evidence that it covers surveillance, detection, and reporting = 1, No evidence of an AMR plan = 0

Current Year Score: 2

The Republic of North Macedonia has a National AMR action plan for the surveillance, detection and reporting of priority AMR pathogens [1, 2]. The "National Strategy for Containment of Antimicrobial Resistance 2012-2016" aims to improve the health status of the population in North Macedonia and secure quality health protection at all levels, through AMR control. In terms of surveillance, the plan aims to "strengthen the system for AMR surveillance and control, and consumption/usage of antibiotics". [2] The plan addresses detection by provisioning for the "preparation and adaptation of guidelines for the selection of strains of multi-resistant microorganisms that should be sent for confirmation to the microbiological laboratories of the Institute of Microbiology at the Medical Faculty of Skopje, and the Institute of Public Health (IPH)". Data on detected AMR are sent to the Institute for Public Health (IPH), which serves as the reference center for the AMR database and monitoring of AMR, and is in charge of communication with international institutions, and providing referral information for antibiotic prescriptions. [2] In terms of Reporting, the plan aims to provide timely and relevant information on the results of AMR tests for key pathogens. It also charges diagnostic laboratories with "arranging and keeping laboratory data and results (preferably in the database) that will allow timely clinical end epidemiological monitoring of the susceptibility of pathogen agents, with referral information for the antibiotic prescribers". The plan also aims to "introduce IT technology in healthcare institutions with respect to fast data exchange on AMR".

There is evidence that meetings of a Multisectoral Committee for control of AMR were held in October-November 2016, which has started a process of preparing a strategy and action plan for control of AMR 2016-2020 [3]. According to the 2019 World Health Organization (WHO) Joint External Evaluation Report on the Republic of North Macedonia, in 2016 a new national strategy for 2017-2021 was adopted by a multidisciplinary team working on the issue, but this has not yet been adopted by the government as national strategy. [4]

There is no evidence of an updated national AMR action plan in the WHO library, on the Ministry of Health's website, nor the Institute of Public Health's (IPH) website [5, 6, 7]. There is also no information on when the plan is expected to be completed.

[1] World Health Organization (WHO). 2017. "Global Database for Antimicrobial Resistance Country Self Assessment." [http://amrcountryprogress.org/]. Accessed 14 November 2020.

[2] Ministry of Health of Republic of Macedonia. March 2011. "National Strategy for Containment of Antimicrobial Resistance 2012-2016." [http://extwprlegs1.fao.org/docs/pdf/mac169253.pdf]. Accessed 14 November 2020.

[3] Boshevska, G, and Biljana, C. "Strategy for Antimicrobial Resistance with Action Plan 2017-2020." [http://studiorum.org.mk/evrodijalog/22/pdf/ENG/10_ANG_Boshevska-Celevska.pdf]. Accessed 14 November 2020.

[4] World Health Organization (WHO). 2019. "Joint External Evaluation Report of IHR Core Capacities of the Republic of North Macedonia." [https://apps.who.int/iris/bitstream/handle/10665/325320/WHO-WHE-CPI-2019.59-eng.pdf?sequence=1].

Accessed 14 November 2020.

[5] World Health Organization (WHO). "Library of national action plans." [<http://www.who.int/antimicrobial-resistance/national-action-plans/library/en/>]. Accessed 14 November 2020.

[6] Ministry of Health of Republic of North Macedonia. "Strategies." [<http://zdravstvo.gov.mk/sq/strategiite/>]. Accessed 14 November 2020.

[7] Institute of Public Health (IPH) of Republic of North Macedonia. "Publications." [<http://www.iph.mk/en/multimedia/documents/publications/>]. Accessed 14 November 2020.

1.1.1b

Is there a national laboratory/laboratory system which tests for priority AMR pathogens?

All 7 + 1 priority pathogens = 2 , Yes, but not all 7+1 pathogens = 1 , No = 0

Current Year Score: 1

The Republic of North Macedonia has a laboratory system, with designated sentinel sites, which tests for at least some, if not all priority AMR pathogens. According to the 2019 World Health Organization (WHO) Joint External Evaluation Report on the Republic of North Macedonia, the national laboratory system of the Republic of North Macedonia is well serviced, with 32 human health microbiology laboratories covering the needs of 2.08 million inhabitants in eight districts as well as two laboratories for the analysis of veterinary specimens. A tiered system operates on two levels - national and regional. Regional laboratories provide primary diagnostic services by performing basic bacteriology, serology and parasitology analysis; national laboratories perform both primary and confirmatory testing. [1]

The country participates in the Central Asian and Eastern European Surveillance of Antimicrobial Resistance (CAESAR) and enrolled in the Global AMR Surveillance System (GLASS) in May 2017. The CAESAR network provides a comprehensive system for monitoring the prevalence and trends of antimicrobial resistance to the target group of invasive bacteria (bacteria isolated from blood and liquor - primarily sterile samples) [2, 3]. Its task is to link the national networks of non-European Union (EU) countries, providing easy comparable data for all participating countries in CAESAR and European Antimicrobial Resistance Surveillance Network (EARS-Net).

Isolates followed are etiological agents of infections (isolates of the blood culture and liquor), and the country can test for: Staphylococcus aureus (MRSA); Streptococcus pneumoniae (Pen R PRP); Escherichia coli (ESBL +, carbapenemasis +); Klebsiella pneumoniae (ESBL +, carbapenemasis +); E. faecium and faecalis (VRE); Pseudomonas aeruginosa (multiresistant); and Acinetobacter spp. (multiresistant) [3, 4]. There is no evidence that the country tests for Salmonella spp, Shigella spp, N. gonorrhoea, or Mycobacterium tuberculosis. The GLASS country profile of 2016 on AMR Proportions does not have any available data on these tests. [4]

[1] World Health Organization (WHO). 2019. "Joint External Evaluation Report of IHR Core Capacities of the Republic of North Macedonia." [<https://apps.who.int/iris/bitstream/handle/10665/325320/WHO-WHE-CPI-2019.59-eng.pdf?sequence=1>]. Accessed 14 November 2020.

[2] World Health Organization (WHO). "GLASS Country Profiles, the Former Yugoslav Republic of Macedonia." [<http://apps.who.int/gho/tableau-public/tpc-frame.jsp?id=2004>]. Accessed 14 November 2020.

[3] World Health Organization (WHO). 2018. "Central Asian and Eastern European Surveillance of Antimicrobial Resistance." [<https://www.euro.who.int/en/health-topics/disease-prevention/antimicrobial-resistance/publications/2018/central-asian-and-eastern-european-surveillance-of-antimicrobial-resistance-annual-report-2018-2018>]. Accessed 14 November 2020.

[4] World Health Organization (WHO). "AMR Proportions." [<http://apps.who.int/gho/tableau-public/tpc-frame.jsp?id=2004>]. Accessed 14 November 2020.

1.1.1c

Does the government conduct environmental detection or surveillance activities (e.g., in soil, waterways) for antimicrobial residues or AMR organisms?

Yes = 1, No = 0

Current Year Score: 0

There is no public evidence that the government conducts detection or surveillance activities (e.g. in soil, waterways, etc.) for antimicrobial residues or AMR organisms. The Ministry of Environment and Physical Planning, Ministry of Health, and Ministry of Agriculture, Forestry and Water Economy do not provide any public information about testing soil and waterways for AMR pathogens [1, 2, 3]. There is also no mention of surveillance activities for antimicrobial residues or AMR in the "National Strategy for Containment of Antimicrobial Resistance 2012-2016." [4].

A review of the World Health Organization's (WHO) database for antimicrobial resistance country self-assessment, also did not provide any evidence of surveillance activities for antimicrobial residues or AMR in soil, waterways, etc. [5]. Furthermore, there are no reports of such detection or surveillance by the Institute of Public Health of Republic of Macedonia.

There is evidence that Institute of Public Health laboratories conduct test on pesticide residues, but no evidence on antimicrobial residues or AMR [6]. In the 2019 WHO Joint External Evaluation Report on the Republic of North Macedonia, there is no evidence that the government conducts environmental detection or surveillance activities (e.g. in soil, waterways) for antimicrobial residues or AMR organisms. According to the JEE report, an integrated One Health surveillance and reporting system should be established that involves regular communication between the human, animal, wildlife and environmental health sectors to increase effectiveness and efficiency in reporting to international officials. [7]

[1] Ministry of Environment and Physical Planning of Republic of North Macedonia. [<http://www.moepp.gov.mk/?lang=AL>]. Accessed 14 November 2020.

[2] Ministry of Health of Republic of North Macedonia. [<http://zdravstvo.gov.mk/sq/home-main/>]. Accessed 14 November 2020.

[3] Ministry of Agriculture, Forestry and Water Economy of Republic of North Macedonia. [<http://www.mzsv.gov.mk/al.aspx>]. Accessed 14 November 2020.

[4] Ministry of Health of Republic of Macedonia. March 2011. "National Strategy for Containment of Antimicrobial Resistance 2012-2016." [<http://extwprlegs1.fao.org/docs/pdf/mac169253.pdf>]. Accessed 14 November 2020.

[5] World Health Organization (WHO). 2017. "Global Database for Antimicrobial Resistance Country Self Assessment." [<http://amrcountryprogress.org/>]. Accessed 14 November 2020.

[6] Institute of Public Health of Republic of North Macedonia (IPH). "Laboratory for Contaminants and Eco-toxicology." [<http://iph.mk/en/laboratory-for-contaminants-and-eco-toxicology/>]. Accessed 14 November 2020.

[7] World Health Organization (WHO). 2019. "Joint External Evaluation Report of IHR Core Capacities of the Republic of North Macedonia." [<https://apps.who.int/iris/bitstream/handle/10665/325320/WHO-WHE-CPI-2019.59-eng.pdf?sequence=1>]. Accessed 14 November 2020.

1.1.2 Antimicrobial control

1.1.2a

Is there national legislation or regulation in place requiring prescriptions for antibiotic use for humans?

Yes = 2, Yes, but there is evidence of gaps in enforcement = 1, No = 0

Current Year Score: 2

Antibiotics are prescription medication for human use in the Republic of North Macedonia. [1] As per "Law on Medicinal Products and Medical Devices" from 2007, and amended in 2016, under Article 13 a distinction is made between medicine issued in a pharmacy only on a prescription, and medicine that is issued and/or sold without a prescription over the counter and used only in a health institution. A drug that is classified as a prescription drug, in a pharmacy and a pharmacy station must be issued on a medical prescription. This is the category where antibiotics fall [2]. Medicines issued or sold without prescription are those with a wide range of therapeutic indications, low toxicity, little overdose risk, with insignificant interactions, well-known indications for patients and suitable for self-healing [1]. Based on a review of the websites of the Ministry of Health, Institute for Public Health and media outlets there is no evidence of gaps in enforcement of relevant legislation. [3, 4, 5, 6]

[1] Republic of North Macedonia. "Law on Medicinal Products and Medical Devices (Official Gazette 106/07, 88/10, 36/11, 53/11, 136/11, 11/12, 147/13, 164/13, 27/14, 43/14, 88/15, 121/2014, 113/15, 154/15, 228/15, 7/16, 53/16)."

[<http://zdravstvo.gov.mk/wp-content/uploads/2018/01/ZAKON-ZA-LEKOVITE-I-MEDITSINSKITE-SREDSTVA-zakluchno-so-br.-53-od-2016.pdf>]. Accessed 14 November 2020.

[2] World Health Organization (WHO). "Pharmaceutical Sector Country Profile Questionnaire Former Yugoslav Republic of Macedonia." [http://www.who.int/medicines/areas/coordination/TheRofMacedonia_country_profile.pdf]. Accessed 14 November 2020.

[3] Ministry of Health of Republic of North Macedonia. [<http://zdravstvo.gov.mk/sq/home-main/>]. Accessed 14 November 2020.

[4] Institute of Public Health (IPH) of Republic of North Macedonia. "Publications." [<http://www.iph.mk/en/>]. Accessed 14 November 2020.

[5] Nova Makedonija. "Antibiotics - proper use for the best effect and prevention of unwanted effects and antibiotic resistance!." [<https://www.novamakedonija.com.mk/pecatenozdanie/%D0%B0%D0%BD%D1%82%D0%B8%D0%B1%D0%B8%D0%BE%D1%82%D0%B8%D1%86%D0%B8-%D0%BF%D1%80%D0%B0%D0%B2%D0%B8%D0%BB%D0%BD%D0%B0-%D1%83%D0%BF%D0%BE%D1%82%D1%80%D0%B5%D0%B1%D0%B0-%D0%B7%D0%B0-%D0%BD%D0%B0%D1%98/>]. Accessed 14 November 2020.

[6] DW. "When you really need to take antibiotics." [<https://www.dw.com/mk/%D0%BA%D0%BE%D0%B3%D0%B0-%D0%BD%D0%B0%D0%B2%D0%B8%D1%81%D1%82%D0%B8%D0%BD%D0%B0-%D1%82%D1%80%D0%B5%D0%B1%D0%B0-%D0%B4%D0%B0-%D0%BF%D1%80%D0%B8%D0%BC%D0%B0%D1%82%D0%B5-%D0%B0%D0%BD%D1%82%D0%B8%D0%B1%D0%B8%D0%BE%D1%82%D0%B8%D1%86%D0%B8/a-51415115>]. Accessed 14 November 2020.

1.1.2b

Is there national legislation or regulation in place requiring prescriptions for antibiotic use for animals?

Yes = 2 , Yes, but there is evidence of gaps in enforcement = 1 , No = 0

Current Year Score: 2

The Republic of North Macedonia has national legislation in place requiring prescriptions for antibiotic use for animals. [1] Law on Veterinary Medical Products from 2010, with latest amendments in 2018, under Article 37 requires that all veterinary medical products containing antimicrobial agents are prescription-only medicines. Veterinary medical products containing antimicrobial agents are provided by wholesaler distributors that hold a marketing authorization as well as by manufacturers to retailers of veterinary medicinal products (veterinary pharmacies) and veterinary organizations. Only veterinarians are entitled to sell veterinary medical products to animal owners/farmers. Veterinarians have to confirm the distribution of veterinary drugs to owners of food-producing animals if the animals are used for food production. Medicated feeds also have

to be prescribed by veterinarians [1, 2]. Based on a review of the websites of the Ministry of Agriculture and media outlets there is no evidence of gaps in enforcement of relevant legislation. [3, 4]

[1] Republic of North Macedonia. 2018. "Law on Veterinary Medical Products (Official Gazette 42/10, 136/11, 53/16, 149/15, 241/18)." [<http://extwprlegs1.fao.org/docs/pdf/mac150924.pdf>]. Accessed 14 November 2020.

[2] Romel, Vele, Krleska-Veleva Natasa. 2013. "Practical Use of Registered Veterinary Medical Products in Macedonia in Identifying the Risk of Developing of Antimicrobial Resistance." *Mac Vet Rev* 36. 1:5-12. [<https://macvetrev.mk/LoadArticlePdf/63>]. Accessed 14 November 2020.

[3] Ministry of Agriculture, Forestry and Water Economy of Republic of North Macedonia. [<http://www.mzsv.gov.mk/al.aspx>]. Accessed 14 November 2020.

[4] Slobodna Evropa. "Antibiotics are taken and when needed and when not needed, the bacteria become resistant." [<https://www.slobodnaevropa.mk/a/28919403.html>]. Accessed 14 November 2020.

1.2 ZOO NOTIC DISEASE

1.2.1 National planning for zoonotic diseases/pathogens

1.2.1a

Is there national legislation, plans, or equivalent strategy documents on zoonotic disease?

Yes = 1 , No = 0

Current Year Score: 1

The Republic of North Macedonia has legislation on zoonotic disease. According to the 2019 WHO Joint External Evaluation Report of the Republic of North Macedonia, there is no national multisectoral policy or strategy on zoonoses. [1] However, Law No. 113 "On Veterinary Health" of 20 September 2007, includes the principles and procedures for the implementation of activities related to protection from zoonosis [2]. It lays out procedures for monitoring, diagnosing, treating and eradicating diseases in animals to protect the public health from zoonotic diseases.

Furthermore, Law No. 66 "On Protecting the Population from Contagious Disease", of 16 September 2004, regulates disease outbreak prevention measures, early detection, prevention of transmission and eradication of contagious diseases and infections, and monitoring the implementation of measures aimed at protecting the population from contagious diseases. It also establishes the rights and duties of healthcare organizations, legal and natural entities [3]. Under Article 17, the law requires that immediately after a set diagnosis, the doctor must report to the competent office for health protection a case or death from a list of diseases, among which are anthrax, brucellosis, rabies, etc. Article 22 of the law requires that "the office for health protection must report to the competent body for veterinary health any case of human disease caused by zoonosis". Furthermore, Article 23 requires that a microbiological laboratory must report to the competent office for health protection any case of isolation or diagnosis of pathogens including zoonotic pathogens such as brucella spp, Escherichia coli, listeria monocytogenes, salmonella paratyphi, salmonella typhi, etc.

[1] World Health Organization (WHO). 2019. "Joint External Evaluation Report of IHR Core Capacities of the Republic of North Macedonia." [<https://apps.who.int/iris/bitstream/handle/10665/325320/WHO-WHE-CPI-2019.59-eng.pdf?sequence=1>]. Accessed 14 November 2020.

[2] Republic of North Macedonia. Law No. 113 of 20 September 2007. "On Veterinary Health." [http://www.fva.gov.mk/jdownloads/zakon_za_veterinarno_zdravstvo/zakon_za_veterinarno_zdravstvo.pdf]. Accessed 14 November 2020.

[3] Republic of North Macedonia. 2016. "Law on Protecting the Population from Contagious Disease (Official Gazette 66/04,

139/08, 99/09, 149/14, 150/15, 37/16)." [<http://zdravstvo.gov.mk/wp-content/uploads/2018/01/ZAKON-ZA-ZASHTITA-NA-NASELENIETO-OD-ZARAZNI-BOLESTI-zakluchno-so-br.-37-od-2016.pdf>]. Accessed 14 November 2020.

1.2.1b

Is there national legislation, plans or equivalent strategy document(s) which includes measures for risk identification and reduction for zoonotic disease spillover events from animals to humans?

Yes = 1 , No = 0

Current Year Score: 0

The Republic of North Macedonia does not have national legislation, plans or equivalent strategy document(s) that include measures for risk identification and reduction for zoonotic disease spillover events from animals to humans. The 2015 Law on Veterinary Health, 2016 Law on Protecting the Population from Contagious Disease and the 2019 World Health Organization (WHO) Joint External Evaluation Report on the Republic of North Macedonia do not have references to measures for risk identification and reduction for zoonotic disease spillover events from animals to humans. [1, 2, 3] This information is also not available on the websites of the Ministry of Health and Ministry of Agriculture. [4, 5]

[1] Republic of North Macedonia. 2015. "Law on Veterinary Health (Official Gazette 153/15)." [<https://docs.googleusercontent.com/docs/securesc/jbmqb7rr8rid1kjinlphrobic0mpgcv06/83t00bhl0j48fkukm1hieklleddajo60/1604768700000/16614190090344306114/04026950584739337890Z/1G3EnUJE7sMBQiwI3CmRtF6CC-bvcoYoK?e&nonce=cd3ag7kkfmmmk&user=04026950584739337890Z&hash=kccjou0geq7eiskm43lk2dlp83bibrri>]. Accessed 14 November 2020.

[2] Republic of North Macedonia. 2016. "Law on Protecting the Population from Contagious Disease (Official Gazette 66/04, 139/08, 99/09, 149/14, 150/15, 37/16)." [<http://zdravstvo.gov.mk/wp-content/uploads/2018/01/ZAKON-ZA-ZASHTITA-NA-NASELENIETO-OD-ZARAZNI-BOLESTI-zakluchno-so-br.-37-od-2016.pdf>]. Accessed 14 November 2020.

[3] World Health Organization (WHO). 2019. "Joint External Evaluation Report of IHR Core Capacities of the Republic of North Macedonia." [<https://apps.who.int/iris/bitstream/handle/10665/325320/WHO-WHE-CPI-2019.59-eng.pdf?sequence=1>]. Accessed 14 November 2020.

[4] Ministry of Health of Republic of North Macedonia. [<http://zdravstvo.gov.mk/sq/home-main/>]. Accessed 14 November 2020.

[5] Ministry of Agriculture, Forestry and Water Economy of Republic of North Macedonia. [<http://www.mzsv.gov.mk/al.aspx>]. Accessed 14 November 2020.

1.2.1c

Is there national legislation, plans, or guidelines that account for the surveillance and control of multiple zoonotic pathogens of public health concern?

Yes = 1 , No = 0

Current Year Score: 1

The Republic of North Macedonia has legislation and national programs that account for the surveillance and control of multiple zoonotic pathogens of public health concern. Law No. 113 "On Veterinary Health", of 20 September 2007, lays out procedures for surveillance, monitoring, diagnosing, treating and eradication of diseases in animals in order to protect public health from zoonotic diseases [1]. Under Article 51, the law requires examination of an outbreak or suspected outbreak of animal disease. The law also makes provisions for the surveillance, control, prevention and eradication of disease, which include establishment of a surveillance system through collection of epidemiological data in the epizootic region under Article 64, taking laboratory samples, epidemiological examination to determine sources of disease and transmission,

possibility of disease spreading, monitoring of animal inventory and identification of suspected or diseased animals, recording of movement of animals, restriction of animal movement, treatment, vaccination, supervision by veterinary officials, etc. Furthermore, Law No. 66 "On Protecting the Population from Contagious Disease", of 16 September 2004, under Articles 22 and 23, requires that any case of human disease caused by zoonosis be reported, and that a microbiological laboratory reports any case of isolation or diagnosis of pathogens including zoonotic pathogens such as brucella spp, Escherichia coli, listeria monocytogenes, salmonella paratyphi, salmonella typhi, etc. [2]. As part of the plans for harmonization of the national legislation with the European Union (EU) legislation, North Macedonia has prepared the "National Program for Adoption of the Acquis Communautaire Revision (NPAACR) 2009", which outlines various programs for the prevention and eradication of zoonotic disease such as bovine brucellosis and tuberculosis, brucellosis in sheep and goats, transmissible encephalopathy and avian influenza [3]. The NPAACR reports that the country has transposed the European Union Directive No.2003/99/EC "On the Monitoring of Zoonosis and Zoonotic Agents" of 17 November 2003. [4] The Directive lays out the rules for surveillance of zoonosis and zoonotic agents and includes viral zoonosis like rabies, influenza virus, etc., bacterial zoonosis like borreliosis, tuberculosis, etc., and parasitic zoonosis like toxoplasmosis, cysticercosis, etc.

[1] Republic of North Macedonia. 2015. "Law on Veterinary Health (Official Gazette 153/15)." [<https://doc-14-24-docs.googleusercontent.com/docs/securesc/jbmqb7rr8rid1kjinlphrobic0mpgcv06/83t00bhl0j48fkukm1hieklleddajo60/1604768700000/16614190090344306114/04026950584739337890Z/1G3EnUJE7sMBQiwI3CmRtF6CC-bvcoYoK?e&nonce=cd3ag7kkfmmmk&user=04026950584739337890Z&hash=kccjou0geq7eiskm43lk2dlp83bibrri>]. Accessed 14 November 2020.

[2] Republic of North Macedonia. 2016. "Law on Protecting the Population from Contagious Disease (Official Gazette 66/04, 139/08, 99/09, 149/14, 150/15, 37/16)." [<http://zdravstvo.gov.mk/wp-content/uploads/2018/01/ZAKON-ZA-ZASHTITA-NA-NASELENIETO-OD-ZARAZNI-BOLESTI-zakluchno-so-br.-37-od-2016.pdf>]. Accessed 14 November 2020.

[3] Government of Republic of North Macedonia. 29 May 2009. "National Programme for Adoption of the Acquis Communautaire Revision 2009." [https://www.esiweb.org/pdf/macedonia_NPAA%202009.pdf]. Accessed 14 November 2020.

[4] European Parliament and Council. Directive No. 2003/99/EC of 17 November 2003. "On the Monitoring of Zoonosis and Zoonotic Agents." [<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32003L0099&from=en>]. Accessed 14 November 2020.

1.2.1d

Is there a department, agency, or similar unit dedicated to zoonotic disease that functions across ministries?

Yes = 1 , No = 0

Current Year Score: 0

The Republic of North Macedonia does not have an agency dedicated to zoonotic disease that functions across ministries.

The Food and Veterinary Agency (FVA) is an autonomous body of public administration, which functions as the sole agency responsible for controlling the safety of food and feed, implementing, controlling, supervising and monitoring of veterinary activities in the area of animal health care, animal well-being, veterinary public health, and control of the laboratories that support the needs of the Agency. [1] The FVA was created by merging the Directorate for Veterinary Purposes at the Ministry of Agriculture, Forestry and Water Economy and the Food Directorate of the Ministry of Health. There is also the Sector for Control and Monitoring of Communicable Diseases at the Institute of Public Health (IPH) of Macedonia, which has as its priority the control and prevention of communicable diseases and the provision of epidemiological services in the public health centers of the country, including zoonotic disease. Reducing the incidence of Brucellosis and other zoonoses is one of the priority objectives of the sector in the field of epidemiology. [2, 3] The two institutions cooperate in coordinating

activities for prevention and control of zoonotic disease, but no specific coordination mechanisms are outlined, and they operate as independent authorities and do not share staff, budgets, etc. According to the 2019 WHO Joint External Evaluation Report of the Republic of North Macedonia, there is traditionally good cooperation between the health and veterinary sectors, and this has been formalized in recent years by intersectoral Memoranda of Cooperation in 2013 and 2015. Multisectoral committees/bodies include the Committee for Communicable Diseases at the MOH and the National Center for Disease Control at the FVA. These meet ad hoc to implement coordinated activities, including joint risk assessments for zoonotic disease and other events. [4] On the websites of the Ministry of Health and the Ministry of Agriculture there is no additional information about a department, agency, or similar unit dedicated to zoonotic disease that functions across ministries. [5, 6]

[1] Food and Veterinary Agency (FVA) of Republic of North Macedonia. 29 November 2013. "Organizational Chart." [http://www.fva.gov.mk/index.php?option=com_content&view=article&id=273&Itemid=194&lang=mk]. Accessed 14 November 2020.

[2] Institute of Public Health (IPH) of Republic of North Macedonia. "Sector for Control and Monitoring of Communicable Diseases." [<http://www.iph.mk/en/sector-for-control-and-monitoring-of-communicable-diseases/>]. Accessed 14 November 2020.

[3] Institute of Public Health (IPH) of Republic of North Macedonia. "Department for Monitoring and Surveillance of Communicable Diseases." [<http://www.iph.mk/en/sector-for-control-and-monitoring-of-communicable-diseases/department-for-monitoring-and-surveillance-of-communicable-diseases/>]. Accessed 14 November 2020.

[4] World Health Organization (WHO). 2019. "Joint External Evaluation Report of IHR Core Capacities of the Republic of North Macedonia." [<https://apps.who.int/iris/bitstream/handle/10665/325320/WHO-WHE-CPI-2019.59-eng.pdf?sequence=1>]. Accessed 14 November 2020.

[5] Ministry of Health of Republic of North Macedonia. [<http://zdravstvo.gov.mk/>]. Accessed 14 November 2020.

[6] Ministry of Agriculture, Forestry and Water Management of Republic of North Macedonia. [<http://www.mzsv.gov.mk/>]. Accessed 14 November 2020.

1.2.2 Surveillance systems for zoonotic diseases/pathogens

1.2.2a

Does the country have a national mechanism (either voluntary or mandatory) for owners of livestock to conduct and report on disease surveillance to a central government agency?

Yes = 1, No = 0

Current Year Score: 1

The Republic of North Macedonia has a national mechanism for owners of livestock to conduct and report on disease surveillance to a central government agency. [1] Regulation has been adopted in accordance with the Council Directive No. 82/894/EC "On the Notification of Animal Diseases within the Community" of 21 December 1982 for notification, control, and eradication of compulsory zoonotic diseases. [2,3] Law No.113 "On Veterinary Health" of 20 September 2007 [4] and the subsequent Regulation by the Ministry of Agriculture, Forestry and Waste No.110 "Regulation on the Manner and Procedure of Reporting of Compulsory Notifiable Diseases" of 20 August 2010, [5] require that compulsory notifiable diseases of animals be reported by animal owners to the Veterinary Directorate of the Food and Veterinary Agency. Animal owners have an obligation to report to the official veterinarian, who has the qualifications required by law, in case of suspected animal disease. The official veterinarian as per Article 15 of Law No.113 "On Veterinary Health" of 20 September 2007, immediately reports to the director of the veterinary directorate. [4] The official veterinarian keeps records in electronic or other forms and submits a report to the director of the veterinary directorate. From the law, it appears that the animal owner has to physically go to the official veterinary to report the disease. There is no further evidence provided in the law on the type of

the reporting mechanism. There is also no further evidence provided on the website of the food and veterinary agency on the means through which the animal owners report to the official veterinary. [6]

[1] European Council (EC). Council Directive No. 82/894/EC of 21 December 1982. "On the Notification of Animal Diseases within the Community." [<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31982L0894&from=EN>]. Accessed 14 November 2020.

[2] Government of Republic of North Macedonia. 29 May 2009. "National Programme for Adoption of the Acquis Communautaire Revision 2009" [https://www.esiweb.org/pdf/macedonia_NPAA%202009.pdf]. Accessed 14 November 2020.

[3] Food and Veterinary Agency. "Lumpy Skin Disease in the Republic of Macedonia." [https://ec.europa.eu/food/sites/food/files/animals/docs/reg-com_ahw_20160503_pres_lumpy-skin-disease-macedonia.pdf]. Accessed 14 November 2020.

[4] Republic of North Macedonia. 2015. "Law on Veterinary Health (Official Gazette 153/15)." [<https://doc-14-24-docs.googleusercontent.com/docs/securesc/jbmqb7rr8rid1kjinlphrobic0mpgcv06/83t00bhl0j48fkukm1hieklleddajo60/1604768700000/16614190090344306114/04026950584739337890Z/1G3EnUJE7sMBQiwI3CmRtF6CC-bvcoYoK?e&nonce=cd3ag7kfkfmmmk&user=04026950584739337890Z&hash=kccjou0geq7eiskm43lk2dlp83bibrri>]. Accessed 14 November 2020.

[5] Ministry of Agriculture and Waste Management of Republic of North Macedonia. Regulation No. 110 of 20 August 2010. "Regulation on the Manner and Procedure of Reporting of Compulsory Notifiable Diseases." [<http://www.fva.gov.mk/images/Pravilnik-zadlozitelno.PDF>]. Accessed 14 November 2020.

[6] Food and Veterinary Agency (FVA). [<http://www.fva.gov.mk/index.php?lang=mk>]. Accessed 14 November 2020.

1.2.2b

Is there legislation and/or regulations that safeguard the confidentiality of information generated through surveillance activities for animals (for owners)?

Yes = 1 , No = 0

Current Year Score: 0

There are no specific protections for the confidentiality of information collected through animal surveillance activities. Although there is a law covering personal data protections, Law on Personal Data Protection, adopted in 2011 with its last amendments from 2018, it does not address protections for property or owned livestock. [1] Animal health and/or disease are not included under the special category for which processing of personal data is prohibited, such as data relating to the health condition of the people, including genetic data, biometric data or data referring to sexual life. Furthermore, as per the "Overview of the integration and functioning of the Health Information System and the Civil Registration and Vital Statistics System, Republic of Macedonia", the disease registries currently kept by Institute of Public Health, as well as the new registries introduced in the Law No.20 "On Record Keeping in the Field of Healthcare" of 2009, do not meet personal data protection standards. [2] There is also no mention of safeguarding the confidentiality of information generated through surveillance activities for animals (for owners) in the legislation for notification, control and eradication of compulsory zoonotic disease covered under the Council Directive No. 82/894/EC "On the Notification of Animal Diseases within the Community" of 21 December 1982 [3] , Law No.113 "On Veterinary Health" of 20 September 2007 [4] and the subsequent Regulation by the Ministry of Agriculture, Forestry and Waste No.110 "Regulation on the Manner and Procedure of Reporting of Compulsory Notifiable Diseases" of 20 August 2010. [5] On the websites of the Ministry of Health and Ministry of Agriculture there is no additional information about legislation and/or regulations that safeguard the confidentiality of information generated through surveillance activities for animals (for owners). [6, 7]

[1] Republic of North Macedonia. 2018. "Law on Personal Data Protection (Official Gazette 2247 7/2005, 103/2008, 124/2008, 124/2010, 135/2011, 43/2014, 153/2015, 99/2016, 64/2018)."

[https://dzlp.mk/sites/default/files/u4/zakon_za_zashtita_na_lichnite_podatoci.pdf]. Accessed 14 November 2020.

[2] World Health Organization (WHO) Regional Office for Europe and WHO Country Office in Skopje. December 2012.

"Overview of the integration and functioning of the Health Information System and the Civil Registration and Vital Statistics System, Republic of Macedonia."

[http://studiorum.org.mk/h2020_workshop/Rabotni_Dokumenti/general/eng/13_ENG_Report_HIS_in_MKD.pdf]. Accessed 14 November 2020.

[3] European Council (EC). Council Directive No. 82/894/EC of 21 December 1982. "On the Notification of Animal Diseases within the Community." [<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31982L0894&from=EN>]. Accessed 14 November 2020.

[4] Republic of North Macedonia. 2015. "Law on Veterinary Health (Official Gazette 153/15)." [<https://docs.googleusercontent.com/docs/securesc/jbmqb7rr8rid1kjinlphrobic0mpgcv06/83t00bh0j48fkukm1hieklleddajo60/1604768700000/16614190090344306114/04026950584739337890Z/1G3EnUJE7sMBQiwI3CmRtF6CC-bvcoYoK?e&nonce=cd3ag7kkfmmmk&user=04026950584739337890Z&hash=kccjou0geq7eiskm43lk2dlp83bibrri>]. Accessed 14 November 2020.

[5] Ministry of Agriculture and Waste Management of Republic of North Macedonia. Regulation No. 110 of 20 August 2010. "Regulation on the Manner and Procedure of Reporting of Compulsory Notifiable Diseases."

[<http://www.fva.gov.mk/images/Pravilnik-zadlozitelno.PDF>]. Accessed 14 November 2020.

[6] Ministry of Health of Republic of North Macedonia. [<http://zdravstvo.gov.mk/>]. Accessed 14 November 2020.

[7] Ministry of Agriculture, Forestry and Water Management of Republic of North Macedonia. [<http://www.mzsv.gov.mk/>]. Accessed 14 November 2020.

1.2.2c

Does the country conduct surveillance of zoonotic disease in wildlife (e.g., wild animals, insects, other disease vectors)?

Yes = 1 , No = 0

Current Year Score: 1

The Republic of North Macedonia conducts surveillance of zoonotic disease in wildlife. The Sector for Control and Monitoring of Communicable Diseases of the Institute of Public Health (IPH) of the Republic of North Macedonia conducts monitoring of the epidemiological situation for malaria and other parasitic diseases, vector-borne diseases such as West Nile virus and dengue through weekly reports of the World Health Organization. [1, 2] The IPH has undertaken epidemiological measures (although no details of such measures are provided) to prevent the introduction and spread of malaria in the country [2], and reducing the risk of spread of other parasitic diseases, vector-borne diseases such as West Nile virus and dengue.

