Bulgaria

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

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: 1

A Bulgarian AMR action plan was formerly developed by the Bulgarian government in 2019, but it is not publicly available. [1] There is no national plan uploaded to the WHO Library of national action plans on AMR. [2] However, the Alliance for the Prudent Use of Antibiotics (APUA) confirms that the Action Plan to Combat Antimicrobial Resistance in Bulgaria 2020-2024 aims to introduce antimicrobial stewardship and the surveillance of AMR, coupled with the implementation of epidemiological control measures. [1] The Plan was prepared by an expert group within the Ministry of Health with representatives from the following backgrounds: human medicine, veterinary medicine and environmental science. The Plan is built on a one-health approach and encompasses concrete actions in legislation, education, competent use, control, awareness and research. [1]

A relevant National Action Plan Against Antimicrobial Resistance exclusively covering the veterinary and food sectors was also put forward in 2017 by the Bulgarian Food Safety Agency. Covering the period up to 2021, the Plan outlines six strategic goals which show commitment towards strengthening existing AMR databases, building on knowledge and evidence obtained through observation, monitoring and research, as well as enhancing coordination measures and actions around AMR monitoring and reporting in the country. [3]

[1] Alliance for the Prudent Use of Antibiotics. 2019. “Bulgaria”. [https://apua.org/bulgaria]. Accessed 11 October 2020.
[2] World Health Organization. “Antimicrobial resistance – Library of national action plans”. [https://www.who.int/antimicrobial-resistance/national-action-plans/library/en/]. Accessed 11 October 2020.
[3] Bulgarian Food Safety Agency. 2017. “National Action Plan Against Antimicrobial Resistance (Национален план за действие срещу антимикробната резистентност)” http://www.babh.government.bg/userfiles/files/vmp_plan.pdf. Accessed 11 October 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 laboratory system in Bulgaria tests for seven out of the 7+1 priority AMR pathogens identified by the World Health Organization. Evidence gathered from the website of the National Center of Infectious and Parasitic Diseases (NCIPD) confirms the existence of a sentinel surveillance system under which the following pathogens can be tested for: E.coli, S.

aureus, S.pneumoniae, Salmonella spp., Shigella spp., N. gonorrheae and Mycobacterium tuberculosis. [1]

The National Reference Laboratories (NRL), based in the capital Sofia and responsible for the above pathogens, are part of the Microbiology Department of the NCIPD. A total of three NRLs work on the AMR priority pathogens – the NRL of Enteric infections, pathogenic cocci and diphtheria, the NRL of Tuberculosis and the NRL of Molecular biology. [2] The work of the NRLs on the AMR priority pathogens is also referenced in the 2007 Tariff for the Fees Collected by the Bodies of State Health Control and National Centers for the Problems of Public Health under the Health Act, last amended in February 2018, which lists the applicable fees collected from private individuals and legal entities for services offered in relation to the ARM pathogens in question. [3]

[1] National Center of Infectious and Parasitic Diseases. 2020. [https://www.ncipd.org]. Accessed 11 October 2020.
[2] National Center of Infectious and Parasitic Diseases. 2020. "Department of Microbilogy". [https://www.ncipd.org/index.php?option=com_k2&view=item&layout=item&id=181&Itemid=1206&lang=en].Accessed 11 October 2020.
[3] Ministry of Health. 2018. "Tariff for the Fees Collected by the Bodies of State Health Control and National Centers for the Problems of Public Health under the Health Act (Тарифа за таксите, които се събират от органите на държавния здравен контрол и националните центрове по проблемите на общественото здраве по закона за здравето)". [https://lex.bg/laws/ldoc/2135567454]. Accessed 11 October 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 insufficient evidence of environmental detection or surveillance activities for antimicrobial residues or AMR organisms taking place in Bulgaria, including by the environmental agency (the Ministry of Environment and Water). While no concrete information was found to demonstrate that detection or surveillance is currently taking place, recent publications on the website of the Ministry of Agriculture, Food and Forests reveal that as of early 2020 discussions on are increasingly taking place at a legislative and administrative level on the implications of antimicrobial residues or AMR organisms on the environment and via the environment in line with the one-health approach promoted by the European Commission. [1]

Currently, the WHO Library of national action plans on AMR does not include a Bulgarian national plan. [2] In addition, the Ministry of Health, the Ministry of Environment and Water, the Executive Environment Agency and the Bulgarian Food Safety Agency (BFSA) were also searched for evidence of the above. [3][4][5] [6]While none were found to contain explicit indications of AMR detection or surveillance activities in air, waterways, soils and forests, the 2017 National Action Plan Against Antimicrobial Resistance and the 2020 Guide to the Rational and Responsible Use of Antimicrobial Products in Veterinary Medicine and Practice, published by the BFSA, both recognise that there is an awareness of the problem and its impediment on maintaining an AMR-neutral environment. [6]

[1] Ministry of Agriculture, Food and Forestry. "Antimicrobial Resistance". [https://www.mzh.government.bg/bg/politiki-i-programi/politiki-i-strategii/politiki-po-agrohranitelnata-veriga/antimikrobna-rezistentnost/]. Accessed 11 October 2020.
[2] World Health Organization. "Antimicrobial resistance – Library of national action plans". [https://www.who.int/antimicrobial-resistance/national-action-plans/library/en/]. Accessed 11 October 2020.
[3] Ministry of Health. "Antimicrobial Resistance". [https://www.mh.government.bg/bg/search/?q=%D0%90%D0%9D%D0%A2%D0%98%D0%9C%D0%98%D0%9A%D0%A0%D0

%9E%D0%91%D0%9D%D0%90%D0%A2%D0%90+%D0%A0%D0%95%D0%97%D0%98%D0%A1%D0%A2%D0%95%D0%9D%D0%A2%D0%9D%D0%9E%D0%A1%D0%A2]. Accessed 11 October 2020.
[4] Ministry of Environment and Water. [https://www.moew.government.bg/]. Accessed 11 October 2020.
[5] Executive Environment Agency. [http://eea.government.bg/]. Accessed 11 October 2020.
[6] Bulgarian Food Safety Agecny. 2020. "Antimicrobial Resistance".
[http://www.babh.government.bg/bg/Page/antimicrobial_resistance/index/antimicrobial_resistance/%D0%90%D0%BD%D1%82%D0%B8%D0%BC%D0%B8%D0%BA%D1%80%D0%BE%D0%B1]. Accessed 11 October 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: 1

Current legislation published by the Ministry of Health and the Bulgarian Drug Agency requires prescriptions for antibiotic use for humans, however, the implementation of existing laws and regulations needs closer monitoring in practice. [1] The 2007 Medicinal Products in Human Medicine Act, last updated in August 2019, contains the medical instructions and provisions put in place for general practitioners, specialist doctors and pharmacists for dispensing medical products, including antibiotics, on a prescription-only bases for individual patients. [2] In addition, the 2009 Ordinance № 4 on the Conditions and Procedure for Prescribing and Dispensing Medicinal Products was last revised in 2019 and at present gives further guidance on the information that prescriptions need to contain for prescription-only drugs (antibiotics being among them) and the obligations of pharmacists in respecting the rules for their proper distribution to patients. [3]

Discrepancies between the above legislation and the reality on the ground were acutely highlighted by the COVID-19 crisis and mass hysteria over the spread of the virus which took over Bulgaria in the spring of 2020. The disregard for the rules set by both the Act and the Ordinance prompted an official governmental intervention and an increase in on-site inspections, even leading to the temporary closure of some pharmacies where violations were found to be particularly grave. [1]

[1] Mediapool.bg. 2020. "Pharmacies will be shut for selling medical products without prescriptions (Ще затварят аптеките за отпускане на лекарства без рецепта)". [https://www.mediapool.bg/shte-zatvaryat-apteki-za-otpuskane-na-lekarstva-bez-retsepta-news304642.html]. Accessed 11 October 2020.
[2] Ministry of Health. 2020. "Medicinal Products in Human Medicine Act (Закон за лекарствените продукти в хуманната медицина)". [https://www.bda.bg/images/stories/documents/regulations/zakoni/ZLPHM_NEW.pdf]. Accessed 11 October 2020.
[3] Ministry of Health. 2019. "Ordinance № 4 on the Conditions and Procedures of Prescribing and Dispensing Medicinal Products (Наредба №4 от 4 март 2009г. за условията и реда за предписване и отпускане на лекарствените продукти)".
[https://www.bda.bg/images/stories/documents/regulations/naredbi/201910_%D0%9D%D0%B0%D1%80%D0%B5%D0%B4%D0%B1%D0%B0%204.pdf]. Accessed 11 October 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

Publicly available evidence published by the Bulgarian Food Safety Agency (BFSA) confirms that existing legislation requires prescriptions for antibiotic use in animals, and there is no evidence of gaps in enforcement. The 2017 National Action Plan Against Antimicrobial Resistance (AMR) in Bulgaria, applicable to the veterinary and food sector, mandates the BFSA to strengthen its control over the prescription, wholesale, retail trade and marketing of antibiotics and antimicrobial veterinary medicinal products (VMPs). [1] The Action Plan and the 2020 Guide to the Rational and Responsible Use of Antimicrobial Products in Veterinary Medicine and Practice oblige licensed distributors and operators to sell said VMPs only when presented with a valid, verified prescription from an approved registered veterinary practitioner. [2][3] Relevant sections applying to the prescription and general use of antibiotics in animals were also added into the 2006 Veterinary Act when it was last amended in August 2020. [4]

There is no evidence in media outlets or other publicly accessible sources to suggest that these recent regulations are violated or that antibiotics for animals are distributed without prescriptions. The most recent official statics on the use of antibiotics in animals in Bulgaria cover the period from 2011-2017 and thus cannot be used reliably to conclude whether or not the legislation has been successful in reducing illicit practices surrounding the sale of antibiotics in the veterinary field. [5]

[1] Bulgarian Food Safety Agency. 2017. “National Action Plan Against Antimicrobial Resistance (AMR) in Bulgaria”. [https://ec.europa.eu/health/sites/health/files/antimicrobial_resistance/docs/amr_ev_20191015_co06b_en.pdf]. Accessed 11 October 2020.
[2] Bulgarian Food Safety Agency. 2017. “National Action Plan Against Antimicrobial Resistance (Национален план за действие срещу антимикробната резистентност)” http://www.babh.government.bg/userfiles/files/vmp_plan.pdf]. Accessed 11 October 2020.
[3] Bulgarian Food Safety Agency. 2020. “Guide to the Rational and Responsible Use of Antimicrobial Products in Veterinary Medicine and Practice (Ръководство за разумна и отговорна употреба на антимикробни средства във ветеринарната медицина и практика”.
[http://www.babh.government.bg/userfiles/files/VMP/%20%D0%97%D0%90%20%D0%A0%D0%90%D0%97%D0%A3%D0%9C%D0%9D%D0%90%20%D0%98%20%D0%9E%D0%A2%D0%93%D0%9E%D0%92%D0%9E%D0%A0%D0%9D%D0%90%20%D0%A3%D0%9F%D0%9E%D0%A2%D0%A0%D0%95%D0%91%D0%90%20%D0%9D%D0%90%20%D0%90%D0%9D%D0%A2%D0%98%D0%9C%D0%98%D0%9A%D0%A0%D0%9E%D0%91%D0%9D%D0%98%20%D0%A1%D0%A0%D0%95%D0%94%D0%A1%D0%A2%D0%92%D0%90%20Final.pdf]. Accessed 11 October 2020.
[4] Ministry of Agriculture, Food and Forestry. 2020. “Veterinary Act (Закон за ветеринарномедицинската дейност). [https://www.lex.bg/laws/ldoc/2135512300]. Accessed 11 October 2020.
[5] Agri.bg. 2019. “The use of antibiotics in animals is on the rise (Увеличава се употребата на антибиотици в животновъдството у нас)”. [https://agri.bg/novini/rast-na-upotrebata-na-antibiotitsi-v-zhivotnovadstvoto-u-nas]. Accessed 11 October 2020.