[1] Institute of Public Health of Republic of North Macedonia. "Sector for Control and Monitoring of Communicable Diseases." [<http://www.iph.mk/en/sector-for-control-and-monitoring-of-communicable-diseases/>]. Accessed 14 November 2020.

[2] Institute of Public Health of Republic of North Macedonia. "Department for monitoring and surveillance of communicable diseases." [<http://www.iph.mk/en/sector-for-control-and-monitoring-of-communicable-diseases/department-for-monitoring-and-surveillance-of-communicable-diseases/>]. Accessed 14 November 2020.

1.2.3 International reporting of animal disease outbreaks

1.2.3a

Has the country submitted a report to OIE on the incidence of human cases of zoonotic disease for the last calendar year?

Yes = 1 , No = 0

Current Year Score: 0

2019

OIE WAHIS database

1.2.4 Animal health workforce

1.2.4a

Number of veterinarians per 100,000 people

Input number

Current Year Score: 25.63

2018

OIE WAHIS database

1.2.4b

Number of veterinary para-professionals per 100,000 people

Input number

Current Year Score: -

No data available

OIE WAHIS database

1.2.5 Private sector and zoonotic

1.2.5a

Does the national plan on zoonotic disease or other legislation, regulations, or plans include mechanisms for working with the private sector in controlling or responding to zoonoses?

Yes = 1 , No = 0

Current Year Score: 0

There is no evidence that the Republic of North Macedonia has a national plan on zoonotic disease or other legislation, regulations, or plans which include mechanisms for working with the private sector in controlling or responding to zoonoses. [1] There is no mention of such mechanism in Law No.07-3712/1 "On Protecting the Population from Contagious Disease" of 16 September 2004, which is the national legislation that includes zoonosis. The "Health Strategy of the Republic of Macedonia, 2020 Safe, Efficient, and Just Health Care System" also does not make any mention of mechanisms for working with the private sector in controlling or responding to zoonoses. [2] A review of the "National Program for Adoption of the Acquis Communautaire Revision 2009", which is a key document for the European Union (EU) integration process reflecting the dynamics of harmonization of the national legislation with the European law as well as the adjustment of national institutions to the European administrative structures does not include any mentioning of such mechanisms for controlling or responding to zoonoses. [3] There is also no mention of such mechanisms on the website of the Food and Veterinary Agency

of Republic of North Macedonia. [4] The 2019 World Health Organization (WHO) Joint External Evaluation Report of the Republic of North Macedonia does not have a reference related to mechanisms for working with the private sector in controlling or responding to zoonoses. [5] On the websites of the Ministry of Health and Ministry of Agriculture there is no additional information about the national plan on zoonotic disease or other legislation, regulations, or plans that include mechanisms for working with the private sector in controlling or responding to zoonoses. [6, 7]

- [1] Republic of North Macedonia. 2016. "Law on Protecting the Population from Contagious Disease (Official Gazette 66/04, 139/08, 99/09, 149/14, 150/15, 37/16)." [<http://zdravstvo.gov.mk/wp-content/uploads/2018/01/ZAKON-ZA-ZASHTITA-NA-NASELENIETO-OD-ZARAZNI-BOLESTI-zakluchno-so-br.-37-od-2016.pdf>]. Accessed 14 November 2020.
- [2] Ministry of Health of Republic of North Macedonia. February 2007. "Health Strategy of the Republic of Macedonia 2020 Safe, Efficient and Just Health Care System." [http://www.nationalplanningcycles.org/sites/default/files/planning_cycle_repository/the_former_yugoslav_republic_of_macedonia/health_strategy_2020_eng.pdf]. Accessed 14 November 2020.
- [3] Government of Republic of North Macedonia. 29 May 2009. "National Programme for Adoption of the Acquis Communautaire Revision 2009." [https://www.esiweb.org/pdf/macedonia_NPAA%202009.pdf]. Accessed 14 November 2020.
- [4] Food and Veterinary Agency of Republic of North Macedonia. [<http://www.fva.gov.mk/index.php?lang=mk>]. Accessed 14 November 2020.
- [5] World Health Organization (WHO). 2019. "Joint External Evaluation Report of IHR Core Capacities of the Republic of North Macedonia." [<https://apps.who.int/iris/bitstream/handle/10665/325320/WHO-WHE-CPI-2019.59-eng.pdf?sequence=1>]. Accessed 14 November 2020.
- [6] Ministry of Health of Republic of North Macedonia. [<http://zdravstvo.gov.mk/>]. Accessed 14 November 2020.
- [7] Ministry of Agriculture, Forestry and Water Management of Republic of North Macedonia. [<http://www.mzsv.gov.mk/>]. Accessed 14 November 2020.

1.3 BIOSECURITY

1.3.1 Whole-of- government biosecurity systems

1.3.1a

Does the country have in place a record, updated within the past five years, of the facilities in which especially dangerous pathogens and toxins are stored or processed, including details on inventories and inventory management systems of those facilities?

Yes = 1 , No = 0

Current Year Score: 0

There is no evidence of a record of the facilities in which especially dangerous pathogens and toxins are stored or processed, nor on the details on inventories and inventory management systems of those facilities. Although North Macedonia is party to the Biological Weapons Convention, it has not submitted Confidence Building Measures (CBM) since 2010. Access to North Macedonia's CBM reports is restricted, and they are not publicly available. [1] There is no evidence of inventories in which especially dangerous pathogens and toxins are stored and processed on the websites of the Ministry of Health's, the Ministry of Defense's website, the Institute of Public Health of Republic of North Macedonia's, the Ministry of Environment and Physical Planning, the Ministry of Agriculture and the VERTIC database. [2, 3, 4, 5, 6, 7] Furthermore, there is no mention of inventories of facilities of dangerous pathogens and toxins in the "2nd Environmental Performance Review of the Former Yugoslav Republic of Macedonia" developed by the United Nations Economic Commission for Europe (UNECE), which measures the progress made by the country in managing its environment and in addressing upcoming environmental

challenges [8], or the handbook on bio-waste management in the Republic of North Macedonia, prepared by the Netherlands' Agency Ministry of Infrastructure and the Environment. [9] There is also no such evidence in the Law on Environment. [10] According to the 2019 World Health Organization (WHO) Joint External Evaluation Report of the Republic of North Macedonia, there is no active monitoring and/or development of updated records and there is no inventory of pathogens within facilities that conserve or treat dangerous pathogens and toxins. [11]

- [1] United Nations Office at Geneva (UNOG). "Confidence Building Measures - North Macedonia." [https://bwc-ecbm.unog.ch/state/north-macedonia]. Accessed 14 November 2020.
- [2] Ministry of Health of Republic of North Macedonia. [http://zdravstvo.gov.mk/sq/home-main/]. Accessed 14 November 2020.
- [3] Ministry of Defense of Republic of North Macedonia. [http://www.mod.gov.mk/?lang=en]. Accessed 14 November 2020.
- [4] Institute of Public Health (IPH) of Republic of North Macedonia. [http://iph.mk/en/]. Accessed 14 November 2020.
- [5] Ministry of Environment and Physical Planning. [http://www.moepp.gov.mk/?lang=AL]. Accessed 14 November 2020.
- [6] Ministry of Agriculture, Forestry, and Economy of Republic of North Macedonia. [http://www.mzsv.gov.mk/al.aspx]. Accessed 14 November 2020.
- [7] Verification Research, Training and Information Center (VERTIC). Legislative database. "North Macedonia." [https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/n/]. Accessed 14 November 2020.
- [8] United Nations Economic Commission for Europe (UNECE). 2011. "2nd Environmental Performance Review the Former Yugoslav Republic of Macedonia." [http://www.moepp.gov.mk/wp-content/uploads/2017/03/2nd-Environmental-Performance.pdf]. Accessed 14 November 2020.
- [9] Netherlands Agency Ministry of Infrastructure and the Environment. 31 August 2012. "Handbook for Bio-waste Management in Macedonia." [https://limpezapublica.com.br/textos/handbook_biowastemanagement_macedonia_-_ks.pdf]. Accessed 14 November 2020.
- [10] Republic of North Macedonia. 2005. "Law on Environment. (Official Gazette 53/2005)." [http://www.moepp.gov.mk/wp-content/uploads/2014/09/%D0%97%D0%B0%D0%BA%D0%BE%D0%BD%20%D0%B7%D0%B0%20%D0%B6%D0%B8%D0%B2%D0%BE%D1%82%D0%BD%D0%B0%D1%82%D0%B0%20%D1%81%D1%80%D0%B5%D0%B4%D0%B8%D0%BD%D0%B0%20%D0%BA%D0%BE%D0%BD%D1%81%D0%BE%D0%BB%D0%B8%D0%B4%D0%B8%D1%82%D0%B0%D0%BD%20%D1%82%D0%B5%D0%BA%D1%81%D1%82%2019.07.2013.pdf]. Accessed 14 November 2020.
- [11] World Health Organization (WHO). 2019. Joint External Evaluation Report of IHR Core Capacities of the Republic of North Macedonia. [https://apps.who.int/iris/bitstream/handle/10665/325320/WHO-WHE-CPI-2019.59-eng.pdf?sequence=1]. Accessed 14 November 2020.

1.3.1b

Does the country have in place legislation and/or regulations related to biosecurity which address requirements such as physical containment, operation practices, failure reporting systems, and/or cybersecurity of facilities in which especially dangerous pathogens and toxins are stored or processed?

Yes = 1 , No = 0

Current Year Score: 0

There is no evidence of legislation and/or regulations related to biosecurity which address requirements such as physical containment, operation practices, failure reporting systems and/or cybersecurity of facilities in which especially dangerous pathogens and toxins are stored or processed. Although North Macedonia is party to the Biological Weapons Convention, it has not submitted Confidence Building Measures (CBMs) since 2010. Access to Macedonia's CBM reports is restricted, and they are not publicly available. [2] There is no mention of such legislation on the Ministry of Health's website, the Ministry of Defense website, the Institute of Public Health of Republic of North Macedonia website, the Ministry of Environment and

Physical Planning website, the Ministry of Agriculture website or the VERTIC database website [1, 3, 4, 5, 6, 7]. Although there is no specific legislation on biosecurity, there is legislation that broadly deals with biosecurity, such as the Law on Transport of Dangerous Substances of July 2007, which provides the national regulations on the safe and secure transportation of infectious substances (Categories A and B) [8] and Law on Export Control of Dual-Use Goods and Technologies of 2005, which regulates the conditions under which the export, transfer, brokering and transit of dual-use goods and technologies may be conducted, and the powers that state authorities have in carrying out supervision of the export, brokering and transit activities of dual-use goods and technologies [9]. According to the 2019 World Health Organization Joint External Evaluation Report of the Republic of North Macedonia, laws governing biosecurity are not well established. The practice of biosafety is left to individual laboratories, and not all laboratories have written guidance documents for biosafety procedures. [10]

[1] Ministry of Health of Republic of North Macedonia. [<http://zdravstvo.gov.mk/sq/home-main/>]. Accessed 14 November 2020.

[2] United Nations Office at Geneva (UNOG). "Confidence Building Measures - North Macedonia." [<https://bwc-ecbm.unog.ch/state/north-macedonia>]. Accessed 14 November 2020.

[3] Ministry of Defense of Republic of North Macedonia. [<http://www.mod.gov.mk/?lang=en>]. Accessed 14 November 2020.

[4] Institute of Public Health (IPH) of Republic of North Macedonia. [<http://iph.mk/en/>]. Accessed 14 November 2020.

[5] Ministry of Environment and Physical Planning. [<http://www.moep.gov.mk/?lang=AL>]. Accessed 14 November 2020.

[6] Ministry of Agriculture, Forestry, and Economy of Republic of North Macedonia. [<http://www.mzsv.gov.mk/al.aspx>]. Accessed 14 November 2020.

[7] Verification Research, Training and Information Center (VERTIC). Legislative database. "North Macedonia". [<https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/n/>]. Accessed 14 November 2020.

[8] Republic of North Macedonia. 2011. "Law on Transport of Dangerous Substances in the Road and Railway Transport (Official Gazette 92/2007; 147/2008; 161/2009; 17/2011; 54/2011)."

[https://ener.gov.mk/files/propisi_files/plan/59_%D0%97%D0%B0%D0%BA%D0%BE%D0%BD%20%D0%B7%D0%B0%20%D0%BF%D1%80%D0%B5%D0%B2%D0%BE%D0%B7%20%D0%BD%D0%B0%20%D0%BE%D0%BF%D0%B0%D1%81%D0%BD%D0%B8%20%D0%BC%D0%B0%D1%82%D0%B5%D1%80%D0%B8%D0%B8%20%D0%B2%D0%BE%20%D0%BF%D0%B0%D1%82%D0%BD%D0%B8%D0%BE%D1%82%20%D0%B8%20%D0%B6%D0%B5%D0%BB.pdf]. Accessed 14 November 2020.

[9] Republic of North Macedonia. 2016. "Law On Export Control of Dual-Use Goods and Technologies (Official Gazette 82/2005, 84/07, 158/10, 136/11, 199/14, 192/15, 53/16)."

[http://www.economy.gov.mk/Upload/Editor_Upload/Precisten%20tekst%20na%20zakon%20za%20dual%20use%20.pdf]. Accessed 14 November 2020.

[10] World Health Organization (WHO). 2019. "Joint External Evaluation Report of IHR Core Capacities of the Republic of North Macedonia." [<https://apps.who.int/iris/bitstream/handle/10665/325320/WHO-WHE-CPI-2019.59-eng.pdf?sequence=1>]. Accessed 14 November 2020.

1.3.1c

Is there an established agency (or agencies) responsible for the enforcement of biosecurity legislation and regulations?

Yes = 1 , No = 0

Current Year Score: 0

There is no evidence of an established agency specifically responsible for the enforcement of biosecurity legislation and regulations in the country. The Republic of North Macedonia does not have a comprehensive legislative framework to address biosecurity requirements such as physical containment, operation practices, failure reporting systems, or cybersecurity of facilities in which especially dangerous pathogens and toxins are stored or processed. Although North

Macedonia is party to the Biological Weapons Convention, it has not submitted Confidence Building Measures (CBMs) since 2010. Access to North Macedonia's CBM reports is restricted, and they are not publicly available. [1] There is no evidence of such legislation or information regarding biosecurity and biosecurity standards on the websites of the Ministry of Health, the Ministry of Defense, the Institute of Public Health of the Republic of North Macedonia, the Ministry of Environment and Physical Planning, the Ministry of Agriculture, or the VERTIC database [2, 3, 4, 5, 6, 7]. According to the 2019 World Health Organization Joint External Evaluation Report of the Republic of North Macedonia, laws governing biosecurity are not well established and therefore there is no additional information about an established agency specifically responsible for the enforcement of biosecurity legislation and regulations in the country. [8]

[1] United Nations Office at Geneva (UNOG). "Confidence Building Measures - North Macedonia." [https://bwc-ecbm.unog.ch/state/north-macedonia]. Accessed 14 November 2020.

[2] Ministry of Health of Republic of North Macedonia. [http://zdravstvo.gov.mk/sq/home-main/]. Accessed 14 November 2020.

[3] Ministry of Defense of Republic of North Macedonia. [http://www.mod.gov.mk/?lang=en]. Accessed 14 November 2020.

[4] Institute of Public Health (IPH) of Republic of North Macedonia. [http://iph.mk/en/]. Accessed 14 November 2020.

[5] Ministry of Environment and Physical Planning. [http://www.moepp.gov.mk/?lang=AL]. Accessed 14 November 2020.

[6] Ministry of Agriculture, Forestry, and Economy of Republic of North Macedonia. [http://www.mzsv.gov.mk/al.aspx]. Accessed 14 November 2020.

[7] Verification Research, Training and Information Center (VERTIC). Legislative database. "North Macedonia." [https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/n/]. Accessed 14 November 2020.

[8] World Health Organization (WHO). 2019. "Joint External Evaluation Report of IHR Core Capacities of the Republic of North Macedonia." [https://apps.who.int/iris/bitstream/handle/10665/325320/WHO-WHE-CPI-2019.59-eng.pdf?sequence=1]. Accessed 14 November 2020.

1.3.1d

Is there public evidence that shows that the country has taken action to consolidate its inventories of especially dangerous pathogens and toxins into a minimum number of facilities?

Yes = 1 , No = 0

Current Year Score: 0

There is no public evidence that shows that North Macedonia has taken action to consolidate its inventories of especially dangerous pathogens and toxins into a minimum number of facilities. There is no evidence on a record of the facilities in which especially dangerous pathogens and toxins are stored or processed, nor on the details on inventories and inventory management systems of those facilities. Although North Macedonia is party to the Biological Weapons Convention (BWC), it has not submitted Confidence Building Measures (CBM) since 2010. Access to North Macedonia's CBM reports is restricted; they are not publicly available. [1] There is no evidence of these facilities on the websites of the Ministry of Health, Ministry of Defense, Institute of Public Health of Republic of North Macedonia, Ministry of Environment and Physical Planning, and Ministry of Agriculture, or the Verification, Research, Training and Information Center (VERTIC) database website [2, 3, 4, 5, 6, 7]. Furthermore, there is no mention of inventories of facilities of dangerous pathogens and toxins in the "2nd Environmental Performance Review the Former Yugoslav Republic of Macedonia" developed by the United Nations Economic Commission for Europe (UNECE), which measures the progress made by the country in managing its environment and in addressing upcoming environmental challenges [8], or the handbook on bio-waste management in the Republic of Macedonia North prepared by the Netherlands' Agency Ministry of Infrastructure and the Environment [9]. According to the 2019 World Health Organization (WHO) Joint External Evaluation Report of the Republic of North Macedonia, there is no

policy or agreement for dangerous pathogens and toxins to be consolidated into a minimum number of facilities. [10]

- [1] United Nations Office at Geneva (UNOG). "Confidence Building Measures - North Macedonia." [https://bwc-ecbm.unog.ch/state/north-macedonia]. Accessed 14 November 2020.
- [2] Ministry of Health of Republic of North Macedonia. [http://zdravstvo.gov.mk/sq/home-main/]. Accessed 14 November 2020.
- [3] Ministry of Defense of Republic of North Macedonia. [http://www.mod.gov.mk/?lang=en]. Accessed 14 November 2020.
- [4] Institute of Public Health (IPH) of Republic of North Macedonia. [http://iph.mk/en/]. Accessed 14 November 2020.
- [5] Ministry of Environment and Physical Planning. [http://www.moepp.gov.mk/?lang=AL]. Accessed 14 November 2020.
- [6] Ministry of Agriculture, Forestry, and Economy of Republic of North Macedonia. [http://www.mzsv.gov.mk/al.aspx]. Accessed 14 November 2020.
- [7] Verification Research, Training and Information Center (VERTIC). Legislative database. "North Macedonia". [https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/n/]. Accessed 14 November 2020.
- [8] United Nations Economic Commission for Europe (UNECE). 2011. "2nd Environmental Performance Review the Former Yugoslav Republic of Macedonia." [http://www.moepp.gov.mk/wp-content/uploads/2017/03/2nd-Environmental-Performance.pdf]. Accessed 14 November 2020.
- [9] Netherlands Agency Ministry of Infrastructure and the Environment. 31 August 2012. "Handbook for Bio-waste Management in Macedonia." [https://limpezapublica.com.br/textos/handbook_biowastemanagement_macedonia_-_ks.pdf]. Accessed 14 November 2020.
- [10] World Health Organization (WHO). 2019. Joint External Evaluation Report of IHR Core Capacities of the Republic of North Macedonia. [https://apps.who.int/iris/bitstream/handle/10665/325320/WHO-WHE-CPI-2019.59-eng.pdf?sequence=1]. Accessed 14 November 2020.

1.3.1e

Is there public evidence of in-country capacity to conduct Polymerase Chain Reaction (PCR)-based diagnostic testing for anthrax and/or Ebola, which would preclude culturing a live pathogen?

Yes = 1 , No = 0

Current Year Score: 0

There is no public evidence of in-country capacity to conduct Polymerase Chain Reaction (PCR)-based diagnostic testing for anthrax and/or Ebola, which would preclude culturing a live pathogen. There is no evidence of conducting Polymerase Chain Reaction (PCR)-based diagnostic testing for anthrax and/or Ebola on the websites of the Institute of Public Health (IPH) of Republic of North Macedonia, the Ministry of Health, the Ministry of Defense, the Ministry of Agriculture, Forestry and Water Economy, the Food and Veterinary Agency (FVA), and the Faculty of Veterinary Medicine of the Ss.Cyril and Methodius University in Skopje [1, 2, 3, 4, 5, 6].

- [1] Institute of Public Health (IPH) of Republic of North Macedonia. "Virology." [http://iph.mk/en/laboratory/virology/]. Accessed 14 November 2020.
- [2] Ministry of Health of Republic of North Macedonia. [http://zdravstvo.gov.mk/sq/home-main/]. Accessed 14 November 2020.
- [3] Ministry of Defense of Republic of North Macedonia. [http://www.mod.gov.mk/?lang=en]. Accessed 14 November 2020.
- [4] Ministry of Agriculture, Forestry and Water Economy of Republic of North Macedonia. [http://www.mzsv.gov.mk/]. Accessed 14 November 2020.
- [5] Food and Veterinary Agency (FVA). [http://www.fva.gov.mk/index.php?lang=mk]. Accessed 14 November 2020.
- [6] Faculty of Veterinary Medicine of the Ss. Cyril and Methodius University in Skopje. "Laboratory for serology and molecular

diagnostics." [https://fvm.ukim.edu.mk/en/aplikacija/laboratorii/laboratorija-za-serologija-i-molekularna-dijagnostika/]. Accessed 14 November 2020.

1.3.2 Biosecurity training and practices

1.3.2a

Does the country require biosecurity training, using a standardized, required approach, such as through a common curriculum or a train-the-trainer program, for personnel working in facilities housing or working with especially dangerous pathogens, toxins, or biological materials with pandemic potential?

Yes = 1 , No = 0

Current Year Score: 0

There is no evidence that the country requires biosecurity training using a standardized, required approach, such as through a common curriculum or a train-the-trainer program, for personnel working in facilities housing or working with especially dangerous pathogens, toxins, or biological materials with pandemic potential. Although North Macedonia is party to the Biological Weapons Convention, it has not submitted Confidence Building Measures (CBMs) since 2010. Access to North Macedonia's CBM reports is restricted, and they are not publicly available. [1] The country has not passed national laws on biosecurity, and the Ministries of Health, Environment and Physical Planning, the Institute of Public Health and the Verification, Research, Training and Information Center (VERTIC) database do not have information on biosecurity standards or requirements in the country [2, 3, 4, 5, 6]. However, in 2015, the First workshop on Development of knowledge and transfer of best practices for biosecurity/ biosafety / biorisk and management in the Republic of North Macedonia took place organized by the Institute of Public Health of the Republic of Macedonia in collaboration with Insubria Center for International Security of Italy, and Institute of Microbiology and Parasitology, Faculty of Medicine, Skopje [7]. The objectives of the workshop were: (i) transmission of international knowledge and practices for biosafety, biosecurity and bio-risk management in Macedonia, (ii) review the equipment and organization of laboratories for safe and secure management of biological agents, (iii) raising awareness of the importance of biosafety, biosecurity and biorisk management, and (iv) training of laboratory experts for biosecurity and biosafety. There are no additional information about follow up workshops. According to the 2019 World Health Organization (WHO) Joint External Evaluation Report of the Republic of North Macedonia, biosafety and biosecurity training are not in place across all facilities. There is no sustained academic training in institutions for those who maintain or work with dangerous pathogens and/or toxins. There are no financial resources and/or capacities to carry out training on biosafety and biosecurity. [8]

[1] United Nations Office at Geneva (UNOG). "Confidence Building Measures - North Macedonia." [https://bwc-ecbm.unog.ch/state/north-macedonia]. Accessed 14 November 2020.

[2] United Nations Economic Commission for Europe (UNECE). 2011. "2nd Environmental Performance Review the Former Yugoslav Republic of Macedonia." [http://www.moep.gov.mk/wp-content/uploads/2017/03/2nd-Environmental-Performance.pdf]. Accessed 14 November 2020.

[3] Ministry of Health of Republic of North Macedonia. "Legislation." [http://zdravstvo.gov.mk/sq/ligjet/]. Accessed 14 November 2020.

[4] Ministry of Environment and Physical Planning of Republic of North Macedonia. "Legislation." [http://www.moep.gov.mk/?page_id=901&lang=en]. Accessed 14 November 2020.

[5] Institute of Public Health of Republic of North Macedonia (IPH). [http://www.iph.mk/en/]. Accessed 14 November 2020.

[6] Verification Research, Training and Information Center (VERTIC). Legislative database. "North Macedonia". [https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/n/]. Accessed 14 November 2020.

[7] Institute of Public Health of Republic of North Macedonia. 16 April 2015. "First workshop on Development of knowledge

and transfer of best practices for biosecurity/ biosafety / biorisk and management. [<http://www.iph.mk/en/first-workshop-on-development-of-knowledge-and-transfer-of-best-practices-for-biosecurity-biosafety-biorisk-and-management-in-the-republic-of-macedonia/>]. Accessed 14 November 2020.

[8] World Health Organization (WHO). 2019. "Joint External Evaluation Report of IHR Core Capacities of the Republic of North Macedonia". [<https://apps.who.int/iris/bitstream/handle/10665/325320/WHO-WHE-CPI-2019.59-eng.pdf?sequence=1>]. Accessed 14 November 2020.

1.3.3 Personnel vetting: regulating access to sensitive locations

1.3.3a

Do regulations or licensing conditions specify that security and other personnel with access to especially dangerous pathogens, toxins, or biological materials with pandemic potential are subject to the following checks: drug testing, background checks, and psychological or mental fitness checks?

Personnel are subject to all three of these checks = 3, Personnel are subject to two of these checks = 2, Personnel are subject to one of these checks = 1, Personnel are not subject to any of these checks = 0

Current Year Score: 0

There is no evidence on the requirements or licensing conditions specifying that security and other personnel with access to especially dangerous pathogens, toxins, or biological materials with pandemic potential are subject to drug testing, background checks, and psychological or mental fitness checks. Although North Macedonia is party to the Biological Weapons Convention (BWC), it has not submitted Confidence Building Measures (CBMs) since 2010. Access to North Macedonia's CBM reports is restricted, they are not publicly available. [1] The Republic of North Macedonia does not have a legal framework on biosecurity and personnel requirements. There is however legislation that broadly deals with biosecurity such as Law on Transport of Dangerous Substances of July 2007, which provides the national regulations on the safe and secure transport of infectious substances (Categories A and B) and Law on Export Control of Dual-Use Goods and Technologies of 2005, which regulates the conditions under which the export, transfer, brokering and transit of dual-use goods and technologies may be conducted [2, 3]. These laws, however, does not include requirements for checks. There is also no evidence of biosecurity legislation, personnel requirements, or biosecurity standards on the Ministry of Health's website, the Ministry of Defense's website, the Institute of Public Health of Republic of North Macedonia's website, the Ministry of Environment and Physical Planning website, and the Ministry of Agriculture and Verification, Research, Training and Information Center (VERTIC) database websites [4, 5, 6, 7, 8, 9].

[1] United Nations Office at Geneva (UNOG). "Confidence Building Measures - North Macedonia." [<https://bwc-ecbm.unog.ch/state/north-macedonia>]. Accessed 14 November 2020.

[2] Republic of North Macedonia. 2011. "Law on Transport of Dangerous Substances in the Road and Railway Transport (Official Gazette 92/2007; 147/2008; 161/2009; 17/2011, 54/2011)."

[https://ener.gov.mk/files/propisi_files/plan/59_%D0%97%D0%B0%D0%BA%D0%BE%D0%BD%20%D0%B7%D0%B0%20%D0%BF%D1%80%D0%B5%D0%B2%D0%BE%D0%B7%20%D0%BD%D0%B0%20%D0%BE%D0%BF%D0%B0%D1%81%D0%BD%D0%B8%20%D0%BC%D0%B0%D1%82%D0%B5%D1%80%D0%B8%D0%B8%20%D0%B2%D0%BE%20%D0%BF%D0%B0%D1%82%D0%BD%D0%B8%D0%BE%D1%82%20%D0%B8%20%D0%B6%D0%B5%D0%BB.pdf]. Accessed 14 November 2020.

[3] Republic of North Macedonia. 2016. "Law On Export Control of Dual-Use Goods and Technologies (Official Gazette 82/2005, 84/07, 158/10, 136/11, 199/14, 192/15, 53/16)."

[http://www.economy.gov.mk/Upload/Editor_Upload/Precisten%20tekst%20na%20zakon%20za%20dual%20use%20.pdf]. Accessed 14 November 2020.

[4] Ministry of Health of Republic of North Macedonia. [<http://zdravstvo.gov.mk/sq/home-main/>]. Accessed 14 November 2020.

- [5] Ministry of Defense of Republic of North Macedonia. [<http://www.pravda.gov.mk/Default>]. Accessed 14 November 2020.
- [6] Institute of Public Health (IPH) of Republic of Macedonia. [<http://iph.mk/en/>]. Accessed 14 November 2020.
- [7] Ministry of Environment and Physical Planning. [<http://www.moepp.gov.mk/?lang=AL>]. Accessed 14 November 2020.
- [8] Ministry of Agriculture, Forestry, and Economy of Republic of North Macedonia. [<http://www.mzsv.gov.mk/al.aspx>]. Accessed 14 November 2020.
- [9] Verification Research, Training and Information Center (VERTIC). Legislative database. "North Macedonia." [<https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/n/>]. Accessed 14 November 2020.

1.3.4 Transportation security

1.3.4a

Does the country have publicly available information on national regulations on the safe and secure transport of infectious substances (specifically including Categories A and B)?

Yes = 1 , No = 0

Current Year Score: 1

Macedonia has publicly available information on national regulations on the safe and secure transport of infectious substances (Categories A and B). The Law on Transport of Dangerous Substances of July 2007 provides information on the safe and secure transport of infectious substances for the Republic of North Macedonia, includes toxins and infectious substances. The law abides by the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), which provide guidance on transportation of Category A and B substances, as well as the Convention on International Transport by Rail (COTIF) and its Rulebook on international transport of dangerous goods by rail (RID). The law provides for mandatory labelling of vehicles carrying dangerous substances with orange plates and stickers of danger. Also, it mandates proper labelling of containers of vehicles carrying dangerous substances in order to alert other traffic participants. The basic condition to transport the dangerous substances is possession of a permit, issued by the Ministry of Transport and Communications of Republic of North Macedonia at the request of the company or individual that performs the transport. In addition to approval, it is necessary to possess and provide the transport document from the sender to the carrier (ADR-Document), written instructions for dangerous goods that are shipped, ADR Certificate of professional competence of the driver of the dangerous substance, and additional approval from the Ministry of Health for transportation of poisons and infectious substances [2]. Although North Macedonia is party to the Biological Weapons Convention, it has not submitted Confidence Building Measures (CBMs) since 2010. Access to North Macedonia's CBM reports is restricted, they are not publicly available. [3] The Verification, Research, Training and Information Center (VERTIC) database does not have additional information about national regulations on the safe and secure transport of infectious substances (Categories A and B). [4]

[1] Republic of North Macedonia. 2011. "Law on Transport of Dangerous Substances in the Road and Railway Transport (Official Gazette 92/2007; 147/2008; 161/2009; 17/2011; 54/2011)."

[https://ener.gov.mk/files/propisi_files/plan/59_%D0%97%D0%B0%D0%BA%D0%BE%D0%BD%20%D0%B7%D0%B0%20%D0%BF%D1%80%D0%B5%D0%B2%D0%BE%D0%B7%20%D0%BD%D0%B0%20%D0%BE%D0%BF%D0%B0%D1%81%D0%BD%D0%B8%20%D0%BC%D0%B0%D1%82%D0%B5%D1%80%D0%B8%D0%B8%20%D0%B2%D0%BE%20%D0%BF%D0%B0%D1%82%D0%BD%D0%B8%D0%BE%D1%82%20%D0%B8%20%D0%B6%D0%B5%D0%BB.pdf]. Accessed 14 November 2020.

[2] Rechkoska, Gordana et al. 2012. "Transport of Dangerous Substances In the Republic of Macedonia" *Procedia - Social and Behavioral Sciences* 44: 289-300. [<https://core.ac.uk/download/pdf/82097846.pdf>]. Accessed 14 November 2020.

[3] United Nations Office at Geneva (UNOG). "Confidence Building Measures - North Macedonia." [<https://bwc-ecbm.unog.ch/state/north-macedonia>]. Accessed 14 November 2020.

[4] Verification Research, Training and Information Center (VERTIC). Legislative database. "North Macedonia".

[<https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/n/>]. Accessed 14 November 2020.

1.3.5 Cross-border transfer and end-user screening

1.3.5a

Is there legislation and/or regulations in place to oversee the cross-border transfer and end-user screening of especially dangerous pathogens, toxins, and pathogens with pandemic potential?

Yes = 1 , No = 0

Current Year Score: 1

The Republic of North Macedonia has legislation in place to oversee the cross-border transfer and end-user screening of especially dangerous pathogens, toxins and pathogens with pandemic potential. [1] Law on Transport of Dangerous Substances in the Road and Railway Transport, which provides the national regulations on the safe and secure transport of dangerous substances including toxins and infectious disease-causing pathogens in humans or animals, requires issuance for approval of export, import, or inland transportation of toxins and infectious substances. The sender and recipient of toxins and infectious substances must be registered in the Republic of North Macedonia for trade of those substances. In addition it is also necessary to possess approval from the Ministry of Health for transportation of toxins and infectious substances [2]. Furthermore, Law on Export Control of Dual-Use Goods and Technologies regulates the conditions under which the export, transfer, brokering and transit of dual-use goods and technologies may be conducted. Under Article 6, dual-use goods and technologies may be exported only by an issued license for export of dual-use goods and technologies. Under Article 18, the Customs Administration maintains records of all "End User Certificates" verified by the appropriate authorities in the country of import. [3]

[1] Republic of North Macedonia. 2011. "Law on Transport of Dangerous Substances in the Road and Railway Transport (Official Gazette 92/2007; 147/2008; 161/2009; 17/2011; 54/2011)."

[https://ener.gov.mk/files/propisi_files/plan/59_%D0%97%D0%B0%D0%BA%D0%BE%D0%BD%20%D0%B7%D0%B0%20%D0%BF%D1%80%D0%B5%D0%B2%D0%BE%D0%B7%20%D0%BD%D0%B0%20%D0%BE%D0%BF%D0%B0%D1%81%D0%BD%D0%B8%20%D0%BC%D0%B0%D1%82%D0%B5%D1%80%D0%B8%D0%B8%20%D0%B2%D0%BE%20%D0%BF%D0%B0%D1%82%D0%BD%D0%B8%D0%BE%D1%82%20%D0%B8%20%D0%B6%D0%B5%D0%BB.pdf]. Accessed 14 November 2020.

[2] Rechkoska, Gordana et al. 2012. "Transport of Dangerous Substances In the Republic of Macedonia" *Procedia - Social and Behavioral Sciences* 44: 289 300. [<https://core.ac.uk/download/pdf/82097846.pdf>]. Accessed 14 November 2020.

[3] Republic of North Macedonia. 2016. "Law On Export Control of Dual-Use Goods and Technologies (Official Gazette 82/2005, 84/07, 158/10, 136/11, 199/14, 192/15, 53/16)."

[http://www.economy.gov.mk/Upload/Editor_Upload/Precisten%20tekst%20na%20zakon%20za%20dual%20use%20.pdf]. Accessed 14 November 2020.

1.4 BIOSAFETY

1.4.1 Whole-of-government biosafety systems

1.4.1a

Does the country have in place national biosafety legislation and/or regulations?

Yes = 1 , No = 0

Current Year Score: 0

The Republic of North Macedonia does not have in place specific national biosafety legislation and/or regulations. Biosafety development in the Republic of North Macedonia consists of Genetically Modified Organisms (GMO) in an agricultural and environmental perspective as evidenced by Law on Genetically Modified Organisms, and the environmental performance review by the United Nations Economic Commission for Europe (UNECE). The law on GMOs regulates issues regarding biological security in connection with the management of products containing GMOs and genetically modified microorganisms (GMMs), the intentional release of GMOs in the environment or the release of products that contain GMOs on the market, as well as the import, export and trans-boundary movement of GMOs and GMMs. [1, 2] Evidence of biosafety is also not found in Law on Environment, which makes provisions/regulations for hazardous materials and accidents from hazardous materials, but there is no specific mentions or measures for accidents that involve the release of harmful biological substances [3]. Although North Macedonia is party to the Biological Weapons Convention (BWC), it has not submitted Confidence Building Measures (CBMs) since 2010. Access to North Macedonia's CBM reports is restricted, and they are not publicly available. [4] According to the 2019 World Health Organization (WHO) Joint External Evaluation Report of the Republic of North Macedonia, the Republic of North Macedonia has a strong legislative basis for its public health system, and biosafety is no exception. Preventive measures and immunization of workers are covered by a rulebook on the minimum health and safety criteria for workers for risks connected to exposure to biological agents. There is a law on Genetically Modified Organisms (2008, 2013) and there are guidelines for the safe management of medical waste. Laws governing biosecurity are not as well established. The practice of biosafety is left to individual laboratories, and not all laboratories have written guidance documents for biosafety procedures. [5]

[1] Republic of North Macedonia. 2015. "Law on Genetically Modified Organisms (Official Gazette 35/2008; 163/2013; 146/2015)." [<http://aktivirajse.mk/law/zakon-za-genetski-modificirani-organ/>]. Accessed 14 November 2020.

[2] United Nations Economic Commission for Europe (UNECE). 2011. "2nd Environmental Performance Review the Former Yugoslav Republic of Macedonia." [<http://www.moepp.gov.mk/wp-content/uploads/2017/03/2nd-Environmental-Performance.pdf>]. Accessed 14 November 2020.

[3] Republic of North Macedonia. 2005. "Law on Environment. (Official Gazette 53/2005)." [<http://www.moepp.gov.mk/wp-content/uploads/2014/09/%D0%97%D0%B0%BA%D0%BE%D0%BD%20%D0%B7%D0%B0%20%D0%B6%D0%B8%D0%B2%D0%BE%D1%82%D0%BD%D0%B0%D1%82%D0%B0%20%D1%81%D1%80%D0%B5%D0%B4%D0%B8%D0%BD%D0%B0%20%D0%BA%D0%BE%D0%BD%D1%81%D0%BE%D0%BB%D0%B8%D0%B4%D0%B8%D1%82%D0%B0%D0%BD%20%D1%82%D0%B5%D0%BA%D1%81%D1%82%2019.07.2013.pdf>]. Accessed 14 November 2020.

[4] United Nations Office at Geneva (UNOG). "Confidence Building Measures - North Macedonia." [<https://bwc-ecbm.unog.ch/state/north-macedonia>]. Accessed 14 November 2020.

[5] World Health Organization (WHO). 2019. "Joint External Evaluation Report of IHR Core Capacities of the Republic of North Macedonia." [<https://apps.who.int/iris/bitstream/handle/10665/325320/WHO-WHE-CPI-2019.59-eng.pdf?sequence=1>]. Accessed 14 November 2020.

1.4.1b

Is there an established agency responsible for the enforcement of biosafety legislation and regulations?

Yes = 1, No = 0

Current Year Score: 0

There is no established agency responsible for the enforcement of biosafety legislation and regulations, which goes along with the lack of legislation in this regard in the country. [1] Biosafety development in the Republic of North Macedonia consists of Genetically Modified Organisms (GMO) in an agricultural and environmental perspective as evidenced by Law on Genetically Modified Organisms, and the environmental performance review by the United Nations Economic Commission for Europe (UNECE) [2]. In the "National Occupational Safety and Health Profile Report" for the Republic of North Macedonia by the International Labor Organization (ILO), it is reported that specialized institution on risk assessment in regard to

chemical, toxicology, and epidemiology safety does not exist in the country [3]. Although North Macedonia is party to the Biological Weapons Convention, it has not submitted Confidence Building Measures (CBMs) since 2010. Access to North Macedonia's CBM reports is restricted, and they are not publicly available. [4] Furthermore, no evidence of such agency is found on the website of the Ministry of Health and the National Institute of Public Health [5, 6]. The 2019 World Health Organization (WHO) Joint External Evaluation Report of the Republic of North Macedonia does not have a reference related to agency responsible for the enforcement of biosafety legislation and regulations. [7]

[1] Republic of North Macedonia. 2015. "Law on Genetically Modified Organisms (Official Gazette 35/2008; 163/2013; 146/2015)." [<http://aktivirajse.mk/law/zakon-za-genetski-modificirani-organ/>]. Accessed 14 November 2020.

[2] United Nations Economic Commission for Europe (UNECE). 2011. "2nd Environmental Performance Review the Former Yugoslav Republic of Macedonia." [<http://www.moep.gov.mk/wp-content/uploads/2017/03/2nd-Environmental-Performance.pdf>]. Accessed 14 November 2020.

[3] International Labor Organization (ILO). National Occupational Safety and Health Profile Report: Macedonian Occupational Safety and Health Report."

[https://www.ilo.org/dyn/legosh/en/f?p=14100:1100:0::NO::P1100_ISO_CODE3,P1100_SUBCODE_CODE,P1100_YEAR:MKD,,2013]. Accessed 14 November 2020.

[4] United Nations Office at Geneva (UNOG). "Confidence Building Measures - North Macedonia." [<https://bwc-ecbm.unog.ch/state/north-macedonia>]. Accessed 14 November 2020.

[5] Ministry of Health of Republic of North Macedonia. "Legislation." [<http://zdravstvo.gov.mk/sq/ligjet/>]. Accessed 14 November 2020.

[6] Institute of Public Health of Republic of North Macedonia. 16 April 2015. "First workshop on "Development of knowledge and transfer of best practices for biosecurity/ biosafety / biorisk and management." [<http://www.iph.mk/en/first-workshop-on-development-of-knowledge-and-transfer-of-best-practices-for-biosecurity-biosafety-biorisk-and-management-in-the-republic-of-macedonia/>]. Accessed 14 November 2020.

[7] World Health Organization (WHO). 2019. "Joint External Evaluation Report of IHR Core Capacities of the Republic of North Macedonia." [<https://apps.who.int/iris/bitstream/handle/10665/325320/WHO-WHE-CPI-2019.59-eng.pdf?sequence=1>]. Accessed 14 November 2020.

1.4.2 Biosafety training and practices

1.4.2a

Does the country require biosafety training, using a standardized, required approach, such as through a common curriculum or a train-the-trainer program, for personnel working in facilities housing or working with especially dangerous pathogens, toxins, or biological materials with pandemic potential?

Yes = 1 , No = 0

Current Year Score: 0

There is no evidence that the country requires biosafety training, using a standardized, required approach, such as through a common curriculum or a train-the-trainer program, for personnel working in facilities housing or working with especially dangerous pathogens, toxins, or biological materials with pandemic potential. Legislation on biosafety is lacking in the country and it revolves around Genetically Modified Organisms (GMOs). [1] There is no legislation or requirement mentioned on the Ministry of Health website, National Public Health Institute website or the Verification, Research, Training and Information Center (VERTIC) database [2, 3, 4]. Although North Macedonia is party to the Biological Weapons Convention (BWC), it has not submitted Confidence Building Measures (CBM) since 2010. Access to North Macedonia's CBM reports is restricted, so they are not publicly available. [5] There is no evidence of biosafety training requirements in the "National Occupational Safety and Health Profile Report" for the Former Yugoslav Republic of Macedonia by the International Labor

Organization (ILO), and it is reported that a specialized institution on risk assessment in regard to chemical, toxicology, and epidemiology safety does not exist in the country [6]. The only available evidence is of 2015, regarding the "First workshop on Development of knowledge and transfer of best practices for biosecurity/ biosafety / biorisk and management" in the Republic of Macedonia, which aimed at transmission of international knowledge and practices, organization of laboratories for safe and secure management of biological agents, awareness raising of the importance of biosafety, biosecurity and biorisk management, and training of laboratory experts for biosecurity and biosafety [7]. There is no further evidence of the workshop being followed up with the development of a standardized approach to biosafety training. According to the 2019 World Health Organization (WHO) Joint External Evaluation Report of the Republic of North Macedonia, during medical education and specialized training, medical staff are well-trained and follow good biosafety practice, but there is no mechanism to monitor overall practices at the laboratory level. The microbiology laboratory at the Institute of Public Health (IPH) is undergoing accreditation as the National Influenza Center and as part of this process is required to document its biosafety procedures. While there is no regular relevant national training following initial qualifications, some individual staff members are accessing external training offerings, such as: the South Eastern European Influenza Laboratory Management Course (two persons); the Centers for Disease Control and Prevention/Association of Public Health Laboratories Southeast Europe Biosafety Course (two persons); and training on chemical, biological, radiological and nuclear (CBRN) threats (three persons). They also access other national training courses, such as the Knowledge Development and Transfer of Best Practices on Biosafety/Biosecurity/Biorisk Management; training offered within the framework of the EU CBRN Center of Excellence Project 3 (applicable to mixed laboratories, microbiological, biochemical and veterinary laboratories, and laboratories for food investigation and forensics); and internal biosafety training for staff at the IPH. The NRL for the veterinary sector conducts regular training on request, and could be used as a resource for continuing education in laboratory biosafety and biosecurity, with appropriate funding allocated for the purpose. [8]

[1] Republic of North Macedonia. 2015. "Law on Genetically Modified Organisms (Official Gazette 35/2008; 163/2013; 146/2015)." [<http://aktivirajse.mk/law/zakon-za-genetski-modificirani-organ/>]. Accessed 14 November 2020.

[2] Ministry of Health of Republic of Macedonia. "Legislation." [<http://zdravstvo.gov.mk/sq/ligjet/>]. Accessed 14 November 2020.

[3] Institute of Public Health of Republic of Macedonia (IPH). [<http://www.iph.mk/en/>]. Accessed 14 November 2020.

[4] Verification Research, Training and Information Center (VERTIC). Legislative database. "North Macedonia." [<https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/n/>]. Accessed 14 November 2020.

[5] United Nations Office at Geneva (UNOG). "Confidence Building Measures - North Macedonia." [<https://bwc-ecbm.unog.ch/state/north-macedonia>]. Accessed 14 November 2020.

[6] International Labor Organization (ILO). National Occupational Safety and Health Profile Report: Macedonian Occupational Safety and Health Report."

[https://www.ilo.org/dyn/legosh/en/f?p=14100:1100:0::NO::P1100_ISO_CODE3,P1100_SUBCODE_CODE,P1100_YEAR:MKD,,2013]. Accessed 14 November 2020.

[7] Institute of Public Health of Republic of Macedonia. 16 April 2015. "First workshop on Development of knowledge and transfer of best practices for biosecurity/ biosafety / biorisk and management." [<http://www.iph.mk/en/first-workshop-on-development-of-knowledge-and-transfer-of-best-practices-for-biosecurity-biosafety-biorisk-and-management-in-the-republic-of-macedonia/>]. Accessed 14 November 2020.

[8] World Health Organization (WHO). 2019. "Joint External Evaluation Report of IHR Core Capacities of the Republic of North Macedonia." [<https://apps.who.int/iris/bitstream/handle/10665/325320/WHO-WHE-CPI-2019.59-eng.pdf?sequence=1>]. Accessed 14 November 2020.

1.5 DUAL-USE RESEARCH AND CULTURE OF RESPONSIBLE SCIENCE

1.5.1 Oversight of research with especially dangerous pathogens, toxins, pathogens with pandemic potential and/or other dual-use research

1.5.1a

Is there publicly available evidence that the country has conducted an assessment to determine whether ongoing research is occurring on especially dangerous pathogens, toxins, pathogens with pandemic potential and/or other dual-use research?

Yes = 1 , No = 0

Current Year Score: 0

There is no publicly available evidence that the country has conducted an assessment to determine whether ongoing research is occurring on dual-use research. A review of online sources including websites of the Sector for control and monitoring of communicable disease, and Department of monitoring and surveillance of communicable disease, both under the National Institute of Public Health of Republic of North Macedonia, as well as its publications, and the website of National Measures Relating to the Biological Weapons Convention (BWC) and Verification, Research, Training and Information Center (VERTIC) database have not provided evidence on the existence of such assessment [1, 2, 3, 4, 5]. Although North Macedonia is party to the BWC, it has not submitted Confidence Building Measures (CBMs) since 2010. Access to North Macedonia's CBM reports is restricted, they are not publicly available. [6] Furthermore, the Law on Export Control of Dual-Use Goods and Technologies, entered into force on October 2005 with its latest amendments from 2016, does not make provisions for assessing ongoing dual-use research in the country [7]. There is, however, an assessment of research and development activities in the Republic of North Macedonia, but it does not include dual-use research [8]. On the websites of the Ministry of Health, Ministry of Agriculture, Ministry of Science and Ministry of defense there is no additional information about publicly available evidence that the country has conducted an assessment to determine whether ongoing research is occurring on especially dangerous pathogens, toxins, pathogens with pandemic potential and/or other dual-use research. [9, 10, 11, 12]

[1] Institute of Public Health of Republic of North Macedonia. 2018. "Sector for control and monitoring of communicable disease." [http://www.iph.mk/en/sector-for-control-and-monitoring-of-communicable-diseases/]. Accessed August 28 2018.

[2] Institute of Public Health of Republic of North Macedonia. 2018. "Department of monitoring and surveillance of communicable disease." [http://www.iph.mk/en/sector-for-control-and-monitoring-of-communicable-diseases/department-for-monitoring-and-surveillance-of-communicable-diseases/]. Accessed 14 November 2020.

[3] Institute of Public Health of Republic of North Macedonia. 2018. "Publications." [http://www.iph.mk/en/multimedia/documents/publications/]. Accessed 14 November 2020.

[4] National Measures Relating to the Biological Weapons Convention. 2018. "The Former Yugoslav Republic of Macedonia." [https://www.unog.ch/80256EDD006B8954/%28httpAssets%29/7B39AB1C94A4FB12C12571B60051F0F7/%24FILE/compilation3.html#mac]. Accessed 14 November 2020.

[5] Verification Research, Training and Information Center (VERTIC). Legislative database. "North Macedonia." [https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/n/]. Accessed 14 November 2020.

[6] United Nations Office at Geneva (UNOG). "Confidence Building Measures - North Macedonia." [https://bwc-ecbm.unog.ch/state/north-macedonia]. Accessed 14 November 2020.

[7] Republic of North Macedonia. 2016. "Law On Export Control of Dual-Use Goods and Technologies (Official Gazette 82/2005, 84/07, 158/10, 136/11, 199/14, 192/15, 53/16)."

[http://www.economy.gov.mk/Upload/Editor_Upload/Precisten%20tekst%20na%20zakon%20za%20dual%20use%20.pdf]. Accessed 14 November 2020.

- [8] Nikolov, Elenior, M. Bogdanoski, R. Chontev, E. Stoichkova, and Z. Ivanovski. "R&D National Policy in the Republic of Macedonia according to the security related and generally R&D scene Current status and shortfalls." [http://eprints.ugd.edu.mk/6587/1/ugd.edu.mk_private_UserFiles_biljana.kosturanova_Desktop_Elenior%20Nikolov%20%20Trudovi%20za%20UGD%20Repozitorium_04National%20R%26D%20PolicySofija2009.pdf]. Accessed 14 November 2020.
- [9] Ministry of Health of Republic of North Macedonia. [http://zdravstvo.gov.mk/]. Accessed 14 November 2020.
- [10] Ministry of Agriculture, Forestry and Water Management of Republic of North Macedonia. [http://www.mzsv.gov.mk/]. Accessed 14 November 2020.
- [11] Ministry of Education and Science of Republic of North Macedonia. [http://mon.gov.mk/en/]. Accessed 14 November 2020.
- [12] Ministry of Defense of Republic of North Macedonia. [http://www.mod.gov.mk/?lang=en]. Accessed 14 November 2020.

1.5.1b

Is there legislation and/or regulation requiring oversight of research with especially dangerous pathogens, toxins, pathogens with pandemic potential and/or other dual-use research?

Yes = 1 , No = 0

Current Year Score: 0

There is no evidence of the existence of national policy requiring oversight of dual-use research. A review of online sources including websites of the Sector for control and monitoring of communicable disease, and Department of monitoring and surveillance of communicable disease, both under the National Institute of Public Health of Republic of North Macedonia, as well as its publications, the National Measures Relating to the Biological Weapons Convention and the Verification, Research, Training and Information Center (VERTIC) database do not provide evidence on a national policy requiring oversight of dual-use research [1, 2, 3, 4, 5]. Although North Macedonia is party to the Biological Weapons Convention (BWC), it has not submitted Confidence Building Measures (CBMs) since 2010. Access to North Macedonia's CBM reports is restricted, they are not publicly available. [6] Furthermore, the Law on Export Control of Dual-Use Goods and Technologies entered into force on October 2005, also does not make provisions for oversight of dual-use research [7]. On the websites of the Ministry of Health, Ministry of Agriculture, Ministry of Science and Ministry of defense there is no additional information about legislation and/or regulation requiring oversight of research with especially dangerous pathogens, toxins, pathogens with pandemic potential and/or other dual-use research. [8, 9, 10, 11]

- [1] Institute of Public Health of Republic of North Macedonia. 2018. "Sector for control and monitoring of communicable disease." [http://www.iph.mk/en/sector-for-control-and-monitoring-of-communicable-diseases/]. Accessed 14 November 2020.
- [2] Institute of Public Health of Republic of North Macedonia. 2018. "Department of monitoring and surveillance of communicable disease." [http://www.iph.mk/en/sector-for-control-and-monitoring-of-communicable-diseases/department-for-monitoring-and-surveillance-of-communicable-diseases/]. Accessed 14 November 2020.
- [3] Institute of Public Health of Republic of North Macedonia. 2018. "Publications." [http://www.iph.mk/en/multimedia/documents/publications/]. Accessed 14 November 2020. Accessed 14 November 2020.
- [4] National Measures Relating to the Biological Weapons Convention. 2018. "The Former Yugoslav Republic of Macedonia." [https://www.unog.ch/80256EDD006B8954/%28httpAssets%29/7B39AB1C94A4FB12C12571B60051F0F7/%24FILE/compilati on3.html#mac]. Accessed 14 November 2020.
- [5] Verification Research, Training and Information Center (VERTIC). Legislative database. "North Macedonia". [https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/n/]. Accessed 14 November 2020.
- [6] United Nations Office at Geneva (UNOG). "Confidence Building Measures - North Macedonia." [https://bwc-ecbm.unog.ch/state/north-macedonia]. Accessed 14 November 2020.

[7] Republic of North Macedonia. 2016. "Law On Export Control of Dual-Use Goods and Technologies (Official Gazette 82/2005, 84/07, 158/10, 136/11, 199/14, 192/15, 53/16)."

[http://www.economy.gov.mk/Upload/Editor_Upload/Precisten%20tekst%20na%20zakon%20za%20dual%20use%20.pdf]. Accessed 14 November 2020.

[8] Ministry of Health of Republic of North Macedonia. [<http://zdravstvo.gov.mk/>]. Accessed 14 November 2020.

[9] Ministry of Agriculture, Forestry and Water Management of Republic of North Macedonia. [<http://www.mzsv.gov.mk/>]. Accessed 14 November 2020.

[10] Ministry of Education and Science of Republic of North Macedonia. [<http://mon.gov.mk/en/>]. Accessed 14 November 2020.

[11] Ministry of Defense of Republic of North Macedonia. [<http://www.mod.gov.mk/?lang=en>]. Accessed 14 November 2020.

1.5.1c

Is there an agency responsible for oversight of research with especially dangerous pathogens, toxins, pathogens with pandemic potential and/or other dual-use research?

Yes = 1 , No = 0

Current Year Score: 0

There is no evidence that there is an agency responsible for oversight of research with especially dangerous pathogens, pathogens with pandemic potential, and/or other dual-use research. Although there is the Law on Export Control of Dual-Use Goods and Technologies, entered into force on October 2005, it does not make provisions for such agency [1]. The Institute of Public Health of Republic of North Macedonia, runs the laboratory for receipt of biological materials, preparation of maps and disposal of infectious waste [2], whereas the Ministry of Education and Science is responsible for organization, financing, developing and promotion of scientific research, technological development, technical culture, information technology and information systems as well as the international cooperation related to these issues [3], however there is no mentioning of a specific mandate on oversight of dual-use research. Although North Macedonia is party to the Biological Weapons Convention (BWC), it has not submitted Confidence Building Measures (CBMs) since 2010. Access to North Macedonia's CBM reports is restricted, they are not publicly available. [4] The Verification, Research, Training and Information Center (VERTIC) database does not have additional information about an agency responsible for oversight of research with especially dangerous pathogens, pathogens with pandemic potential, and/or other dual-use research [5]. On the websites of the Ministry of Health, Ministry of Agriculture, Ministry of Science and Ministry of defense there is no additional information about an agency responsible for oversight of research with especially dangerous pathogens, toxins, pathogens with pandemic potential and/or other dual-use research. [6, 7, 8, 9]

[1] Republic of North Macedonia. 2016. "Law On Export Control of Dual-Use Goods and Technologies (Official Gazette 82/2005, 84/07, 158/10, 136/11, 199/14, 192/15, 53/16)."

[http://www.economy.gov.mk/Upload/Editor_Upload/Precisten%20tekst%20na%20zakon%20za%20dual%20use%20.pdf]. Accessed 14 November 2020.

[2] Institute of Public Health of Republic of North Macedonia. 2018. "Laboratory for receipt of biological materials, preparation of maps and disposal of infectious waste." [<http://www.iph.mk/en/laboratory-for-receipt-of-biological-materials-preparation-of-maps-and-disposal-of-infectious-waste/>]. Accessed 14 November 2020.

[3] Nikolov, Elenior, M. Bogdanoski, R. Chontev, E. Stoichkova, and Z. Ivanovski. "R&D National Policy in the Republic of Macedonia according to the security related and generally R&D scene - Current status and shortfalls."

[http://eprints.ugd.edu.mk/6587/1/_ugd.edu.mk_private_UserFiles_biljana.kosturanova_Desktop_Elenior%20Nikolov%20%20Trudovi%20za%20UGD%20Repozitorium_04National%20R%26D%20PolicySofija2009.pdf]. Accessed 14 November 2020.

[4] United Nations Office at Geneva (UNOG). "Confidence Building Measures - North Macedonia." [<https://bwc-ecbm.unog.ch/state/north-macedonia>]. Accessed 14 November 2020. Accessed 14 November 2020.

- [5] Verification Research, Training and Information Center (VERTIC). Legislative database. "North Macedonia." [https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/n/]. Accessed 14 November 2020.
- [6] Ministry of Health of Republic of North Macedonia. [http://zdravstvo.gov.mk/]. Accessed 14 November 2020.
- [7] Ministry of Agriculture, Forestry and Water Management of Republic of North Macedonia. [http://www.mzsv.gov.mk/]. Accessed 14 November 2020.
- [8] Ministry of Education and Science of Republic of North Macedonia. [http://mon.gov.mk/en/]. Accessed 14 November 2020.
- [9] Ministry of Defense of Republic of North Macedonia. [http://www.mod.gov.mk/?lang=en]. Accessed 14 November 2020.

1.5.2 Screening guidance for providers of genetic material

1.5.2a

Is there legislation and/or regulation requiring the screening of synthesized DNA (deoxyribonucleic acid) against lists of known pathogens and toxins before it is sold?

Yes = 1 , No = 0

Current Year Score: 0

There is no evidence of national legislation, regulation, policy, or other guidance, requiring the screening of synthesized DNA against lists of known pathogens and toxins before it is sold. Evidence of such regulations is not found in the Ministry of Health website, National Institute of Public Health and Vertic database websites, or studies on genetics in North Macedonia [1, 2, 3, 4]. Although North Macedonia is party to the Biological Weapons Convention (BWC), it has not submitted Confidence Building Measures (CBMs) since 2010. Access to North Macedonia's CBM reports is restricted, they are not publicly available. [5] The focus of biosafety in the Republic of North Macedonia is on Genetically Modified Organisms (GMOs), as is its legislation [6]. There is, however, legislation on export control of dual-use goods and technologies as per Law on Export Control of Dual-Use Goods and Technologies, entered into force on October 2005 [7], and on protection of patients' rights as per Law on the Protection of Patient's Rights, entered into force in 2008 [8], but they do not make reference to screening of synthesized DNA before it is sold. The law on patient's rights states that the actions on human genome for other than preventive, diagnostic, and therapeutic purposes without proper genetic counselling are forbidden. On the websites of the Ministry of Health, Ministry of Agriculture, Ministry of Science and Ministry of Defense there is no additional information about legislation and/or regulation requiring the screening of synthesized DNA (deoxyribonucleic acid) against lists of known pathogens and toxins before it is sold. [9, 10, 11, 12]

- [1] Ministry of Health of Republic of North Macedonia. "Legislation." [http://zdravstvo.gov.mk/sq/ligjet/]. Accessed 14 November 2020.
- [2] Institute of Public Health of Republic of North Macedonia (IPH). [http://www.iph.mk/en/]. Accessed 14 November 2020.
- [3] Verification Research, Training and Information Center (VERTIC). Legislative database. "North Macedonia." [https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/n/]. Accessed 14 November 2020.
- [4] Sukarova, Elena and Aleksandar Petlichkovski. 2018. "Genetics in Macedonia-Following the International Trends." *Molecular Genetics & Genomic Medicine* 6. 1:9-14. [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5823678/]. Accessed 14 November 2020.
- [5] United Nations Office at Geneva (UNOG). "Confidence Building Measures - North Macedonia." [https://bwc-ecbm.unog.ch/state/north-macedonia]. Accessed 14 November 2020.
- [6] Republic of North Macedonia. 2015. "Law on Genetically Modified Organisms (Official Gazette 35/2008; 163/2013; 146/2015)." [http://aktivirajse.mk/law/zakon-za-genetski-modificirani-organ/]. Accessed 14 November 2020.

[7] Republic of North Macedonia. 2016. "Law on Export Control of Dual-Use Goods and Technologies (Official Gazette 82/2005, 84/07, 158/10, 136/11, 199/14, 192/15, 53/16)."

[http://www.economy.gov.mk/Upload/Editor_Upload/Precisten%20tekst%20na%20zakon%20za%20dual%20use%20.pdf]. Accessed 14 November 2020.

[8] Republic of North Macedonia. 2011. "Law on the Protection of Patients' Rights (Official Gazette 82/2008, 12/2009, 53/2011)." [<http://zdravstvo.gov.mk/wp-content/uploads/2012/12/zakon-za-zastita-na-pravata-na-pacientite-precisten.pdf>]. Accessed 14 November 2020.

[9] Ministry of Health of Republic of North Macedonia. [<http://zdravstvo.gov.mk/>]. Accessed 14 November 2020.

[10] Ministry of Agriculture, Forestry and Water Management of Republic of North Macedonia. [<http://www.mzsv.gov.mk/>]. Accessed 14 November 2020.

[11] Ministry of Education and Science of Republic of North Macedonia. [<http://mon.gov.mk/en/>]. Accessed 14 November 2020.

[12] Ministry of Defense of Republic of North Macedonia. [<http://www.mod.gov.mk/?lang=en>]. Accessed 14 November 2020.

1.6 IMMUNIZATION

1.6.1 Vaccination rates

1.6.1a

Immunization rate (measles/MCV2)

Immunization rate (measles/MCV2), 95% or greater = 2, 80-94.9% = 1, Less than 80%, or no data = 0

Current Year Score: 1

2019

World Health Organization

1.6.1b

Are official foot-and-mouth disease (FMD) vaccination figures for livestock publicly available through the OIE database?

Yes = 1, No = 0

Current Year Score: 1

2020

OIE WAHIS database

Category 2: Early detection and reporting for epidemics of potential international concern

2.1 LABORATORY SYSTEMS STRENGTH AND QUALITY

2.1.1 Laboratory testing for detection of priority diseases

2.1.1a

Does the national laboratory system have the capacity to conduct diagnostic tests for at least 5 of the 10 WHO-defined core tests?

Evidence they can conduct 5 of the 10 core tests and these tests are named = 2, Evidence they can conduct 5 of the 10 core tests and the tests are not named = 1, No evidence they can conduct 5 of the 10 core tests = 0

Current Year Score: 2

There is public evidence that the national laboratory system of the Republic of North Macedonia has capacity in diagnostic testing of 5 out of 10 World Health Organization (WHO)-defined core tests. According to the 2019 WHO Joint External Evaluation Report of the Republic of North Macedonia, five out of 10 core tests are performed: polymerase chain reaction (PCR) for influenza, serology for human immunodeficiency virus (HIV), microscopy for *M. tuberculosis*, bacterial culture for *Salmonella enterica* serovar Typhi (Typhoid), and rapid testing for *Plasmodium* spp (malaria). Testing for polio culture is not performed in North Macedonia, the WHO has declared North Macedonia a polio-free country and assigned a reference laboratory in Bulgaria to test any suspected polio specimens from North Macedonia. The final four core tests are still not defined. The laboratory system is able to cover a comprehensive range of 52 out of 56 notifiable diseases, in accordance with the Law on Protection of the Population against Communicable Diseases. [1]. The polymerase chain reaction (PCR) testing for Influenza virus; serology for HIV are conducted at the laboratory of virology at the Institute of Public Health (IPH) of Republic of North Macedonia. The microscopy for mycobacterium tuberculosis is conducted at the Institute of Lung Disease and Tuberculosis (ILDIT). The serological identification of bacteria of the genus *Salmonella* is conducted at the laboratory of microbiology at IPH, while *Salmonella* spp typing is conducted at the Food Institute of the Faculty of Veterinary Medicine [2]. There is no evidence provided on the country-defined tests on the Institute of Public Health (IPH) of Republic of Macedonia's website [3].

[1] World Health Organization (WHO). 2019. "Joint External Evaluation Report of IHR Core Capacities of the Republic of North Macedonia." [<https://apps.who.int/iris/bitstream/handle/10665/325320/WHO-WHE-CPI-2019.59-eng.pdf?sequence=1>]. Accessed 14 November 2020.

[2] National Institute for Public Health and Environment (RIVM) of the Netherlands. 2014. "Eighteenth EURL-Salmonella interlaboratory comparison study (2013) on typing of *Salmonella* spp.." [<https://www.rivm.nl/bibliotheek/rapporten/2014-0009.pdf>]. Accessed 14 November 2020.

[3] Institute of Public Health (IPH) of Republic of North Macedonia. [<http://iph.mk/en/>]. Accessed 14 November 2020.

2.1.1b

Is there a national plan, strategy or similar document for conducting testing during a public health emergency, which includes considerations for testing for novel pathogens, scaling capacity, and defining goals for testing?

Yes, there is evidence of a plan, and it includes considerations for testing for novel pathogens, scaling capacity, and defining goals for testing = 2, Yes, there is evidence of a plan, but there is insufficient evidence that it includes considerations for testing for novel pathogens, scaling capacity, and defining goals for testing = 1, No evidence of a plan = 0

Current Year Score: 0

There is no evidence that North Macedonia has a national plan, strategy or similar document for conducting testing during a public health emergency, which includes considerations for testing for novel pathogens, scaling capacity, and defining goals for testing. Websites of the Ministries of Health, Agriculture, Defense and Institute for Public Health do not reference such a national plan, strategy or similar document. [1, 2, 3, 4] In addition, the Law on Protecting the Population from Contagious Disease, Law on the Protection of Patients' Rights, Preparation and response plan on the healthcare system when dealing with emergency, crisis condition and disasters and the 2019 World Health Organization (WHO) Joint External Evaluation Report of the Republic of North Macedonia make no reference to a such a document. [5, 6, 7, 8].

[1] Ministry of Health of Republic of North Macedonia. "Legislation." [<http://zdravstvo.gov.mk/sq/ligjet/>]. Accessed 14 November 2020.

[2] Ministry of Defense of Republic of North Macedonia. [<http://www.mod.gov.mk/?lang=en>]. Accessed 14 November 2020.

[3] Ministry of Agriculture, Forestry and Water Economy of Republic of North Macedonia. [<http://www.mzsv.gov.mk/>]. Accessed 14 November 2020.

[4] Institute of Public Health of Republic of North Macedonia (IPH). [<http://www.iph.mk/en/>]. Accessed 14 November 2020.

[5] Republic of North Macedonia. 2016. "Law on Protecting the Population from Contagious Disease (Official Gazette 66/04, 139/08, 99/09, 149/14, 150/15, 37/16)." [<http://zdravstvo.gov.mk/wp-content/uploads/2018/01/ZAKON-ZA-ZASHTITA-NA-NASELENIETO-OD-ZARAZNI-BOLESTI-zakluchno-so-br.-37-od-2016.pdf>]. Accessed 14 November 2020.

[6] Republic of North Macedonia. 2011. "Law on the Protection of Patients' Rights (Official Gazette 82/2008, 12/2009, 53/2011)." [<http://zdravstvo.gov.mk/wp-content/uploads/2012/12/zakon-za-zastita-na-pravata-na-pacientite-precisten.pdf>]. Accessed 14 November 2020.

[7] Republic of North Macedonia. Ministry of Health. 2017. "Preparation and response plan on the healthcare system when dealing with emergency, crisis condition and disasters." [<http://iph.mk/wp-content/uploads/2017/08/Plan-za-podgotvenost-i-odgovor-pri-krizni-sostojbi-i-katastrofi.pdf>]. Accessed 14 November 2020.

[8] World Health Organization (WHO). 2019. "Joint External Evaluation Report of IHR Core Capacities of the Republic of North Macedonia." [<https://apps.who.int/iris/bitstream/handle/10665/325320/WHO-WHE-CPI-2019.59-eng.pdf?sequence=1>]. Accessed 14 November 2020.