1.2 ZOONOTIC 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 2019-2021 National Program for Prophylaxis, Surveillance, Control and Eradication of Zoonotic Pathogens constitutes Bulgaria’s national plan on zoonotic diseases. The Program does explicitly mention zoonoses as a risk to human health in the

context of preventing the transmission of zoonotic pathogens from animal populations to humans and in identifying the particular hazards posed by some of the more life-threating zoonoses. [1]

The Program was published by the Bulgarian Food Safety Agency and includes a list of fifteen zoonotic diseases which command special attention and require close monitoring and speedy interventions if confirmed in animals. These include: Anthrax, African Swine Fever, Rabies, Infectious epididymitis, Avian influenza, Classical swine fever, Newcastle Disease, West Nile Fever, Tuberculosis of the Ruminants. [1] Separate sub-programs have also been published by the BFSA, detailing the concrete approach to the above zoonoses. [2]

[1] Bulgarian Food Safety Agency. 2019. "2019-2021 National Program for Prophylaxis, Surveillance, Control and Eradication of Zoonotic Pathogens (Национална програма за профилактика, надзор, контрол и ликвидиране на болестите по животните, включително зоонозите 2019-2021)". [http://bfsa.bg/userfiles/files/ZJ/DPP19-21/3_0_NPBJZ%202019%20-%202021_12.2018%20
[3].pdf]. Accessed 11 October 2020.
[2] Bulgarian Food Safety Agency. "Animal Healthcare (Здравеопазване на животните)". [http://bfsa.bg/bg/Page/NPBJZ19-21/index/NPBJZ19-21/%D0%9D%D0%B0%D1%86%D0%B8%D0%BE%D0%BD%D0%B0%D0%BB%D0%BD%D0%B0]. Accessed 11 October 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: 1

Measures for risk identification and reduction for zoonotic disease spillover events from animals to humans are contained in the 2019-2021 National Program for Prophylaxis, Surveillance, Control and Eradication of Zoonotic Pathogens. The Program details the governmental approach in reducing the transmission risk for various zoonoses from animals to humans and outlines the concrete roles of state bodies such as the Ministry of Agriculture, Food and Forests, the Ministry of Health, the Bulgarian Food Safety Agency (BFSA), the National Center of Infectious and Parasitic Diseases (NCIPD), as well as private individuals and corporate entities, should zoonotic infections be proven. The Program assesses the spillover risks for Anthrax, African Swine Fever, Rabies, Infectious epididymitis, Avian influenza, Classical swine fever, Newcastle Disease, West Nile Fever, Tuberculosis of the Ruminants and other more infrequently encountered zoonotic diseases, detailing particular preventative spillover measures such as disinfection, disinsection or deratization (and including an annual budget for this). The document also includes risk mitigation provisions such as vaccination requirements, prophylactic sampling and testing aimed at minimizing transmission risks. [1]

Spillover events are also addressed by the 2003 Ordinance № 44 on the Veterinary and Sanitary requirements for Animal Markets. The Ordinance contains measures which directly target at reducing risk of infectious disease spillover events. These include sanitary and veterinary requirements mandating for disinfection schedules, animal movement, waste and wastewater treatment, safe transport and entrance, isolation and veterinary rooms, and other measures. [2]

In addition, the 2018 Ordinance № 1 on the Terms and Procedure for Carrying Out Disinfections, Disinsections and Deratizations provides further details on how zoonotic disease spillovers can be minimalized using one of the three methods mentioned above – disinfection, disinsection or deratization (DDD) – to tackle and terminate pathogenic microorganisms of public health concern. The Ordinance stipulates that DDDs may be ordered by either the Minister of Health or the Minister of

Agriculture, Food and Forests. [3]

[1] Bulgarian Food Safety Agency. 2019. "2019-2021 National National Program for Prophylaxis, Surveillance, Control and Eradication of Zoonotic Pathogens (Национална програма за профилактика, надзор, контрол и ликвидиране на болестите по животните, включително зоонозите 2019-2021)". [http://bfsa.bg/userfiles/files/ZJ/DPP19-21/3_0_NPBJZ%202019%20-%202021_12.2018%20
[3].pdf]. Accessed 11 October 2020.
[2] Ministry of Agriculture and Forestry. 2003. "Ordinance № 44 of October 29, 2003 on the Veterinary and Sanitary requirements for Animal Markets (Наредба № 44 от 29 Октомври 2003 Г. За Ветеринарно-Санитарните Изисквания Към Пазарите За Животни". [https://www.lex.bg/laws/ldoc/2135474338]. Accessed 29 April 2021.
[3] Ministry of Health. 2018. "Ordinance № 1 on the Conditions and Procedures for Carrying Out Disinfections, Disinsections and Deratizations (Наредба №1 за условията и реда за извършване на дезинфекции, дезинсекции и дератизации)". [https://www.mh.government.bg/media/filer_public/2018/01/19/naredba1-5-01-2018-uslovia-red-ddd.pdf]. Accessed 11 October 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

An updated national plan containing provisions for the surveillance and control of multiple zoonotic pathogens of public health concern was published in 2019. The 2019-2021 National Program for Prophylaxis, Surveillance, Control and Eradication of Zoonotic Pathogens includes a list of fifteen zoonotic diseases identified as causing a range of risks to human health and includes specific measures for the surveillance and control of the following most notable illnesses: Anthrax, African Swine Fever, Rabies, Infectious epididymitis, Avian influenza, Classical swine fever, Newcastle Disease, West Nile Fever, Bovine Tuberculosis. [1]

Further, more detailed guidelines for the surveillance and control of these zoonoses have been published by the Bulgarian Food Safety Agency (BFSA), most which were updated in 2019 or 2020. The documents also include instructions for official control, information on disease hotspots in Bulgaria and the European Union at large, as well as a list of BFSA-licensed laboratories. [2] A new draft ordinance on the surveillance and monitoring of zoonoses, their prophylaxis, control and eradication was also put up for public discussion by the Ministry of Health in June 2020. [3]

[1] Bulgarian Food Safety Agency. 2019. "2019-2021 National Program for Prophylaxis, Surveillance, Control and Eradication of Zoonotic Pathogens (Национална програма за профилактика, надзор, контрол и ликвидиране на болестите по животните, включително зоонозите 2019-2021)". [http://bfsa.bg/userfiles/files/ZJ/DPP19-21/3_0_NPBJZ%202019%20-%202021_12.2018%20
[3].pdf]. Accessed 11 October 2020.
[2] Bulgarian Food Safety Agency. "Animal Healthcare (Здравеопазване на животните)". [http://bfsa.bg/bg/Page/NPBJZ19-21/index/NPBJZ19-21/%D0%9D%D0%B0%D1%86%D0%B8%D0%BE%D0%BD%D0%B0%D0%BB%D0%BD%D0%B0]. Accessed 11 October 2020.
[3] Credoweb.2020. "Ministry of Health has a new ordinance project for the surveillance of zoonozes (МЗ с нов проект на наредба за надзор на зоонозите)". [https://www.credoweb.bg/publication/123328/mz-s-nov-proekt-na-naredba-za-nadzor-na-zoonozite]. Accessed 11 October 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

There is insufficient evidence that the government of Bulgaria has an agency dedicated to zoonotic disease that functions across ministries.

The Risk Assessment Center on Food Chain (RACFC) is a cross-ministerial, cross-sectoral governmental body. The Center is governed by a management board made up of two Deputy Ministers of Agriculture, Food and Forestry, two Deputy Ministers of Health and the independently appointed executive director of the RACFC. According to its mission statement, the RACFC organizes and prepares scientific risk assessments through independent, transparent and impartial analysis of issues that directly or indirectly relate to animal and plant health. [1] While the RACFC receives its funding from the Ministry of Agriculture, Food and Forestry, the 2016 Food Chain Risk Assessment Center Act (updated in 2017) stipulates that data collection and reporting involve the joint efforts of multiple ministries and specialist governmental agencies when required for the research and scientific evaluations of food chain risks. According to the Act, the RACFC also develops cross-ministerial and cross-sectoral recommendations concerning the training of employees of institutions, implementing the state policy on food chain and employees of bodies, implementing official control under relevant European Commission regulations. [2] However, the center is not dedicated to zoonotic disease.

The Animal Health and Welfare Directorate within the Bulgarian Food and Safety Agency (in itself a subsidiary agency of the Ministry of Agriculture, Food and Forestry) is another dedicated department committed to developing programs for the prophylaxis, control and eradication of zoonoses, ensuring the public remains protected from the transmission of zoonotic diseases. [3] The specialist Medical Arachnoenthomology and Zoology with Disinsection and Deratization laboratory within the National Center of Infections and Parasitic Diseases also conducts work related to zoonotic diseases and acts in an advisory capacity to the Ministry of Health in drafting ordinances and other guidance material on the topic of zoonoses. [4]

[1] Risk Assessment Center on Food Chain. “Managing Board (Управителен съвет)”. [https://corhv.government.bg/?cat=15]. Accessed 11 October 2020.
[2] Risk Assessment Center on Food Chain. 2017. "Risk Assessment Food Chain Act (Закон за Центъра за оценка на риска по хранителната верига)". [https://corhv.government.bg/?cat=59]. Accessed 14 November 2020.
[3] Bulgarian Food Safety Agency. “Animal Health and Welfare Directorate (Дирекция Здравеопазване и хуманно отношение към животните и конрол на фуражите”).
[http://www.babh.government.bg/bg/Page/83/index/83/%D0%94%D0%B8%D1%80%D0%B5%D0%BA%D1%86%D0%B8%D1%8F%20%D0%97%EF%BF%BD]. Accessed 11 October 2020.
[3] National Center of Infectious and Parasitic Diseases. “Laboratory Medical Arachnoenthomology and Zoology with Disinsection and Deratization”.
[https://www.ncipd.org/index.php?option=com_k2&view=item&layout=item&id=234&Itemid=1250&lang=bg]. Accessed 11 October 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

There is a mandatory mechanism for owners of livestock to conduct and report on disease surveillance to a central governmental agency. According to provisions in article 55 of the 2006 Veterinary Act, last amended in August 2020, the owners, caretakers, transporters and traders of animals are obliged to promptly notify the Bulgarian Food Safety Agency (BFSA) if suspicions of contagious zoonotic diseases arise. [1]

A section of the website of the BFSA is dedicated to animal diseases subject to compulsory surveillance and reporting, containing detailed instructions to livestock owners for cases when a disease is either suspected or confirmed. Both endemic diseases, such as tuberculosis, and exotic ones, such as foot-and-mouth disease, must be reported to BFSA even where only a single animal is suspected to have contracted the illness. According to the page, livestock owners may use one of several channels to communicate with the BFSA: contact a licensed veterinary practitioner via their Regional Directorate for Food Safety, call a centralised hotline number or use the BFSA's e-services. The complete list of zoonozes subject to compulsory reporting is published on the BFSA's website. [2]

[1] Ministry of Agriculture, Food and Forestry. 2020. "Veterinary Act (Закон за ветеринарномедицинската дейност). [https://www.lex.bg/laws/ldoc/2135512300]. Accessed 11 October 2020.
[2] Bulgarian Food Safety Agency. "Official Control (Официален контрол)". [http://www.babh.government.bg/bg/Object/highlight_new/view/13/%D0%91%D0%BE%D0%BB%D0%B5%D1%81%D1%82%D0%B8%20%D0%BF%D0%BE]. Accessed 11 October 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 is no publicly accessible evidence which suggests that information generated through surveillance activities for animals is kept confidential. The 2006 Veterinary Act, last amended in August 2020, and instructions provided to livestock owners on the website of the Bulgarian Food Safety Agency (BFSA) do not address the issue of confidentiality in reporting on animal diseases. [1] [2] While patient confidentiality is referenced in the 2019 Bulgarian Veterinary Union Code for Good Veterinary Practice and Professional Ethics of the Veterinarian, Article 50 of the Veterinary Act obliges the BFSA to publicly provide details on the emergence of any zoonotic disease in the country. [3][1] Recent media publications on zoonoses appear to confirm the official full disclosure policy, particularly in relation to a 2019 swine fever outbreak as reports frequently mention the general location and often the name of the farm where an outbreak was confirmed. [4] The websites of the Ministry of Agriculuture, Food and Forestry, and the Ministry of Health contain no additional relevant information on the topic. [5][6]

[1] Ministry of Agriculture, Food and Forestry. 2020. "Veterinary Act (Закон за ветеринарномедицинската дейност). [https://www.lex.bg/laws/ldoc/2135512300]. Accessed 11 October 2020.
[2] Bulgarian Food Safety Agency. "Official Control (Официален контрол)". [http://www.babh.government.bg/bg/Object/highlight_new/view/13/%D0%91%D0%BE%D0%BB%D0%B5%D1%81%D1%82%D0%B8%20%D0%BF%D0%BE]. Accessed 11 October 2020.
[3] Bulgarian Veterinary Union. 2019. "Code for Good Veterinary Practice and Professional Ethics of the Veterinarian (Кодекс за добра ветеринарномедицинска практика и професионална етика на ветеринара)". [https://dv.parliament.bg/DVWeb/showMaterialDV.jsp?idMat=136651]. Accessed 11 October 2020.
[4] News.bg. 2019. "A firs case of Swine fever is confirmed in southwest Bulgaria (Потвърдиха първи случай на чума по

свинете в Югозападна България)". [https://news.bg/economics/potvardiha-parvi-sluchay-na-chuma-po-svinete-v-yugozapadna-balgariya.html]. Accessed 11 October 2020.
[5] Ministry of Health. "Home". [https://www.mh.government.bg/bg/]. Accessed 11 October 2020.
[6] Ministry of Agriculture, Food and Forestry. "Home". [https://www.mzh.government.bg/bg/]. Accessed 11 October 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

Zoonotic diseases in wildlife are subject to surveillance by the Bulgarian Food Safety Agency (BFSA) as stipulated by the 2019-2021 National Program for Prophylaxis, Surveillance, Control and Eradication of Zoonotic Pathogens. The Program contains provisions for monitoring wildlife, with a particular focus on wild boars, birds and dogs, and covers the following most commonly encountered zoonotic diseases: rabies, influenza, African Swine Fever, Newcastle Disease, West Nile Fever, foot-and-mouth disease and tuberculosis. [1]

Furthermore, several National Reference Laboratories studying zoonoses in wildlife operate under the umbrella of the National Diagnostic Research Veterinary Medical Institute "Prof. Dr. G. Pavlov". [2] Their work is further complemented by the specialist Medical Arachnoenthomology and Zoology with Disinsection and Deratization laboratory within the National Center of Infections and Parasitic Diseases and its work on zoonotic diseases transmitted by rodents. [3] Risk assessments and analytical work on zoonoses as observed in wildlife species can also be accessed on the website of the Risk Assessment Center on Food Chain. [4]