2.1.2 Laboratory quality systems

2.1.2a

Is there a national laboratory that serves as a reference facility which is accredited (e.g., International Organization for Standardization [ISO] 15189:2003, U.S. Clinical Laboratory Improvement Amendments [CLIA])?

Yes = 1 , No = 0

Current Year Score: 1

There is evidence that the national reference laboratory is accredited both by the WHO and by the Institute for Accreditation of the Republic of North Macedonia. The Center of Reference Laboratories (CRL), which is an organizational technical department that unites all laboratories in the Institute of Public Health of Republic of North Macedonia is accredited by the Institute for Accreditation of the Republic of North Macedonia [1]. The Laboratory of virology and molecular diagnostics, which is one of the laboratories of the CRL, is the only one of its kind in North Macedonia, established for monitoring, investigation and laboratory diagnosis of viral diseases. [2] Since 2005 the laboratory has been accredited by the WHO National Laboratory for Measles and Rubella in North Macedonia. [3] According to the 2019 World Health Organization (WHO) Joint External Evaluation Report of the Republic of North Macedonia, there are currently two national systems for laboratory accreditation. The first is offered by the Institute for Accreditation, from which laboratories can request and pay

for accreditation. The health insurance scheme reimburses costs for laboratory services from accredited laboratories. Very few laboratories have taken up this option due to the expense. The other option is offered by the Agency for Accreditation and has just been introduced as part of an overall program to accredit all institutions in the health sector. [4]

[1] Institute of Public Health (IPH) Republic of North Macedonia. "Center of Reference Laboratories."

[<http://www.iph.mk/en/center-for-reference-laboratories/>]. Accessed 14 November 2020.

[2] Institute for Accreditation of the Republic of North Macedonia. "Testing Laboratories."

[http://www.iarm.gov.mk/index.php?option=com_content&view=article&id=160&Itemid=122&lang=en]. Accessed 14 November 2020.

[3] Institute of Public Health (IPH) of Republic of North Macedonia. "Laboratory of virology and molecular diagnostics."

[www.iph.mk/en/laboratory-of-virology-and-molecular-diagnostics/]. Accessed 14 November 2020.

[4] World Health Organization (WHO). 2019. "Joint External Evaluation Report of IHR Core Capacities of the Republic of North Macedonia." [<https://apps.who.int/iris/bitstream/handle/10665/325320/WHO-WHE-CPI-2019.59-eng.pdf?sequence=1>]. Accessed 14 November 2020.

2.1.2b

Is there a national laboratory that serves as a reference facility which is subject to external quality assurance review?

Yes = 1 , No = 0

Current Year Score: 1

The national reference laboratory in the country is subject to external quality assurance review. The Center of Reference Laboratories (CRL), which is an organizational technical department that unites all laboratories in the Institute of Public Health of Republic of North Macedonia is accredited by the Institute for Accreditation of the Republic of Macedonia [1]. The Laboratory of virology and molecular diagnostics, which is one of the laboratories of the Center of Reference Laboratories, has been accredited as the National Laboratory for Measles and Rubella in North Macedonia by the World Health Organization (WHO) since 2005. It is also included in the WHO External quality assessment for detection of influenza viruses since 2006 [2].

[1] Institute for Accreditation of the Republic of North Macedonia. "Testing Laboratories."

[http://www.iarm.gov.mk/index.php?option=com_content&view=article&id=160&Itemid=122&lang=en]. Accessed 14 November 2020.

[2] Institute of Public Health (IPH) Republic of North Macedonia. "Laboratory of virology and molecular diagnostics."

[<http://www.iph.mk/en/laboratory-of-virology-and-molecular-diagnostics/>]. Accessed 14 November 2020.

2.2 LABORATORY SUPPLY CHAINS

2.2.1 Specimen referral and transport system

2.2.1a

Is there a nationwide specimen transport system?

Yes = 1 , No = 0

Current Year Score: 0

In the Republic of North Macedonia there is no nationwide specimen transport system. According to the 2019 World Health Organization (WHO) Joint External Evaluation Report of the Republic of North Macedonia a transportation system is in place

for specimens that are sent to laboratories in Skopje for primary or confirmatory diagnostic testing. The transportation of specimens by rail and road is supported by law. Air transport is not yet covered. However, specimen referral and transport system is scored with grade 3, which means that coverage of the country is less than 80%. [1] On the websites of the Ministry of Health and Institute for Public Health there are no information about a nationwide specimen transport system. [2, 3, 4, 5, 6, 7]

[1] World Health Organization (WHO). 2019. "Joint External Evaluation Report of IHR Core Capacities of the Republic of North Macedonia." [https://apps.who.int/iris/bitstream/handle/10665/325320/WHO-WHE-CPI-2019.59-eng.pdf?sequence=1]. Accessed 14 November 2020.

[2] Institute of Public Health (IPH) of Republic of Macedonia. "Laboratory for receipt of biological materials, preparation of maps and disposal of infectious waste." [http://www.iph.mk/laboratorija-za-priem-na-bioloski-materijali-podgotovka-na-podlogi-i-dispozicija-na-infektiven-otpad/]. Accessed 14 November 2020.

[3] Institute of Public Health (IPH) of Republic of Macedonia. "Center for Reference Laboratories." [http://www.iph.mk/en/center-for-reference-laboratories/]. Accessed 14 November 2020.

[4] Institute of Public Health (IPH) of Republic of Macedonia. "Virology." [http://www.iph.mk/en/laboratory/virology/]. Accessed 14 November 2020.

[5] Institute of Public Health (IPH) of Republic of Macedonia. "Microbiology." [http://www.iph.mk/en/laboratory/microbiology/]. Accessed 14 November 2020.

[6] Institute of Public Health (IPH) of Republic of Macedonia. "Parasitology." [http://www.iph.mk/en/laboratory/parasitology/]. Accessed 14 November 2020.

[7] Ministry of Health of Republic of Macedonia. [http://www.moh.gov.mk/]. Accessed 14 November 2020.

2.2.2 Laboratory cooperation and coordination

2.2.2a

Is there a plan in place to rapidly authorize or license laboratories to supplement the capacity of the national public health laboratory system to scale-up testing during an outbreak?

Yes = 2 , Yes, but there is evidence of gaps in implementation = 1 , No = 0

Current Year Score: 0

North Macedonia does not have a plan in place to rapidly authorize or license laboratories to supplement the capacity of the national public health laboratory system to scale-up testing during an outbreak. The Law on Protecting the Population from Contagious Disease, Law on the Protection of Patients' Rights, Preparation and response plan on the healthcare system when dealing with emergency, crisis condition and disasters and the 2019 World Health Organization (WHO) Joint External Evaluation Report of the Republic of North Macedonia do not have information about a plan to rapidly authorize or license laboratories to supplement the capacity of the national public health laboratory system to scale-up testing during an outbreak. [1, 2, 3, 4] Websites of the Ministries of Health, Agriculture, Defense and Institute for Public Health do not have a reference to a plan in place to rapidly authorize or license laboratories to supplement the capacity of the national public health laboratory system to scale-up testing during an outbreak. [5, 6, 7, 8]

[1] Republic of North Macedonia. 2016. "Law on Protecting the Population from Contagious Disease (Official Gazette 66/04, 139/08, 99/09, 149/14, 150/15, 37/16)." [http://zdravstvo.gov.mk/wp-content/uploads/2018/01/ZAKON-ZA-ZASHTITA-NA-NASELENIETO-OD-ZARAZNI-BOLESTI-zakluchno-so-br.-37-od-2016.pdf]. Accessed 14 November 2020.

[2] Republic of North Macedonia. 2011. "Law on the Protection of Patients' Rights (Official Gazette 82/2008, 12/2009, 53/2011)." [http://zdravstvo.gov.mk/wp-content/uploads/2012/12/zakon-za-zastita-na-pravata-na-pacientite-precisten.pdf]. Accessed 14 November 2020.

[3] Republic of North Macedonia. Ministry of Health. 2017. "Preparation and response plan on the healthcare system when dealing with emergency, crisis condition and disasters." [<http://iph.mk/wp-content/uploads/2017/08/Plan-za-podgotvenost-i-odgovor-pri-krizni-sostojbi-i-katastrofi.pdf>]. Accessed 14 November 2020.

[4] World Health Organization (WHO). 2019. "Joint External Evaluation Report of IHR Core Capacities of the Republic of North Macedonia." [<https://apps.who.int/iris/bitstream/handle/10665/325320/WHO-WHE-CPI-2019.59-eng.pdf?sequence=1>]. Accessed 14 November 2020.

[5] Ministry of Health of Republic of North Macedonia. "Legislation." [<http://zdravstvo.gov.mk/sq/ligjet/>]. Accessed 14 November 2020.

[6] Ministry of Defense of Republic of North Macedonia. [<http://www.mod.gov.mk/?lang=en>]. Accessed 14 November 2020.

[7] Ministry of Agriculture, Forestry and Water Economy of Republic of North Macedonia. [<http://www.mzsv.gov.mk/>]. Accessed 14 November 2020.

[8] Institute of Public Health of Republic of North Macedonia (IPH). [<http://www.iph.mk/en/>]. Accessed 14 November 2020.

2.3 REAL-TIME SURVEILLANCE AND REPORTING

2.3.1 Indicator and event-based surveillance and reporting systems

2.3.1a

Is there evidence that the country is conducting ongoing event-based surveillance and analysis for infectious disease?

Yes, there is evidence of ongoing event-based surveillance and evidence that the data is being analyzed on a daily basis = 2,
Yes, there is evidence of ongoing event-based surveillance, but no evidence that the data are being analyzed on a daily basis = 1, No = 0

Current Year Score: 1

North Macedonia is conducting ongoing event-based surveillance and analysis for infectious disease. In North Macedonia, public health surveillance is strongly regulated by specific, comprehensive legislation. The competent institutions have been established according to legal acts, with cofunding from the national budget through priority national health programs and the national health insurance fund. The system of communicable disease prevention and control is based on an established network of 10 regional centers of public health. Both indicator-based and event-based surveillance have been in place for several years. Event-based surveillance is done by reviewing notification reports and information collected from other sources, on a daily basis, at local, regional and national levels. A weekly teleconference of regional epidemiologists has been recently introduced. [1]. However, based on the analysis of the Ministry of Health and Institute for Public Health websites it cannot be concluded that the data are being analyzed on a daily basis. [2, 3].

[1] World Health Organization (WHO). 2019. "Joint External Evaluation Report of IHR Core Capacities of the Republic of North Macedonia." [<https://apps.who.int/iris/bitstream/handle/10665/325320/WHO-WHE-CPI-2019.59-eng.pdf?sequence=1>]. Accessed 14 November 2020.

[2] Ministry of Health of Republic of North Macedonia. "Legislation." [<http://zdravstvo.gov.mk/sq/ligjet/>]. Accessed 14 November 2020.

[3] Institute of Public Health of Republic of North Macedonia (IPH). [<http://www.iph.mk/en/>]. Accessed 14 November 2020.

2.3.1b

Is there publicly available evidence that the country reported a potential public health emergency of international concern (PHEIC) to the WHO within the last two years?

Yes = 1, No = 0

Current Year Score: 0

There is no publicly available evidence that North Macedonia has reported a potential public health emergency of international concern (PHEIC) to the WHO within the last two years. On 30th January 2020 the WHO Director-General declared the novel coronavirus outbreak a public health emergency of international concern (PHEIC), WHO's highest level of alarm. [1] In February 2020 North Macedonia reported the first case of Covid-19. [2, 3]

[1] World Health Organization (WHO). Timeline: WHO's Covid-19 response.

[<https://www.who.int/emergencies/diseases/novel-coronavirus-2019/interactive-timeline/>] Accessed 23 July 2020

[2] World Health Organization (WHO). Health Emergency Dashboard. North Macedonia.

[<https://extranet.who.int/publicemergency>] Accessed 14 November 2020.

[3] Ministry of Health of Republic of North Macedonia. COVID/19. [<http://zdravstvo.gov.mk/korona-virus/>]. Accessed 14 November 2020.

2.3.2 Interoperable, interconnected, electronic real-time reporting systems

2.3.2a

Does the government operate an electronic reporting surveillance system at both the national and the sub-national level?

Yes = 1 , No = 0

Current Year Score: 1

The government of the Republic of North Macedonia operates an electronic reporting surveillance system at the national and sub-national level. The Institute of Public Health of Republic of North Macedonia conducts regular surveillance of communicable disease through the Department for Monitoring and Surveillance of Communicable Disease through collecting, analyzing and processing data on communicable disease [1]. The early warning system ALERT serves as the electronic reporting surveillance system at the national and sub-national level for epidemics detection and response. It includes all the primary health care institutions in the country. In May 2003, the World Health Organization (WHO) supported the health authorities of the Republic of North Macedonia in laying out a plan of action for the implementation of an electronic early warning system [2]. The early warning system ALERT relies on reporting of eight syndromes by primary care facilities. Data are analyzed weekly at the regional level and transmitted to national epidemiologists. Reporting units all are comprised of primary care physicians, and there are ten regional surveillance units, which include the regional Public Health Institutions and their epidemiological departments. At the regional level, data are computerized and electronically transmitted to the National Public Health Institute through ALERT [3]. According to the 2019 WHO Joint External Evaluation Report of the Republic of North Macedonia syndromic data are reported to the electronic ALERT system weekly and published along with analyses of trends. [4]

[1] Institute of Public Health of Republic of Macedonia. "Department for monitoring and surveillance of communicable disease." [<http://iph.mk/en/sector-for-control-and-monitoring-of-communicable-diseases/department-for-monitoring-and-surveillance-of-communicable-diseases/>]. Accessed 14 November 2020.

[2] World Health Organization (WHO). "Early warning system."

[<http://www.who.int/csr/labepidemiology/projects/earlywarnsystem/en/>]. Accessed 14 November 2020.

[3] Stikova, Elisaveta, Dragan Gjorgjev, and Zarko Karadzovski. 2010. "Strengthening the Early-Warning Function of the Surveillance System: The Macedonian Experience". *Emerging and Endemic Pathogens*: 45-58. [https://link.springer.com/chapter/10.1007%2F978-90-481-9637-1_6]. Accessed 14 November 2020.

[4] World Health Organization (WHO). 2019. "Joint External Evaluation Report of IHR Core Capacities of the Republic of North Macedonia." [<https://apps.who.int/iris/bitstream/handle/10665/325320/WHO-WHE-CPI-2019.59-eng.pdf?sequence=1>].

Accessed 14 November 2020.

2.3.2b

Does the electronic reporting surveillance system collect ongoing or real-time laboratory data?

Yes = 1, No = 0

Current Year Score: 0

The early warning system ALERT, which is North Macedonia's electronic reporting surveillance system at the national and sub-national level, does not collect real-time data. The Institute of Public Health of Republic of North Macedonia conducts regular surveillance of communicable disease through the Department for Monitoring and Surveillance of Communicable Disease through collecting, analyzing and processing data on communicable disease [1]. The reporting process includes a written, standardized reporting form through which primary care physicians report weekly the aggregated number of new cases to the corresponding collecting units at the municipality level, or directly to the local and regional surveillance units [2]. They send aggregated data by mail or fax. Data are then analyzed weekly at the regional level and transmitted to national epidemiologists. At the regional level, the data is computerized and electronically transmitted to the National Public Health Institute through ALERT. According to the 2019 World Health Organization (WHO) Joint External Evaluation (JEE) Report of the Republic of North Macedonia syndromic data are reported to the electronic ALERT system weekly and published along with analyses of trends. The JEE report does not have a reference to collection of real-time data. [4]

[1] Institute of Public Health of Republic of Macedonia (IPH). "Department for monitoring and surveillance of communicable disease." [<http://iph.mk/en/sector-for-control-and-monitoring-of-communicable-diseases/department-for-monitoring-and-surveillance-of-communicable-diseases/>]. Accessed 14 November 2020.

[2] Stikova, Elisaveta, Dragan Gjorgjev, and Zarko Karadzovski. 2010. "Strengthening the Early-Warning Function of the Surveillance System: The Macedonian Experience". *Emerging and Endemic Pathogens*: 45-58. [https://link.springer.com/chapter/10.1007%2F978-90-481-9637-1_6]. Accessed 14 November 2020.

[3] World Health Organization (WHO). 2019. "Joint External Evaluation Report of IHR Core Capacities of the Republic of North Macedonia." [<https://apps.who.int/iris/bitstream/handle/10665/325320/WHO-WHE-CPI-2019.59-eng.pdf?sequence=1>]. Accessed 14 November 2020.

2.4 SURVEILLANCE DATA ACCESSIBILITY AND TRANSPARENCY

2.4.1 Coverage and use of electronic health records

2.4.1a

Are electronic health records commonly in use?

Electronic health records are commonly in use = 2, Electronic health records are not commonly in use, but there is evidence they are used = 1, No evidence electronic health records are in use = 0

Current Year Score: 2

Electronic health records are commonly in use in the Republic of North Macedonia. The country implemented the Integrated Health Information System in 2013 [1]. A unified coding system and the Diagnostic Related Groups in hospital care were first implemented in 2009 followed by the electronic health records, and the electronic health card in 2013. The electronic health records allow access to a live dashboard to see referrals, prescriptions and requests in real time. Until June 2014, 1.5 million electronic health cards were issued, covering 80% of insured persons. [2] The system has rapidly expanded from a pilot

project to become a key part of public and private health care in the Republic of North Macedonia.

[1] European Observatory on Health Systems and Policies. 2017. "The Former Yugoslav Republic of Macedonia Health System Review". Health Systems in Transition 19. 3. [http://www.euro.who.int/__data/assets/pdf_file/0006/338955/Macedonia-HiT-web.pdf]. Accessed 14 November 2020.

[2] World Health Organization (WHO). "The Former Yugoslav Republic of Macedonia E-health in practice." [<http://www.euro.who.int/en/countries/the-former-yugoslav-republic-of-macedonia/news/news/2016/03/e-health-in-practice>]. Accessed 14 November 2020.

2.4.1b

Does the national public health system have access to electronic health records of individuals in their country?

Yes = 1 , No = 0

Current Year Score: 1

The national public health system has access to electronic health records of individuals in the country. The country has put in place an Integrated Health Information system, as part of an integrated health care information system with unified coding systems and electronic health records and cards that includes various institutions such as the Ministry of Health, Health Insurance Fund of North Macedonia, Centers for Public Health, public hospitals, general practitioners, insured people, pharmacies. Both the Health Insurance Fund of North Macedonia and the Directorate of e-Health under the Ministry of Health can access to health records to improve functionality of the electronic system. [1] A unified coding system and the Diagnosis-related Groups (a standardized system of patient classification) in hospital care were first implemented in 2009 followed by the electronic health records and the electronic health card in 2013 . In order to protect personal data, the platform is operated through a level-privilege access to medical records. [2]

[1] Gavrilov, Goce, and Danco Davcev. 2011. "Concept of Healthcare Information System in Macedonia-Electronic Health Card System". ICT Innovations. [<http://proceedings.ictinnovations.org/attachment/paper/222/concept-of-healthcare-information-system-in-macedonia---electronic-health-card-system.pdf>]. Accessed 14 November 2020.

[2] European Observatory on Health Systems and Policies. 2017. "The Former Yugoslav Republic of Macedonia Health System Review". Health Systems in Transition 19. 3. [http://www.euro.who.int/__data/assets/pdf_file/0006/338955/Macedonia-HiT-web.pdf]. Accessed 14 November 2020.

2.4.1c

Are there data standards to ensure data is comparable (e.g., ISO standards)?

Yes = 1 , No = 0

Current Year Score: 1

There are data standards to ensure data is comparable. The Integrated Health Information System uses unified coding systems and electronic health records and cards. A unified coding system was implemented in 2009 [1]. Furthermore, the system architecture has been formalized through the European standard, defined by the European Committee for Standardization and Technical Committee 251 (CEN/TC251), which is responsible for medical informatics, and ENV 12967-1 (a standard set by CEN on Healthcare Information Systems Architecture enabling all parts of the local and geographical system to operate on a common information heritage of the organization). Other standards pertaining to different parts of the system include ICD-10 for International Statistical Classification of Diseases, HL7 Health Level 7 for Electronic Health Records-System Functional Model [2].

[1] European Observatory on Health Systems and Policies. 2017. "The Former Yugoslav Republic of Macedonia Health System Review". Health Systems in Transition 19. 3. [http://www.euro.who.int/__data/assets/pdf_file/0006/338955/Macedonia-HiT-web.pdf]. Accessed 14 November 2020.

[2] Gavrilov, Goce, and Danco Davcev. 2011. "Concept of Healthcare Information System in Macedonia-Electronic Health Card System". ICT Innovations. [<http://proceedings.ictinnovations.org/attachment/paper/222/concept-of-healthcare-information-system-in-macedonia---electronic-health-card-system.pdf>]. Accessed 14 November 2020.

2.4.2 Data integration between human, animal, and environmental health sectors

2.4.2a

Is there evidence of established mechanisms at the relevant ministries responsible for animal, human, and wildlife surveillance to share data (e.g., through mosquito surveillance, brucellosis surveillance)?

Yes = 1 , No = 0

Current Year Score: 0

There is no evidence of established mechanisms at the agencies responsible for animal and human surveillance to share data. There is evidence of collaboration between the agencies, but not of a specific mechanisms for data sharing. [1]The department for monitoring and surveillance of communicable diseases at the Institute of Public Health (IPH) of Republic of Macedonia is responsible for monitoring and controlling communicable diseases by collecting, analyzing and processing data on infectious diseases. It also monitors the situation of brucellosis in the country and coordinates activities of control and regulatory measures for prevention activities with the Food and Veterinary Agency, which is responsible for animal health. The Department for monitoring and surveillance of communicable diseases prepares the draft annual program on public health, brucellosis and immunization and submits it to the Ministry of Health. There is no evidence of such mechanisms on the websites of the Ministry of Health and the Food and Veterinary Agency. [2, 3] According to the 2019 World Health Organization (WHO) Joint External Evaluation Report of the Republic of North Macedonia, the surveillance system, which is basically comprehensive and which is intended to be sensitive, does not therefore efficiently support monitoring of most disease. Even though there is no formal cooperation between the human and animal sectors, informal collaboration works well on a day-to-day basis. In the case of a suspected outbreak, a multidisciplinary team is established. [4]

[1] Institute of Public Health of Republic of North Macedonia. "Department for monitoring and surveillance of communicable diseases." [<http://www.iph.mk/en/sector-for-control-and-monitoring-of-communicable-diseases/department-for-monitoring-and-surveillance-of-communicable-diseases/>]. 14 November 2020.

[2] Ministry of Health of Republic of North Macedonia. [<http://zdravstvo.gov.mk/>]. Accessed 14 November 2020.

[3] Food and Veterinary Agency (FVA). [<http://www.fva.gov.mk/index.php?lang=mk>]. Accessed 14 November 2020.

[4] World Health Organization (WHO). 2019. "Joint External Evaluation Report of IHR Core Capacities of the Republic of North Macedonia." [<https://apps.who.int/iris/bitstream/handle/10665/325320/WHO-WHE-CPI-2019.59-eng.pdf?sequence=1>]. Accessed 14 November 2020.

2.4.3 Transparency of surveillance data

2.4.3a

Does the country make de-identified health surveillance data on infectious diseases publicly available via reports (or other format) on government websites (such as the Ministry of Health, Ministry of Agriculture, or similar)?

Yes = 1 , No = 0

Current Year Score: 1

North Macedonia makes de-identified health surveillance data on disease outbreaks publicly available via reports of the Institute of Public Health (IPH) of Republic of North Macedonia. IPH publishes diseases reports on communicable diseases outbreaks including influenza, and measles, and information reports on hemorrhagic fever, Zika (providing information on the symptoms of the diseases and the countries and territories with the outbreaks), as well as noncommunicable diseases reports [1]. The influenza reports are published weekly on the institutes' web site. They include information on the number of cases, comparisons with the previous week and previous season, distribution of influenza cases by week and the distribution of the typical epidemic curve of the season, distribution of patients by age-group, regions of registered influenza, and number of sample materials received for laboratory diagnostics. There are regular reports on the situation of measles for 2018/2019 season, on the situation of influenza for 2018/2019/2020 season etc. They include number of identified cases, types of symptoms, number of patient hospitalizations, vaccine effectiveness, residency of affected people.

[1] Institute of Public Health (IPH) of Republic of Macedonia. "Diseases Reports." [http://www.iph.mk/en/multimedia/diseases-reports/]. Accessed 14 November 2020.

2.4.3b

Does the country make de-identified COVID-19 surveillance data (including details such as daily case count, mortality rate, etc) available via daily reports (or other formats) on government websites (such as the Ministry of Health, or similar)?

Yes = 1 , No = 0

Current Year Score: 1

North Macedonia makes de-identified health surveillance data on Covid-19 publicly available via daily reports (or other format) published on the website of the Ministry of Health. These reports provide the latest information related to Covid-19, such as number of tested people, number of confirmed cases in last 24 hours, deaths in last 24 hours, number of hospitalized patients on ventilator, etc. [1]

[1] Ministry of Health of Republic of North Macedonia. COVID/19. [http://zdravstvo.gov.mk/korona-virus/]. Accessed 14 November 2020.

2.4.4 Ethical considerations during surveillance

2.4.4a

Is there legislation and/or regulations that safeguard the confidentiality of identifiable health information for individuals, such as that generated through health surveillance activities?

Yes = 1 , No = 0

Current Year Score: 1

The Republic of North Macedonia has legislation in place that safeguard the confidentiality of identifiable health information for individuals, such as that generated through health surveillance activities. Law on Personal Data Protection of 2011, with its latest amendments from 2018, under Article 2 classifies personal data revealing health conditions or sexual habits as Special category of personal data . The law does not specify any particular health conditions. Article 8 prohibits processing of personal data that fall under the "Special category of personal data". Exceptions are only made when it is needed for the purposes of medical prevention, diagnosis, treatment or management with a public health institution and is carried out by a person whose profession is to provide medical protection under oath of secrecy to the data revealed to him/her during the

performance of his/her profession. The processing of special personal data categories should be specially marked and protected [1].

[1] Republic of North Macedonia. 2018. "Law on Personal Data Protection (Official Gazette 7/2005, 103/2008, 124/2008, 124/2010, 135/2011, 43/2014, 153/2015, 99/2016, 64/2018)."

[https://dzlp.mk/sites/default/files/u4/zakon_za_zashtita_na_lichnite_podatoci.pdf]. Accessed 14 November 2020.

2.4.4b

Is there legislation and/or regulations safeguarding the confidentiality of identifiable health information for individuals, such as that generated through health surveillance activities, include mention of protections from cyber attacks (e.g., ransomware)?

Yes = 1, No = 0

Current Year Score: 1

Legislation safeguarding the confidentiality of identifiable health information for individuals, such as that generated through health surveillance activities, include mention of protections from cyber attacks in the Republic of North Macedonia. The legal framework represented by Law on Personal Data Protection of 2011, with its latest amendments from 2018, regulates the protection of personal data as fundamental freedoms and rights of the citizens, and especially the rights to privacy as related to the processing of personal data. Article 8 of the law provisions that the "Special categories of personal data", which among others includes personal data revealing health conditions and sexual habits, may be transmitted through a telecommunication network only if they are specially protected by cryptographic methods, in a way in which they are not readable when transmitted [1]. The law does not specify particular health conditions.

[1] Republic of North Macedonia. 2018. "Law on Personal Data Protection (Official Gazette 7/2005, 103/2008, 124/2008, 124/2010, 135/2011, 43/2014, 153/2015, 99/2016 ? 64/2018)."

[https://dzlp.mk/sites/default/files/u4/zakon_za_zashtita_na_lichnite_podatoci.pdf]. Accessed 14 November 2020.

2.4.5 International data sharing

2.4.5a

Has the government made a commitment via public statements, legislation and/or a cooperative agreement to share surveillance data during a public health emergency with other countries in the region?

Yes, commitments have been made to share data for more than one disease = 2, Yes, commitments have been made to share data only for one disease = 1, No = 0

Current Year Score: 0

The Government of Montenegro has not made a commitment via public statements, legislation and/or a cooperative agreement to share surveillance data during a public health emergency with other countries in the region for one or more diseases. However, the Republic of North Macedonia is a member of the Southeastern European Health Network (SEEHN) established in 2001 as a cooperative effort among the governments of Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Moldova, Montenegro, Romania and Serbia. In 2002, SEEHN initiated a communicable diseases project aimed at strengthening both national and regional surveillance systems with a focus on cross-border collaboration and sharing of surveillance data. As part of its Communicable Diseases Surveillance Network Strategic Plan, the network aims to develop and deepen regional cooperation, with a focus on common cross-border technical capacity required to deal with potential outbreaks and ensuring proper implementation of the 2005 International Health Regulations. The network also collaborates

on Laboratory Capacity and Information Exchange, where a regional influenza diagnostic center was opened at the Cantacuzino Institute, Romania [1]. Furthermore, the network's Skopje Pledge includes strengthening regional collaboration and coordination preparedness planning for emerging priorities and to put this forward as a priority for action within the Southeastern European Health Network [2]. There is no further evidence provided on the websites of the Ministry of Health, and the Institute of Public Health. [3, 4]

[1] Bino, Silvia, et. al. 2013. "Southeastern European Health Network (SEEHN) Communicable Diseases Surveillance: A Decade of Bridging Trust and Collaboration." *Emerging Health Threats Journal* 6.

[<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3557907/>]. Accessed 14 November 2020.

[2] World Health Organization (WHO). November 2005. "The Skopje Pledge."

[http://www.euro.who.int/__data/assets/pdf_file/0005/99743/E88513.pdf?ua=1]. Accessed 14 November 2020.

[3] Ministry of Health of Republic of North Macedonia. [<http://zdravstvo.gov.mk/>]. Accessed 14 November 2020.

[4] Institute of Public Health (IPH) of Republic of North Macedonia. [<http://www.iph.mk/en/>]. Accessed 14 November 2020.

2.5 CASE-BASED INVESTIGATION

2.5.1 Case investigation and contact tracing

2.5.1a

Is there a national system in place to provide support at the sub-national level (e.g. training, metrics standardization and/or financial resources) to conduct contact tracing in the event of a public health emergency?

Yes, there is evidence that the national government supports sub-national systems to prepare for future public health emergencies = 2, Yes, there is evidence that the national government supports sub-national systems, but only in response to active public health emergencies = 1, No = 0

Current Year Score: 0

There is no evidence that North Macedonia has a national system in place to provide support at the sub-national level (e.g. training, metrics standardization and/or financial resources) to conduct contact tracing in the event of an active or future public health emergency. The 2019 World Health Organization (WHO) Joint External Evaluation Report of the Republic of North Macedonia and the websites of the Ministry of Health and Institute of Public Health do not have information about a national system in place to provide support at the sub-national level (e.g. training, metrics standardization and/or financial resources) to conduct contact tracing in the event of a public health emergency. [1, 2, 3] One of the special measures to protect the population from infectious diseases are, defined in the article 13 of the Law on Protecting the Population from Contagious Disease is early detection of sources, reservoirs and routes of transmission. However, there are no specific provisions in the Law how to provide support at the sub-national level (e.g. training, metrics standardization and/or financial resources) to conduct contact tracing in the event of a public health emergency. [4]

[1] World Health Organization (WHO). 2019. "Joint External Evaluation Report of IHR Core Capacities of the Republic of North Macedonia." [<https://apps.who.int/iris/bitstream/handle/10665/325320/WHO-WHE-CPI-2019.59-eng.pdf?sequence=1>]. Accessed 14 November 2020.

[2] Ministry of Health of Republic of North Macedonia. [<http://zdravstvo.gov.mk/>]. Accessed 14 November 2020.

[3] Institute of Public Health (IPH) of Republic of North Macedonia. [<http://www.iph.mk/en/>]. Accessed 14 November 2020.

[4] Republic of North Macedonia. 2016. "Law on Protecting the Population from Contagious Disease (Official Gazette 66/04, 139/08, 99/09, 149/14, 150/15, 37/16)." [<http://zdravstvo.gov.mk/wp-content/uploads/2018/01/ZAKON-ZA-ZASHTITA-NA-NASELENIETO-OD-ZARAZNI-BOLESTI-zakluchno-so-br.-37-od-2016.pdf>]. Accessed 14 November 2020.

2.5.1b

Does the country provide wraparound services to enable infected people and their contacts to self-isolate or quarantine as recommended, particularly economic support (paycheck, job security) and medical attention?

Yes, both economic support and medical attention are provided = 2, Yes, but only economic support or medical attention is provided = 1, No = 0

Current Year Score: 2

North Macedonia provides wraparound services to enable infected people and their contacts to self-isolate or quarantine as recommended, particularly economic support (paycheck, job security) and medical attention. One of the special measures to protect the population from infectious diseases, defined in the articles 28-32 of the Law on Protecting the Population from Contagious Disease, is health isolation, surveillance and quarantine. According to article 44 of the same law, cases and suspected cases recommended to self-isolate have the right to medical attention. [1] According to articles 8 and 9 of the Law on health insurance, cases and suspected cases recommended to self-isolate have the right to medical attention. In addition, according to article 12 of the Law on health insurance, employees have the right to salary compensation during temporary incapacity to work due to illness and injury, as well as the right to reimbursement of travel expenses. [2] The 2019 World Health Organization (WHO) Joint External Evaluation Report for the Republic of North Macedonia and the websites of the Ministry of Health, Ministry of Economy and Institute for Public Health do not have information about wraparound services. [3, 4, 5]

[1] Republic of North Macedonia. 2016. "Law on Protecting the Population from Contagious Disease (Official Gazette 66/04, 139/08, 99/09, 149/14, 150/15, 37/16)." [<http://zdravstvo.gov.mk/wp-content/uploads/2018/01/ZAKON-ZA-ZASHTITA-NA-NASELENIETO-OD-ZARAZNI-BOLESTI-zakluchno-so-br.-37-od-2016.pdf>]. Accessed 14 November 2020.

[2] Republic of North Macedonia. 2013. "Law on Health Insurance (Official Gazette 65/2012, 16/2013, 91/2013)." [[http://www.fzo.org.mk/WBStorage/Files/Zakon%20za%20zdravstveno%20oiguruvanje%20\(Interen%20precisten%20tekst\).pdf](http://www.fzo.org.mk/WBStorage/Files/Zakon%20za%20zdravstveno%20oiguruvanje%20(Interen%20precisten%20tekst).pdf)]. Accessed 14 November 2020.

[3] World Health Organization (WHO). 2019. "Joint External Evaluation Report of IHR Core Capacities of the Republic of North Macedonia." [<https://apps.who.int/iris/bitstream/handle/10665/325320/WHO-WHE-CPI-2019.59-eng.pdf?sequence=1>]. Accessed 14 November 2020.

[4] Ministry of Health of Republic of North Macedonia. [<http://zdravstvo.gov.mk/>]. Accessed 14 November 2020.

[5] Ministry of Economy of Republic of North Macedonia. [<http://www.economy.gov.mk/>]. Accessed 14 November 2020.

2.5.1c

Does the country make de-identified data on contact tracing efforts for COVID-19 (including the percentage of new cases from identified contacts) available via daily reports (or other format) on government websites (such as the Ministry of Health, or similar)?

Yes = 1, No = 0

Current Year Score: 0

North Macedonia does not make de-identified data on contact tracing efforts for Covid-19 (including the percentage of new cases from identified contacts) available via daily reports (or other formats) on government websites. The Ministry of Health website provides the latest information and daily reports related to Covid-19 in North Macedonia. [1] However, these sources do not include de-identified data on contact tracing.

[1] Ministry of Health of Republic of North Macedonia. COVID/19. [<http://zdravstvo.gov.mk/korona-virus/>]. Accessed 14 November 2020.

2.5.2 Point of entry management

2.5.2a

Is there a joint plan or cooperative agreement between the public health system and border control authorities to identify suspected and potential cases in international travelers and trace and quarantine their contacts in the event of a public health emergency?

Yes, plan(s)/agreement(s) are in place to prepare for future public health emergencies = 2, Yes, but plan(s)/agreement(s) are in place only in response to active public health emergencies = 1, No = 0

Current Year Score: 0

In the Republic of North Macedonia there is no evidence of a joint plan or cooperative agreement between the public health system and border control authorities to identify suspected and potential cases in international travelers and trace and quarantine their contacts in the event of an active or future public health emergency. The 2019 World Health Organization (WHO) Joint External Evaluation (JEE) Report of the Republic of North Macedonia does not specify such agreements. According to the JEE report, the Republic of North Macedonia has regulations that outline the obligations of different sectors to cooperate in emergency situations. There are several MOUs between the Ministry of the Interior - a stakeholder in emergency response - and the MOH. The Ministry of the Interior and other State administrative bodies participate in prevention, early warning and response to the risks and dangers that can cause crisis situations, in accordance with the Law on Crisis Management and other relevant laws. An MOU and Cooperation has been signed between the CMC and the MOH. Standard operating procedures are being prepared and drafted that will detail operational issues. There have been several examples of joint operations over the past few years, including responses to the migrant crisis and a case of poisoning occurring in a factory. As one of the measures, the JEE report suggests that protocols and communication procedures should be developed for specific emergency situations that require multisectoral approaches. These procedures should include both public health and security authorities. [1] Law on Crisis Management, websites of the Ministry of Health and Interior do not have additional information about a joint plan or cooperative agreement between the public health system and border control authorities to identify suspected and potential cases in international travelers and trace and quarantine their contacts in the event of a public health emergency. [2, 3, 4]

[1] World Health Organization (WHO). 2019. "Joint External Evaluation Report of IHR Core Capacities of the Republic of North Macedonia." [<https://apps.who.int/iris/bitstream/handle/10665/325320/WHO-WHE-CPI-2019.59-eng.pdf?sequence=1>]. Accessed 14 November 2020.

[2] Republic of North Macedonia. 2005. "Law on Crisis Management (Official Gazette 29/05)." [<http://www.macefdr.gov.mk/files/dokumenti/pzrdo/Zakon%20za%20upravuvanje%20so%20krizi%202005.pdf>]. Accessed 14 November 2020.

[3] Ministry of Health of Republic of North Macedonia. [<http://zdravstvo.gov.mk/>]. Accessed 14 November 2020.

[4] Ministry of Interior of Republic of North Macedonia. [<https://mvr.gov.mk/default>]. Accessed 14 November 2020.

2.6 EPIDEMIOLOGY WORKFORCE

2.6.1 Applied epidemiology training program, such as the field epidemiology training program, for public health professionals and veterinarians (e.g., Field Epidemiology Training Program [FETP] and Field Epidemiology Training Program for Veterinarians [FETPV])

2.6.1a

Does the country meet one of the following criteria?

- Applied epidemiology training program (such as FETP) is available in country
- Resources are provided by the government to send citizens to another country to participate in applied epidemiology training programs (such as FETP)

Needs to meet at least one of the criteria to be scored a 1 on this measure. , Yes for both = 1 , Yes for one = 1 , No for both = 0

Current Year Score: 1

There is evidence that the Republic of North Macedonia participates in epidemiology training programs by sending participants from its health institutions. North Macedonia has participated in the Mediterranean Program for Intervention Epidemiology Training (MediPIET) implemented by the Eastern Mediterranean Public Health Network (EMPHNET). MediPIET aims to benefit 17 non-European Union (EU) partner countries covered by the EU Enlargement and southern European Neighborhood policies[1]. The MediPIET program is designed to train national trainers and supervisors from participating public health institutions who are currently working in field epidemiology, and is funded by the European Commission. The country is also part of the Network for the Control of Public Health Threats in the Mediterranean Regions and South East Europe (EpiSouth) Training in Public Health and Applied Epidemiology in the Mediterranean Countries and Balkans. Participants in the EpiSouth are key professionals working at the central level of their national surveillance institutions [2]. Although there is no specific mention of government financing for participants, the partners of the programs from the country are health institutions such as the Institute of Public Health of the Republic of North Macedonia, Institute for Health Protection, Clinic for Infectious Disease [2, 3]. According to the 2019 World Health Organization (WHO) Joint External Evaluation Report of the Republic of North Macedonia there is a well-established FETP in the country, provided with the collaboration of the Robert Koch Institute in Germany. Veterinary staff can also access this program. In collaboration with the European Center for Disease Control (ECDC), four IPH physicians have each received a two-year field epidemiology fellowship through the Mediterranean Program for Intervention Epidemiology Training (MediPIET) project framework. [4] The websites of the Ministry of Health, the Institute of Public Health, and the Food and Veterinary Agency do not provide any evidence on the availability of applied epidemiology training program in the country [5, 6, 7].

[1] Mediterranean Programme for Intervention Epidemiology Training (MediPIET). 2017. "Early Detection and Rapid Response to Biological and other Public Health Threats: 10 Years for a Regional Field Epidemiology Training Programme (FETP)." [http://medi Piet.eu/wp-content/uploads/2017/03/Concept-note-Regional-FETP-10-years_MediPIET.pdf]. Accessed 14 November 2020.

[2] Network for the Control of Public Health Threats in the Mediterranean Regions and South East Europe (EpiSouth). April 2010. "Training in Public Health and Applied Epidemiology in the Mediterranean Countries and Balkans." [http://www.episouth.org/output/wp5/2_EpiSouth%20Strategic%20document%20on%20Training%20Rev%20luglio%202010.pdf]. Accessed 14 November 2020.

[3] Network for the Control of Public Health Threats in the Mediterranean Regions and South East Europe (EpiSouth). "FYROM Former Yugoslav Republic of Macedonia." [<http://www.episouthnetwork.org/content/fyrom-former-yugoslav-republic-macedonia>]. Accessed 14 November 2020.

[4] World Health Organization (WHO). 2019. "Joint External Evaluation Report of IHR Core Capacities of the Republic of North

Macedonia." [https://apps.who.int/iris/bitstream/handle/10665/325320/WHO-WHE-CPI-2019.59-eng.pdf?sequence=1]. Accessed 14 November 2020.

[5] Ministry of Health of Republic of Macedonia. [http://zdravstvo.gov.mk/]. Accessed 14 November 2020.

[6] Institute of Public Health (IPH) of Republic of Macedonia. [http://www.iph.mk/en/]. Accessed 14 November 2020.

[7] Food and Veterinary Agency (FVA). [http://www.fva.gov.mk/index.php?lang=mk]. Accessed 14 November 2020.

2.6.1b

Are the available field epidemiology training programs explicitly inclusive of animal health professionals or is there a specific animal health field epidemiology training program offered (such as FETPV)?

Yes = 1 , No = 0

Current Year Score: 0

The available field epidemiology training programs are not explicitly inclusive of animal health professionals, and there is no evidence of a specific animal health field epidemiology training program offered (such as the Field Epidemiology Training Program for Veterinarians (FETPV). [1]The Mediterranean Program for Intervention Epidemiology Training (MediPIET) implemented by the Eastern Mediterranean Public Health Network (EMPHNET), where the Republic of North Macedonia participates does not report on offering animal health field epidemiology training program (such as FETPV). There is also no evidence of FETPV from the Network for the Control of Public Health Threats in the Mediterranean Regions and South East Europe (EpiSouth), which provides training in Public Health and Applied Epidemiology in the Mediterranean Countries and Balkans [2, 3]. The 2019 World Health Organization (WHO) Joint External Evaluation Report of the Republic of North Macedonia and websites of the Ministry of Agriculture and Food and Veterinary Agency do not have additional information about a specific animal health field epidemiology training program. [4, 5, 6]

[1] Mediterranean Programme for Intervention Epidemiology Training (MediPIET). 2017. "Early Detection and Rapid Response to Biological and other Public Health Threats: 10 Years for a Regional Field Epidemiology Training Programme (FETP)." [http://medi Piet.eu/wp-content/uploads/2017/03/Concept-note-Regional-FETP-10-years_MediPIET.pdf]. Accessed 14 November 2020.

[2] Network for the Control of Public Health Threats in the Mediterranean Regions and South East Europe (EpiSouth). April 2010. "Training in Public Health and Applied Epidemiology in the Mediterranean Countries and Balkans." [http://www.episouth.org/output/wp5/2_EpiSouth%20Strategic%20document%20on%20Training%20Rev%20luglio%202010.pdf]. Accessed 14 November 2020.

[3] Network for the Control of Public Health Threats in the Mediterranean Regions and South East Europe (EpiSouth). "FYROM Former Yugoslav Republic of Macedonia." [http://www.episouthnetwork.org/content/fyrom-former-yugoslav-republic-macedonia]. Accessed 14 November 2020.

[4] World Health Organization (WHO). 2019. "Joint External Evaluation Report of IHR Core Capacities of the Republic of North Macedonia." [https://apps.who.int/iris/bitstream/handle/10665/325320/WHO-WHE-CPI-2019.59-eng.pdf?sequence=1]. Accessed 14 November 2020.

[5] Ministry of Agriculture, Forestry and Water Economy of Republic of North Macedonia. [http://www.mzsv.gov.mk/al.aspx]. Accessed 14 November 2020.

[6] Food and Veterinary Agency (FVA). [http://www.fva.gov.mk/index.php?lang=mk]. Accessed 14 November 2020.

2.6.2 Epidemiology workforce capacity

2.6.2a

Is there public evidence that the country has at least 1 trained field epidemiologist per 200,000 people?

Yes = 1 , No = 0

Current Year Score: 0

2020

Completed JEE assessments; Economist Impact analyst qualitative assessment based on official national sources, which vary by country

Category 3: Rapid response to and mitigation of the spread of an epidemic

3.1 EMERGENCY PREPAREDNESS AND RESPONSE PLANNING

3.1.1 National public health emergency preparedness and response plan

3.1.1a

Does the country have an overarching national public health emergency response plan in place which addresses planning for multiple communicable diseases with epidemic or pandemic potential?

Evidence that there is a plan in place, and the plan is publicly available = 2, Evidence that the plan is in place, but the plan is not publicly available OR, Disease-specific plans are in place, but there is no evidence of an overarching plan = 1, No evidence that such a plan or plans are in place = 0

Current Year Score: 2

North Macedonia has an overarching national public health emergency response plan in place which addresses planning for multiple communicable diseases with epidemic or pandemic potential, which is publicly available. The "Preparation and response plan on the healthcare system when dealing with emergency, crisis condition and disasters", which was adopted in 2017, serves as the national public health emergency response plan covering health emergency situations. The plan enables fast, timely and comprehensive action on the part of the health system and all other entities in accordance with the emergency situation, crisis and/or disaster, including epidemic or pandemic. [1] According to the 2019 World Health Organization (WHO) Joint External Evaluation Report of the Republic of North Macedonia, in 2017 as part of emergency preparedness measures, the health sector also developed a comprehensive emergency preparedness and response plan, with standard operating procedures and clearly defined roles and responsibilities. [2]

[1] Republic of North Macedonia. Ministry of Health. 2017. "Preparation and response plan on the healthcare system when dealing with emergency, crisis condition and disasters." [<http://iph.mk/wp-content/uploads/2017/08/Plan-za-podgotvenost-i-odgovor-pri-krizni-sostojbi-i-katastrofi.pdf>]. Accessed 14 November 2020.

[2] World Health Organization (WHO). 2019. "Joint External Evaluation Report of IHR Core Capacities of the Republic of North Macedonia." [<https://apps.who.int/iris/bitstream/handle/10665/325320/WHO-WHE-CPI-2019.59-eng.pdf?sequence=1>]. Accessed 14 November 2020.

3.1.1b

If an overarching plan is in place, has it been updated in the last 3 years?

Yes = 1 , No /no plan in place= 0

Current Year Score: 1

North Macedonia has an overarching national public health emergency response plan in place which addresses planning for multiple communicable diseases with epidemic or pandemic potential, which has been updated in the last 3 years and which is publicly available. "Preparation and response plan on the healthcare system when dealing with emergency, crisis condition and disasters", which serves as the national public health emergency response plan covering health emergency situations, has been adopted in 2017. [1] According to the 2019 World Health Organization (WHO) Joint External Evaluation Report of the Republic of North Macedonia, in 2017, as part of emergency preparedness measures, the health sector also developed a comprehensive emergency preparedness and response plan, with standard operating procedures and clearly defined roles and responsibilities. [2]

[1] Republic of North Macedonia. Ministry of Health. 2017. "Preparation and response plan on the healthcare system when dealing with emergency, crisis condition and disasters." [<http://iph.mk/wp-content/uploads/2017/08/Plan-za-podgotvenost-i-odgovor-pri-krizni-sostojbi-i-katastrofi.pdf>]. Accessed 14 November 2020.

[2] World Health Organization (WHO). 2019. "Joint External Evaluation Report of IHR Core Capacities of the Republic of North Macedonia." [<https://apps.who.int/iris/bitstream/handle/10665/325320/WHO-WHE-CPI-2019.59-eng.pdf?sequence=1>]. Accessed 14 November 2020.

3.1.1c

If an overarching plan is in place, does it include considerations for pediatric and/or other vulnerable populations?

Yes = 1 , No /no plan in place= 0

Current Year Score: 1

North Macedonia has an overarching national public health emergency response plan in place which addresses planning for multiple communicable diseases with epidemic or pandemic potential, which includes considerations for pediatric and/or other vulnerable populations. According to the "Preparation and response plan on the healthcare system when dealing with emergency, crisis condition and disasters", which is a publicly available document, in emergencies, crises and disasters, women, adolescents and children are most at risk. Many of the negative health effects, especially for these vulnerable groups can be prevented if health services are timely planned and available during a crisis. Annex 8 of the document defines a minimum package of measures for women, girls and children (e.g. expand medical services, psychosocial and legal assistance, provide antenatal care services and postnatal care services etc.). [1]

[1] Republic of North Macedonia. Ministry of Health. 2017. "Preparation and response plan on the healthcare system when dealing with emergency, crisis condition and disasters." [<http://iph.mk/wp-content/uploads/2017/08/Plan-za-podgotvenost-i-odgovor-pri-krizni-sostojbi-i-katastrofi.pdf>]. Accessed 14 November 2020.

3.1.1d

Does the country have a publicly available plan in place specifically for pandemic influenza preparedness that has been updated since 2009?

Yes = 1 , No = 0

Current Year Score: 1

2020

WHO Strategic Partnership for IHR and Health Security (SPH)

3.1.2 Private sector involvement in response planning

3.1.2a

Does the country have a specific mechanism(s) for engaging with the private sector to assist with outbreak emergency preparedness and response?

Yes = 1, No = 0

Current Year Score: 0

The Republic of North Macedonia does not have a specific mechanism for engaging with the private sector to assist with outbreak emergency preparedness and response. The "Preparation and response plan on the healthcare system when dealing with emergency, crisis condition and disasters", which serves as the national public health emergency response plan, mentions that private sector can be engaged in case of emergency situations with large number of casualties. However, the plan does not prescribe any specific mechanism for engaging with the private sector to assist with outbreak emergency preparedness and response. [1] There is only evidence of the business community being involved in the thematic working groups for the "National Platform of Disaster Risk Reduction" [2]. There is also no evidence provided for a specific mechanism for engaging with the private sector to assist with outbreak emergency preparedness and response in the Ministry of Health's website, and the Crisis Management Center's (CUK) website [3, 4].

[1] Republic of North Macedonia. Ministry of Health. 2017. "Preparation and response plan on the healthcare system when dealing with emergency, crisis condition and disasters." [<http://iph.mk/wp-content/uploads/2017/08/Plan-za-podgotvenost-i-odgovor-pri-krizni-sostojbi-i-katastrofi.pdf>]. Accessed 14 November 2020.

[2] Hyogo Framework for Action (HFA). "The Former Yugoslav Republic of Macedonia National progress report on the implementation of the Hyogo Framework for Action 2013-2015." [https://www.preventionweb.net/files/42977_MKD_NationalHFAprogress_2013-15.pdf]. Accessed 14 November 2020.

[3] Ministry of Health of Republic of North Macedonia. [<http://www.moh.gov.mk/>]. Accessed 14 November 2020.

[4] Crisis Management Center's (CUK) of Republic of North Macedonia. [<http://www.cuk.gov.mk/mk/home-2.html?id=1184>]. Accessed 14 November 2020.

3.1.3 Non-pharmaceutical interventions planning

3.1.3a

Does the country have a policy, plan and/or guidelines in place to implement non-pharmaceutical interventions (NPIs) during an epidemic or pandemic?

Yes, a policy, plan and/or guidelines are in place for more than one disease= 2, Yes, but the policy, plan and/or guidelines exist only for one disease = 1, No = 0

Current Year Score: 0

There is no publicly available evidence that North Macedonia has a policy, plan and/or guidelines in place to implement non-pharmaceutical interventions (NPIs) during an epidemic or pandemic for one or more diseases. Article 13 of the Law on Protecting the Population from Contagious Disease, as one of the measures mentions disinfection, disinsection and deratization. However, the Law does not have any other reference to NPIs. [1] The 2019 World Health Organization (WHO) Joint External Evaluation Report of the Republic of North Macedonia and websites of the Ministry of Health, Crisis

Management Center's and Institute for Public Health do not have information about NPIs. [2, 3, 4, 5, 6]

- [1] Republic of North Macedonia. 2016. "Law on Protecting the Population from Contagious Disease (Official Gazette 66/04, 139/08, 99/09, 149/14, 150/15, 37/16)." [<http://zdravstvo.gov.mk/wp-content/uploads/2018/01/ZAKON-ZA-ZASHTITA-NA-NASELENIETO-OD-ZARAZNI-BOLESTI-zakluchno-so-br.-37-od-2016.pdf>]. Accessed 14 November 2020.
- [2] Republic of North Macedonia. Ministry of Health. 2017. "Preparation and response plan on the healthcare system when dealing with emergency, crisis condition and disasters." [<http://iph.mk/wp-content/uploads/2017/08/Plan-za-podgotvenost-i-odgovor-pri-krizni-sostojbi-i-katastrofi.pdf>]. Accessed 14 November 2020.
- [3] Republic of North Macedonia. Ministry of Health. 2017. "Preparation and response plan on the healthcare system when dealing with emergency, crisis condition and disasters." [<http://iph.mk/wp-content/uploads/2017/08/Plan-za-podgotvenost-i-odgovor-pri-krizni-sostojbi-i-katastrofi.pdf>]. Accessed 14 November 2020.
- [4] Ministry of Health of Republic of North Macedonia. [<http://www.moh.gov.mk/>]. Accessed 14 November 2020.
- [5] Crisis Management Center's (CUK) of Republic of North Macedonia. [<http://www.cuk.gov.mk/mk/home-2.html?id=1184>]. Accessed 14 November 2020.
- [6] Institute of Public Health (IPH) of Republic of North Macedonia. [<http://www.iph.mk/en/>]. Accessed 14 November 2020.
- [7] Ministry of Health of Republic of North Macedonia. COVID/19. [<http://zdravstvo.gov.mk/korona-virus/>]. Accessed 14 November 2020.

3.2 EXERCISING RESPONSE PLANS

3.2.1 Activating response plans

3.2.1a

Does the country meet one of the following criteria?

- Is there evidence that the country has activated their national emergency response plan for an infectious disease outbreak in the past year?
- Is there evidence that the country has completed a national-level biological threat-focused exercise (either with WHO or separately) in the past year?

Needs to meet at least one of the criteria to be scored a 1 on this measure. , Yes for both = 1 , Yes for one = 1 , No for both = 0

Current Year Score: 0

There is insufficient evidence that North Macedonia has activated its national emergency response plan in the past year. However, authorities in North Macedonia have extended the nationwide state of emergency until June 13, which was initially introduced in mid-March to stem the spread of coronavirus disease (Covid-19). [1, 2] However, there are no evidence that the "Preparation and response plan on the healthcare system when dealing with emergency, crisis condition and disasters" was activated because of Covid-19. [4, 5, 6] According to the World Health Organization (WHO) Strategic Partnership Portal, a tabletop (TTX) exercise in North Macedonia was organized in September 2020. [3] There are no publicly available information on the websites of the Ministry of Health, Institute for Public Health, Crisis Management Center's (CMC) about a national-level biological threat-focused exercise. [4, 5, 6]

[1] World Health Organization (WHO). Health Emergency Dashboard. North Macedonia.

[<https://extranet.who.int/publicemergency>] Accessed 14 November 2020.

[2] Ministry of Health of Republic of North Macedonia. COVID/19. [<http://zdravstvo.gov.mk/korona-virus/>]. Accessed 14 November 2020.

[3] World Health Organization (WHO) Strategic Partnership Portal. "Health Security Calendar."

[<https://extranet.who.int/sph/simulation-exercise>]. Accessed 14 November 2020.

[4] Ministry of Health of Republic of North Macedonia. [<http://www.moh.gov.mk/>]. Accessed 14 November 2020.

[5] Crisis Management Center (CMC) of Republic of North Macedonia. [<http://www.cuk.gov.mk/mk/home-2.html?id=1184>]. Accessed 14 November 2020.

[6] Institute of Public Health (IPH) of Republic of North Macedonia. [<http://www.iph.mk/en/>]. Accessed 14 November 2020.

3.2.1b

Is there evidence that the country in the past year has identified a list of gaps and best practices in response (either through an infectious disease response or a biological-threat focused exercise) and developed a plan to improve response capabilities?

Yes, the country has developed and published a plan to improve response capacity = 2 , Yes, the country has developed a plan to improve response capacity, but has not published the plan = 1 , No = 0

Current Year Score: 0

There is no evidence that North Macedonia has undergone an exercise to identify a list of gaps and best practices in response (either through an infectious disease response or a biological-threat focused exercise) and developed a plan to improve response capabilities. The World Health Organization (WHO) Strategic Partnership Portal does not have any details on completed after action reviews for the Republic of North Macedonia. According to the WHO Strategic Partnership Portal, a tabletop (TTX) exercise in North Macedonia was organized in September 2020. [1, 2]. The Ministry of Health has not published any information about identifying gaps in response to a public health emergency [3].

[1] World Health Organization (WHO) Strategic Partnership Portal. "Simulation Exercise."

[<https://extranet.who.int/sph/simulation-exercise>]. Accessed 14 November 2020.

[2] World Health Organization (WHO) Strategic Partnership Portal. "Health Security Calendar."

[<https://extranet.who.int/sph/calendar>]. Accessed 14 November 2020.

[3] Ministry of Health of Republic of North Macedonia. [<http://www.moh.gov.mk/>]. Accessed 14 November 2020.

3.2.2 Private sector engagement in exercises

3.2.2a

Is there evidence that the country in the past year has undergone a national-level biological threat-focused exercise that has included private sector representatives?

Yes = 1 , No = 0

Current Year Score: 0

There is no evidence that North Macedonia has, in the past year, undergone a national-level biological threat-focused exercise that has included private sector representatives. According to information available on World Health Organization (WHO) Strategic Partnership Portal, North Macedonia has not, in the past year, undergone such an exercise that included private sector representatives. [1] There is no publicly available information on the websites of the Ministry of Health, Ministry of Agriculture and Institute for Public Health. [2, 3, 4]

[1] World Health Organization (WHO) Strategic Partnership Portal. "Simulation Exercise."

[<https://extranet.who.int/sph/simulation-exercise>]. Accessed 14 November 2020.

[2] Ministry of Health of Republic of North Macedonia. [<http://www.moh.gov.mk/>]. Accessed 14 November 2020.

[3] Ministry of Agriculture, Forestry and Water Economy of Republic of North Macedonia. [<http://www.mzsv.gov.mk/al.aspx>].

Accessed 14 November 2020.

[4] Institute of Public Health (IPH) of Republic of North Macedonia. [<http://www.iph.mk/en/>]. Accessed 14 November 2020.

3.3 EMERGENCY RESPONSE OPERATION

3.3.1 Emergency response operation

3.3.1a

Does the country have in place an Emergency Operations Center (EOC)?

Yes = 1 , No = 0

Current Year Score: 1

The country has in place an Emergency Operations Center (EOC) known as the Crisis Management Center (CMC), which handles the activities for prevention and management of crisis situations, including epidemics of quarantine and other contagious diseases of the people and animals. Its main functions include: (i) prevention through assessment, education and exercise for all subjects, (ii) public alert of Early Warning, (iii) mitigation through handling a crisis situation, management and make all coordination between all subjects in the Crisis Management System, (iv) recovery, and (v) international coordination [1, 2, 3]. According to the 2019 World Health Organization (WHO) Joint External Evaluation Report of the Republic of North Macedonia, the national CMC and an additional eight regional and 34 municipal CMCs distributed throughout the country work together to coordinate risk management activities. [4]

[1] Republic of North Macedonia. 2005. "Law on Crisis Management (Official Gazette 29/05)."

[<http://www.macedrr.gov.mk/files/dokumenti/pzrdo/Zakon%20za%20upravuvanje%20so%20krizi%202005.pdf>]. Accessed 14 November 2020.

[2] Crisis Management Center (CMS) of Republic of Macedonia. [<http://www.cuk.gov.mk/mk/>]. Accessed 14 November 2020.

[3] Government of the Republic of Macedonia. 2010. "Crisis Management System (CMS) in the Republic of Macedonia." [http://open_jicareport.jica.go.jp/pdf/12068433_02.pdf]. Accessed 14 November 2020.

[4] World Health Organization (WHO). 2019. "Joint External Evaluation Report of IHR Core Capacities of the Republic of North Macedonia." [<https://apps.who.int/iris/bitstream/handle/10665/325320/WHO-WHE-CPI-2019.59-eng.pdf?sequence=1>]. Accessed 14 November 2020.

3.3.1b

Is the Emergency Operations Center (EOC) required to conduct a drill for a public health emergency scenario at least once per year or is there evidence that they conduct a drill at least once per year?

Yes = 1 , No = 0

Current Year Score: 0

There is no evidence that the Emergency Operations Center (EOC) is required to conduct a drill for a public health emergency scenario at least once per year or is there evidence that they conduct a drill at least once per year. The Emergency Operations Center known as the Crisis Management Center (CMC) in the Former Yugoslav Republic of Macedonia is required to conduct drills, training, and exercises. Law on Crisis Management of 22 April 2005 has provisions for training, exercises and other activities designed for prevention and handling crisis situations. Under Article 10 of this law, the Ministries and the other state administrative bodies, the public enterprises, as well as the trade companies that are of special importance for acting in a crisis situation and the municipalities and the City of Skopje, shall have the responsibility to participate in the training, exercises and other activities designed for prevention and handling crisis situations [1]. There is evidence of drills

taking place in the city of Skopje for evacuation drill from the city mall [2], as well as national training exercises on crisis management in cooperation with engineering corps of the United States such as "Holistic Response Vodno 2018", which took place 17-2 14 November 2020 [3]. While drills are performed, there's no stated requirement for an annual review.

[1] Republic of North Macedonia. 2005. "Law on Crisis Management (Official Gazette 29/05)."

[<http://www.macedrr.gov.mk/files/dokumenti/pzrdo/Zakon%20za%20upravuvanje%20so%20krizi%202005.pdf>]. Accessed 14 November 2020.

[2] Faktor. 17 February 2014. "Evacuation drill in Skopje City Mall." [<https://faktor.mk/vezhba-evakuacija-vo-skopje-siti-mol-utre/feed/frchkovski-grubo-go-napadna-crvenkovski-poradi-neubedliviot-stav>]. Accessed 14 November 2020.

[3] Crisis Management Center of Republic of Macedonia (CMC). 19 September 2018. "The Director of the Crisis Management Center Agron Buxhaku will participate in today's training "Holistic Response Vodno 2018."

[<http://www.cuk.gov.mk/mk/%D0%BE%D0%B4%D0%BD%D0%BE%D1%81%D0%B8-%D1%81%D0%BE-%D1%98%D0%B0%D0%B2%D0%BD%D0%BE%D1%81%D1%82%D0%B0-3/lajme.html>]. Accessed 14 November 2020.

3.3.1c

Is there public evidence to show that the Emergency Operations Center (EOC) has conducted within the last year a coordinated emergency response or emergency response exercise activated within 120 minutes of the identification of the public health emergency/scenario?

Yes = 1 , No = 0

Current Year Score: 0

There is no public evidence to show that the Crisis Management Center, which serves as the country's Emergency Operations Center can conduct, or has conducted within the last year, a coordinated emergency response or emergency response exercise activated within 120 minutes of the identification of the public health emergency/scenario. There is however evidence that on November 18, 2014, at the airport "Alexander the Great, a simulation exercise was held in order to make the first test of standard operating protocols (SOP) regarding the treatment, communication and coordination of the health system on possible occurrence of dangerous infectious diseases -Ebola. The simulation exercise resulted from the coordinated efforts of the Institute for Public Health, Public Health Center in Skopje, Crisis Management Center, Emergency Medical Services, Skopje Airport, Directorate for Protection and Rescue, Ministry of the Interior, Red Cross, and other relevant partners [1]. There is no evidence of such exercise on the websites of the Ministry of Health, Ministry of Defense, and Institute of Public Health (IPH) [2, 3, 4].

[1] Institute of Public Health of Republic of Macedonia (IPH). 21 November 2014. "Successful Ebola simulation exercise organized in The former Yugoslav Republic of Macedonia." [<http://www.iph.mk/en/successful-ebola-simulation-exercise-organized-in-the-former-yugoslav-republic-of-macedonia/>]. Accessed 14 November 2020.

[2] Ministry of Health of Republic of Macedonia. [<http://zdravstvo.gov.mk/sq/home-main/>]. Accessed 14 November 2020.

[3] Ministry of Defence. [http://morm.gov.mk/?page_id=48&lang=en]. Accessed 14 November 2020.

[4] Institute of Public Health (IPH) of Republic of Macedonia. [<http://iph.mk/>]. Accessed 14 November 2020.

3.4 LINKING PUBLIC HEALTH AND SECURITY AUTHORITIES

3.4.1 Public health and security authorities are linked for rapid response during a biological event

3.4.1a

Does the country meet one of the following criteria?

- Is there public evidence that public health and national security authorities have carried out an exercise to respond to a potential deliberate biological event (i.e., bioterrorism attack)?
- Are there publicly available standard operating procedures, guidelines, memorandums of understanding (MOUs), or other agreements between the public health and security authorities to respond to a potential deliberate biological event (i.e., bioterrorism attack)?

Needs to meet at least one of the criteria to be scored a 1 on this measure., Yes for both = 1, Yes for one = 1, No for both = 0

Current Year Score: 0

In the Republic of North Macedonia there is insufficient publicly available evidence of standard operating procedures, guidelines, memorandums of understanding (MOUs), or other agreements between the public health and security authorities to respond to a potential deliberate biological event (i.e. bioterrorism attack).

According to the 2019 World Health Organization (WHO) Joint External Evaluation Report of the Republic of North Macedonia, the Republic of North Macedonia has regulations that outline the obligations of different sectors to cooperate in emergency situations. There are several MOUs between the Ministry of the Interior - a stakeholder in emergency response - and the Ministry of Health. The Ministry of the Interior and other State administrative bodies participate in prevention, early warning and response to the risks and dangers that can cause crisis situations, in accordance with the Law on Crisis Management and other relevant laws. An MOU and Cooperation has been signed between the Crisis Management Center (CMC) and the Ministry of Health (MOH). Standard operating procedures are being prepared and drafted that will detail operational issues. [1] The CMC is an independent body of the state administration established to ensure consultations, coordination, timely response, efficiency and proper use of resources available in the event of a crisis, and to provide timely, quality and realistic assessment of the security threats to the Republic of North Macedonia from risks and dangers. [2] Standard operational procedures exist for health in terms of epidemics, epizootics, epiphytotics, mass food poisoning and chemicals poisoning [3]. There is no evidence that public health and national security authorities have carried out an exercise to respond to a potential deliberate biological event (i.e., bioterrorism attack). An exercise aimed at strengthening the operational readiness of Macedonian Army engineers as well as of chemical, biological, radiological and nuclear defense units has taken place between the Republic of North Macedonia Army and the US Army [4]. According to the WHO Strategic Partnership Portal, the country was scheduled for 25th September 2020 to conduct a TTX simulation exercise, but the exercise was canceled due to the Covid-19 pandemic. [5] Websites of the Ministry of Health, Ministry of Defense, CMC and Institute for Public Health do not have information about an exercise to respond to a potential deliberate biological event (i.e. bioterrorism attack). [6, 7, 8, 9]

[1] World Health Organization (WHO). 2019. "Joint External Evaluation Report of IHR Core Capacities of the Republic of North Macedonia." [<https://apps.who.int/iris/bitstream/handle/10665/325320/WHO-WHE-CPI-2019.59-eng.pdf?sequence=1>]. Accessed 14 November 2020.

[2] Crisis Management Center (CMS) of Republic of Macedonia. [<http://www.cuk.gov.mk/mk/%D0%B7%D0%B0-%D0%BD%D0%B0%D1%81/%D0%B7%D0%B0%D0%B4%D0%B0%D1%87%D0%B8,-%D1%84%D1%83%D0%BD%D0%BA%D1%86%D0%B8%D1%98%D0%B0-%D0%B8-%D1%86%D0%B5%D0%BB%D0%B8.html>]. Accessed 14 November 2020.

- [3] Hyogo Framework for Action (HFA). "The Former Yugoslav Republic of Macedonia National progress report on the implementation of the Hyogo Framework for Action 2013-2015." [https://www.preventionweb.net/files/42977_MKD_NationalHFAprogress_2013-15.pdf]. Accessed 14 November 2020.
- [4] BalkanInsight. 28 July 2017. "Macedonia Hosts Joint Military Exercise With US Troops." [<http://www.balkaninsight.com/en/article/macedonia-us-attend-joint-military-exercise-07-28-2017>]. Accessed 14 November 2020.
- [5] World Health Organization (WHO) Strategic Partnership Portal. "Simulation Exercise." [<https://extranet.who.int/sph/simulation-exercise>]. Accessed 14 November 2020.
- [6] Ministry of Health of Republic of Macedonia. [<http://zdravstvo.gov.mk/sq/home-main/>]. Accessed 14 November 2020.
- [7] Ministry of Defense of Republic of Macedonia. [http://morm.gov.mk/?page_id=48&lang=en]. Accessed 14 November 2020.
- [8] Crisis Management Center (CMS) of Republic of Macedonia. [<http://www.cuk.gov.mk/mk/>]. Accessed 14 November 2020.
- [9] Institute of Public Health (IPH) of Republic of Macedonia. [<http://iph.mk/>]. Accessed 14 November 2020.