[1] Bulgarian Food Safety Agency. 2019. "2019-2021 National Program for Prophylaxis, Surveillance, Control and Eradication of Zoonotic Pathogens (Национална програма за профилактика, надзор, контрол и ликвидиране на болестите по животните, включително зоонозите 2019-2021)". [http://bfsa.bg/userfiles/files/ZJ/DPP19-21/3_0_NPBJZ%202019%20-%202021_12.2018%20
[3].pdf]. Accessed 11 October 2020.
[2] National Diagnostic Research Veterinary Medical Institute "Prof. Dr. G.Pavlov". 2019. "Documents – National Centers". [https://www.ndnivmi.bg/en/national-reference-center/center-1/sekcia-parazitologia-i-ddd]. Accessed 11 October 2020.
[3] National Center of Infectious and Parasitic Diseases. "Laboratory Medical Arachnoenthomology and Zoology with Disinsection and Deratization".
[https://www.ncipd.org/index.php?option=com_k2&view=item&layout=item&id=234&Itemid=1250&lang=bg]. Accessed 11 October 2020.
[4] Risk Assessment Center on Food Chain. "Zoonozes". [https://corhv.government.bg/?cat=70&news_id=712]. Accessed 11 October 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: 82.06

2018

OIE WAHIS database

1.2.4b

Number of veterinary para-professionals per 100,000 people

Input number

Current Year Score: 12.33

2018

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 insufficient evidence that 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 in Bulgaria. The 2019-2021 National Program for Prophylaxis, Surveillance, Control and Eradication of Zoonotic Pathogens includes provisions regarding the division of responsibility between the public and private sector in controlling and combating zoonotic diseases. The Program describes in detail the role of private farms in responding to the emergence of various zoonoses in livestock, birds and others, with the goal of outlining the payment mechanisms and available funding for activities identified as essential in curbing the spread of pathogens. [1]

The 2002 Hunting and Game Conservation Act, last revised in 2019, is another regulation which mentions the public-private dynamic in controlling zoonoses in wildlife. According to Article 54 of the Act, it lies within the realm of responsibilities of the Bulgarian Food Safety Agency(BFSA) to call on private hunters and groups to assist with the control of zoonoses should emergency epizootic situations emerge with funding provided exclusively by the Ministry of Agriculture, Food and Forests. [2]

Additionally, the BFSA website has multiple registers of private companies enlisted in some of the following key areas related zoonotic disease prevention, control and response: veterinary practices, laboratories, animal transport on short and long journeys, shelters, live animal markets and animal tagging and tracking. [3] The websites of the Ministry of Agriculuture, Food and Forestry, and the Ministry of Health contain no additional relevant information on the topic. [4,5]

[1] Bulgarian Food Safety Agency. 2019. "2019-2021 National Program for Prophylaxis, Surveillance, Control and Eradication of Zoonotic Pathogens (Национална програма за профилактика, надзор, контрол и ликвидиране на болестите по животните, включително зоонозите 2019-2021)". [http://bfsa.bg/userfiles/files/ZJ/DPP19-21/3_0_NPBJZ%202019%20-%202021_12.2018%20
[3].pdf]. Accessed 11 October 2020.
[2] Ministry of Agriculture, Food and Forestry. 2019. "Hunting and Game Conservation Act (Закон за лова и опазване на дивеча)". [https://www.lex.bg/laws/ldoc/2134941184]. Accessed 11 October 2020.
[3] Bulgarian Food Safety Agency. "Registers (Регистри)".
[http://bfsa.bg/bg/Object/site_register/view/5/%D0%97%D0%B4%D1%80%D0%B0%D0%B2%D0%B5%D0%BE%D0%BF%D0%B0%D0%B2]. Accessed 11 October 2020.
[4] Ministry of Health. "Home". [https://www.mh.government.bg/bg/]. Accessed 11 October 2020.
[5] Ministry of Agriculture, Food and Forestry. "Home". [https://www.mzh.government.bg/bg/]. Accessed 11 October 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: 1

Multiple publicly accessible regulations and legislations suggest that records are kept and regularly updated of the following facilities (including their inventories) where dangerous pathogens and toxins are stored or processed: licenced storage facilities, specialist laboratories (human health) and veterinary laboratories. The 2011 Ordinance on the Order and Method for the Storage of Hazardous Chemicals and Mixtures and its accompanying guidance on both storage requirements and governmental control and evaluation methods, published by the Ministry of Environment and Water, suggest that the inventories of all licensed facilities are regularly updated and shared with the relevant control bodies within the Ministry. [1] A complete register of all comprehensive permits granted to legal entities operating with toxins or other hazardous materials, including dangerous pathogens, is issued by the Ministry and accessible online, including all applicable documentation. The above information is regularly updated (the latest revisions were carried out in August 2020) and includes details on inventories, inventories management systems and the relevant biosecurity processes carried out at individual facilities.[2]

Furthermore, the Ministry of Health has published the 1999 Medical Facilities Act (updated in August 2020), the 2010 Ordinance № 4 for the Approval of the Medical Standard on Microbiology and the 2013 Ordinance № 5 for the Approval of the Medical Standard on Virology confirming each laboratory licenced to work with dangerous pathogens must have its own updated register for the storing, movement, categorization, processing and the destruction of all relevant lab samples. [3] [4] [5] The Executive Agency for Medical Supervision monitors the work of said laboratories and has included them in a publicly available register of medical facilities in each of Bulgaria's 28 provinces. [6]

In addition, the Bulgarian Food Safety Agency (BFSA) has a 2018 Operational Plan for the Liquidation of Animal Diseases confirming that veterinary laboratories must maintain an up-to-date list of all stored and liquidated lab samples and test results, which are then included in a more comprehensive register managed by an internal epizootic operational team within the BFSA. [7]

Lastly, the Confidence-Building Measures Declaration for 2019 states that the National Diagnostic Research Veterinary Medicine Institute and the Department of Microbiology at the National Centre of Infectious and Parasitic Diseases meet the biosafety levels 2 and 3, but provides no further details. [8] The Verification Research, Training and Information Center's database of country-specific legislation on biological weapons and materials also mentions that Bulgaria has a 1973 Regulation for the Production, Trade, Stockpiling, Transportation and Use of Highly Poisonous Substances, but in fact this regulation has not been in force since 1999. [9] [10]

[1] Ministry of Environment and Water. “Storage of Chemicals (Съхранение на химикали”. [https://www.moew.government.bg/bg/prevantivna-dejnost/himichni-vestestva/suhranenie-na-himikali/]. Accessed 11 October 2020.
[2] Ministry of Environment and Water. “Registers (Регистри)”. [http://registers.moew.government.bg/kr/]. Accessed 11 October 2020.
[3] Ministry of Health. 2020. “Medical Facilities Act (Закон за лечебните заведения)”. [https://www.lex.bg/bg/laws/ldoc/2134670848]. Accessed 11 October 2020.
[4] Ministry of Health. 2010. “Ordinance № 4 for the Approval of the Medical Standard on Microbiology (Наредба №4 за утвърждаване на медицински стандарт Микробиология)”. [https://www.mh.government.bg/media/filer_public/2015/11/18/microbiologiq.pdf]. Accessed 11 October 2020.
[5] Ministry of Health. 2013. “Ordinance № 5 for the Approval of the Medical Standard on Virology (Наредба №5 за утвърждаване на медицински стандарт Вирусология)”. [https://www.mh.government.bg/media/filer_public/2015/11/18/virusologiq.pdf]. Accessed 11 October 2020.
[6] Executive Agency for Medical Supervision. “Registrations”. [https://iamn.bg/%D1%80%D0%B5%D0%B3%D0%B8%D1%81%D1%82%D1%80%D0%B0%D1%86%D0%B8%D0%BE%D0%BD%D0%BD%D0%B0-%D0%B4%D0%B5%D0%B9%D0%BD%D0%BE%D1%81%D1%82/]. Accessed 11 October 2020.
[7] Bulgarian Food Safety Agency. 2018. “Operational Plan for the Liquidation of Animal Diseases (Оперативен план за ликвидиране на болестите по животните)”. [http://www.babh.government.bg/userfiles/files/ZJ/CP/00%20Contigency%20plan_part%20I_2018%20rev.pdf]. Accessed 11 October 2020.
[8] Biolgogical Weapons Convention. 2019. “Declaration On The Confidence-Building Measures As Agreed At The Third Review Conference Of The Parties To The Convention On The Prohibition Of The Development, Production And Stockpiling Of Bacteriological (Biological) And Toxin Weapons And On Their Destruction”. [https://bwc-ecbm.unog.ch/ru/system/files/form-pdf/bwc_cbm_2019_bulgaria.pdf]. Accessed 11 October 2020.
[9] Verification Research, Training and Information Center. "BWC Legislation Database. B." [https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/b/]. Accessed 14 November 2020.
[10] State Gazette. 1999. "Regulation Repealing the Regulation for the Production, Trade, Stockpiling, Transportation and Use of Highly Poisonous Substances (Правилника за отменяне на Правилника за производство, търговия, съхранение, пренасяне и употреба на силно действащи отровни вещества)". [https://www.ciela.net/svobodna-zona-darjaven-vestnik/document/-19642880/issue/711?i18n-id=2]. 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: 1

Current legislation and regulations address biosecurity and cover physical containment, operational practices, failure reporting systems, as well as some limited cybersecurity measures. As stated by Ordiance № 181 of 20 July 2009 on the Identification of Strategic Sites and Activities Relevant to National Security (updated in 2019) and the Decree № 256 of 10 October 2019 on the Adoption of an Ordinance on the Conditions and Procedures for Determining the Measures for Protecting Information and Communication Systems of Strategic Sites of National Security Importance and for Implementing Control Measures, relevant strategic sites processing or storing especially dangerous pathogens or toxins in the fields of agriculture, ecology and healthcare have been identified that meet the above biosecurity requirements. According to these documents all biosecurity measures at individual sites are shared with the State Agency for National Security with a detailed description of all applicable systems which must include a minimum of ten protective and preventative measures determined by the Agency. A register of these sites and the concrete biosecurity measures is kept by the Agency, however it is classified and not publicly available as confirmed by the Decree. [1] [2] In its annual report, the Agency states that the biosecurity requirements, recommendations and standards, shared by institutions such as the Bulgarian Food Safety Agency and applicable to facilities where especially dangerous pathogens or toxins are encountered, stored or processed, are generally well-enforced, nonetheless there were a few intances where biosecurity regulations were violated and especially dangerous toxins were unlawfully released or misused. [3]

Bulgaria's 2019 Declaration on Confidence-Building Measures states that Bulgaria's biosecurity regulations are included in the 2003 Ministry of Health Instruction on Work with Causative Agents of Bacterial, Fungal and Viral Infections with a High Medical and Epidemic Risk. While the Instructions do not explicitly mention biosecurity and often include biosafety features, they do discuss laboratories' operational practices and the rules for the physical containment of samples and test animals in a biosecurity context, with no information on failure reporting systems or cybersecurity of the facilities. [4] [5] The Verification Research, Training and Information Center's database of legislation related to biological weapons and materials contains no relevant information. [6]

[1] State Agency of National Security. 2019 "Ordiance № 181 of 20 July 2009 on the Identification of Strategic Sites and Activities Relevant to National Security (Постановление № 181 от 20 юли 2009 г. За определяне на стратегическите обекти и дейности, които са от значение за националната сигурност)". [https://www.lex.bg/en/laws/ldoc/2135641101]. Accessed 09 December 2020.
[2] State Agency of National Security. 2019. "Decree № 256 of 10 October 2019 on the Adoption of an Ordinance on the Conditions and Procedures for Determining the Measures for Protecting Information and Communication Systems of Strategic Sites of National Security Importance and for Implementing Control Measures (Постановление № 256 от 10 октомври 2019 Г. за приемане на Наредба за условията и реда за определяне на мерките за защита на информационните и комуникационните системи на стратегическите обекти от значение за националната сигурност и за осъществяването на контрол)".
[https://dv.parliament.bg/DVWeb/showMaterialDV.jsp;jsessionid=27B001A0650E0385500D9A91A9754C27?idMat=142035]. Accessed 09 December 2020.
[3] State Agency of National Security. 2020. "Annual Report (Годишен доклад)".
[https://www.gov.bg/files/common/_%D0%94%D0%90%D0%9D%D0%A1%20%D0%B7%D0%B0%202019.pdf]. Accessed 10 December 2020.