3.5 RISK COMMUNICATIONS

3.5.1 Public communication

3.5.1b

Does the risk communication plan (or other legislation, regulation or strategy document used to guide national public health response) outline how messages will reach populations and sectors with different communications needs (eg different languages, location within the country, media reach)?

Yes = 1 , No = 0

Current Year Score: 0

There is insufficient evidence that Macedonia has a strategy (or other legislation, regulation or strategy document used to guide national public health response) that outlines how messages will reach populations and sectors with different communications needs (e.g. different languages, location within country, media reach, etc. As per Law No.07-1537/1 "On Crisis Management of 22 April 2005, the Crisis Management Center has its own systems for communications and system for public alert [1]. This includes one state level radio, 34 independent local radio networks, emergency call centers, electronic sirens grouped in 30 independent Public Alert Systems, and mass media communication [1, 2]. The Crisis Management Center has 35 Regional Centers covering 85 municipalities. Although no specific language provisions are made, there are two formal languages in the country, Macedonian and Albanian. There is no further evidence to outline how communication needs of different populations will be addressed.

[1] Republic of Macedonia. Law No. 07-1537/1 of 22 April 2005. "On Crisis Management."

[https://www.preventionweb.net/files/7645_LawoncrisismanagementRepublicofMacedonia.pdf]. Accessed 29 August 2020.

[2] Crisis Management Centre of Republic of Macedonia. 2012. "E-112, Emergency Call System in Republic of Macedonia." [<http://www.eena.org/ressource/static/files/3-fyrom.pdf>]. Accessed 30 August 2020.

3.5.1 Risk communication planning

3.5.1a

Does the country have in place, either in the national public health emergency response plan or in other legislation, regulation, or strategy documents, a section detailing a risk communication plan that is specifically intended for use during a public health emergency?

Yes = 1 , No = 0

Current Year Score: 1

North Macedonia has in place, either in the national public health emergency response plan or in other legislation, regulation, or strategy documents, a section detailing a risk communication plan that is specifically intended for use during a public health emergency.

Section V, articles 37-44, of the Law on Crisis Management of 22 April 2005, is elaborating communication between the state authorities in case of emergency and how they should reach population. [1] This includes one state level radio, 34 independent local radio networks, emergency call centers, electronic sirens grouped in 30 independent Public Alert Systems, and mass media communication. The Crisis Management Center (CMC) has 35 Regional Centers covering 85 municipalities. Although no specific language provisions are made, there are two formal languages in the country, Macedonian and Albanian. [1, 2]

According to the 2019 World Health Organization (WHO) Joint External Evaluation Report of the Republic of North Macedonia, North Macedonia has a clear and comprehensive set of laws, preparedness and response plans and standard operating procedures that define all the necessary roles, responsibilities and interactions concerning risk communication. They cover risk communication between government institutions, and between these institutions and stakeholders outside government. They include the Public Health Law, the Preparedness and Response Plan of the Health Care System When Coping With Emergencies, Crises and Disasters and several sets of standard operating plans (SOPs) describing the flow of information between different partners. The IHR National Focal Point at the Institute for Public Health (IPH) is included in this legislation. The Ministry of Health coordinates the flow of information with a range of government sectors, the IPH and CMC. The CMC can call on a network of regional crisis centers to manage risk communication and disseminate information to the public about risks and the unfolding of events during an emergency. The Food and Veterinary Agency is responsible for communicating with the public about foodborne outbreaks or food safety problems, and the Protection and Rescue Directorate plays an important role in communicating during natural disasters.

As a nongovernmental partner, the Red Cross of North Macedonia plays another important role in promoting community resilience and protective measures among affected communities. Although intersectoral cooperation and exchange of information is embedded in the system, the wide variety of communication channels (websites, social media platforms, information campaigns, etc.) is not streamlined and is managed separately by individual institutions and organizations, with varying degrees of success. This results in an information landscape that can be difficult for the public to navigate in an unfolding emergency. Individual websites do, however, offer valuable, comprehensive and timely information about risks and preventive measures and present these messages in a professional and attractive manner. Social media platforms such as Facebook are used mainly to disseminate the same information, but most pages fail to engage or interact with their followers, resulting in low outreach and low impact of messages. [3]

[1] Republic of North Macedonia. 2005. "Law on Crisis Management (Official Gazette 29/05)."

[<http://www.macedrr.gov.mk/files/dokumenti/pzrdo/Zakon%20za%20upravuvanje%20so%20krizi%202005.pdf>]. Accessed 14 November 2020.

[2] Crisis Management Centre of Republic of Macedonia. 2012. "E-112, Emergency Call System in Republic of Macedonia." [<http://www.eena.org/ressource/static/files/3-fyrom.pdf>]. Accessed 30 August 2018.

[3] World Health Organization (WHO). 2019. "Joint External Evaluation Report of IHR Core Capacities of the Republic of North Macedonia." [<https://apps.who.int/iris/bitstream/handle/10665/325320/WHO-WHE-CPI-2019.59-eng.pdf?sequence=1>]. Accessed 14 November 2020.

3.5.1c

Does the risk communication plan (or other legislation, regulation or strategy document used to guide national public health response) designate a specific position within the government to serve as the primary spokesperson to the public during a public health emergency?

Yes = 1 , No = 0

Current Year Score: 0

In North Macedonia the risk communication plan and relevant legislation do not designate a specific position within the government to serve as the primary spokesperson to the public during a public health emergency. Law on Crisis Management does not mention such position. [1] Preparation and response plan on the healthcare system when dealing with emergency, crisis condition and disasters mentions a specific position within the government to serve as the primary spokesperson to the public only in case of floods. [2] Websites of the Ministry of Health, Defense, Crisis Management Center and Institute for Public Health do not have further information about a specific position within the government to serve as the primary spokesperson to the public during a public health emergency. [3, 4, 5, 6]

[1] Republic of North Macedonia. 2005. "Law on Crisis Management (Official Gazette 29/05)."

[<http://www.macefdr.gov.mk/files/dokumenti/pzrdo/Zakon%20za%20upravuvanje%20so%20krizi%202005.pdf>]. Accessed 14 November 2020.

[2] Republic of North Macedonia. Ministry of Health. 2017. "Preparation and response plan on the healthcare system when dealing with emergency, crisis condition and disasters." [<http://iph.mk/wp-content/uploads/2017/08/Plan-za-podgotvenost-i-odgovor-pri-krizni-sostojbi-i-katastrofi.pdf>]. Accessed 14 November 2020.

[3] Ministry of Health of Republic of Macedonia. [<http://zdravstvo.gov.mk/sq/home-main/>]. Accessed 14 November 2020.

[4] Ministry of Defense of Republic of Macedonia. [http://morm.gov.mk/?page_id=48&lang=en]. Accessed 14 November 2020.

[5] Crisis Management Center (CMS) of Republic of Macedonia. [<http://www.cuk.gov.mk/mk/>]. Accessed 14 November 2020.

[6] Institute of Public Health (IPH) of Republic of Macedonia. [<http://iph.mk/>]. Accessed 14 November 2020.

3.5.2 Public communication

3.5.2a

In the past year, is there evidence that the public health system has actively shared messages via online media platforms (e.g. social media, website) to inform the public about ongoing public health concerns and/or dispel rumors, misinformation or disinformation?

Public health system regularly shares information on health concerns = 2, Public health system shares information only during active emergencies, but does not regularly utilize online media platforms = 1, Public health system does not regularly utilize online media platforms, either during emergencies or otherwise = 0

Current Year Score: 1

There is evidence that the public health system has actively shared messages via online media platforms (e.g. social media, website) to inform the public about ongoing public health concerns and/or dispel rumors, misinformation or disinformation. On the websites of the Ministry of Health and Institute for Public Health there are evidence that the public health system has actively shared messages to inform the public about ongoing active emergencies, such as Covid-19. Active sharing of messages concerning Covid-19 is ensured through the website of the Ministry of Health. This website provides latest information related to Covid-19 in North Macedonia. Besides the latest statistical data, the website also provides recommendations about preventive measures (e.g. avoid close contact with people with symptoms of a respiratory infection (fever, sneezing, cough, runny nose, difficult breathing or other), even inside your home; keep the recommended distance of

at least one meter between yourself and others; use a face mask to cover your mouth and nose when staying indoors etc.).

[1] On the website of the Institute for Public Health there are monthly reports on the acute infectious diseases in the Republic of Northern Macedonia. [2] Ministry of Health and Institute for Public Health have social media pages [3, 4]. On the websites of the Ministry of Health and Institute for Public Health, as well as their Facebook pages, there is no evidence that the public health system has actively shared messages via online media platforms to inform the public about dispel rumors, misinformation or disinformation [1, 2, 3, 4]

[1] Ministry of Health of Republic of Macedonia. "Covid-19". [<http://zdravstvo.gov.mk/korona-virus/>]. Accessed 14 November 2020.

[2] Institute of Public Health (IPH) of Republic of Macedonia. "Annual reports." [<http://iph.mk/multimedija/mesecni-bilteni/>]. Accessed 14 November 2020.

[3] Ministry of Health of Republic of Macedonia. "Facebook". [<https://www.facebook.com/zdravstvomk/>]. Accessed 14 November 2020.

[4] Institute of Public Health (IPH) of Republic of Macedonia. "Facebook". [<https://www.facebook.com/iph.mk/>]. Accessed 14 November 2020.

3.5.2b

Is there evidence that senior leaders (president or ministers) have shared misinformation or disinformation on infectious diseases in the past two years?

No = 1, Yes = 0

Current Year Score: 1

There are no evidence that senior leaders (president or ministers) have shared misinformation or disinformation on infectious diseases in the past two years. Based on the review of the websites of the President of North Macedonia, Ministry of Health, Institute for Public Health and media outlets there are no such evidence. [1, 2, 3, 4, 5]

[1] President of the Republic of North Macedonia. [<https://pretsedatel.mk/en/homepage/>]. Accessed 14 November 2020.

[2] Ministry of Health of Republic of Macedonia. [<http://zdravstvo.gov.mk/sq/home-main/>]. Accessed 14 November 2020.

[3] Institute of Public Health (IPH) of Republic of Macedonia. [<http://iph.mk/>]. Accessed 14 November 2020.

[4] Balkans Aljazeera. [<http://balkans.aljazeera.net/>]. Accessed 14 November 2020.

[5] META MK. [<https://meta.mk/>]. Accessed 14 November 2020.

3.6 ACCESS TO COMMUNICATIONS INFRASTRUCTURE

3.6.1 Internet users

3.6.1a

Percentage of households with Internet

Input number

Current Year Score: 79.17

2019

International Telecommunication Union (ITU)

3.6.2 Mobile subscribers

3.6.2a

Mobile-cellular telephone subscriptions per 100 inhabitants

Input number

Current Year Score: 98.65

2019

International Telecommunication Union (ITU)

3.6.3 Female access to a mobile phone

3.6.3a

Percentage point gap between males and females whose home has access to a mobile phone

Input number

Current Year Score: 2.06

2018-2019

Gallup; Economist Impact calculation

3.6.4 Female access to the Internet

3.6.4a

Percentage point gap between males and females whose home has access to the Internet

Input number

Current Year Score: 3.96

2018-2019

Gallup; Economist Impact calculation

3.7 TRADE AND TRAVEL RESTRICTIONS

3.7.1 Trade restrictions

3.7.1a

In the past year, has the country issued a restriction, without international/bilateral support, on the export/import of medical goods (e.g. medicines, oxygen, medical supplies, PPE) due to an infectious disease outbreak?

Yes = 0, No = 1

Current Year Score: 1

There are no evidence that In the past year, North Macedonia has issued a restriction, without international/bilateral support, on the export/import of medical goods (e.g. medicines, oxygen, medical supplies, PPE) due to an infectious disease

outbreak. On the websites of the Ministry of Health, Institute for Public Health, Ministry of Economy and Customs Office there are no information about such restrictions. [1, 2, 3, 4]

[1] Ministry of Health of Republic of Macedonia. [<http://zdravstvo.gov.mk/sq/home-main/>]. Accessed 14 November 2020.

[2] Institute of Public Health (IPH) of Republic of Macedonia. [<http://iph.mk/>]. Accessed 14 November 2020.

[3] Ministry of Economy of Republic of Macedonia. [<http://www.economy.gov.mk/>]. Accessed 14 November 2020.

[4] Ministry of Economy of Republic of Macedonia "Customs Office". [<http://www.customs.gov.mk/index.php/mk/>]. Accessed 14 November 2020.

3.7.1b

In the past year, has the country issued a restriction, without international/bilateral support, on the export/import of non-medical goods (e.g. food, textiles, etc) due to an infectious disease outbreak?

Yes = 0, No = 1

Current Year Score: 1

In the past year, there is no evidence that North Macedonia has issued a restriction on the export/import of non-medical goods (e.g. food, textiles, etc.) from another country, stating that was due to the risk posed by an infectious disease outbreak. On the websites of the Ministry of Health, Ministry of Foreign Affairs and Ministry of Interior there is no information about such restrictions. [1, 2, 3] In addition, the World Health Organization (WHO) Disease Outbreak News, World Organization for Animal Health (OIE) Weekly disease information do not have a reference related to a restriction on the export/import of non-medical goods due to an infectious disease outbreak. [4, 5]

[1] Ministry of Health of Republic of Macedonia. [<http://zdravstvo.gov.mk/sq/home-main/>]. Accessed 14 November 2020.

[2] Ministry of Foreign Affairs of Republic of Macedonia. [<https://www.mfa.gov.mk/en>]. Accessed 14 November 2020.

[3] Ministry of Interior of Republic of Macedonia. [<https://mvr.gov.mk/default>]. Accessed 14 November 2020.

[4] World Health Organization (WHO). "Diseases outbreak per country". [<https://www.who.int/csr/don/archive/country/en/>] Accessed 14 November 2020.

[5] World Organization for Animal Health (OIE). "Weekly Disease Information".

[https://www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI] Accessed 14 November 2020.

3.7.2 Travel restrictions

3.7.2a

In the past year, has the country implemented a ban, without international/bilateral support, on travelers arriving from a specific country or countries due to an infectious disease outbreak?

Yes = 0, No = 1

Current Year Score: 0

In the past year, North Macedonia has implemented a ban, without international/bilateral support, on travelers arriving from a specific country or countries due to an infectious disease outbreak. In February 2020 North Macedonia has reported first case of Covid-19 and outbreak is still ongoing. [1, 2] On its 27th session, organized on 24th March 2020, the Government of North Macedonia has introduced a ban on travelers entering North Macedonia due to Covid-19 outbreak. [3]

[1] World Health Organization (WHO). Health Emergency Dashboard. North Macedonia.

[<https://extranet.who.int/publicemergency>] Accessed 14 November 2020.

[2] Ministry of Health of Republic of North Macedonia. COVID/19. [<http://zdravstvo.gov.mk/korona-virus/>]. Accessed 14 November 2020.

[3] Government of North Macedonia. Deputy Prime Minister. "Government's 27th session." [<https://vicepremier-ekonomija.gov.mk/?q=en/node/685>]. Accessed 14 November 2020.

Category 4: Sufficient and robust health sector to treat the sick and protect health workers

4.1 HEALTH CAPACITY IN CLINICS, HOSPITALS, AND COMMUNITY CARE CENTERS

4.1.1 Available human resources for the broader healthcare system

4.1.1a

Doctors per 100,000 people

Input number

Current Year Score: 287.36

2015

WHO; national sources

4.1.1b

Nurses and midwives per 100,000 people

Input number

Current Year Score: 379.17

2015

WHO; national sources

4.1.1c

Does the country have a health workforce strategy in place (which has been updated in the past five years) to identify fields where there is an insufficient workforce and strategies to address these shortcomings?

Yes = 1 , No = 0

Current Year Score: 0

The Republic of North Macedonia does not have a public workforce strategy in place to identify fields where there is an insufficient workforce and strategies to address these shortcomings. The existing strategies are more broad-based and

include the Employment Strategy 2016-2020, [1] which aims at increasing employment, the quality of jobs and productivity with a special emphasis on vulnerable groups, the Employment and Social Reform Program 2020, [2] which focuses on the priorities and reforms in the labor market, employment, education, human capital and skills, and social policy, and the "Skills Vision 2020 through the Skills for Future", [3] which is an initiative to help in the development of human resources in line with the European Union 2020 Strategy. There is also a Country Strategy Paper 2014-2020, which aims at strengthening education and training to build skills for jobs and increase the quality and access of education for all by supporting comprehensive European Union lifelong learning [4]. The "Skills 2020 Former Yugoslav Republic of Macedonia" mentions that there is a substantial under-supply of labor with Higher Education (HE) in particular in health care, whereas no particular mention is made regarding public workforce strategy for public health in the other documents. Websites of the Ministry of Health, Ministry of Labor and Ministry of Education do not have additional information about a health workforce strategy in place (which has been updated in the past five years) to identify fields where there is an insufficient workforce and strategies to address these shortcomings. [5, 6, 7]

[1] Republic of North Macedonia. December 2019. "Economic Reform Programme 2020-2022."

[<https://www.finance.gov.mk/files/6%20draft%20ERP%202020%2005122019%20EN.pdf>]. Accessed 14 November 2020.

[2] European Training Foundation. 23 September 2014. "Skills 2020 Former Yugoslav Republic of Macedonia."

[https://www.etf.europa.eu/sites/default/files/m/FB5A115CA74D506CC1257D5E0036D21F_FRAME%20Skills%202020%20former%20Yugoslav%20Republic%20Macedonia.pdf]. Accessed 14 November 2020.

[3] Republic of North Macedonia. July 2017. "Employment and Social Reform Programme."

[[http://www.mtsp.gov.mk/content/word/esrp_dokumenti/ESRP%20Macedonia%20-%20final%20\(ENG\).pdf](http://www.mtsp.gov.mk/content/word/esrp_dokumenti/ESRP%20Macedonia%20-%20final%20(ENG).pdf)]. Accessed 14 November 2020.

[4] European Training Foundation. 2018. "Former Yugoslav Republic of Macedonia ETF Country Strategy Paper 2017-2020, 2018 Updates." [https://www.etf.europa.eu/sites/default/files/m/EFD5EC349CAEDBADC125821F0054DD95_CSP%202017-2020%20MK_Updates%202018.pdf]. Accessed 14 November 2020.

[5] Ministry of Health of Republic of North Macedonia. [<http://zdravstvo.gov.mk/>]. Accessed 14 November 2020.

[6] Ministry of Labor and Social Policy of Republic of North Macedonia. [<https://www.mtsp.gov.mk/>]. Accessed 14 November 2020.

[7] Ministry of Education and Science of Republic of North Macedonia. [<http://mon.gov.mk/en/>]. Accessed 14 November 2020.

4.1.2 Facilities capacity

4.1.2a

Hospital beds per 100,000 people

Input number

Current Year Score: 428

2017

WHO/World Bank; national sources

4.1.2b

Does the country have the capacity to isolate patients with highly communicable diseases in a biocontainment patient care unit and/or patient isolation room/unit located within the country?

Yes = 1, No = 0

Current Year Score: 1

North Macedonia has the capacity to isolate patients with highly communicable diseases in patient isolation facility located within the country. The isolation units have negative pressure rooms. As per "Law on Protecting the Population from Contagious Disease" of 16 September 2004, with latest amendments from 2016, provisions are made for the quarantine of patients with highly communicable diseases, where "quarantine" involves "isolation which comprises movement limitation for diseased persons or persons under suspicion or contacts with persons diseased from certain high risk diseases accommodated in premises which lower the risk of disease spreading to the lowest possible level, in the presence of personnel who use adequate protective means and a specific regime of movement and behavior". [1] Under Article 13, special measures for protection against contagious diseases include isolation, healthcare monitoring, quarantine, transportation and compulsory treatment. Under Article 28, persons infected by contagious diseases that may be directly transmitted to other persons should be isolated during medical treatment. Decisions for quarantine isolation, quarantine location and duration of the isolation are adopted by the Minister upon a prior proposal from the Committee for contagious diseases. In terms of capacity, there is evidence that the Institute of Lung Disease and Tuberculosis (ILD TB) has separate isolation rooms for the patients [2]. There is also evidence that Acibadem Sistina Hospital, a major medical facility in Skopje, has facilities for isolating patients with infectious diseases and that pose a high risk of spreading, including a negative pressure room [3].

[1] Republic of North Macedonia. 2016. "Law on Protecting the Population from Contagious Disease (Official Gazette 66/04, 139/08, 99/09, 149/14, 150/15, 37/16)." [<http://zdravstvo.gov.mk/wp-content/uploads/2018/01/ZAKON-ZA-ZASHTITA-NA-NASELENIETO-OD-ZARAZNI-BOLESTI-zakluchno-so-br.-37-od-2016.pdf>]. Accessed 14 November 2020.

[2] World Health Organization (WHO). September 2016. "Review of the national tuberculosis program in former Yugoslav Republic of Macedonia." [http://www.euro.who.int/__data/assets/pdf_file/0015/336120/Macedonia-NTP-review-2016.pdf]. Accessed 14 November 2020.

[3] Acibadem Sistina Hospital. "Surgical Intensive Care." [<https://acibademsistina.mk/en/department/surgical-intensive-care/>] Accessed 14 November 2020.

4.1.2c

Does the country meet one of the following criteria?

- Is there evidence that the country has demonstrated capacity to expand isolation capacity in response to an infectious disease outbreak in the past two years?

- Is there evidence that the country has developed, updated or tested a plan to expand isolation capacity in response to an infectious disease outbreak in the past two years?

Yes = 1, No = 0

Current Year Score: 0

There is no evidence that North Macedonia has demonstrated capacity to expand isolation capacity in response to an infectious disease outbreak in the past two years or that there evidence that North Macedonia has developed, updated or tested a plan to expand isolation capacity in response to an infectious disease outbreak in the past two years. Preparation and response plan on the healthcare system when dealing with emergency, crisis condition and disasters, as well as websites of the Ministry of Health, Crisis Management Center and Institute of Public Health do not have information about capacities to expand isolation capacity in response to an infectious disease outbreak in the past two years or that there evidence that North Macedonia has developed, updated or tested a plan to expand isolation capacity in response to an infectious disease outbreak in the past two years. [1, 2, 3, 4]

[1] Republic of North Macedonia. Ministry of Health. 2017. "Preparation and response plan on the healthcare system when dealing with emergency, crisis condition and disasters." [<http://iph.mk/wp-content/uploads/2017/08/Plan-za-podgotvenost-i-odgovor-pri-krizni-sostojbi-i-katastrofi.pdf>]. Accessed 25 April 2021.

[2] Ministry of Health of Republic of North Macedonia. [<http://www.moh.gov.mk/>]. Accessed 25 April 2021.

[3] Crisis Management Center's (CMC) of Republic of North Macedonia. [<http://www.cuk.gov.mk/mk/home-2.html?id=1184>]. Accessed 25 April 2021.

[4] Institute of Public Health (IPH) of Republic of North Macedonia. [<http://www.iph.mk/en/>]. Accessed 25 April 2021.

4.2 SUPPLY CHAIN FOR HEALTH SYSTEM AND HEALTHCARE WORKERS

4.2.1 Routine health care and laboratory system supply

4.2.1a

Is there a national procurement protocol in place which can be utilized by the Ministries of Health and Agriculture for the acquisition of laboratory supplies (e.g. equipment, reagents and media) and medical supplies (e.g. equipment, PPE) for routine needs?

Yes for both laboratory and medical supply needs = 2, Yes, but only for one = 1, No = 0

Current Year Score: 2

In the Republic of North Macedonia there is a national procurement protocol in place which can be utilized by the Ministries of Health and Agriculture for the acquisition of laboratory supplies (such as equipment, reagents and media) and medical supplies (e.g. equipment, PPE) for routine needs. Each institution including the Ministry of Health and the Ministry of Agriculture, Fishery and Water Economy prepares an annual public procurement plan, which contains information on the overall needs for public contracts during the year by types of needed supplies including equipment, reagents and media, needed services and works, expected commencement period of the contract award procedure, estimated value of the public contract, framework agreement procedure, and type of contract award procedure [1]. The procurement system is a centralized electronic system with one location for all e-procurement in the country that is available online. The procurement system contains information about the public procurement procedures, including relevant health and agricultural authorities and laboratory supplies [2]. The electronic system enables electronic submission, storing, opening and evaluation of the bids, and it allows for open calls, restricted calls, and auctions. The procurement procedures are guided by "Law on Public Procurement" of 2019, which sets out the manner and procedure for awarding public procurement contracts [3].

[1] Minister of Finance of Republic of North Macedonia. "Guidelines on the form and the contents of the annual plan for public procurement." [<http://www.bjn.gov.mk/podzakonski-akti-zjn/pravilnik-za-godisen-plan-za-javni-nabavki/>]. Accessed 14 November 2020.

[2] Electronic System of Public Procurement. [<https://www.e-nabavki.gov.mk/PublicAccess/Home.aspx#/home>]. Accessed 14 November 2020.

[3] Republic of North Macedonia. 2019. "Law on Public Procurement (Official Gazette24/19)." [http://www.bjn.gov.mk/wp-content/uploads/2019/05/ZJN_Sluzben-vesnik_24-2018-od-01.02.2019.pdf]. Accessed 14 November 2020.

4.2.2 Stockpiling for emergencies

4.2.2a

Does the country have a stockpile of medical supplies (e.g. MCMs, medicines, vaccines, medical equipment, PPE) for national use during a public health emergency?

Yes = 2, Yes, but there is limited evidence about what the stockpile contains = 1, No = 0

Current Year Score: 0

There is no evidence that North Macedonia has a stockpile of medical supplies (e.g. medical countermeasures (MCM), medicines, vaccines, medical equipment, Personal Protective Equipment (PPE)) for national use during a public health emergency. There is no evidence of a stockpile of medical supplies in the Ministry of Health's "Health Strategy of the Republic of Macedonia 2020", the legislation of protection from contagious disease presented in "Law on Protecting the Population from Contagious Disease", "National Platform of the Republic of Macedonia for Disaster Risk Reduction 2010", which outlines the risk reduction strategy and response and "Preparation and response plan on the healthcare system when dealing with emergency, crisis condition and disasters", which only defines that the Ministry of Health is responsible for preparing the procedures for providing stocks to be stored in secure and easily accessible locations. [1, 2, 3, 4]. There is no further evidence provided on the websites of the Ministry of Health, Ministry Defense, Ministry of Internal Affairs, the Crisis Management Center, and the North Macedonia Agency for Medicines and Medical Devices. [5, 6, 7, 8, 9] During Covid-19 pandemic North Macedonia has received medical supplies from its international partners, such as the EU and NATO. Procured items included furnished and equipped triage containers, ventilators and devices for artificial ventilation, Covid-19 test kits, laboratory equipment, personal protective equipment and other items essential for the response. [10, 11]

[1] Ministry of Health of Republic of Macedonia. February 2007. "Health Strategy of the Republic of Macedonia 2020." [http://zdravje2020.mk/doc/Zdravje2020_ENG-20mart2017.pdf]. Accessed 14 November 2020.

[2] Republic of North Macedonia. 2016. "Law on Protecting the Population from Contagious Disease (Official Gazette 66/04, 139/08, 99/09, 149/14, 150/15, 37/16)." [<http://zdravstvo.gov.mk/wp-content/uploads/2018/01/ZAKON-ZA-ZASHTITA-NA-NASELENIETO-OD-ZARAZNI-BOLESTI-zakluchno-so-br.-37-od-2016.pdf>]. Accessed 14 November 2020.

[3] Republic of Macedonia. 2010. "National Platform of the Republic of Macedonia for Disaster Risk Reduction 2010." [<http://www.macedfrr.gov.mk/files/publications/NPDRR.III.Edition.pdf>]. Accessed 14 November 2020.

[4] Republic of North Macedonia. Ministry of Health. 2017. "Preparation and response plan on the healthcare system when dealing with emergency, crisis condition and disasters." [<http://iph.mk/wp-content/uploads/2017/08/Plan-za-podgotvenost-i-odgovor-pri-krizni-sostojbi-i-katastrofi.pdf>]. Accessed 14 November 2020.

[5] Ministry of Health of Republic of North Macedonia. [<http://zdravstvo.gov.mk/>]. Accessed 14 November 2020.

[6] Ministry of Defense of Republic of North Macedonia. [<http://morm.gov.mk/?lang=en>]. Accessed 14 November 2020.

[7] Ministry of Internal Affairs of Republic of North Macedonia. [<http://www.mvr.gov.mk/>]. Accessed 14 November 2020.

[8] Crisis Management Center (CMC) of Republic of North Macedonia. [<http://www.cuk.gov.mk/mk/%D0%BF%D0%BE%D1%87%D0%B5%D1%82%D0%BD%D0%BO-2.html>]. Accessed 14 November 2020.

[9] North Macedonian Agency for Medicines and Medical Devices (MALMED). [<https://malmed.gov.mk/>]. Accessed 14 November 2020.

[10] European Western Balkans. October 2020. "EU sends further protective equipment to North Macedonia and Montenegro." [<https://europeanwesternbalkans.com/2020/10/13/eu-sends-further-protective-equipment-to-north-macedonia-and-montenegro/>]. Accessed 14 November 2020.

[11] Anadolu Agency (AA). October 2020. "North Macedonia to receive Covid-19 aid from NATO." [<https://www.aa.com.tr/en/europe/north-macedonia-to-receive-covid-19-aid-from-nato/2000505>]. Accessed 14 November 2020.

4.2.2b

Does the country have a stockpile of laboratory supplies (e.g. reagents, media) for national use during a public health emergency?

Yes = 2, Yes, but there is limited evidence about what the stockpile contains = 1, No = 0

Current Year Score: 0

There is no evidence that the country has a stockpile of laboratory supplies (e.g. reagents, media) for national use during a public health emergency. There is no evidence of a stockpile of laboratory supplies in the Ministry of Health's "Health Strategy of the Republic of Macedonia 2020", the legislation of protection from contagious disease presented in "Law on Protecting the Population from Contagious Disease", the "National Platform of the Republic of Macedonia for Disaster Risk Reduction 2010", which outlines the risk reduction strategy and response, nor the "Preparation and response plan on the healthcare system when dealing with emergency, crisis condition and disasters", which only defines that the Ministry of Health is responsible for preparing the procedures for providing stocks to be stored in secure and easily accessible locations. [1, 2, 3, 4]. There is no further evidence provided on the websites of the Ministry of Health, Ministry Defense, Ministry of Internal Affairs, the Crisis Management Center, and the North Macedonia Agency for Medicines and Medical Devices. [5, 6, 7, 8, 9] During Covid-19 pandemic North Macedonia has received medical supplies from its international partners, such as the European Union (EU). Procured items included furnished and equipped triage containers, ventilators and devices for artificial ventilation, Covid-19 test kits, laboratory equipment, personal protective equipment and other items essential for the response. [10]

[1] Ministry of Health of Republic of Macedonia. February 2007. "Health Strategy of the Republic of Macedonia 2020." [http://zdravje2020.mk/doc/Zdravje2020_ENG-20mart2017.pdf]. Accessed 14 November 2020.

[2] Republic of North Macedonia. 2016. "Law on Protecting the Population from Contagious Disease (Official Gazette 66/04, 139/08, 99/09, 149/14, 150/15, 37/16)." [<http://zdravstvo.gov.mk/wp-content/uploads/2018/01/ZAKON-ZA-ZASHTITA-NA-NASELENIETO-OD-ZARAZNI-BOLESTI-zakluchno-so-br.-37-od-2016.pdf>]. Accessed 14 November 2020.

[3] Republic of Macedonia. 2010. "National Platform of the Republic of Macedonia for Disaster Risk Reduction 2010." [<http://www.macefdr.gov.mk/files/publications/NPDRR.III.Edition.pdf>]. Accessed 14 November 2020.

[4] Republic of North Macedonia. Ministry of Health. 2017. "Preparation and response plan on the healthcare system when dealing with emergency, crisis condition and disasters." [<http://iph.mk/wp-content/uploads/2017/08/Plan-za-podgotvenost-i-odgovor-pri-krizni-sostojbi-i-katastrofi.pdf>]. Accessed 14 November 2020.

[5] Ministry of Health of Republic of North Macedonia. [<http://zdravstvo.gov.mk/>]. Accessed 14 November 2020.

[6] Ministry of Defense of Republic of North Macedonia. [<http://morm.gov.mk/?lang=en>]. Accessed 14 November 2020.

[7] Ministry of Internal Affairs of Republic of North Macedonia. [<http://www.mvr.gov.mk/>]. Accessed 14 November 2020.

[8] Crisis Management Center (CMC) of Republic of North Macedonia. [<http://www.cuk.gov.mk/mk/%D0%BF%D0%BE%D1%87%D0%B5%D1%82%D0%BD%D0%B0-2.html>]. Accessed 14 November 2020.

[9] North Macedonian Agency for Medicines and Medical Devices (MALMED). [<https://malmed.gov.mk/>]. Accessed 14 November 2020.

[10] United Nations Office for the Coordination of Humanitarian Affairs (OCHA). September 2020. "Strengthening responses to Covid-19 in the Western Balkans". [<https://malmed.gov.mk/>]. Accessed 14 November 2020.

4.2.2c

Is there evidence that the country conducts or requires an annual review of the national stockpile to ensure the supply is sufficient for a public health emergency?

Yes = 1, No = 0

Current Year Score: 0

There is no evidence that North Macedonia conducts or requires an annual review of the national stockpile to ensure the supply is sufficient for a public health emergency. Such requirements are not conducted in the Ministry of Health's "Health Strategy of the Republic of Macedonia 2020", or the legislation on protection from contagious disease presented in "Law on Protecting the Population from Contagious Disease" and "National Platform of the Republic of Macedonia for Disaster Risk Reduction 2010", which outlines the risk-reduction strategy and response, or the "Preparation and response plan on the healthcare system when dealing with emergency, crisis condition and disasters", which only clarifies that the Ministry of Health is responsible for preparing the procedures for providing stocks to be stored in secure and easily accessible locations. [1, 2, 3, 4]. There is no further evidence provided on the websites of the Ministry of Health, Ministry of Defense, Ministry of Internal Affairs, the Crisis Management Center, and the North Macedonia Agency for Medicines and Medical Devices. [5, 6, 7, 8, 9]

[1] Ministry of Health of Republic of Macedonia. February 2007. "Health Strategy of the Republic of Macedonia 2020." [http://zdravje2020.mk/doc/Zdravje2020_ENG-20mart2017.pdf]. Accessed 14 November 2020.

[2] Republic of North Macedonia. 2016. "Law on Protecting the Population from Contagious Disease (Official Gazette 66/04, 139/08, 99/09, 149/14, 150/15, 37/16)." [<http://zdravstvo.gov.mk/wp-content/uploads/2018/01/ZAKON-ZA-ZASHTITA-NA-NASELENIETO-OD-ZARAZNI-BOLESTI-zakluchno-so-br.-37-od-2016.pdf>]. Accessed 14 November 2020.

[3] Republic of Macedonia. 2010. "National Platform of the Republic of Macedonia for Disaster Risk Reduction 2010." [<http://www.macefdrr.gov.mk/files/publications/NPDRR.III.Edition.pdf>]. Accessed 14 November 2020.

[4] Republic of North Macedonia. Ministry of Health. 2017. "Preparation and response plan on the healthcare system when dealing with emergency, crisis condition and disasters." [<http://iph.mk/wp-content/uploads/2017/08/Plan-za-podgotvenost-i-odgovor-pri-krizni-sostojbi-i-katastrofi.pdf>]. Accessed 14 November 2020.

[5] Ministry of Health of Republic of North Macedonia. [<http://zdravstvo.gov.mk/>]. Accessed 14 November 2020.

[6] Ministry of Defense of Republic of North Macedonia. [<http://morm.gov.mk/?lang=en>]. Accessed 14 November 2020.

[7] Ministry of Internal Affairs of Republic of North Macedonia. [<http://www.mvr.gov.mk/>]. Accessed 14 November 2020.

[8] Crisis Management Center (CMC) of Republic of North Macedonia.

[<http://www.cuk.gov.mk/mk/%D0%BF%D0%BE%D1%87%D0%B5%D1%82%D0%BD%D0%B0-2.html>]. Accessed 14 November 2020.

[9] North Macedonian Agency for Medicines and Medical Devices (MALMED). [<https://malmed.gov.mk/>]. Accessed 14 November 2020.

4.2.3 Manufacturing and procurement for emergencies

4.2.3a

Does the country meet one of the following criteria?

- Is there evidence of a plan/agreement to leverage domestic manufacturing capacity to produce medical supplies (e.g. MCMs, medicines, vaccines, equipment, PPE) for national use during a public health emergency?

- Is there evidence of a plan/mechanism to procure medical supplies (e.g. MCMs, medicines, vaccines, equipment, PPE) for national use during a public health emergency?

Needs to meet at least one of the criteria to be scored a 1 on this measure., Yes for both = 1, Yes for one = 1, No for both = 0

Current Year Score: 1

There is no evidence that North Macedonia has a plan/agreement to leverage domestic manufacturing capacity to produce medical supplies (e.g. Medical Countermeasures (MCM), medicines, vaccines, equipment, PPE) for national use during a public health emergency. However, there is evidence that North Macedonia has a plan/mechanism to procure medical

supplies (e.g. MCMs, medicines, vaccines, equipment, PPE) for national use during a public health emergency.

"Preparation and response plan on the healthcare system when dealing with emergency, crisis condition and disasters", under section 2.2, envisages that the Agency for Drugs and Medical Devices, in case of emergencies, crises and disasters, can respond immediately with all its facilities and supply additional urgent drugs and medical devices in increased quantities, but all measures refer to import of medical supplies. [1] Law on Protection of Population from Infectious Diseases, Health Strategy of the Republic of Macedonia 2020, as well as websites of the Ministry of Health, Agency for Medicines and Medical Devices, Institute for Public Health and Chamber of Commerce do not have additional information about leveraging domestic manufacturing capacity to produce medical supplies nor a plan/mechanism to procure medical supplies for national use during a public health emergency [2, 3, 4, 5, 6, 7] North Macedonia has been part of the European Union (EU) Joint Procurement Agreement for Medical Countermeasures, which ensures that member states have access to MCM from abroad if necessary when a serious cross-border threat to health is registered. The agreement aims to "secure more equitable access to specific medical countermeasures and improved security of supply", as well as balancing prices for EU member states. It is also designed to ensure acquisition of vaccines, antivirals and medical countermeasures for serious cross-border threats to health [8].

[1] Republic of North Macedonia. Ministry of Health. 2017. "Preparation and response plan on the healthcare system when dealing with emergency, crisis condition and disasters." [<http://iph.mk/wp-content/uploads/2017/08/Plan-za-podgotvenost-i-odgovor-pri-krizni-sostojbi-i-katastrofi.pdf>]. Accessed 14 November 2020.

[2] Republic of North Macedonia. 2016. "Law on Protecting the Population from Contagious Disease (Official Gazette 66/04, 139/08, 99/09, 149/14, 150/15, 37/16)." [<http://zdravstvo.gov.mk/wp-content/uploads/2018/01/ZAKON-ZA-ZASHTITA-NA-NASELENIETO-OD-ZARAZNI-BOLESTI-zakluchno-so-br.-37-od-2016.pdf>]. Accessed 14 November 2020.

[3] Ministry of Health of Republic of Macedonia. February 2007. "Health Strategy of the Republic of Macedonia 2020." [http://zdravje2020.mk/doc/Zdravje2020_ENG-20mart2017.pdf]. Accessed 14 November 2020.

[4] Ministry of Health of Republic of North Macedonia. [<http://zdravstvo.gov.mk/>]. Accessed 14 November 2020.

[5] Institute of Public Health (IPH) of Republic of Macedonia. [<http://iph.mk/>]. Accessed 14 November 2020.

[6] North Macedonian Agency for Medicines and Medical Devices (MALMED). [<https://malmed.gov.mk/>]. Accessed 14 November 2020.

[7] Chamber of Commerce of North Macedonia. [<http://www.mchamber.org.mk/default.aspx?mid=1&lng=1>]. Accessed 14 November 2020.

[8] European Commission. "Joint Procurement Of Medical Countermeasures."

[https://ec.europa.eu/health/preparedness_response/joint_procurement_en]. Accessed 3 September 2020

4.2.3b

Does the country meet one of the following criteria?

- Is there evidence of a plan/agreement to leverage domestic manufacturing capacity to produce laboratory supplies (e.g. reagents, media) for national use during a public health emergency?

- Is there evidence of a plan/mechanism to procure laboratory supplies (e.g. reagents, media) for national use during a public health emergency?

Needs to meet at least one of the criteria to be scored a 1 on this measure., Yes for both = 1, Yes for one = 1, No for both = 0

Current Year Score: 0

There is no evidence that North Macedonia has a plan/agreement to leverage domestic manufacturing capacity to produce laboratory supplies (e.g. reagents, media) for national use during a public health emergency or a plan/mechanism to procure laboratory supplies (e.g. reagents, media) for national use during a public health emergency. "Preparation and response plan on the healthcare system when dealing with emergency, crisis condition and disasters", under section 2.2, envisages that the

Agency for Drugs and Medical Devices in case of emergencies, crises and disasters, can respond immediately with all its facilities and supply additional urgent drugs and medical devices in increased quantities, but all measures refer to import of medical supplies. [1] Law on Protection of Population from Infectious Diseases, Health Strategy of the Republic of Macedonia 2020, as well as websites of the Ministry of Health, Agency for Medicines and Medical Devices, Institute for Public Health and Chamber of Commerce do not have additional information about leveraging domestic manufacturing capacity to produce laboratory supplies (e.g. reagents, media) for national use during a public health emergency or a plan/mechanism to procure laboratory supplies (e.g. reagents, media) for national use during a public health emergency. [2, 3, 4, 5, 6, 7]

[1] Republic of North Macedonia. Ministry of Health. 2017. "Preparation and response plan on the healthcare system when dealing with emergency, crisis condition and disasters." [<http://iph.mk/wp-content/uploads/2017/08/Plan-za-podgotvenost-i-odgovor-pri-krizni-sostojbi-i-katastrofi.pdf>]. Accessed 14 November 2020.

[2] Republic of North Macedonia. 2016. Law on Protecting the Population from Contagious Disease (Official Gazette 66/04, 139/08, 99/09, 149/14, 150/15, 37/16)." [<http://zdravstvo.gov.mk/wp-content/uploads/2018/01/ZAKON-ZA-ZASHTITA-NA-NASELENIETO-OD-ZARAZNI-BOLESTI-zakluchno-so-br.-37-od-2016.pdf>]. Accessed 14 November 2020.

[3] Ministry of Health of Republic of Macedonia. February 2007. "Health Strategy of the Republic of Macedonia 2020." [http://zdravje2020.mk/doc/Zdravje2020_ENG-20mart2017.pdf]. Accessed 14 November 2020.

[4] Ministry of Health of Republic of North Macedonia. [<http://zdravstvo.gov.mk/>]. Accessed 14 November 2020.

[5] Institute of Public Health (IPH) of Republic of Macedonia. [<http://iph.mk/>]. Accessed 14 November 2020.

[6] North Macedonian Agency for Medicines and Medical Devices (MALMED). [<https://malmed.gov.mk/>]. Accessed 14 November 2020.

[7] Chamber of Commerce of North Macedonia. [<http://www.mchamber.org.mk/default.aspx?mid=1&lng=1>]. Accessed 14 November 2020.

4.3 MEDICAL COUNTERMEASURES AND PERSONNEL DEPLOYMENT

4.3.1 System for dispensing medical countermeasures (MCM) during a public health emergency

4.3.1a

Does the country have a plan, program, or guidelines in place for dispensing medical countermeasures (MCM) for national use during a public health emergency (i.e., antibiotics, vaccines, therapeutics and diagnostics)?

Yes = 1 , No = 0

Current Year Score: 0

There is no evidence that North Macedonia has a plan, program, or guidelines in place for dispensing medical countermeasures (MCM) for national use during a public health emergency (i.e., antibiotics, vaccines, therapeutics and diagnostics). The "Preparation and response plan on the healthcare system when dealing with emergency, crisis conditions and disasters", under section 2.2, envisages that the Agency for Drugs and Medical Devices, in case of emergencies, crises and disasters, can respond immediately with all its facilities and supply additional urgent drugs and medical devices in increased quantities. [1]

Neither the Law on Protection of Population from Infectious Diseases, Health Strategy of the Republic of Macedonia 2020, nor the websites of the Ministry of Health, Agency for Medicines and Medical Devices or Institute for Public Health have additional information about a plan, program, or guidelines in place for dispensing medical countermeasures (MCM) for national use during a public health emergency. [2, 3, 4, 5, 6]

- [1] Republic of North Macedonia. Ministry of Health. 2017. "Preparation and response plan on the healthcare system when dealing with emergency, crisis condition and disasters." [<http://iph.mk/wp-content/uploads/2017/08/Plan-za-podgotvenost-i-odgovor-pri-krizni-sostojbi-i-katastrofi.pdf>]. Accessed 14 November 2020.
- [2] Republic of North Macedonia. 2016. "Law on Protecting the Population from Contagious Disease (Official Gazette 66/04, 139/08, 99/09, 149/14, 150/15, 37/16)." [<http://zdravstvo.gov.mk/wp-content/uploads/2018/01/ZAKON-ZA-ZASHTITA-NA-NASELENIETO-OD-ZARAZNI-BOLESTI-zakluchno-so-br.-37-od-2016.pdf>]. Accessed 14 November 2020.
- [3] Ministry of Health of Republic of Macedonia. February 2007. "Health Strategy of the Republic of Macedonia 2020." [http://zdravje2020.mk/doc/Zdravje2020_ENG-20mart2017.pdf]. Accessed 14 November 2020.
- [4] Ministry of Health of Republic of North Macedonia. [<http://zdravstvo.gov.mk/>]. Accessed 14 November 2020.
- [5] Institute of Public Health (IPH) of Republic of Macedonia. [<http://iph.mk/>]. Accessed 14 November 2020.
- [6] North Macedonian Agency for Medicines and Medical Devices (MALMED). [<https://malmed.gov.mk/>]. Accessed 14 November 2020.

4.3.2 System for receiving foreign health personnel during a public health emergency

4.3.2a

Is there a public plan in place to receive health personnel from other countries to respond to a public health emergency?

Yes = 1, No = 0

Current Year Score: 0

There is no publicly available evidence that a public plan is in place to receive health personnel from other countries to respond to a public health emergency. However, the Republic of North Macedonia is part of the European Union (EU) Civil Protection Mechanism (EUCPM) through which it receives health personnel from other countries in response to a public health emergency. Membership in the EUCPM is the responsibility of the Protection and Rescue Directorate of North Macedonia [1, 2]. The Mechanism was set up to enable coordinated assistance from participating states to victims of natural and manmade disasters in Europe and elsewhere. It currently includes all 28 EU Member States in addition to Iceland, Montenegro, Norway, Serbia, North Macedonia and Turkey. Furthermore, established under the EUCPM as part of the European Emergency Response Capacity is the European Medical Corps, which enables quick deployment of teams and equipment from EU Member States to provide medical assistance and public health expertise in response to emergencies inside and outside the EU including emergency medical teams, public health teams, mobile laboratories, etc. [3]. However, there is no specific or detailed operational plan for deploying the health personnel when they arrive from other countries. There is also no public evidence of a plan for receiving health personnel from other countries to respond to a public health emergency provided by the Ministry of Health, the Ministry of Defense, or the Crisis Management Center [4, 5, 6].

- [1] Knowledge for Resilient Society. "Protection and Rescue Directorate of Macedonia." [<http://kforce.uns.ac.rs/consortium-members/member-partner/99-protection-and-rescue-directorate-of-macedonia.html>]. Accessed 14 November 2020.
- [2] European Civil Protection and Humanitarian Aid Operations. "EU Civil Protection Mechanism." [http://ec.europa.eu/echo/what/civil-protection/mechanism_en]. Accessed 14 November 2020.
- [3] European Civil Protection and Humanitarian Aid Operations. April 2018. "European Medical Corps ECHO Factsheet." [http://ec.europa.eu/echo/files/aid/countries/factsheets/thematic/European_Medical_Corps_en.pdf]. Accessed 14 November 2020.
- [4] Ministry of Health of Republic of North Macedonia. "Strategies." [<http://zdravstvo.gov.mk/sq/strategijite/>]. Accessed 14 November 2020.
- [5] Ministry of Defense of Republic of North Macedonia. [<http://morm.gov.mk/?lang=en>]. Accessed 14 November 2020.
- [6] Crisis Management Center (CMC) of Republic of North Macedonia.

[<http://www.cuk.gov.mk/mk/%D0%BF%D0%BE%D1%87%D0%B5%D1%82%D0%BD%D0%B0-2.html>]. Accessed 14 November 2020.

4.4 HEALTHCARE ACCESS

4.4.1 Access to healthcare

4.4.1a

Does the constitution explicitly guarantee citizens' right to medical care?

Guaranteed free = 4, Guaranteed right = 3, Aspirational or subject to progressive realization = 2, Guaranteed for some groups, not universally = 1, No specific provision = 0

Current Year Score: 3

2020

World Policy Analysis Center

4.4.1b

Access to skilled birth attendants (% of population)

Input number

Current Year Score: 99.9

2016

WHO/World Bank/United Nations Children's Fund (UNICEF)

4.4.1c

Out-of-pocket health expenditures per capita, purchasing power parity (PPP; current international \$)

Input number

Current Year Score: 295.74

2017

WHO Global Health Expenditure database

4.4.2 Paid medical leave

4.4.2a

Are workers guaranteed paid sick leave?

Paid sick leave = 2, Unpaid sick leave = 1, No sick leave = 0

Current Year Score: 2

2020

4.4.3 Healthcare worker access to healthcare

4.4.3a

Has the government issued legislation, a policy, or a public statement committing to provide prioritized healthcare services to healthcare workers who become sick as a result of responding to a public health emergency?

Yes = 1 , No = 0

Current Year Score: 0

There is no evidence that the government has issued legislation, a policy or a public statement committing to provide prioritized healthcare services to healthcare workers who become sick as a result of responding to a public health emergency. A review of the national health strategy by the Ministry of Health [1], legislation on contagious disease [2], national platform on disaster risk reduction [3], preparation and response plan on the healthcare system when dealing with emergency, crisis conditions and disasters [4], review by the European Observatory on Health Systems and Policies [5], and national occupational safety and health profile by the International Labor Organization [6] did not provide evidence of the existence of such legislation. However, the country's "Operational Plan and Guidelines: Risk Management in Case of Pandemic Influenza in the Republic of Macedonia" requires the consideration of vaccinating healthcare workers when the vaccine becomes available [7].

[1] Ministry of Health of Republic of North Macedonia. February 2007. "Health Strategy of the Republic of Macedonia 2020." [http://zdravje2020.mk/doc/Zdravje2020_ENG-20mart2017.pdf]. Accessed 14 November 2020.

[2] Republic of North Macedonia. 2016. "Law on Protecting the Population from Contagious Disease (Official Gazette 66/04, 139/08, 99/09, 149/14, 150/15, 37/16)." [http://zdravstvo.gov.mk/wp-content/uploads/2018/01/ZAKON-ZA-ZASHTITA-NA-NASELENIETO-OD-ZARAZNI-BOLESTI-zakluchno-so-br.-37-od-2016.pdf]. Accessed 14 November 2020.

[3] Republic of Macedonia. 2010. "National Platform of the Republic of Macedonia for Disaster Risk Reduction 2010." [http://www.macedfrr.gov.mk/files/publications/NPDRR.III.Edition.pdf]. Accessed 14 November 2020.

[4] Republic of North Macedonia. Ministry of Health. 2017. "Preparation and response plan on the healthcare system when dealing with emergency, crisis condition and disasters." [http://iph.mk/wp-content/uploads/2017/08/Plan-za-podgotvenost-i-odgovor-pri-krizni-sostojbi-i-katastrofi.pdf]. Accessed 14 November 2020.

[5] European Observatory on Health Systems and Policies. 2017. "The Former Yugoslav Republic of Macedonia Health System Review." Health Systems in Transition 19.3. [http://www.euro.who.int/__data/assets/pdf_file/0006/338955/Macedonia-HiT-web.pdf]. Accessed 14 November 2020.

[6] International Labor Organization (ILO). National Occupational Safety and Health Profile Report: Macedonian Occupational Safety and Health Report." [https://www.ilo.org/dyn/legosh/en/f?p=14100:1100:0::NO::P1100_ISO_CODE3,P1100_SUBCODE_CODE,P1100_YEAR:MKD,,2013]. Accessed 14 November 2020.

[7] Republic of North Macedonia. September 2013. "Operational Plan and Guidelines: Risk Management in Case of Pandemic Influenza in the Republic of Macedonia." [http://iph.mk/wp-content/uploads/2014/09/MKD-National-Pandemic-Plan-2013.pdf]. Accessed 14 November 2020.

4.5 COMMUNICATIONS WITH HEALTHCARE WORKERS DURING A PUBLIC HEALTH EMERGENCY

4.5.1 Communication with healthcare workers

4.5.1a

Is there a system in place for public health officials and healthcare workers to communicate during a public health emergency?

Yes = 1 , No = 0

Current Year Score: 1

North Macedonia has a system in place for public health officials and healthcare workers to communicate during a public health emergency.

According to the 2019 World Health Organization (WHO) Joint External Evaluation Report of the Republic of North Macedonia, North Macedonia has clear, well-structured standard operating procedures used by general practitioners (GPs) and hospitals to alert their local PHC in case of a suspected public health emergency. Local centers alert their regional counterparts, who will in turn inform the Ministry of Health (MOH) and Institute of Public Health (IPH), including the NFP. The MOH assesses the situation and decides whether the health emergency is of international concern. If so, it asks the IPH to notify the WHO. All actors involved seem to have a clear understanding of their roles and responsibilities and of the importance of notifying possible threats to public health. Coordination, communication and advocacy have been built into standard operating procedures and accompanying legislation, creating awareness about the importance of the International Health Regulation (2005). The need to cope with serious natural disasters and crises in the past has reinforced awareness of, and attention to, the importance of the IHR. The same bottom-up system of communication for notifying possible threats is used in a top-down manner when managing a crisis situation. [1]

The Covid-19 pandemic underlined the urgent need for fast, effective and strategic intelligence on epidemics and health, and networking mechanisms that can provide support to those working in public health across North Macedonia. In August 2020, the North Macedonian MOH and IPH inaugurated the new Epidemics and Public Health Emergency Operations Center in Skopje. The Center will provide centralized, real-time information, monitoring and reporting, and advice on the response to public health events and emergencies. Bringing together epidemiological expertise from the Institute of Public Health, it will offer digital solutions for an early-warning system to report and detect disease and public health events in a timely way. Ultimately, the Center will improve surveillance and coordination among epidemiologists, laboratory staff and public health experts across the 10 other public health centers and 21 units in North Macedonia. [2]

[1] World Health Organization (WHO). 2019. "Joint External Evaluation Report of IHR Core Capacities of the Republic of North Macedonia." [<https://apps.who.int/iris/bitstream/handle/10665/325320/WHO-WHE-CPI-2019.59-eng.pdf?sequence=1>]. Accessed 14 November 2020.

[2] World Health Organization (WHO). 2019. "North Macedonia - Epidemics and Public Health Emergency Operations Centre opens in North Macedonia." [<https://www.euro.who.int/en/countries/north-macedonia/news/news/2021/8/epidemics-and-public-health-emergency-operations-centre-opens-in-north-macedonia>]. Accessed 14 November 2020.

4.5.1b

Does the system for public health officials and healthcare workers to communicate during an emergency encompass healthcare workers in both the public and private sector?

Yes = 1 , No = 0

Current Year Score: 0

In North Macedonia, there is no evidence that the system for public health officials and healthcare workers to communicate during an emergency encompass healthcare workers in both the public and private sector. According to the 2019 World Health Organization (WHO) Joint External Evaluation Report of the Republic of North Macedonia, North Macedonia has a clear and comprehensive set of laws, preparedness and response plans and standard operating procedures that define all the necessary roles, responsibilities and interactions concerning risk communication. They cover risk communication between government institutions, and between these institutions and stakeholders outside government. However, there is no reference to communication with the private sector. [1] Section 3.3 entitles "Communication during emergencies, crises and disasters" of the "Preparation and response plan on the healthcare system when dealing with emergency, crisis condition and disasters" details a risk communication plan that is specifically intended for use during a public health emergencies. In this section, communication with media, key partners and within the health sector is emphasized. However, communication with the private sector is not directly mentioned. [2] Neither the Law on Protecting the Population from Contagious Disease, nor the websites of the Ministry of Health and Institute for Public Health have additional information about the system for public health officials and healthcare workers to communicate during an emergency encompassing healthcare workers in both the public and private sector. [3, 4, 5]

[1] World Health Organization (WHO). 2019. "Joint External Evaluation Report of IHR Core Capacities of the Republic of North Macedonia." [https://apps.who.int/iris/bitstream/handle/10665/325320/WHO-WHE-CPI-2019.59-eng.pdf?sequence=1]. Accessed 14 November 2020.

[2] World Health Organization (WHO). 2019. "Joint External Evaluation Report of IHR Core Capacities of the Republic of North Macedonia." [https://apps.who.int/iris/bitstream/handle/10665/325320/WHO-WHE-CPI-2019.59-eng.pdf?sequence=1]. Accessed 14 November 2020.

[3] Republic of North Macedonia. 2016. "Law on Protecting the Population from Contagious Disease (Official Gazette 66/04, 139/08, 99/09, 149/14, 150/15, 37/16)." [http://zdravstvo.gov.mk/wp-content/uploads/2018/01/ZAKON-ZA-ZASHTITA-NA-NASELENIETO-OD-ZARAZNI-BOLESTI-zakluchno-so-br.-37-od-2016.pdf]. Accessed 14 November 2020.

[4] Ministry of Health of Republic of North Macedonia. [http://zdravstvo.gov.mk/]. Accessed 14 November 2020.

[5] Institute of Public Health (IPH) of Republic of Macedonia. [http://iph.mk/]. Accessed 14 November 2020.

4.6 INFECTION CONTROL PRACTICES AND AVAILABILITY OF EQUIPMENT

4.6.1 Healthcare associated infection (HCAI) prevention and control programs

4.6.1a

Is there evidence that the national public health system is monitoring for and tracking the number of healthcare associated infections (HCAI) that take place in healthcare facilities?

Yes = 1 , No = 0

Current Year Score: 0

There is insufficient evidence of a national public health system monitoring for and tracking the number of healthcare-associated infections (HCIAAs) that take place in healthcare facilities.

There is no evidence of reporting by the Institute of Public Health (IPH) on the number of HCIAAs that take place in healthcare facilities [1]. There is no evidence provided on the Ministry of Health's website [2] of a monitoring and tracking system for

HCIAs, and no such system is mentioned in the "National Strategy for Containment of Antimicrobial Resistance 2012-2016" [3, 4]. However, there is some information about healthcare workers who have contracted Covid-19 through their work. [5]. According to the 2019 World Health Organization (WHO) Joint External Evaluation Report for the Republic of North Macedonia, there are national and local commissions for the control of HCAs and a person responsible for infection control. A strategy for the control and prevention of HCAs should be developed and implemented. This should include the stipulation that the national commission for the control of HCAs develops defined goals and a strategy, and that hospital commissions are functional everywhere. It should also take into account the need for measures to address stigmatization around reporting HCAs. All hospitals should have professionals trained in the prevention and control of HCAs on their staff and a relevant national training program should be developed. [6]

[1] Institute of Public Health (IPH) of Republic of North Macedonia. "Diseases Reports." [http://www.iph.mk/en/multimedia/diseases-reports/]. Accessed 14 November 2020.

[2] Ministry of Health of Republic of North Macedonia. [http://zdravstvo.gov.mk/sq/home-main/]. Accessed 14 November 2020.

[3] World Health Organization (WHO). 2017. "Global Database for Antimicrobial Resistance Country Self Assessment." [http://amrcountryprogress.org/]. Accessed 22 August 2018.

[4] Ministry of Health of Republic of North Macedonia. March 2011. "National Strategy for Containment of Antimicrobial Resistance 2012-2016." [http://extwprlegs1.fao.org/docs/pdf/mac169253.pdf]. Accessed 23 August 2018.

[5] Government of Republic of North Macedonia. Covid-19 official website. [https://koronavirus.gov.mk/]. Accessed 23 August 2018.

[6] World Health Organization (WHO). 2019. "Joint External Evaluation Report of IHR Core Capacities of the Republic of North Macedonia." [https://apps.who.int/iris/bitstream/handle/10665/325320/WHO-WHE-CPI-2019.59-eng.pdf?sequence=1]. Accessed 14 November 2020.

4.7 CAPACITY TO TEST AND APPROVE NEW MEDICAL COUNTERMEASURES

4.7.1 Regulatory process for conducting clinical trials of unregistered interventions

4.7.1a

Is there a national requirement for ethical review (e.g., from an ethics committee or via Institutional Review Board approval) before beginning a clinical trial?

Yes = 1 , No = 0

Current Year Score: 1

There is a national requirement for ethical review from an ethics committee before beginning a clinical trial. [1] Under "Law on Medicinal Products and Medical Devices", of 2007, last amended in 2016, there are two provisions in regard to ethical review. Under Article 54, clinical trials of medicinal products should be performed in accordance with the ethical principles of the Declaration of Helsinki and other signed international agreements, principles of good clinical practice in clinical trials and with mandatory and guaranteed protection of personal data and rights of persons involved in the trials. In addition, under Article 58, the application for clinical trials should contain a positive opinion of the Ethical Committee among other requirements. The Ministry of Health is in charge of establishing the Ethical Committee.

[1] Republic of North Macedonia. "Law on Medicinal Products and Medical Devices (Official Gazette 106/07, 88/10, 36/11, 53/11, 136/11, 11/12, 147/13, 164/13, 27/14, 43/14, 88/15, 121/2014, 113/15, 154/15, 228/15, 7/16, 53/16)."

[<http://zdravstvo.gov.mk/wp-content/uploads/2018/01/ZAKON-ZA-LEKOVITE-I-MEDITSINSKITE-SREDSTVA-zakluchno-so-br.-53-od-2016.pdf>]. Accessed 14 November 2020.

4.7.1b

Is there an expedited process for approving clinical trials for unregistered medical countermeasures (MCM) to treat ongoing epidemics?

Yes = 1 , No = 0

Current Year Score: 0

There is no evidence of an expedited process for approving clinical trials for unregistered medical countermeasures to treat ongoing pandemics. Legal provisions are only in reference to authorization for import of medicinal products during exceptional cases, including infections. The Law on Medicinal Products and Medical Devices of 2007, last amended in 2016, states under Article 79 that the Medicines Agency should issue an authorization for import of medicinal products in certain situations, which include medicinal products that are needed in exceptional cases, e.g. infections, poisoning, radiation etc. or in other cases concerning the interest of protection of public health for which marketing authorization has not been issued [1]. There is also no evidence provided on the websites of the Ministry of Health or Ministry of Education and Science on this issue [2, 3].

[1] Republic of North Macedonia. "Law on Medicinal Products and Medical Devices (Official Gazette 106/07, 88/10, 36/11, 53/11, 136/11, 11/12, 147/13, 164/13, 27/14, 43/14, 88/15, 121/2014, 113/15, 154/15, 228/15, 7/16, 53/16)."

[<http://zdravstvo.gov.mk/wp-content/uploads/2018/01/ZAKON-ZA-LEKOVITE-I-MEDITSINSKITE-SREDSTVA-zakluchno-so-br.-53-od-2016.pdf>]. Accessed 14 November 2020.

[2] Ministry of Health of Republic of North Macedonia. [<http://zdravstvo.gov.mk/sq/home-main/>]. Accessed 14 November 2020.

[3] Ministry of Education and Science of Republic of North Macedonia. [<http://mon.gov.mk/en/>]. Accessed 14 November 2020.

4.7.2 Regulatory process for approving medical countermeasures

4.7.2a

Is there a government agency responsible for approving new medical countermeasures (MCM) for humans?

Yes = 1 , No = 0

Current Year Score: 1

The Republic of North Macedonia has a governmental agency responsible for approving new medical countermeasures for humans. The Agency for Drugs and Medical Means (MALMED) is the government agency responsible for approving new medical countermeasures for humans. [1]The agency aims to ensure the protection of health in the area of medicines and medical devices through efficient implementation of the regulation and supervision, as well as informing experts and the wider public. The agency was established on 16 September 2014 based on "Law on Medicinal Products and Medical Devices" as an independent public administration body [2]. The functions of the agency include, among others: (i) issuing authorizations for the manufacture of medicinal products, (ii) issuing approvals for the manufacture of medical devices, (iii) issuing permits for distribution, retail of medicines and medical devices, and placing on the market of medicinal products, (iv) approving advertising for medical products, (v) maintaining a register of medicines and medical devices and manufacturers in Macedonia, and (vi) issuing authorizations and/or notifications for clinical trials of medicinal products, medical aids, and medical devices [2, 3]. The law does not provide a specific mention of medical countermeasures or approving products

specifically for use during health emergencies, however under Article 79 MALMED may issue an authorization for import of medicinal products, for which marketing authorization has not been issued, in exceptional cases that include the interest of protecting public health.

[1] Macedonian Agency for Drugs and Medical Means (MALMED). [<https://malmed.gov.mk/%d0%b7%d0%b0-%d0%bd%d0%b0%d1%81/>]. Accessed 14 November 2020.

[2] Republic of North Macedonia. "Law on Medicinal Products and Medical Devices (Official Gazette 106/07, 88/10, 36/11, 53/11, 136/11, 11/12, 147/13, 164/13, 27/14, 43/14, 88/15, 121/2014, 113/15, 154/15, 228/15, 7/16, 53/16)." [<http://zdravstvo.gov.mk/wp-content/uploads/2018/01/ZAKON-ZA-LEKOVITE-I-MEDITSINSKITE-SREDSTVA-zakluchno-so-br.-53-od-2016.pdf>]. Accessed 14 November 2020.

[3] World Health Organization(WHO). "The Former Yugoslav Republic of Macedonia." [http://www.who.int/medical_devices/countries/regulations/mkd.pdf]. Accessed 14 November 2020.

4.7.2b

Is there an expedited process for approving medical countermeasures (MCM) for human use during public health emergencies?

Yes = 1 , No = 0

Current Year Score: 1

There is an expedited process for approving medical countermeasures for human use during public health emergencies. [1] As per the Law on Medicinal Products and Medical Devices, under Article 31, the Agency for Drugs and Medical Means (MALMED), in the exceptional cases of objective and justifiable reasons concerning public health (rare diseases, ethical aspects and life-threatening diseases), if an appropriate medicinal product is unavailable, may issue conditional marketing authorization for the period until the end of the circumstances. This period cannot exceed 1 year. The law does not provide a specific mention of medical countermeasures or approving products specifically for use during health emergencies, however under Article 79 MALMED may issue an authorization for import of medicinal products, for which marketing authorization has not been issued, in exceptional cases that include the interest of protecting public health. The agency's website does not provide any specific information on the expedited process for approving medical countermeasures for human use during public health emergencies [2], but it does provide the legislation on medical products and medical devices, which stipulates the expedited process.

[1] Republic of North Macedonia. "Law on Medicinal Products and Medical Devices (Official Gazette 106/07, 88/10, 36/11, 53/11, 136/11, 11/12, 147/13, 164/13, 27/14, 43/14, 88/15, 121/2014, 113/15, 154/15, 228/15, 7/16, 53/16)." [<http://zdravstvo.gov.mk/wp-content/uploads/2018/01/ZAKON-ZA-LEKOVITE-I-MEDITSINSKITE-SREDSTVA-zakluchno-so-br.-53-od-2016.pdf>]. Accessed 14 November 2020.

[2] Macedonian Agency for Drugs and Medical Means (MALMED). "Placing medicines on the market." [<https://malmed.gov.mk/%d1%81%d1%82%d0%b0%d0%b2%d0%b0%d1%9a%d0%b5-%d0%bd%d0%b0-%d0%bb%d0%b5%d0%ba%d0%be%d0%b2%d0%b8-%d0%b2%d0%be-%d0%bf%d1%80%d0%be%d0%bc%d0%b5%d1%82/>]. Accessed 14 November 2020.

Category 5: Commitments to improving national capacity, financing plans to address gaps, and adhering to global norms

5.1 INTERNATIONAL HEALTH REGULATIONS (IHR) REPORTING COMPLIANCE AND DISASTER RISK REDUCTION

5.1.1 Official IHR reporting

5.1.1a

Has the country submitted IHR reports to the WHO for the previous calendar year?

Yes = 1 , No = 0

Current Year Score: 1

2020

World Health Organization

5.1.2 Integration of health into disaster risk reduction

5.1.2a

Are epidemics and pandemics integrated into the national risk reduction strategy or is there a standalone national disaster risk reduction strategy for epidemics and pandemics?

Yes = 1 , No = 0

Current Year Score: 1

Pandemics are integrated into the national risk reduction strategy. The country has in place the "National Platform of the Republic of Macedonia for Disaster Risk Reduction 2010", which serves as the country's national risk reduction strategy. The national platform includes a platform for prevention and management of epidemics, a specialized platform on health-related risks coordinated by the Ministry of Health [1, 2, 3].

[1] Republic of North Macedonia. 2010. "National Platform of the Republic of Macedonia for Disaster Risk Reduction 2010." [http://www.macefdr.gov.mk/files/publications/NPDRR_III_Edition.pdf]. Accessed 14 November 2020.