[4] Confidence Building Measures. 2019. "Declaration on the confidence-building measures as agreed at the third review conference of the parties to the convention on the prohibition of the development, production and stockpiling of bacteriological (biological) and toxin weapons and on their destruction". [https://bwc-ecbm.unog.ch/system/files/form-pdf/bwc_cbm_2019_bulgaria.pdf]. Accessed 11 October 2020.
[5] Ministry of Health. 2003. "Instruction No.5 from19.11.2003 of the Ministry of Health on the work with causative agents of bacterial, fungal and viral infections with a high medical and epidemic risk (Инструкция № 5 от 19 ноември 2003 г. За работа с причинители на бактериални, гъбични и вирусни инфекции с висок медицински и епидемичен риск)". [https://www.ciela.net/svobodna-zona-darjaven-vestnik/document/2135474924/issue/2065/instruktsiya-%E2%84%96-5-ot-19-noemvri-2003-g-za-rabota-s-prichiniteli-na-bakterialni-gabichni-i-virusni-infektsii-s-visok-meditsinski-i-epidemichen-risk]. Accessed 10 December 2020.
[6] Verification Research, Training and Information Center. "BWC Legislation Database. B." [https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/b/]. 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: 1

There are multiple governmental bodies responsible for enforcing biosecurity legislation and regulation with the main one being the Bulgarian Food Safety Agency (BFSA). Units within the administrative structure of the BFSA as well as veterinary practitioners working for and with the Agency exercise control over biosecurity matters and ensure that both private individuals and legal entities engaging in activities of biosecurity importance involving work with especially dangerous pathogens and toxins abide by the existing laws and regulations and follow the approved rules for the protection, control of and accountability of biological agents, toxins and biological materials and information to prevent the unauthorized possession, loss, theft, misuse, diversion or intentional release. [1]

Other dedicated units within both the Ministry of Health, Ministry of Agriculture, Food and Forestry and to some extent the Ministry of Environment and Water also ensure and enforce biosecurity standards across sectors such as storage facilities for toxic and hazardous materials, laboratories for human health and specialist veterinary laboratories with a biosecurity focus on operational requirements, protection and containment measures for high-consequence biological agents and toxins. [2] [3] [4]

Some of the above-mentioned facilities also report on biosecirty matters to the State Agency of National Security when the sites have been identified as strategic sites of national security importance in line with the criteria set out by the Agency. [5] [6]

Bulgaria's Confidence-Building Measures Declaration for 2019 and the Verification Research, Training and Information Center's country-specific database were also consulted and found to contain no further evidence on the above. [7] [8]

[1] Bulgarian Food Safety Agency. “About us (За нас)”. [http://www.babh.government.bg/bg/Page/zarazni-bolesti/index/zarazni-bolesti/%D0%97%D0%B0%D1%80%D0%B0%D0%B7%D0%BD%D0%B8%20%D0%B1%D0%BE%EF%BF%BD]. Accessed 11 October 2020.
[2] Ministry of Health. 2018. “Ordinance № 1 on the Conditions and Procedures for Carrying Out Disinfections, Disinsections and Deratizations (Наредба №1 за условията и реда за извършване на дезинфекции, дезинсекции и дератизации)”.

[https://www.mh.government.bg/media/filer_public/2018/01/19/naredba1-5-01-2018-uslovia-red-ddd.pdf]. Accessed 11 October 2020.
[3] Bulgarian Food Safety Agency. 2018. “Operational Plan for the Liquidation of Animal Diseases (Оперативен план за ликвидиране на болестите по животните)”.
[http://www.babh.government.bg/userfiles/files/ZJ/CP/00%20Contigency%20plan_part%20I_2018%20rev.pdf]. Accessed 11 October 2020.
[4] Ministry of Environment and Water. “Storage of Chemicals (Съхранение на химикали”.
[https://www.moew.government.bg/bg/prevantivna-dejnost/himichni-vestestva/suhranenie-na-himikali/]. Accessed 11 October 2020.
[5] State Agency of National Security. 2019 "Ordiance № 181 of 20 July 2009 on the Identification of Strategic Sites and Activities Relevant to National Security (ПОСТАНОВЛЕНИЕ № 181 ОТ 20 ЮЛИ 2009 Г. ЗА ОПРЕДЕЛЯНЕ НА СТРАТЕГИЧЕСКИТЕ ОБЕКТИ И ДЕЙНОСТИ, КОИТО СА ОТ ЗНАЧЕНИЕ ЗА НАЦИОНАЛНАТА СИГУРНОСТ)".
[https://www.lex.bg/en/laws/ldoc/2135641101]. Accessed 09 December 2020.
[6] State Agency of National Security. 2019. "Decree № 256 of 10 October 2019 on the Adoption of an Ordinance on the Conditions and Procedures for Determining the Measures for Protecting Information and Communication Systems of Strategic Sites of National Security Importance and for Implementing Control Measures (ПОСТАНОВЛЕНИЕ № 256 ОТ 10 ОКТОМВРИ 2019 Г. за приемане на Наредба за условията и реда за определяне на мерките за защита на информационните и комуникационните системи на стратегическите обекти от значение за националната сигурност и за осъществяването на контрол)".
[https://dv.parliament.bg/DVWeb/showMaterialDV.jsp;jsessionid=27B001A0650E0385500D9A91A9754C27?idMat=142035]. Accessed 09 December 2020.
[7] Biolgogical Weapons Convention. 2019. “Declaration On The Confidence-Building Measures As Agreed At The Third Review Conference Of The Parties To The Convention On The Prohibition Of The Development, Production And Stockpiling Of Bacteriological (Biological) And Toxin Weapons And On Their Destruction”. [https://bwc-ecbm.unog.ch/ru/system/files/form-pdf/bwc_cbm_2019_bulgaria.pdf]. Accessed 11 October 2020.
[8] Verification Research, Training and Information Center. "BWC Legislation Database. B."
[https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/b/]. 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 publicly available evidence to suggest that Bulgaria has taken action to consolidate its inventories of especially dangerous pathogens and toxins into a minimum number of facilities. Although regulations such as the 2011 Ordinance on the Procedure and Methods for the Storage of Hazardous Chemicals and Mixtures (and its accompanying guidance on both storage requirements and governmental control and evaluation methods, published by the Ministry of Environment and Water), the 2018 Operational Plan for the Liquidation of Animal Diseases and the 2015 Ordinance on the Requirements for Collecting and Treating Waste in Health Institutions (updated in 2018) strictly outline how toxins and dangerous pathogens must be stored, there is no indication in either of the documents that Bulgaria has taken measures to reduce the number of facilities managing the inventories of the above. [1] [2] [3] Based on evidence from these three document, it can be concluded that facilities must abide by strict rules and meet numerous criteria in order to obtain a permit, but their exact number is not publicly confirmed. [1][2][3] The websites of the Minsitry of Health, the Ministry of Defense and the Ministry of Agriculture, Food and Forestry, as well as Bulgaria's Confidence-Building Measures Declaration for 2019 and the

Verification Research, Training and Information Center's country-specific database, contain no evidence that Bulgaria has taken action to consolidate its inventories of especially dangerous pathogens and toxins into a minimum number of facilities. [4] [5] [6] [7] [8]

[1] Ministry of Environment and Water. 2011. “Ordinance on the Order and Method for the Storage of Hazardous Chemicals and Mixtures (Наредба за реда и начина за съхранение на опасните химични вещества и смеси)”. [https://www.moew.government.bg/static/media/ups/articles/attachments/Naredba_syhranenie_OXVS52e10caab1ef0799ae6f6382f02227d0.pdf]. Accessed 11 October 2020.
[2] Bulgarian Food Safety Agency. 2018. “Operational Plan for the Liquidation of Animal Diseases (Оперативен план за ликвидиране на болестите по животните)”. [http://www.babh.government.bg/userfiles/files/ZJ/CP/00%20Contigency%20plan_part%20I_2018%20rev.pdf]. Accessed 11 October 2020.
[3] Ministry of Health. 2018. “Ordinance on the Requirements for Collecting and Treating Waste in Health Institutions (Наредба за изискванията към дейността по събиране и третиране на отпадъци на територията на лечебните и здравните заведения)”. [https://www.lex.bg/laws/ldoc/2136443163]. Accessed 11 October 2020.
[4] Ministry of Health. “Home”. [https://www.mh.government.bg/bg/]. Accessed 11 October 2020.
[5] Ministry of Defence. "Home". [https://www.mod.bg/en/index.php]. Accessed 14 November 2020.
[6] Ministry of Agriculture, Food and Forestry. “Home”. [https://www.mzh.government.bg/bg/]. Accessed 11 October 2020.
[7] Biolgogical Weapons Convention. 2019. “Declaration On The Confidence-Building Measures As Agreed At The Third Review Conference Of The Parties To The Convention On The Prohibition Of The Development, Production And Stockpiling Of Bacteriological (Biological) And Toxin Weapons And On Their Destruction”. [https://bwc-ecbm.unog.ch/ru/system/files/form-pdf/bwc_cbm_2019_bulgaria.pdf]. Accessed 11 October 2020.
[8] Verification Research, Training and Information Center. "BWC Legislation Database. B." [https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/b/]. 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: 1

Publicly accessible evidence confirms that Polymerase Chain Reaction (PCR)-based diagnostic testing is carried out for both anthrax and Ebola. The Bulgarian Food Safety Agency (BFSA) and the laboratories working under its umbrella have technical capacity to conduct PCR tests for anthrax. [1] According to the Ministry of Health, the BFSA is responsible for setting the benchmark tariffs and fees for all relevant laboratory and testing services, including PCR diagnosis of anthrax, as stipulated by the 2011 Bulgarian Food Safety Agency Act (last amended in 2016). [2] The BFSA fees/pricelist is approved by the Council of Ministers and universally applied across the network of laboratories. [2] The National Reference Laboratory for Special Bacterial Pathogens within the National Center of Infections and Parasitic Diseases also conducts tests for anthrax, however, only once live pathogens have been cultured. [3]
As for Ebola, the private Acibadem CityClinic Tokuda Hospital is licenced to carry out PCR-diagnostic testing using a RealStartFILOVIRUSTypeRT-PCRKit 1.0 produced in Hamburg, Germany by the biotechnological company AltonaDiagnosticsGmbH. [4]

[1] Bulgarian Food Safety Agency. “Documents”. [http://www.babh.government.bg/bg/Page/tariffs/index/tariffs/%D0%A2%D0%B0%D1%80%D0%B8%D1%84%D0%B8].

Accessed 11 October 2020.
[2] Bulgarian Food Safety Agency. 2016. “Bulgarian Food Safety Agency Act (Закон за Българската Агенция по безопастност на храните)”. [https://www.mzh.government.bg/MZH/Libraries/%D0%97%D0%96%D0%91%D0%A5-_%D0%BD%D0%B0%D1%86_%D0%B7%D0%B0%D0%BA%D0%BE%D0%BD%D0%BE%D0%B4%D0%B0%D1%82%D0%B5%D0%BB%D1%81%D1%82%D0%B2%D0%BE/%D0%97%D0%90%D0%9A%D0%9E%D0%9D_%D0%B7%D0%B0_%D0%91%D0%90%D0%91%D0%A5.sflb.ashx]. Accessed 11 October 2020.
[3] National Center of Infectious and Parasitic Diseases. “NRL for Special Bacterial Pathogens”. [https://www.ncipd.org/index.php?option=com_k2&view=item&id=213:nrl-for-biohazard-level-iii-infections&lang=en]. Accessed 11 October 2020.
[4] Acibadem CityClinic Tokuda Hospital. “Ebola test (Тест за Ебола)”. [https://www.tokudabolnica.bg/bg/clinical-laboratory/ebola-test]. Accessed 11 October 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 trainthe-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: 1

Standardized biosecurity training involving a common curriculum has been adopted for personnel working in facilities where especially dangerous toxins and pathogens are encountered and/or stored. The 2011 Ordinance on the Order and Method for the Storage of Hazardous Chemicals and Mixtures, issued by the Ministry of Environment and Water, stipulates that a standardized biosecurity protocol requiring biosecurity training must be followed at any facility working with especially dangerous pathogens. The document refers to biosecurity measures in the context of the protection, control of and accountability for high-consequence biological agents and toxins, with explicit provisions for the development of pertinent instructions and training for the prevention of loss, misuse and diversion of said materials. [1]

The 2018 Operational Plan for the Liquidation of Animal Diseases, adopted by the BFSA, is another regulating document that stipulates that standardized biosecurity training be implemented throughout facilities where especially dangerous toxins and pathogens are encountered and/or stored. In the case of licensed laboratories, both initial training and refresher courses on biosecurity follow a common curriculum, aimed at harmonizing diagnostic techniques across the European Union. [2]

The 2006 Ordinance № 44 on the Veterinary Medical Requirements for Livestock Facilities (last updated in January 2020) obliges the owners and managers of farm compounds for various livestock to provide standardized personnel training on all provisions of the Ordinance, including biosecurity and the applicable measures on physical containment, operation practices and failure reporting systems. [3] In addition, the 2018 Ordinance № 1 on the Conditions and Procedures for Carrying Out Disinfections, Disinsections and Deratizations confirms that in order to ensure the highest levels of biosecurity, the above operations may be carried out only by qualified veterinarians, trained under a common curriculum. [4]

A train-the-trainer approach on biosecurity is used in hunting and provided by Regional Directorates of Food Safety as stated by the relevant biosecurity instructions, published on the BFSA website. [5]

The Verification Research, Training and Information Center's database of legislation related to biological weapons and

materials were also consulted and found to contain no relevant information on the above. [6]

[1] Ministry of Environment and Water. 2011. "Ordinance on the Order and Method for the Storage of Hazardous Chemicals and Mixtures (Наредба за реда и начина за съхранение на опасните химични вещества и смеси)". [https://www.moew.government.bg/static/media/ups/articles/attachments/Naredba_syhranenie_OXVS52e10caab1ef0799ae6f6382f02227d0.pdf]. Accessed 11 October 2020.
[2] Bulgarian Food Safety Agency. 2018. "Operational Plan for the Liquidation of Animal Diseases (Оперативен план за ликвидиране на болестите по животните)". [http://www.babh.government.bg/userfiles/files/ZJ/CP/00%20Contigency%20plan_part%20I_2018%20rev.pdf]. Accessed 11 October 2020.
[3] Ministry of Agriculture, Food and Forestry. 2020. "Ordinance № 44 on the Veterinary Medical Requirements for Livestock Facilities (Наредба №44 за ветеринарномедицинските изисквания към животновъдните обекти)". [https://lex.bg/laws/ldoc/2135525777]. Accessed 11 October 2020.
[4] Ministry of Health. 2018. "Ordinance № 1 on the Conditions and Procedures for Carrying Out Disinfections, Disinsections and Deratizations (Наредба №1 за условията и реда за извършване на дезинфекции, дезинсекции и дератизации)". [https://www.mh.government.bg/media/filer_public/2018/01/19/naredba1-5-01-2018-uslovia-red-ddd.pdf]. Accessed 11 October 2020.
[5] Bulgarian Food Safety Agency. 2012. "Instructions on Biosecruty for Hunters on the Initial Treatment of Game and the Collection and Submission of Laboratory Diagnostic Tests (Инструкция за прилагане от ловците на мерки за био-сигурност при първична обработка на отстрелян дивеч и взимане и изпращане на проби за лабораторна диагностика)". [http://www.babh.government.bg/userfiles/files/ZJ/CP/27%20Instruction%20bio-security%20hunters.pdf]. Accessed 11 October 2020.
[6] Verification Research, Training and Information Center. "BWC Legislation Database. B." [https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/b/]. 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