[2] United Nations Office for Disaster Risk Reduction (UNISDR). "The Former Yugoslav Republic of Macedonia." [<https://www.unisdr.org/partners/countries/mkd>]. Accessed 14 November 2020.

[3] Hyogo Framework for Action (HFA). "The Former Yugoslav Republic of Macedonia National progress report on the implementation of the Hyogo Framework for Action 2013-2015." [https://www.preventionweb.net/files/42977_MKD_NationalHFAprogress_2013-15.pdf]. Accessed 14 November 2020.

5.2 CROSS-BORDER AGREEMENTS ON PUBLIC HEALTH AND ANIMAL HEALTH EMERGENCY RESPONSE

5.2.1 Cross-border agreements

5.2.1a

Does the country have cross-border agreements, protocols, or MOUs with neighboring countries, or as part of a regional group, with regards to public health emergencies?

Yes = 2, Yes, but there is evidence of gaps in implementation = 1, No = 0

Current Year Score: 2

The Republic of North Macedonia is part of a regional group and has MOUs with neighboring countries with regard to public health emergencies. [1]The Republic of North Macedonia along with Albania, Kosovo, and Montenegro are part of the GHP Project "GETPrepaReD" (Global Emergency Training and support for Preparedness and Response to Disease outbreaks), which is a project of GHP Program of the Federal Ministry of Health of Germany. GET PrepaReD supports partner countries with advancement of surveillance systems for the early detection of outbreaks, development of crisis plans, practical training on the epidemiology of infectious disease, fast assembly of crisis centers to ensure communication and coordination in the event of health emergencies, deploying international experts, etc. The Institute of Public Health of North Macedonia has also signed a Memorandum of Understanding with RKI on bilateral cooperation between the two institutes within the GETPrepaReD project in the Global Health Program [2]. The focus of this cooperation is to support the strengthening of surveillance systems for infectious diseases, to develop and implement outbreak prevention policies, training in infection epidemiology, and to implement the International Health Regulations. Furthermore, the Republic of North Macedonia is a member of the Southeastern European Health Network. The network aims to develop and deepen regional cooperation, with a focus on common cross-border technical capacity required to deal with potential outbreaks and ensuring proper implementation of the 2005 International Health Regulation (IHR). The network also collaborates on Laboratory Capacity and Information Exchange [3, 4]. Based on the review of the websites of the Ministry of Health, Institute for Public Health and media outlets there are no evidence of gaps in implementation of these agreements. [5, 6] The Republic of North Macedonia, together with Albania, Bosnia and Herzegovina, Bulgaria, Israel, Montenegro, the Republic of Moldova, Romania and Serbia, is part of the Subregional Cooperation Strategy (SCS), which has as one of its objectives, "to ensure emergency preparedness and response in South-eastern Europe Health Network (SEEHN) member countries". [7] In November 2020, Serbia, Albania and North Macedonia signed a memorandum of understanding and cooperation to fight the coronavirus pandemic together.[8]

[1] Federal Ministry of Health of German Bundestag. "GHP Programme, GETPrepaReD."

[<https://ghpp.de/en/projects/getprepared/>]. Accessed 14 November 2020.

[2] Federal Ministry of Health of German Bundestag. "Memorandum of Understanding between the RKI and the Institute of Public Health (IPH), Macedonia." [<https://ghpp.de/en/projects/getprepared/memorandum-of-understanding-between-the-rki-and-the-institute-of-public-health-iph-macedonia/>]. Accessed 14 November 2020.

[3] Bino, Silvia, et al. 2013. "Southeastern European Health Network (SEEHN) Communicable Diseases Surveillance: A Decade of Bridging Trust and Collaboration." *Emerging Health Threats Journal* 6. [<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3557907/>]. Accessed 14 November 2020.

[4] World Health Organization (WHO). November 2005. "The Skopje Pledge."

[http://www.euro.who.int/__data/assets/pdf_file/0005/99743/E88513.pdf?ua=1]. Accessed 14 November 2020.

[5] Ministry of Health of Republic of North Macedonia. [<http://zdravstvo.gov.mk/sq/home-main/>]. Accessed 14 November 2020.

[6] Institute of Public Health (IPH) of Republic of North Macedonia. "Diseases Reports."

[<http://www.iph.mk/en/multimedia/diseases-reports/>]. Accessed 14 November 2020.

[7] World Health Organization (WHO). 2018. "Subregional Cooperation Strategy (SCS) 2018-2023."

[https://www.euro.who.int/__data/assets/pdf_file/0003/392772/seehn-scs-2018-2023-eng.pdf]. Accessed 14 November 2020.

[8] Euroactiv. "Serbia, Albania, North Macedonia to fight Covid-19 together." [<http://zdravstvo.gov.mk/sq/home-main/>]. Accessed 14 November 2020.

5.2.1b

Does the country have cross-border agreements, protocols, or MOUs with neighboring countries, or as part of a regional group, with regards to animal health emergencies?

Yes = 2, Yes, but there is evidence of gaps in implementation = 1, No = 0

Current Year Score: 0

There is insufficient evidence that the Republic of North Macedonia has cross-border agreements, protocols or MOUs with neighboring countries, or as part of a regional group, with regard to animal health emergencies. The country is a member of the South-eastern European Health Network [1]. The network aims to develop and deepen regional cooperation, with a focus on common cross-border technical capacity required to deal with potential disease outbreaks in both human and animals and ensuring proper implementation of the 2005 International Health Regulation (IHR). The network also collaborates on laboratory capacity and information exchange. The network sought to increase regional capacity to rapidly detect clusters of human cases of avian influenza and monitor the spread of avian influenza viruses in both human and animal populations by improving integrated surveillance systems and building laboratory capacity [2, 3]. As part of its Communicable Diseases Surveillance Network, leading coordinators for the network from each country have been appointed in consultation with respective ministries of health in order to be supported by teams of experts in various animal and human health areas [3]. In all this evidence, there is nothing clearly stated about animal health emergency cooperation. Websites of the Ministry of Health, Crisis Management Center and Ministry of Agriculture do not have additional information about cross-border agreements, protocols, or MOUs with neighboring countries, or as part of a regional group, with regard to animal health emergencies. [4, 5, 6]

[1] Southeastern-Europe Health Network (SEEHN). [<http://seehn.org/about-the-see-health-network/>]. Accessed 14 November 2020.

[2] Southeastern-Europe Health Network (SEEHN). "RHDC on Communicable Diseases Control and Surveillance and IHR implementation in SEE." [<http://seehn.org/albania>]. Accessed 14 November 2020.

[3] Bino, Silvia, et al. 2013. "Southeastern European Health Network (SEEHN) Communicable Diseases Surveillance: A Decade of Bridging Trust and Collaboration". *Emerging Health Threats Journal* 6. [<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3557907/>]. Accessed 14 November 2020.

[4] Ministry of Health of Republic of North Macedonia. [<http://www.moh.gov.mk/>]. Accessed 14 November 2020.

[5] Crisis Management Center (CMC) of Republic of North Macedonia. [<http://www.cuk.gov.mk/mk/home-2.html?id=1184>]. Accessed 14 November 2020.

[6] Ministry of Agriculture, Forestry and Water Management of Republic of North Macedonia. [<http://www.mzsv.gov.mk/>]. Accessed 14 November 2020.

5.3 INTERNATIONAL COMMITMENTS

5.3.1 Participation in international agreements

5.3.1a

Does the county have signatory and ratification (or same legal effect) status to the Biological Weapons Convention?

Signed and ratified (or action having the same legal effect) = 2, Signed = 1, Non-compliant or not a member = 0

Current Year Score: 2

2021

Biological Weapons Convention

5.3.1b

Has the country submitted confidence building measures for the Biological Weapons Convention in the past three years?

Yes = 1 , No = 0

Current Year Score: 0

2021

Biological Weapons Convention

5.3.1c

Has the state provided the required United Nations Security Council Resolution (UNSCR) 1540 report to the Security Council Committee established pursuant to resolution 1540 (1540 Committee)?

Yes = 1 , No = 0

Current Year Score: 1

2021

Biological Weapons Convention

5.3.1d

Extent of United Nations Security Council Resolution (UNSCR) 1540 implementation related to legal frameworks and enforcement for countering biological weapons:

Very good (60+ points) = 4, Good (45–59 points) = 3, Moderate (30–44 points) = 2, Weak (15–29 points) = 1, Very weak (0–14 points) or no matrix exists/country is not party to the BWC = 0

Current Year Score: 3

2021

Biological Weapons Convention

5.3.2 Voluntary memberships

5.3.2a

Does the country meet at least 2 of the following criteria?

- Membership in Global Health Security Agenda (GHSA)
- Membership in the Alliance for Country Assessments for Global Health Security and IHR Implementation (JEE Alliance)
- Membership in the Global Partnership Against the Spread of Weapons and Materials of Mass Destruction (GP)
- Membership in the Australia Group (AG)
- Membership in the Proliferation Security Initiative (PSI)

Needs to meet at least two of the criteria to be scored a 1 on this measure. , Yes for five = 1 , Yes for four = 1 , Yes for three = 1 , Yes for two = 1 , Yes for one = 0 , No for all = 0

Current Year Score: 0

2021

Global Health Security Agenda; JE Alliance; Global Partnership; Australia Group; PSI

5.4 JOINT EXTERNAL EVALUATION (JEE) AND PERFORMANCE OF VETERINARY SERVICES PATHWAY (PVS)

5.4.1 Completion and publication of a Joint External Evaluation (JEE) assessment and gap analysis

5.4.1a

Has the country completed a Joint External Evaluation (JEE) or precursor external evaluation (e.g., GHSA pilot external assessment) and published a full public report in the last five years?

Yes = 1 , No = 0

Current Year Score: 1

2021

WHO Strategic Partnership for IHR and Health Security (SPH); Global Health Security Agenda

5.4.1b

Has the country completed and published, within the last five years, either a National Action Plan for Health Security (NAPHS) to address gaps identified through the Joint External Evaluation (JEE) assessment or a national GHSA roadmap that sets milestones for achieving each of the GHSA targets?

Yes = 1 , No = 0

Current Year Score: 0

2021

WHO Strategic Partnership for IHR and Health Security (SPH); Global Health Security Agenda

5.4.2 Completion and publication of a Performance of Veterinary Services (PVS) assessment and gap analysis

5.4.2a

Has the country completed and published a Performance of Veterinary Services (PVS) assessment in the last five years?

Yes = 1 , No = 0

Current Year Score: 0

2021

OIE PVS assessments

5.4.2b

Has the country completed and published a Performance of Veterinary Services (PVS) gap analysis in the last five years?

Yes = 1 , No = 0

Current Year Score: 0

2021

OIE PVS assessments

5.5 FINANCING

5.5.1 National financing for epidemic preparedness

5.5.1a

Is there evidence that the country has allocated national funds to improve capacity to address epidemic threats within the past three years?

Yes = 1 , No = 0

Current Year Score: 0

There is no evidence that North Macedonia has allocated national funds to improve capacity to address epidemic threats within the past three years. Analysis of the national budget for 2020, 2019 and 2018 confirms that the state has allocated funds to improve capacity to address emergency situations, but it cannot be confirmed that these allocations include funds to improve capacity to address epidemic threats. [1, 2, 3] In May 2020, after the emergency situation was declared in North Macedonia due to the Covid-19 outbreak, the government adopted a Decree allocating additional funds in response to the pandemic. [4] On the websites of the Ministry of Finance, Ministry of Health, Ministry of Agriculture and Crisis Management Center there is no additional information about national funds to improve capacity to address epidemic threats within the past three years. [5, 6, 7, 8]

[1] Ministry of Finance of the Republic of North Macedonia. 2019. "National budget for 2020." [https://finance.gov.mk/files/Budget_na_RSM_2020.pdf]. Accessed 14 November 2020.

[2] Ministry of Finance of the Republic of North Macedonia. 2018. "National budget for 2019." [https://www.finance.gov.mk/files/u6/BUDZET_2019_%28SL._VESNIK%29_ZA_OBJAVUVANJE_0.pdf]. Accessed 14 November 2020.

- [3] Ministry of Finance of the Republic of North Macedonia. 2017. "National budget for 2018." [https://www.finance.gov.mk/files/u6/BUDZET%202018%20%28sl.%20Ovesnik%29%20-%2022.12.2017.pdf]. Accessed 14 November 2020.
- [4] Ministry of Finance of the Republic of North Macedonia. 2020. "Decree to amend the budget of the Republic of North Macedonia for 2020 time of emergency." [https://finance.gov.mk/files/Uredba_za_dopolnuvanje_na_budget2020.pdf]. Accessed 14 November 2020.
- [5] Ministry of Finance of Republic of North Macedonia. [https://www.finance.gov.mk/mk/Budget_RSM_2020]. Accessed 14 November 2020.
- [6] Ministry of Health of Republic of North Macedonia. [http://zdravstvo.gov.mk/sq/home-main/]. Accessed 14 November 2020.
- [7] Ministry of Agriculture, Forestry and Water Economy of Republic of North Macedonia. [http://www.mzsv.gov.mk/al.aspx]. Accessed 14 November 2020.
- [8] Crisis Management Center (CMS) of Republic of North Macedonia. [http://www.cuk.gov.mk/mk/]. Accessed 14 November 2020.

5.5.2 Financing under Joint External Evaluation (JEE) and Performance of Veterinary Services (PVS) reports and gap analyses

5.5.2a

Does the Joint External Evaluation (JEE) report, National Action Plan for Health Security (NAPHS), and/or national GHSA roadmap allocate or describe specific funding from the national budget (covering a time-period either in the future or within the past five years) to address the identified gaps?

Yes = 1 , No/country has not conducted a JEE = 0

Current Year Score: 0

2021

WHO Strategic Partnership for IHR and Health Security (SPH); Global Health Security Agenda

5.5.2b

Does the Performance of Veterinary Services (PVS) gap analysis and/or PVS assessment allocate or describe specific funding from the national budget (covering a time-period either in the future or within the past five years) to address the identified gaps?

Yes = 1 , No/country has not conducted a PVS = 0

Current Year Score: 0

2021

OIE PVS assessments

5.5.3 Financing for emergency response

5.5.3a

Is there a publicly identified special emergency public financing mechanism and funds which the country can access in the face of a public health emergency (such as through a dedicated national reserve fund, an established agreement with the

World Bank pandemic financing facility/other multilateral emergency funding mechanism, or other pathway identified through a public health or state of emergency act)?

Yes = 1, No = 0

Current Year Score: 0

There is no publicly identified special emergency public financing mechanism or funds that North Macedonia can access in the face of a public health emergency. The national budget of North Macedonia has allocations for emergency situations, but it cannot be confirmed that these funds also include a public health emergency. [1, 2, 3] Websites of the Ministry of Finance, Ministry of Health and Crisis Management Center do not have information about special emergency public financing mechanisms or funds which the country can access in the event of a public health emergency. [4, 5, 6] North Macedonia is not International Development Association (IDA)-eligible country. [7] North Macedonia is one of the beneficiaries outside of the EU of the EU civil protection mechanism, whose objective is to strengthen cooperation in the field of civil protection, with a view to improve prevention, preparedness and response to disasters. [8]

[1] Ministry of Finance of the Republic of North Macedonia. 2019. "National budget for 2020."

[https://finance.gov.mk/files/Budget_na_RSM_2020.pdf]. Accessed 14 November 2020.

[2] Ministry of Finance of the Republic of North Macedonia. 2018. "National budget for 2019."

[https://www.finance.gov.mk/files/u6/BUDZET_2019_%28SL._VESNIK%29_ZA_OBJAVUVANJE_0.pdf]. Accessed 14 November 2020.

[3] Ministry of Finance of the Republic of North Macedonia. 2017. "National budget for 2018."

[https://www.finance.gov.mk/files/u6/BUDZET%202018%20%28sl.%20vesnik%29%20-%2022.12.2017.pdf]. Accessed 14 November 2020.

[4] Ministry of Finance of Republic of North Macedonia. [https://www.finance.gov.mk/mk/Budget_RSM_2020]. Accessed 14 November 2020.

[5] Ministry of Health of Republic of North Macedonia. [http://zdravstvo.gov.mk/sq/home-main/]. Accessed 14 November 2020.

[6] Crisis Management Center (CMS) of Republic of North Macedonia. [http://www.cuk.gov.mk/mk/]. Accessed 14 November 2020.

[7] International Development Association (IDA). Borrowing Countries. [https://ida.worldbank.org/about/borrowing-countries]. Accessed 14 November 2020.

[8] European Union (EU) Civil Protection Mechanism. [https://ec.europa.eu/echo/what/civil-protection/mechanism_en]. Accessed 14 November 2020.

5.5.4 Accountability for commitments made at the international stage for addressing epidemic threats

5.5.4a

Is there evidence that senior leaders (president or ministers), in the past three years, have made a public commitment either to:

- Support other countries to improve capacity to address epidemic threats by providing financing or support?
- Improve the country's domestic capacity to address epidemic threats by expanding financing or requesting support to improve capacity?

Needs to meet at least one of the criteria to be scored a 1 on this measure., Yes for both = 1, Yes for one = 1, No for both = 0

Current Year Score: 0

Political leaders in North Macedonia have not made a public commitment in the past three years to improve its own domestic capacity to address epidemic threats by requesting support to improve capacity. However, North Macedonia requested assistance through NATO's Euro-Atlantic Disaster Response Coordination Center (EADRCC) for surgical masks, protective suits and other equipment on 30 March to fight the Covid-19 pandemic. [1] There is no evidence that senior leaders in North Macedonia have made a public commitment to support other countries to improve capacity to address epidemic threats by providing financing or support in the past three years. Websites of the Ministries of Health, Ministry of Foreign Affairs and the World Health Organization do not provide evidence of such commitments. [2, 3, 4]

[1] European Western Balkan. 2020. "Stoltenberg welcomes the support of NATO allies to North Macedonia in Covid-19 fight". [<https://europeanwesternbalkans.com/2020/04/08/stoltenberg-welcomes-the-support-of-nato-allies-to-north-macedonia-in-covid-19-fight/>]. Accessed 14 November 2020.

[2] Ministry of Finance of Republic of North Macedonia. [https://www.finance.gov.mk/mk/Budget_RSM_2020]. Accessed 14 November 2020.

[3] Ministry of Foreign Affairs of Republic of North Macedonia. [<https://www.mfa.gov.mk/en>]. Accessed 14 November 2020.

[4] World Health Organization (WHO). "North Macedonia". [<https://www.euro.who.int/en/countries/north-macedonia>]. Accessed 14 November 2020.

5.5.4b

Is there evidence that the country has, in the past three years, either:

- Provided other countries with financing or technical support to improve capacity to address epidemic threats?
- Requested financing or technical support from donors to improve the country's domestic capacity to address epidemic threats?

Needs to meet at least one of the criteria to be scored a 1 on this measure., Yes for both = 1, Yes for one = 1, No for both = 0

Current Year Score: 1

There is evidence that North Macedonia has requested financing or technical support from donors to improve the country's domestic capacity to address epidemic threats. There is evidence via the Global Health Security Funding Tracker that North Macedonia has invested donor funds to improve domestic capacity to address epidemic threats. The tracker notes that North Macedonia received funding from multiple donors to enhance its capacity on global security preparedness for 2014-2020 in the amount of US\$64 million. [1] In addition, during the Covid-19 outbreak, North Macedonia requested assistance through NATO's Euro-Atlantic Disaster Response Coordination Center (EADRCC) for surgical masks, protective suits and other equipment on 30 March 2020 to fight Covid-19 pandemic. [2] However, Global Health Security Funding Tracker and the websites of the Ministry of Health and Ministry of Foreign Affairs, as well as World Health Organization website do not have information about providing other countries with financing or technical support to improve capacity to address epidemic threats. [1, 3, 4, 5]

[1] Global Health Security Funding Tracker. [<https://tracking.ghscosting.org/details/1016/recipient>]. Accessed 14 November 2020.

[2] European Western Balkans. 2020. "Stoltenberg welcomes the support of NATO allies to North Macedonia in Covid-19 fight". [<https://europeanwesternbalkans.com/2020/04/08/stoltenberg-welcomes-the-support-of-nato-allies-to-north-macedonia-in-covid-19-fight/>]. Accessed 14 November 2020.

[3] Ministry of Finance of Republic of North Macedonia. [https://www.finance.gov.mk/mk/Budget_RSM_2020]. Accessed 14 November 2020.

[4] Ministry of Foreign Affairs of Republic of North Macedonia. [<https://www.mfa.gov.mk/en>]. Accessed 14 November 2020.

[5] World Health Organization (WHO). "North Macedonia". [<https://www.euro.who.int/en/countries/north-macedonia>].

Accessed 14 November 2020

5.5.4c

Is there evidence that the country has fulfilled its full contribution to the WHO within the past two years?

Yes = 1 , No = 0

Current Year Score: 0

2021

Economist Impact analyst qualitative assessment based on official national sources, which vary by country

5.6 COMMITMENT TO SHARING OF GENETIC AND BIOLOGICAL DATA AND SPECIMENS

5.6.1 Commitment to sharing genetic data, clinical specimens, and/or isolated specimens (biological materials) in both emergency and nonemergency research

5.6.1a

Is there a publicly available plan or policy for sharing genetic data, clinical specimens, and/or isolated specimens (biological materials) along with the associated epidemiological data with international organizations and/or other countries that goes beyond influenza?

Yes = 1 , No = 0

Current Year Score: 0

There is no publicly available plan or policy for sharing genetic data, epidemiological data, clinical specimens, and/or isolated specimens (biological materials) along with the associated epidemiological data with international organizations and/or other countries that goes beyond influenza. [1] There is no mention of such a plan or policy in the "Health Strategy of the Republic of Macedonia 2020". Furthermore, there are no data provided by the Republic of North Macedonia to the European Union (EU) Laboratory Capability Monitoring System as part of the European Center for Disease Prevention and Control (ECDC) [2]. There is also no evidence found on the websites of the Ministry of Health and Ministry of Agriculture, Forestry and Water Economy [3, 4].

[1] Ministry of Health of Republic of Macedonia. February 2007. "Health Strategy of the Republic of Macedonia 2020." [http://zdravje2020.mk/doc/Zdravje2020_ENG-20mart2017.pdf]. Accessed 14 November 2020.

[2] European Centre for Disease Prevention and Control (ECDC). 2018. "EU Laboratory Capability Monitoring System (EULabCap): Report on 2016 survey of EU/EEA country capabilities and capacities." [<https://ecdc.europa.eu/en/publications-data/eu-laboratory-capability-monitoring-system-eulabcap-report-2016-survey-eueea>]. Accessed 14 November 2020.

[3] Ministry of Health of Republic of Macedonia. [<http://zdravstvo.gov.mk/>]. Accessed 14 November 2020.

[4] Ministry of Agriculture, Forestry and Water Economy of Republic of Macedonia. [<http://www.mzsv.gov.mk/>]. Accessed 14 November 2020.

5.6.1b

Is there public evidence that the country has not shared samples in accordance with the Pandemic Influenza Preparedness (PIP) framework in the past two years?

Yes = 0, No = 1

Current Year Score: 1

Based on a Review of the Pandemic Influenza Preparedness (PIP) Framework issued by the World Health Organization (WHO) in 2017, there are no references to North Macedonia not having shared samples in accordance with the PIP framework. In addition, there is no media coverage stating that Bosnia and Herzegovina has not shared influenza samples. [1] As part of its "Operational Plan and Guidelines: Risk Management in Case of Pandemic Influenza in the Republic of Macedonia" of September 2013, the country includes sharing samples, data and information with the WHO. [2] Furthermore, as reported by WHO in the "Meeting of the PIP Framework Advisory Group" of April 2018, there is no evidence of refusal to provide samples in accordance with the PIP framework. [3]

[1] World Health Organization (WHO). "Review of the Pandemic Influenza Preparedness Framework." [https://apps.who.int/gb/ebwha/pdf_files/WHA70/A70_17-en.pdf]. Accessed 14 November 2020.

[2] Republic of North Macedonia. 2013. "Operational Plan and Guidelines: Risk Management in Case of Pandemic Influenza in the Republic of Macedonia." [http://iph.mk/wp-content/uploads/2014/09/MKD-National-Pandemic-Plan-2013.pdf]. Accessed 14 November 2020.

[3] World Health Organization (WHO). 2018. "Meeting of the Pandemic Influenza Preparedness Framework Advisory Group." [http://www.who.int/influenza/pip/advisory_group/PIPAG_MR_Apr2018.pdf]. Accessed 14 November 2020.

5.6.1c

Is there public evidence that the country has not shared pandemic pathogen samples during an outbreak in the past two years?

Yes = 0, No = 1

Current Year Score: 1

Based on a review of information from World Health Organization reports and website and media coverage, there is no evidence that North Macedonia has not shared pandemic pathogen samples during an outbreak in the past two years. [1, 2, 3] There is no evidence that North Macedonia has not shared Covid-19 samples during the pandemic. [4]

[1] World Health Organization (WHO). [http://www.who.int]. Accessed 14 November 2020.

[2] World Health Organization (WHO). "Disease Outbreak News, Former Yugoslav Republic of Macedonia." [http://www.who.int/csr/don/archive/country/mkd/en/]. Accessed 27 August 2018.

[3] World Health Organization (WHO). 13 April 2016. "Policy Statement on Data Sharing by the World Health Organization in the Context of Public Health Emergencies." [http://www.who.int/ihr/procedures/SPG_data_sharing.pdf]. Accessed 14 November 2020.

[4] World Health Organization (WHO). "Covid-19". [https://covid19.who.int/region/euro/country/mk]. Accessed 30 October 2020.

Category 6: Overall risk environment and vulnerability to biological threats

6.1 POLITICAL AND SECURITY RISK

6.1.1 Government effectiveness

6.1.1a

Policy formation (Economist Intelligence score; 0-4, where 4=best)

Input number

Current Year Score: 2

2020

Economist Intelligence

6.1.1b

Quality of bureaucracy (Economist Intelligence score; 0-4, where 4=best)

Input number

Current Year Score: 1

2020

Economist Intelligence

6.1.1c

Excessive bureaucracy/red tape (Economist Intelligence score; 0-4, where 4=best)

Input number

Current Year Score: 3

2020

Economist Intelligence

6.1.1d

Vested interests/cronyism (Economist Intelligence score; 0-4, where 4=best)

Input number

Current Year Score: 1

2020

Economist Intelligence

6.1.1e

Country score on Corruption Perception Index (0-100, where 100=best)

Input number

Current Year Score: 35

2020

Transparency International

6.1.1f

Accountability of public officials (Economist Intelligence score; 0-4, where 4=best)

Input number

Current Year Score: 1

2020

Economist Intelligence

6.1.1g

Human rights risk (Economist Intelligence score; 0-4, where 4=best)

Input number

Current Year Score: 2

2020

Economist Intelligence

6.1.2 Orderly transfers of power

6.1.2a

How clear, established, and accepted are constitutional mechanisms for the orderly transfer of power from one government to another?

Very clear, established and accepted = 4, Clear, established and accepted = 3, One of the three criteria (clear, established, accepted) is missing = 2, Two of the three criteria (clear, established, accepted) are missing = 1, Not clear, not established, not accepted = 0

Current Year Score: 1

2021

Economist Intelligence

6.1.3 Risk of social unrest

6.1.3a

What is the risk of disruptive social unrest?

Very low: Social unrest is very unlikely = 4, Low: There is some prospect of social unrest, but disruption would be very limited = 3, Moderate: There is a considerable chance of social unrest, but disruption would be limited = 2, High: Major social unrest is likely, and would cause considerable disruption = 1, Very high: Large-scale social unrest on such a level as to seriously challenge government control of the country is very likely = 0

Current Year Score: 2

2021

Economist Intelligence

6.1.4 Illicit activities by non-state actors

6.1.4a

How likely is it that domestic or foreign terrorists will attack with a frequency or severity that causes substantial disruption?

No threat = 4, Low threat = 3, Moderate threat = 2, High threat = 1, Very high threat = 0

Current Year Score: 2

2021

Economist Intelligence

6.1.4b

What is the level of illicit arms flows within the country?

4 = Very high, 3 = High, 2 = Moderate, 1 = Low, 0 = Very low

Current Year Score: 2

2020

UN Office of Drugs and Crime (UNODC)

6.1.4c

How high is the risk of organized criminal activity to the government or businesses in the country?

Very low = 4, Low = 3, Moderate = 2, High = 1, Very high = 0

Current Year Score: 2

2021

Economist Intelligence

6.1.5 Armed conflict

6.1.5a

Is this country presently subject to an armed conflict, or is there at least a moderate risk of such conflict in the future?

No armed conflict exists = 4, Yes; sporadic conflict = 3, Yes; incursional conflict = 2, Yes, low-level insurgency = 1, Yes; territorial conflict = 0

Current Year Score: 4

2021

Economist Intelligence

6.1.6 Government territorial control

6.1.6a

Does the government's authority extend over the full territory of the country?

Yes = 1, No = 0

Current Year Score: 1

2021

Economist Intelligence

6.1.7 International tensions

6.1.7a

Is there a threat that international disputes/tensions could have a negative effect?

No threat = 4, Low threat = 3, Moderate threat = 2, High threat = 1, Very high threat = 0

Current Year Score: 2

2021

Economist Intelligence

6.2 SOCIO-ECONOMIC RESILIENCE

6.2.1 Literacy

6.2.1a

Adult literacy rate, population 15+ years, both sexes (%)

Input number

Current Year Score: 97.8

2014

United Nations Development Programme (UNDP); United Nations Educational, Scientific and Cultural Organization (UNESCO);
The Economist Intelligence Unit

6.2.2 Gender equality

6.2.2a

United Nations Development Programme (UNDP) Gender Inequality Index score

Input number

Current Year Score: 0.67

2018

United Nations Development Programme (UNDP); The Economist Intelligence Unit

6.2.3 Social inclusion

6.2.3a

Poverty headcount ratio at \$1.90 a day (2011 PPP) (% of population)

Input number

Current Year Score: 1.9

2017

World Bank; Economist Impact

6.2.3b

Share of employment in the informal sector

Greater than 50% = 2, Between 25-50% = 1, Less than 25% = 0

Current Year Score: 0

According to a Labor force survey from 2019, informal employment in North Macedonia is 13.8%. [1] According to the Economic Reform Program 2020-2022, informal employment in North Macedonia is 18.6% [2] World Bank does not have information about informal employment in North Macedonia. [3]

[1] International Labor Organization. 2019. "Overview of the informal economy in North Macedonia."

[https://www.ilo.org/wcmsp5/groups/public/---europe/---ro-geneva/---sro-budapest/documents/genericdocument/wcms_751316.pdf]. Accessed 14 November 2020.

[2] Republic of North Macedonia. December 2019. "Economic Reform Programme 2020-2022."

[<https://www.finance.gov.mk/files/6%20draft%20ERP%202020%2005122019%20EN.pdf>]. Accessed 14 November 2020.

[3] World Bank. "Informal Employment." [<https://data.worldbank.org/indicator/SL.ISV.IFRM.ZS>]. Accessed 14 November 2020.

6.2.3c

Coverage of social insurance programs (% of population)

Scored in quartiles (0-3, where 3=best)

Current Year Score: 3

2016, or latest available

World Bank; Economist Impact calculations

6.2.4 Public confidence in government

6.2.4a

Level of confidence in public institutions

Input number

Current Year Score: 1

2021

Economist Intelligence Democracy Index

6.2.5 Local media and reporting

6.2.5a

Is media coverage robust? Is there open and free discussion of public issues, with a reasonable diversity of opinions?

Input number

Current Year Score: 2

2021

Economist Intelligence Democracy Index

6.2.6 Inequality

6.2.6a

Gini coefficient

Scored 0-1, where 0=best

Current Year Score: 0.33

Latest available.

World Bank; Economist Impact calculations

6.3 INFRASTRUCTURE ADEQUACY

6.3.1 Adequacy of road network

6.3.1a

What is the risk that the road network will prove inadequate to meet needs?

Very low = 4, Low = 3, Moderate = 2, High = 1, Very high = 0

Current Year Score: 2

2021

Economist Intelligence

6.3.2 Adequacy of airports

6.3.2a

What is the risk that air transport will prove inadequate to meet needs?

Very low = 4, Low = 3, Moderate = 2, High = 1, Very high = 0

Current Year Score: 2

2021

Economist Intelligence

6.3.3 Adequacy of power network

6.3.3a

What is the risk that power shortages could be disruptive?

Very low = 4, Low = 3, Moderate = 2, High = 1, Very high = 0

Current Year Score: 2

2021

Economist Intelligence

6.4 ENVIRONMENTAL RISKS

6.4.1 Urbanization

6.4.1a

Urban population (% of total population)

Input number

Current Year Score: 58.21

2019

World Bank

6.4.2 Land use

6.4.2a

Percentage point change in forest area between 2006–2016

Input number

Current Year Score: 1.67

2008-2018

World Bank; Economist Impact

6.4.3 Natural disaster risk

6.4.3a

What is the risk that the economy will suffer a major disruption owing to a natural disaster?

Very low = 4, Low = 3, Moderate = 2, High = 1, Very high = 0

Current Year Score: 2

2021

Economist Intelligence

6.5 PUBLIC HEALTH VULNERABILITIES

6.5.1 Access to quality healthcare

6.5.1a

Total life expectancy (years)

Input number

Current Year Score: 75.69

2018

United Nations; World Bank, UNICEF; Institute for Health Metrics and Evaluation (IHME); Central Intelligence Agency (CIA)
World Factbook

6.5.1b

Age-standardized NCD mortality rate (per 100 000 population)

Input number

Current Year Score: 733.7

2019

WHO

6.5.1c

Population ages 65 and above (% of total population)

Input number

Current Year Score: 14.09

2019

World Bank

6.5.1d

Prevalence of current tobacco use (% of adults)

Input number

Current Year Score: 27.43

2018

World Bank

6.5.1e

Prevalence of obesity among adults

Input number

Current Year Score: 22.4

2016

WHO

6.5.2 Access to potable water and sanitation

6.5.2a

Percentage of homes with access to at least basic water infrastructure

Input number

Current Year Score: 93.14

2017

UNICEF; Economist Impact

6.5.2b

Percentage of homes with access to at least basic sanitation facilities

Input number

Current Year Score: 99

2017

UNICEF; Economist Impact

6.5.3 Public healthcare spending levels per capita

6.5.3a

Domestic general government health expenditure per capita, PPP (current international \$)

Input number

Current Year Score: 615.18

2018

WHO Global Health Expenditure database

6.5.4 Trust in medical and health advice

6.5.4a

Trust medical and health advice from the government

Share of population that trust medical and health advice from the government , More than 80% = 2, Between 60-80%, or no data available = 1, Less than 60% = 0

Current Year Score: 0

2018

Wellcome Trust Global Monitor 2018

6.5.4b

Trust medical and health advice from medical workers

Share of population that trust medical and health advice from health professionals , More than 80% = 2, Between 60-80%, or no data available = 1, Less than 60% = 0

Current Year Score: 1

2018

Wellcome Trust Global Monitor 2018