All employed people in Bulgaria are subject to background checks and psychological and mental fitness checks, but there is no public evidence of additional checks specifically for security or other personnel with access to especially dangerous pathogens, toxins or biological materials with pandemic potential. According to the 1987 Labour Code, amended in July 2020, all employed people are obliged to present a complete certificate of medical fitness, including a psychological assessment and a detailed medical history, to their employer prior to signing a contract. [1] [2] While this initial cost for issuing the certificate is paid for by the employee, any obligatory periodical check-ups performed thereafter are covered by the employer. [1] [2]

Background checks are also required for most professions, as explained by the Sofia Regional Court. They are issued by local Criminal Record Bureaus on paper or electronically by the Ministry of Justice and have a validity of six months. The

background checks issued for employement purposes are identical to the ones required for the issuance of special permits (for weapon ownership, for example). [3]

The Minsitry of Health, the Ministry of Defence and the Ministry of Agriculture, Food and Forestry and their associate agencies, as well as Bulgaria's Confidence-Building Measures Declaration for 2019 and the Verification Research, Training and Information Center's country-specific database were consulted and found to contain no evidence of any specific requirements for security or other personnel with access to especially dangerous pathogens, toxins or biological materials with pandemic potential.. [4] [5] [6] [7] [8]

[1] Ministry of Labour and Social Policy. 2020. “Labour Code (Кодекс на Труда)”. [https://www.lex.bg/laws/ldoc/1594373121]. Accessed 11 October 2020.
[2] Pariteni. 2020. “When do we need a medical certificate for work (Кога ни трябва медицинско за работа)”. [https://www.pariteni.bg/novini/rabota/koga-ni-triabva-medicinsko-za-rabotata-234437]. Accessed 11 October 2020.
[3] Sofia Regional Court. “Criminal Office (Бюро за Съдимост)”. [https://www.srs.justice.bg/219-%D0%91%D1%8E%D1%80%D0%BE_%D0%B7%D0%B0_%D1%81%D1%8A%D0%B4%D0%B8%D0%BC%D0%BE%D1%81%D1%82]. Accessed 11 October 2020.
[4] Ministry of Health. “Home”. [https://www.mh.government.bg/bg/]. Accessed 11 October 2020.
[5] Ministry of Defence. "Home". [https://www.mod.bg/en/index.php]. Accessed 14 November 2020.
[6] Ministry of Agriculture, Food and Forestry. “Home”. [https://www.mzh.government.bg/bg/]. Accessed 11 October 2020.
[7] Biolgogical Weapons Convention. 2019. “Declaration On The Confidence-Building Measures As Agreed At The Third Review Conference Of The Parties To The Convention On The Prohibition Of The Development, Production And Stockpiling Of Bacteriological (Biological) And Toxin Weapons And On Their Destruction”. [https://bwc-ecbm.unog.ch/ru/system/files/form-pdf/bwc_cbm_2019_bulgaria.pdf]. Accessed 11 October 2020.
[8] Verification Research, Training and Information Center. "BWC Legislation Database. B." [https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/b/]. 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

There is publicly available information on three relevant regulations which mandate the safe and secure transport of infectious substances, including Category A and B, for rail, air and road transport. Put forward by the Ministry of Transport, Information Technology and Communication (previously named the Ministry of Transport and Communication), the 1999 Ordinance №18 for the Safe Transport of Dangerous Goods by Air (amended 2017), the 2001 Ordinance №46 for the Rail Transport of Dangerous Goods (amended 2019) and the 2004 Ordinance №40 on the Conditions and Procedures For the Safe Vehicle Transport of Dangerous Goods all include provisions for the transport of infectious substances. [1] [2] [3]

While the regulations themselves prefer to reference the UN classification codes, the terms Category A and B are used more rarely especially in support documents for substances under Class 6.2 – Infections Substances. The most comprehensive regulation containing provisions for Category A and B (including the relevant UN classification codes for each) is the Regulation for the International Carriage of Dangerous Goods by Rail as ratified by the Bulgarian Parliament in 2006. [4] [5]

[6]

[1] Ministry of Transport, Information technology and Communication. 2017. “Ordinance №18 for the Safe Transport of Dangerous Goods by Air (Наредба № 18 от 4 март 1999 г. за безопасен превоз на опасни товари по въздуха)”. [https://www.lex.bg/laws/ldoc/-549702655]. Accessed 11 October 2020.
[2] Ministry of Transport, Information technology and Communication. 2019. “Ordinance №46 for the Rail Transport of Dangerous Goods (Наредба № 46 от 30 ноември 2001 г. за железопътен превоз на опасни товари)”. [https://www.lex.bg/laws/ldoc/-549136382]. Accessed 11 October 2020.
[3] Ministry of Transport, Information technology and Communication. 2019. “Ordinance №40 on the Conditions and Procedures For the Safe Vehicle Transport of Dangerous Goods (Наредба № 40 от 14 януари 2004 г. за условията и реда за извършване на автомобилен превоз на опасни товари)”. [https://lex.bg/laws/ldoc/2135479823]. Accessed 11 October 2020.
[4] Ministry of Transport, Information technology and Communication. “Normative documents (Нормативни документи)”. https://www.mtitc.government.bg/bg/category/161]. Accessed 11 October 2020.
[5] Ministry of Transport, Information technology and Communication. “Part 1 – General Provisions (Част 1 – Общи разпоредби)”. [https://www.mtitc.government.bg/upload/docs/part_1.pdf]. Accessed 11 October 2020.
[6] Ministry of Transport, Information technology and Communication. “Part 2 – General Provisions (Част 2 – Общи разпоредби)”. [https://www.mtitc.government.bg/upload/docs/Part2_all.pdf]. Accessed 11 October 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

Legislation overseeing the cross-border transport and end-user screening of dangerous pathogens and other toxic substances is in place and includes provisions for the issuance of certificates of approval. The cross-border transfer and end-user screening of especially dangerous pathogens, toxins and pathogens with pandemic potential is governed by both European and domestic regulations, namely by the European Council Regulation (EC) № 428/2009 Setting up a Community Regime for the Control of Exports, Transfer, Brokering and Transit of Dual-Use Items (updated in 2019), Bulgarian 2012 Law on the Export of Defense-Related and Dual-Use Products and Technologies (updated in 2019) and the Bulgarian 2000 Law on the Prohibition of Chemical Weapons and on the Control of Toxic Chemicals and their Precursors (amended 2019). [1] [2] [3]
In practice, the issuance of documentation and permits related to the cross-border transport and end-user screening of the above substances is managed by the International Controlled Trade and Security Directorate within the Ministry of Economy. [4]

[1] European Commission. 2019. “Council Regulation (EC) № 428/2009 Setting up a Community Regime for the Control of Exports, Transfer, Brokering and Transit of Dual-Use Items”. [https://eur-lex.europa.eu/legal-content/BG/TXT/?uri=CELEX:32009R0428]. Accessed 11 October 2020.
[2] Ministry of Economy. 2019. “Law on the Export of Defense-Related and Dual-Use Products and Technologies (Закон за експортния контрол на продукти, свързани с отбраната и на изделия и технологии с двойна употреба)”. [https://www.lex.bg/laws/ldoc/2135725113]. Accessed 11 October 2020.
[3] Ministry of Economy. 2019. “Law on the Prohibition of Chemical Weapons and on the Control of Toxic Chemicals and their Precursors (Закон за забрана на химическото оръжие и за контрол на токсичните химически вещества и техните

прекурсори)". [https://www.lex.bg/bg/laws/ldoc/2134905344]. Accessed 11 October 2020.
[4] Ministry of Economy. "Control on international trade (Международно контролирана търговия)". [https://www.mi.government.bg/bg/services/izdavane-na-razresheniya-za-iznos-na-izdeliya-i-tehnologii-s-dvoina-upotreba-28-c64-1.html]. Accessed 11 October 2020.
[5] Ministry of Economy. "Control on international trade (Международно контролирана търговия)". [https://mi.government.bg/bg/services/izgotvyane-na-stanovishta-po-klasificirane-na-izdeliya-i-tehnologii-s-dvoina-upotreba-ot-prilojenie-i-na-41-c64-2.html]. Accessed 11 October 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: 1

Bulgaria has national biosafety legislation and regulations. The 2002 Ordinance №4 of the Ministry of Labor and Social Policy and the Ministry of Health on the Protection of Workers from Risks Related to Exposure to Biological Agents at Work, and the 2003 Instruction №5 of the Ministry of Health on Working with Causative Agents of Bacterial, Fungal and Viral Infections with High Medical and Epidemic Risks both cover biosafety. [1] Together with recent Guidance on Laboratory Testing for 2019-nCov Infections in Humans, published by the Ministry of Health, provisions in the above documents are in line with the latest rules set out in the WHO Laboratory Biosafety Manual, accepted as the benchmark standard across the European Union. [2] [3]

Furthermore, as confirmed by Bulgaria's 2019 Declaration on Confidence-Building Measures, the relevant document is the Ordinance No. 4 of 14 October 2002 of the Ministry of Labour and Social Affairs and the Ministry of Health, with which the agencies enacted the European Parliament's Directive on the Protection of Workers from Risks Related to Exposure to Biological Agents at Work [4][5][6]. The Directive's aim is "the protection of workers against risks to their health and safety, including the prevention of such risks, arising or likely to arise from exposure to biological agents at work" [5]. It divides biological agents – including highly communicable pathogenic material – into four risk groups, and includes provisions related to the reduction of the risks of exposure, to hygiene and individual protection, and to the information and training of workers [5]. It further requires employers to keep a list of workers exposed to dangerous biological material and to notify to the competent authority all first-time use of dangerous (groups 2, 3, and 4) biological material [5].

In addition, the Ministry of Agriculture, Food and Forestry has also published several regulations including provisions on biosafety matters relating to zoonoses, most notably the 2018 Operational Plan for the Liquidation of Animal Diseases, the 2005 Ordinance № 18 on the Measures for the Prevention, Control and Eradication of African Swine Fever and the 2006 Ordinance № 44 on the Veterinary Medical Requirements for Livestock Facilities (revised in January 2020). [7] [8] [9]

[1] Biolgogical Weapons Convention. 2018. "Declaration On The Confidence-Building Measures As Agreed At The Third Review Conference Of The Parties To The Convention On The Prohibition Of The Development, Production And Stockpiling Of Bacteriological (Biological) And Toxin Weapons And On Their Destruction". [https://bwc-ecbm.unog.ch/ru/system/files/form-pdf/bwc_cbm_2019_bulgaria.pdf]. Accessed 11 October 2020.
[2] Ministry of Health. 2020. "Guidance on Laboratory Testing for 2019-nCov Infections in Humans (Лабораторни изследвания за 2019n-CoV при съмнение за инфекция при хора)".

[https://www.mh.government.bg/media/filer_public/2020/02/09/laboratorni_izsledvaniia_za_nov_koronavirus_2019_2019-ncov_pri_smnenie_za_infektsiia_pri_khora.pdf]]. Accessed 11 October 2020.
[3] European Commission. 2013. “Council Decision 2013/668/CFSP of 18 November 2013 in support of World Health Organisation activities in the area of biosafety and biosecurity in the framework of the European Union Strategy against the proliferation of Weapons of Mass Destruction”. [https://eur-lex.europa.eu/legal-content/BG/TXT/HTML/?uri=CELEX:32013D0668&from=FR]. Accessed 11 October 2020.
[4] Ministry of Labour and Social Affairs Republic of Bulgaria. Ordinance 4 of 2002. "For the protection of workers from risks related to exposure to biological agents at work (НАРЕДБА № 4 ОТ 14 ОКТОМВРИ 2002 Г. ЗА ЗАЩИТА НА РАБОТЕЩИТЕ ОТ РИСКОВЕ, СВЪРЗАНИ С ЕКСПОЗИЦИЯ НА БИОЛОГИЧНИ АГЕНТИ ПРИ РАБОТА)".[https://fcbzr.org/modules/download.php?file_id=5506]. Accessed 03 December 2020.
[5] European Parliament. 2000. "Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work". [https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32000L0054]. Accessed 03 December 2020.
[6] Confidence Building Measures. 2019. "Declaration on the confidence-building measures as agreed at the third review conference of the parties to the convention on the prohibition of the development, production and stockpiling of bacteriological (biological) and toxin weapons and on their destruction". [https://bwc-ecbm.unog.ch/system/files/form-pdf/bwc_cbm_2019_bulgaria.pdf]. Accessed 11 October 2020.
[7] Bulgarian Food Safety Agency. 2018. “Operational Plan for the Liquidation of Animal Diseases (Оперативен план за ликвидиране на болестите по животните)”. [http://www.babh.government.bg/userfiles/files/ZJ/CP/00%20Contigency%20plan_part%20I_2018%20rev.pdf]. Accessed 11 October 2020.
[8] Ministry of Agriculture, Food and Forestry. 2005. “Ordinance № 18 on the Measures for the Prevention, Control and Eradication of African Swine Fever (Наредба № 18 от 14 декември 2005 г. за мерките за профилактика, ограничаване и ликвидиране на болестта африканска чума по свинете и за условията и реда за прилагането им)”. [https://dv.parliament.bg/DVWeb/showMaterialDV.jsp?idMat=1300]. Accessed 11 October 2020.
[9] Ministry of Agriculture, Food and Forestry. 2020. “Ordinance № 44 on the Veterinary Medical Requirements for Livestock Facilities (Наредба №44 за ветеринарномедицинските изисквания към животновъдните обекти)”. [https://lex.bg/laws/ldoc/2135525777]. Accessed 11 October 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: 1

Biosafety legislation and regulations are enforced by multiple state bodies. According to the 2002 Ordinance №4 of the Ministry of Labor and Social Policy and the Ministry of Health on the Protection of Workers from Risks Related to Exposure to Biological Agents at Work, Regional Labor Inspectories, working under the umbrella of the Ministry of Labor and Social Affairs, monitor that biosafety regulations are respected and implemented across all relevant facilities under their jurisdiction. [1] Furthermore, the Bulgarian Food Safety Agency (BFSA) has competencies over biosafety matters when it comes to the supervision of livestock facilities as well as licenced veterinary laboratories across the country. The biosafety enforcement responsibilities of the BFSA are documented by the 2006 Ordinance № 44 on the Veterinary Medical Requirements for Livestock Facilities (amended January 2020) and by the 2018 Operational Plan for the Liquidation of Animal Diseases. [2] [3]

[1] Ministry of Labor and Social Policy. 2003. “Ordinance №4 on the Protection of Workers from Risks Related to Exposure to Biological Agents at work (Наредба № 4 от 14 октомври 2002 г. за защита на работещите от рискове, свързани с

експозиция на биологични агенти при работа)". [https://lex.bg/bg/laws/ldoc/2135460632]. Accessed 11 October 2020.
[2] Ministry of Agriculture, Food and Forestry. 2020. "Ordinance № 44 on the Veterinary Medical Requirements for Livestock Facilities (Наредба №44 за ветеринарномедицинските изисквания към животновъдните обекти)". [https://lex.bg/laws/ldoc/2135525777]. Accessed 11 October 2020.
[3] Bulgarian Food Safety Agency. 2018. "Operational Plan for the Liquidation of Animal Diseases (Оперативен план за ликвидиране на болестите по животните)". [http://www.babh.government.bg/userfiles/files/ZJ/CP/00%20Contigency%20plan_part%20I_2018%20rev.pdf]. Accessed 11 October 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 trainthe-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: 1

Biosafety training is required for personnel working in facilities housing or working with especially dangerous pathogens, toxins, or biological materials with pandemic potential. A country-wide curriculum covering a total of six areas of biosafety importance is mandated by Article 11 of the 2002 Ordinance №4 of the Ministry of Labor and Social Policy and the Ministry of Health on the Protection of Workers from Risks Related to Exposure to Biological Agents at Work. As stipulated, all biosafety training is regularly updated and includes instructions on the following: potential health risks, exposure prevention measures, workplace and work equipment hygiene requirement, appropriate protective equipment use, incident prevention and incident response. [1]

Moreover, the Bulgarian Food Safety Agency (BFSA) has complemented the framework of the Ordinance with additional biosafety training requirements applicable to livestock facilities and veterinary laboratories as mandated by the 2018 Operational Plan for the Liquidation of Animal Diseases. Under the Ordinance, BFSA developed a total of nineteen practical guidelines, forming a standardized curriculum, for personnel working in livestock facilities and laboratories where dangerous pathogens are encountered and/or worked with. [2]

[1] Ministry of Labor and Social Policy. 2003. "Ordinance №4 on the Protection of Workers from Risks Related to Exposure to Biological Agents at work (Наредба № 4 от 14 октомври 2002 г. за защита на работещите от рискове, свързани с експозиция на биологични агенти при работа)". [https://lex.bg/bg/laws/ldoc/2135460632]. Accessed 11 October 2020.
[2] Bulgarian Food Safety Agency. 2018. "Operational Plan for the Liquidation of Animal Diseases (Оперативен план за ликвидиране на болестите по животните)". [http://www.babh.government.bg/userfiles/files/ZJ/CP/00%20Contigency%20plan_part%20I_2018%20rev.pdf]. Accessed 11 October 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 insufficient publicly available evidence that Bulgaria has performed an assessment of research occurring on especially dangerous pathogens, toxins, pathogens with pandemic potential and other dual-use research. According to the website of the Institute for Nuclear Research and Nuclear Energy, part of the Bulgarian Academy of Sciences, since 2008 courses have been organized, where participants are provided with current information on dual-use research both in the country and internationally, so as to increase the pool of state experts on dual-use research and to effectively include them in future critical assessments of what research is being conducted using dual-use materials. [1] Further evidence in support of the above can be found in the annual reports of the Interministerial Commission for Export Control and Non-Proliferation of Weapons of Mass Destruction, where assessments of dual-use research are implicitly mentioned within a wider European context. [2]

In addition, research on especially dangerous pathogens, toxins and pathogens with pandemic potential is subject to assessment both within the governmental organizations responsible for the research and also by their parent institutions, namely the Ministry of Health and the Ministry of Agriculture, Food and Forestry. The relevant agencies conducting scientific research on dangerous pathogens and toxins are the National Center of Infections and Parasitic Diseases, the Risk Assessment Center of Food Chain and the Pavlov National Diagnostic Research Veterinary Medical Institute. These agencies publish details on the concrete research taking place on their respective websites. [3] [4] [5]

Bulgaria's Confidence-Building Measures Declaration for 2019 and the Verification Research, Training and Information Center's country-specific database contain no additional evidence on the above. [6] [7]

[1] Institute for Nuclear Researches and Nuclear Energy. “News (Новини)”. [http://www.inrne.bas.bg/index.php?option=com_content&view=article&id=265&Itemid=301]. Accessed 11 October 2020.
[2] Interministerial Commission for Export Control and Non-Proliferation of Weapons of Mass Destruction. 2019. “Annual report (Годишен доклад)”. [http://www.exportcontrol.bg/docs/Report_MK_2018.pdf]. Accessed 11 October 2020.
[3] National Center of Infectious and Parasitic Diseases. “About us (За нас)”. [https://ncipd.org/index.php?option=com_k2&view=item&id=103:za-ntzzpb&lang=bg]. Accessed 11 October 2020.
[4] Risk Assessment Center of Food Chain. “Biological Threats (Биологични опасности)”. [https://corhv.government.bg/?cat=28]. Accessed 11 October 2020.
[5] National Diagnostic Research Veterinary Medical Institute “Prof. Dr. G.Pavlov”. “Research (Научноизлседователска дейност)”. [https://www.ndnivmi.bg/bg/activities/research]. Accessed 11 October 2020.
[6] Biolgogical Weapons Convention. 2019. “Declaration On The Confidence-Building Measures As Agreed At The Third Review Conference Of The Parties To The Convention On The Prohibition Of The Development, Production And Stockpiling Of Bacteriological (Biological) And Toxin Weapons And On Their Destruction”. [https://bwc-ecbm.unog.ch/ru/system/files/form-pdf/bwc_cbm_2019_bulgaria.pdf]. Accessed 11 October 2020.
[7] Verification Research, Training and Information Center. "BWC Legislation Database. B."

[https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/b/]. 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 insufficient evidence of regulations requiring the oversight of research with especially dangerous pathogens, toxins, pathogens with pandemic potential and/or other dual-use research in Bulgaria. The 2018 Rulebook for Monitoring and Evaluation of the Scientific Research Activity Carried Out by Higher Education Institutions and Scientific Organizations, published by the Ministry of Education, is the uniform national framework detailing oversight specifics. [1] It is supplemented by data on research put in the Bulgarian Current Research Information System, managed by the National Center for Information and Documentation (NACID), and including details on the following: scientific organizations, researchers, scientific research projects, scientific achievements and results, scientific research competitions, international and national programs, scientific infrastructures, legal persons funded for scientific research and legal persons funding scientific research. [2]

With the Rulebook published in 2018, available information suggests that oversight is also taking place in practice. The National Diagnostic Research Veterinary Medical Institute and the Institute for Nuclear Researches and Nuclear Energy are two examples of the regulation applying to research with especially dangerous pathogens, toxins pathogens with pandemic potential and other dual-use research, as confirmed by NACID registers. [2] [3] [4]

[1] Ministry of Education and Science. “Rulebooks (Правилници)”. https://www.mon.bg/bg/100193]. Accessed 11 October 2020.
[2] Bulgarian Current Research Information System. “Home”. [https://cris.nacid.bg/]. Accessed 11 October 2020.
[3] National Diagnostic Research Veterinary Medical Institute “Prof. Dr. G.Pavlov”. “Research (Научноизлседователска дейност)”. [https://www.ndnivmi.bg/bg/activities/research]. Accessed 11 October 2020.
[4] Institute for Nuclear Researches and Nuclear Energy. “News (Новини)”. [http://www.inrne.bas.bg/index.php?option=com_content&view=article&id=265&Itemid=301]. Accessed 11 October 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 insufficient evidence that Bulgaria has an agency responsible for overseeing the research of especially dangerous pathogens toxins, pathogens with pandemic potential and/or other dual-use research as well as insufficient evidence of legislation mandating oversigh of dual use research. According to the 2018 Rulebook for Monitoring and Evaluation of the Scientific Research Activity Carried Out by Higher Education Institutions and Scientific Organizations, published by the Ministry of Education and Science, the Scientific Research Fund is the national agency performing oversight, monitoring and evaluation of scientific research projects. [1] [2] In order to accurately fulfil its functions, the Scientific Research Fund is reliant on the work of the National Center for Information and Documentation (in itself an agency associated with the

Ministry of Edeucation and Science) and its record-keeping for the following: scientific organizations, researchers, scientific research projects, scientific achievements and results, scientific research competitions, international and national programs, scientific infrastructures, legal persons funded for scientific research and legal persons funding scientific research. [3]

[1] Ministry of Education and Science. "Rulebooks (Правилници)". https://www.mon.bg/bg/100193]. Accessed 11 October 2020.
[2] Scientific Research Fund. "Home". [https://www.fni.bg/]. Accessed 11 October 2020.
[3] Bulgarian Current Research Information System. "Registers". [https://cris.nacid.bg/public]. Accessed 11 October 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: 1

Existing legislation and regulation deal with the screening of synthesized DNA for known pathogens and toxins prior to its release on the Bulgarian market. The 2005 Law on Genetically Modified Organisms (amended in 2017) and the 2005 Ordinance for the Release of Genetically Modified Organisms in the Environment and their Release on the Market (revised in 2017) both assess risks related to the release of synthetic DNA into the environment and on the market and explicitly address pathogens. [1] [2] As stipulated by the Law, DNA screenings for pathogens which may help the spread of infectious diseases are part of a complex procedure of risk assessment, conducted by a GMO Consultative Commission working within the Ministry of Environment and Water, and responsible for issuing GMO licences. Chapter Seven of the Law is dedicated to the rules applied for the traceability and labeling of GMOs and the screening of unique codes prior to a market release, which operators must carry out throgh a standardized system and keep a record of for five years. [1] The Ordinance details the applicable licensing conditions and the requirements for the technical dossiers submitted to the GMO Consultative Commission with all relevant information documented in Section II, Article 5, Paragraph 11. [2]

Work with recombinant DNA is also covered by the 2006 Veterinary Act when it was last amended in August 2020, as it applies to high-tech veterinary medicine products and their production, licencing and release on the market. [3]

Bulgaria's Confidence-Building Measures Declaration for 2019 contains no relevant information. [4]

[1] Ministry of Environment and Water. 2017. "2005 Law on Genetically Modified Organisms (Закон за генетично модифицираните организми)". [https://www.lex.bg/laws/ldoc/2135501153]. Accessed 11 October 2020.
[2] Ministry of Environment and Water. 2017. "Ordinance for the Release of Genetically Modified Organisms in the Environment and their Release on the Market (Наредба за освобождаване на генетично модифицирани организми в околната среда и пускането им на пазара)".
[http://eea.government.bg/bg/legislation/biodiversity/Naredba_osv_GMO_2017.pdf]. Accessed 11 October 2020.
[3] Ministry of Agriculture, Food and Forestry. 2020. "Veterinary Act (Закон за ветеринарномедицинската дейност).
[https://www.lex.bg/laws/ldoc/2135512300]. Accessed 11 October 2020.
[4] Biolgogical Weapons Convention. 2019. "Declaration On The Confidence-Building Measures As Agreed At The Third Review Conference Of The Parties To The Convention On The Prohibition Of The Development, Production And Stockpiling Of Bacteriological (Biological) And Toxin Weapons And On Their Destruction". [https://bwc-ecbm.unog.ch/ru/system/files/form-

pdf/bwc_cbm_2019_bulgaria.pdf]. Accessed 11 October 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

Bulgaria's national laboratory system has the capacity to conduct diagnostic tests for six out of the ten WHO-defined core tests, but there is no evidence that Bulgaria has publicly defined the additional four country-specific tests. A network of

National Reference Laboratories (NRLs) managed by the National Center of Infectious and Parasitic Diseases (itself an agency subordinate to the Ministry of Health) is responsible for completing all diagnostic work. Withing the Department of Virology, the NRL of Influenza and acute respiratory diseases conducts polymerase chain reaction (PCR) testing for influenza. [1] Virus culture for poliovirus is tested for by the NRL of Enterovirus, while the National Reference Confirmation Laboratory for HIV is tasked with conducting serology for HIV, both also part of the Department of Virology. [2] [3] Microscopy for mycobacterium tuberculosis and bacterial culture for Salmonella enteritidis serotype Typhi are performed in the Microbiology Department by the NRL of Tuberculosis and the NRL of Enteric infections, pathogenic cocci and diphtheria, respectively. [4] [5] The NRL for Diagnosis of prasiosis, part of the Department of Parasitology, conducts rapid diagnostic testing for plasmodium spp. (malaria). [6]

[1] National Center of Infectious and Parasitic Diseases. “NRL of Influenza and ARD”. [https://ncipd.org/index.php?option=com_k2&view=item&id=72:nrl-grip-i-orz&lang=bg]. Accessed 11 October 2020.
[2] National Center of Infectious and Parasitic Diseases. “NRL of Enterovirus”. [https://ncipd.org/index.php?option=com_k2&view=item&id=71:enterovirusi&Itemid=1095&lang=bg]. Accessed 11 October 2020.
[3] National Center of Infectious and Parasitic Diseases. “NRL of HIV”. [https://ncipd.org/index.php?option=com_k2&view=item&id=68:hiv-spin&Itemid=1095&lang=bg]. Accessed 11 October 2020.
[4] National Center of Infectious and Parasitic Diseases. “NRL of Tuberculosis”. [https://www.ncipd.org/index.php?option=com_k2&view=item&id=96:tuberkoloza&Itemid=1097&lang=bg]. Accessed 11 October 2020.
[5] National Center of Infectious and Parasitic Diseases. “NRL of Enteric infections, pathogenic cocci and diphtheria”. [https://www.ncipd.org/index.php?option=com_k2&view=item&id=92:chrevni-infekcii&Itemid=1097&lang=bg]. Accessed 11 October 2020.
[6] National Center of Infectious and Parasitic Diseases. “NRL for Diagnosis of prasiosis”. [https://www.ncipd.org/index.php?option=com_k2&view=item&id=100:diagnostika-parazitozi&Itemid=1098&lang=bg]. Accessed 11 October 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: 1

National legislation and strategic documents regulate how testing is conducted during public health emergencies, including provisions for testing for novel pathogens, scaling capacity and defining goals for testing. However, scaling capacity measures are specific to the National Pandemic Plan. The 2005 Health Act updated in July 2020, the 2007 Ordinance №25 on the Conditions and Procedures for Sampling and Conducting Laboratory Tests, Analysis and Expertise, Necessary for the Purposes of State Health Control and the 2006 National Plan for Preparedness for Influenza Pandemics (also known as the National Pandemic Plan) define the procedures set in place for testing for novel pathogens with a high epidemic potential, the expansion of testing with the aims of optimizing diagnostic processes, accelerating detection of the new pandemic virus and securing a maximum number of tests for clinical trials to establish with certainty the gravity of the epidemiological situation. [1] [2] [3]

Specifically, the Health Act details testing provisions as part of contact tracing strategies during public health emergencies caused by both known and novel highly communicable pathogens, stating that testing of known contacts and suspected cases is compulsory and cannot be turned down by any individual. [1] Ordinance №25, on the other hand, states that testing is conducted at the expense of the government when required by a Regional Health Inspection. [2] These provisions are complemented by scaling capacity measures included in the National Pandemic Plan, which stipulates that preserving the operational capacity of laboratories and other medical facilities might require the mobilization of retired personnel and/or medical students. [3]

[1] Ministry of Health. 2020. "Health Act (Закон за здравето)". [https://www.lex.bg/laws/ldoc%20/2135489147]. Accessed 11 October 2020.
[2] Ministry of Health. 2007. "Ordinance №25 on the Conditions and Procedures for Sampling and Conducting Laboratory Tests, Analysis and Expertise, Necessary for the Purposes of State Health Control (Наредба № 25 от 6 юни 2007 г. за условията и реда за вземане на проби и провеждане на лабораторни изследвания, анализи и експертизи, необходими за целите на държавния здравен контрол)". [https://lex.bg/index.php/laws/ldoc/2135555678/]. Accessed 11 October 2020.
[3] Ministry of Health. 2006. "National Plan for Preparedness for Influenza Pandemic (Национален план на Република България за готовност за грипна пандемия)". [http://www.strategy.bg/StrategicDocuments/View.aspx?lang=bg-BG&Id=366]. Accessed 11 October 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

The network of licenced National Reference Laboratories (NRLs) in Bulgaria is ISO accredited. A total of sixteen NRLs are situated in a Laboratory Testing Facility, part of the National Center of Infectious and Parasitic Diseases (NCIPD). According to the NCIPD, the entire Facility is accredited under ISO/IEC 17025 for laboratory diagnostic and applied reference testing in virology, microbiology, immunology, parasitology and epidemiology.[1] [2]
In addition, multiple individual NRLs operate within the structures of the National Center of Public Health and Analyses. As of 2018, all NRLs must be ISO 17025 certified to be defined as such by a decree issued by the Minister of Health. [3] [4]

[1] National Center of Infectious and Parasitic Diseases. "Accreditation". [https://ncipd.org/index.php?option=com_k2&view=item&id=333:accreditation&Itemid=1355&lang=bg]. Accessed 11 October 2020.
[2] Ministry of Health. 2011. " The NCIPD is 130 years old (НЦЗПБ навършва 130 години)". [https://www.mh.government.bg/bg/novini/aktualno/natsionalniiat-tsentr-po-zarazni-i-parazitni-boles/]. Accessed 11 October 2020.
[3] National Center on Public Health and Analysis. "Home". [https://ncpha.government.bg/bg/]. Accessed 11 October 2020.
[4] Zdrave. Net. 2018. "National Reference Laboratories will be established with a Ministerial Order". [https://www.zdrave.net/%D0%9D%D0%BE%D0%B2%D0%B8%D0%BD%D0%B8/%D0%9D%D0%B0%D1%86%D0%B8%D0%BE%D0%BD%D0%B0%D0%BB%D0%BD%D0%B8%D1%82%D0%B5-%D1%80%D0%B5%D1%84%D0%B5%D1%80%D0%B5%D0%BD%D1%82%D0%BD%D0%B8-%D0%BB%D0%B0%D0%B1%D0%BE%D1%80%D0%B0%D1%82%D0%BE%D1%80%D0%B8%D0%B8-%D1%89%D0%B5-

%D1%81%D0%B5-%D0%BE%D0%BF%D1%80%D0%B5%D0%B4%D0%B5%D0%BB%D1%8F%D1%82-%D1%81%D1%8A%D1%81-%D0%B7%D0%B0%D0%BF%D0%BE%D0%B2%D0%B5%D0%B4-%D0%BD%D0%B0-%D0%BC%D0%B8%D0%BD%D0%B8%D1%81%D1%82%D1%8A%D1%80%D0%B0/n6910]. Accessed 11 October 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

There are national reference facilities, part of an established network of National Reference Laboratories (NRLs), which are subject to external quality assurance review in Bulgaria. The National Center of Infectious and Parasitic Diseases (NCIPD), where sixteen NRLs are housed, is a national competent organization of the European Center for Disease Prevention and Control. As such, it is a key element of the surveillance systems in the European Union and itself subject to external quality assurance review. [1] Further quality assessments on the work of the NRLs and the NCIPD are carried out by the Regional Office of the WHO for Europe, Instand and the Robert Koch Institute (Germany), as well as by the Health Protection Agency (United Kingdom). [2]

The 2005 Ordinance №18 on the Criteria, Indicators and Methodology for the Accreditation of Medical Establishments (last updated in 2019) is the regulation mandating for external quality assurance carried out by either a national or a foreign non-profit organization. [3]

[1] Ministry of Health. 2011. " The NCIPD is 130 years old (НЦЗПБ навършва 130 години)". [https://www.mh.government.bg/bg/novini/aktualno/natsionalniiat-tsentr-po-zarazni-i-parazitni-boles/]. Accessed 11 October 2020.
[2] National Center of Infectious and Parasitic Diseases. "Accreditation". [https://ncipd.org/index.php?option=com_k2&view=item&id=333:accreditation&Itemid=1355&lang=bg]. Accessed 11 October 2020.
[3] Ministry of Health. 2019. "Ordinance №18 on the Criteria, Indicators and Methodology for the Accreditation of Medical Establishments (Наредба № 18 от 2005 г. за критериите, показателите и методиката за акредитация на лечебните заведения). [https://www.lex.bg/bg/laws/ldoc/2135506313/]. Accessed 17 October 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

There is no evidence that Bulgaria has a national system for transporting specimens from the site of collection to laboratory facilities. There is no evidence of such a system on the websites of the Ministry of Health or the Public Procurement Agency. [1] [2] However, evidence was found on the website of the Ministry of Health confirming the existence of a specimen transport system in 2010. A public procurement procedure from 2010 and supporting documents published by both the Ministry of Health and the Public Procurement Agency reveal that from 2010 until 2015, an active contract between the

Ministry of Health and the Bulgarian Postal Service secured the transporting of all tuberculosis specimens from their site of collection, located anywhere within Bulgaria, to the National Reference Laboratory of Tuberculosis in Sofia and three more approved laboratories. [3] [4]
The transport of all specimen from sites of collection to laboratories for testing for tuberculosis, malaria and HIV was also carried out from 2015 until 2017 under a separate contract won by the Bulgarian Postal Service. [5] Context searches on the Public Procurement Portal reveal that the Ministry of Health does not have open calls for specimen transporting services at present. [6]

[1] Ministry of Health. [https://www.mh.government.bg/bg/]. Accessed 11 October 2020.
[2] Public Procurement Agency. [https://app.eop.bg/]. Accessed 11 October 2020.
[3] Ministry of Health. 2010. "Contractor selection for courier services (Избор на изпълнители за извършване на куриерски услуги)". [https://www.mh.government.bg/bg/profil-na-kupuvacha/arhiv/protseduri-po-nvmop/izbor-na-izplniteli-za-izvrshvane-na-kurierski-usl/]. Accessed 11 October 2020.
[4] Public Procurement Agency. 2015. "Information: contract for a small public procurement (Информация за сключен договор за малка обществена поръчка)". [(https://www.aop.bg/case2.php?mode=show_doc&doc_id=493738&newver=2]. Accessed 11 October 2020.
[5] Ministry of Health. 2015. " Technical proposal (Техническо предложени)". [https://www.mh.government.bg/media/filer_public/2015/10/01/prilojenija_rd-11_415.pdf ¬]. Accessed 11 October 2020.
[6] Public Procurement Agency. "Search". [https://app.eop.bg/today/reporting/search]. Accessed 11 October 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

There is no publicly available information on the existence of a concrete plan allowing for the rapid authorization and/or licencing of laboratories to supplement the capacity of the national public health laboratory system in order to scale-up testing during an outbreak. Evidence from the 2005 Health Act (last updated in July 2020), the 2007 Ordinance №25 on the Conditions and Procedures for Sampling and Conducting Laboratory Tests, Analysis and Expertise, Necessary for the Purposes of State Health Control and the 2006 National Plan for Preparedness for Influenza Pandemics (also known as the National Pandemic Plan) confirms that the there is a government strategy in place aimed at scaling-up testing, but this applies to strengthening the capacities of existing public and private laboratories. [1] [2] [3] The National Pandemic Plan cites the need for even stricter institutional control over the work of already licences clinical laboratories in times of epidemiological emergencies which can in turn help explain why rapid authorization and licencing procedures are not the focus of policy. [3] The Ministry of Health, the Ministry of Agriculture, Food and Forestry and their associated agencies contain no relevant information on their websites. [4] [5]

[1] Ministry of Health. 2020. "Health Act (Закон за здравето)". [https://www.lex.bg/laws/ldoc%20/2135489147]. Accessed 11 October 2020.
[2]] Ministry of Health. 2007. "Ordinance №25 on the Conditions and Procedures for Sampling and Conducting Laboratory Tests, Analysis and Expertise, Necessary for the Purposes of State Health Control (Наредба № 25 от 6 юни 2007 г. за условията и реда за вземане на проби и провеждане на лабораторни изследвания, анализи и експертизи, необходими за целите на държавния здравен контрол)". [https://lex.bg/index.php/laws/ldoc/2135555678/]. Accessed 11 October

2020.
[3] Ministry of Health. 2006. “National Plan for Preparedness for Influenza Pandemic (Национален план на Република България за готовност за грипна пандемия)”. [http://www.strategy.bg/StrategicDocuments/View.aspx?lang=bg-BG&Id=366]. Accessed 11 October 2020.
[4] Ministry of Health. “Home”. [https://www.mh.government.bg/bg/]. Accessed 11 October 2020.
[5] Ministry of Agriculture, Food and Forestry. “Home”. [https://www.mzh.government.bg/bg/]. Accessed 11 October 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

Bulgaria conducts ongoing event-based surveillance analysis for infectious disease, but there is no evidence that said data are analyzed on a daily basis. The 2005 Health Act (last amended July 2020) covers data collection practices and event-based surveillance, stating that Regional Health Inspections are tasked with organizing surveillance activities following informal, unstructured reports from citizens on events deemed important to public health. During 2020, ongoing event-based surveillance has peaked in importance, with the government relying on reports from the public regarding violations of COVID-19-related regulations and restrictions (such as violations of quarantine and self-isolation rules). New hotlines and improved digital communication channels were introduced in spring 2020 to facilitate event-based surveillance. [2] [3]

In addition, the National Plan for Preparedness for Influenza Pandemic (also known as the National Pandemic Plan, published in 2006) details that, each year, data collected as part epidemiological surveillance of infectious disease are summarized and interpreted on regional and state levels daily between 1 November and 31 March, and weekly between 1 April and 30 October. The Plan, nonetheless, does not explicitly distinguish among the types of data included in these daily/weekly analytical reports. [4]

[1] Ministry of Health. 2020. “Health Act (Закон за здравето)”. [https://www.lex.bg/laws/ldoc%20/2135489147]. Accessed 11 October 2020.
[2] Ministry of Health. 2020. “Contacts (Контакти)”. [https://www.mh.government.bg/bg/kontakti/]. Accessed 11 October 2020.
[3] Vesti.bg. 2020. “Important contact details for questions and signals on COVID-19 (Важни телефони за въпроси и сигнали за COVID-19)”. [https://www.vesti.bg/temi-v-razvitie/tema-koronavirus/vazhni-telefoni-za-vyprosi-i-signali-za-covid-19-6107090]. Accessed 11 October 2020.
[4] Ministry of Health. 2006. “National Plan for Preparedness for Influenza Pandemic (Национален план на Република България за готовност за грипна пандемия)”. [http://www.strategy.bg/StrategicDocuments/View.aspx?lang=bg-BG&Id=366]. Accessed 11 October 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 Bulgaria reported a potential public health emergency of international concern within the last two years including for Covid-19. The World Health Organization's disease outbreak news page, the Bulgarian Ministry of Health and the National Center of Infectious and Parasitic Disease (NCIPD) contain no relevant information on the topic. [1] [2] [3] The NCIPD did report a Crimean-Congo haemorrhagic fever case during the week of 7 June 2020, but this never materialised into a potential public health emergency. [4]

[1] World Health Organization. 2019. “Emergencies preparedness, response”. [https://www.who.int/csr/don/archive/year/2019/en/]. Accessed 11 October 2020.
[2] Ministry of Health. 2020. “News (Актуално)”. [https://www.mh.government.bg/bg/novini/aktualno/]. Accessed 11 October 2020.
[3] National Center of Infectious and Parasitic Diseases. 2020. “News (Актуално)”. [https://www.ncipd.org/index.php?option=com_k2&view=item&id=546:ncov-012020&lang=bg]. Accessed 11 October 2020.
[4] Outbreak News Today. 2020. “Bulgaria reports first Crimean-Congo hemorrhagic fever case of the year”. [http://outbreaknewstoday.com/bulgaria-reports-1st-crimean-congo-hemorrhagic-fever-case-of-the-year-94881/]. Accessed 11 October 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 Bulgarian government operates an electronic reporting surveillance system at both the national and the regional level. According to a 2018 amendment to the 2005 Health Act (last revised in July 2020), a National Health Information System is administrated and managed by the Ministry of Health and contains multiple national and sub-national information records and databases, including a sentinel information surveillance system for infectious diseases. The National Center for Public Health and Analysis (NSPHA) electronically systematizes the information, processed by the surveillance system, to include both some personal data (namely patient diagnosis and characteristics such as age, gender and region) and more general information on the country-wide and regional spread of the disease, clinical records and approved treatments. Input into the electronic system comes from general practitioners and specialist doctors, medical facilities and laboratories. [1] [2] [3] In addition, the National Center of Infectious and Parasitic Diseases assists with providing electronic data from the National Reference Laboratories working under its supervision to both the Ministry of Health and Regional Health Inspections regarding the following diseases: influenza and other respiratory illnesses, rubeola, parotitis and measles. [4]

[1] Ministry of Health. 2020. “Health Act (Закон за здравето)”. [https://www.lex.bg/laws/ldoc%20/2135489147]. Accessed 11 October 2020.
[2] National Center on Public Health and Analyses. 2020. “Annual Report (Годишен доклад)”. [https://ncpha.government.bg/images/___NCPHA/__MainActivities/_AnnualReports/NCPHA_AnnualReport_2019.pdf]. Accessed 11 October 2020.

[3] Ministry of Health. 2006. “National Plan for Preparedness for Influenza Pandemic (Национален план на Република България за готовност за грипна пандемия)”. [http://www.strategy.bg/StrategicDocuments/View.aspx?lang=bg-BG&Id=366]. Accessed 11 October 2020.
[4] National Center on Infectious and Parasitic Diseases. 2020. “Department of Epidemiology – 2020 Priorities (Отдел Епидемиология – Приоритетни дейности през 2020г.)”. [https://ncipd.org/images/UserFiles/File/ENZB/PLAN_RABOTA_OTDEL_ENZB_2020.pdf]. Accessed 11 October 2020.

2.3.2b

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

Yes = 1 , No = 0

Current Year Score: 1

On-going, real-time laboratory data are collected and included in Bulgaria's electronic surveillance system. According to the National Center for Public Health and Analysis (NCPHA) and its National Health Data and Electronic Healthcare Directorate, laboratory and other medico-statistical data are collected daily via a specialist software for medical facilities, hospitals and laboratories, and are then incorporated into operational surveillance information accessed by the Ministry of Health and the Regional Health Inspections. [1] The surveillance system is also fed real-time laboratory data by the National Center of Infectious and Parasitic Diseases, gathered via the Center’s own notification system. [2]

In addition, a sentinel surveillance system for influenza is managed separately, with real-time laboratory data collected and reported daily between 1 November and 31 March each year, and weekly between 1 April and 30 October each year. [3]

[1] National Center on Public Health and Analyses. 2020. “Annual Report (Годишен доклад)”. [https://ncpha.government.bg/images/___NCPHA/__MainActivities/_AnnualReports/NCPHA_AnnualReport_2019.pdf]. Accessed 11 October 2020.
[2] National Center of Infectious and Parasitic Diseases. 2011. “Overview of Communicable Disease Surveillance System in Bulgaria”. [https://www.vhpb.org/files/html/Meetings_and_publications/Presentations/SOFS23.pdf]. Accessed 11 October 2020.
[3] Ministry of Health. 2006. “National Plan for Preparedness for Influenza Pandemic (Национален план на Република България за готовност за грипна пандемия)”. [http://www.strategy.bg/StrategicDocuments/View.aspx?lang=bg-BG&Id=366]. Accessed 11 October 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: 1

Bulgaria has a system of electronic health records, but they are not yet in common use. The national electronic health record system, called the Personalized Information System (PIS), is accessible via the website of the National Health Insurance Fund (NHIF). [1] The PIS is at present not fully comprehensive and interoperable, currently working as a digital dossier for the

patient rather than as an accessible platform for the national public health system. At present, the PIS contains the following patient information: allergies, immunizations, a history of check-ups, laboratory tests, medical procedures, hospitalizations, some prescriptions and dental status. By default, all general pracitioners and all relevant public and private healthcare facilities have access to the PIS and other non-publicly accessible digital health records as they enter the applicable patient data into the systems. [1] An integrated e-health system is currently under development and will begin working by December 2020, covering all basic functionalities such as a health information portal, electronic dossier and electronic prescriptions. Once introduced, the new system will allow general practitioners and specialist doctors to issue prescriptions, referrals and all other paperwork digitally on a platform that can be accessed by other medical professionals, laboratory personnel, pharmacists and patients alike. [2] [3]

[1] National Health Insurance Fund. "Personal Information System (Персонализирана Информационна Система)". [https://pis.nhif.bg/uac/f?p=200:2:5668451287677::NO:2::]. Accessed 11 October 2020.
[2] Actualno.com. 2020. "Electronic Healthcare – Saved? (Електронно здравеопазване – спасен ли е провалът?" [https://www.actualno.com/curious/elektronnoto-zdraveopazvane-spasen-li-e-provalyt-news_1501988.html]. Accessed 11 October 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: 0

At present, the national public health system does not have access to comprehensive electronic health records of individuals, but only to an incomplete health dossier. The National Health Insurance Fund manages the Personalized Information System (PIS), which compiles partial patient information for the following: allergies, immunizations, a history of check-ups, laboratory tests, medical procedures, hospitalizations, some prescriptions and dental status. [1]

As a 2013 European Commission paper notes, PIS records are created by the NHIF mainly with an informational and financial control purpose, and not as a tool to record and share electronic health data for medical purposes [2]. PIS records do not include medical results or detailed diagnoses, nor do they contain information from visits to private medical practitioners [2]. Bulgaria's healthcare sector is managed by the Ministry of Health and funded through the compulsory health insurance system operated by the Bulgarian Health Insurance Fund (BHIF). The Fund collects contributions from the working population and the government makes payments on behalf of those exempt, such as the retired, the unemployed and dependents [3]

According to Ministry of Health records, the National Center of Public Health and Analyses and recent media reports, the national public health system will have complete access to comprehensive individual health records by the end of 2021, as part of the second roll-out phase of the new integrated e-health system. [4] [5] [6]

[1] National Health Insurance Fund. "Personal Information System (Персонализирана Информационна Система)".[https://pis.nhif.bg/uac/f?p=200:2:5668451287677::NO:2::]. Accessed 11 October 2020.
[2] Champoeva, L. 2013. "Overview of the national laws on electronic health records in the EU Member States - National Report for Bulgaria". [https://ec.europa.eu/health/sites/health/files/ehealth/docs/laws_bulgaria_en.pdf]. Accessed 03 December 2020.
[3] Ministry of Health Republic of Bulgaria. Law number 70 of 10 August 2004. "Health Law". [http://www.mh.government.bg/media/filer_public/2018/10/22/zakon-za-zdraweto-2018.pdf]. Accessed 03 December 2020.
[4] Actualno.com. 2020. "Electronic Healthcare – Saved? (Електронно здравеопазване – спасен ли е провалът?") [https://www.actualno.com/curious/elektronnoto-zdraveopazvane-spasen-li-e-provalyt-news_1501988.html]. Accessed 11

October 2020.
[5] Ministry of Health. "Essence of Electronic Healthcare (Същност на електронното здравеопазване)". [https://www.mh.government.bg/media/filer_public/40/ab/40ab5447-cd85-4a9e-85b4-6f3a029909b6/proekt-programa-razvitie-elektronnoto-zdraveopazvane-oktomvri-2014-prilozhenie4.pdf]. Accessed 11 October 2020.
[6] National Center on Public Health and Analysis. "Home". [https://ncpha.government.bg/bg/]. Accessed 11 October 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

Bulgaria employs data standards to ensure data is comparable. The 2016 Ordinance № 11 on the Approval of Health Information Standards Applied by Healthcare Institutions contains provisions for the relevant ISO standards used across a range of fields in health informatics, including the approved requirements for the architecture of electronic healthcare records, the exchange of healthcare dossier data and the use of stored clinical data. As mandated by the Ordinance, the following ISO standards are currently in use: ISO 18308, ISO 13606, ISO 12967, ISO 29585 and ISO 22221. [1]

Some additional voluntary and commonly-used data standards ensuring the comparability of data across the healthcare system are also listed by the Bulgarian Institute of Standardization under a comprehensive health informatics section. [2]

[1] Ministry of Health. 2016. "Ordinance № 11 on the Approval of Health Information Standards Applied by Healthcare Institutions (Наредба № 11 от 4 ноември 2016 г. за утвърждаване на здравноинформационни стандарти, прилагани от лечебните заведения)". [https://www.lex.bg/bg/laws/ldoc/2136936338]. Accessed 11 October 2020.
[2] Bulgarian Institute for Standardization. "Data standards". [https://www.bds-bg.org/standard/index.php?page_number=9&national_committee_id=81&item_from=60]. Accessed 11 October 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 public evidence that the ministries responsible for animal, human, and wildlife surveillance have established mechanisms to share data. There is no evidence of such mechanisms on the websites of the Ministry of Health, the Ministry of Agriculture and Food, or the Ministry of Environment and Water. [1] [2] [3] Furthermore, the Public Registers List (a non-governmental portal financed by the Trust for Civil Society in Central and Eastern Europe) does not list any shared registers or other databases, compiling inter-ministerial data on animal, human and wildlife surveillance matters and involving any of the aforementioned ministries. [4]

Notably, the Risk Assessment Center on Food Chain and the law regulating its structure and activity suggest that cooperation and data exchanges among ministries take place on an ad-hoc basis, and the information produced is processed as part of the workflow of an external governmental body (albeit one working under the supervision of the Ministry of Health and the

Ministry of Agriculture, Food and Forestry) and not by the ministries themselves. [5]

[1] Ministry of Health. "Home". [https://www.mh.government.bg/bg/]. Accessed 11 October 2020.
[2] Ministry of Agriculture, Food and Forestry. "Home". [https://www.mzh.government.bg/bg/]. Accessed 11 October 2020.
[3] Ministry of Environment and Water. "Home". [https://www.moew.government.bg/]. Accessed 11 October 2020.
[4] Trust for Civil Society in Central and Eastern Europe. "Public Registers (Публични регистри)". [http://www.publicregisters.info/]. Accessed 11 October 2020.
[5] Risk Assessment Center on Food Chain. 2020. "Risk Assessment Center on Food Chain Act (Закон за Центъра за оценка на риска по хранителната верига)". [https://corhv.government.bg/?cat=59]. Accessed 11 October 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

De-identified health surveillance data on disease outbreaks are made publicly available via weekly reports published on the website of the Ministry of Health. According to the 2005 Health Act (last updated in July 2020), health information can be disclosed to third parties, including the general public, for the purposes of medical statistical analysis, provided any personal patient data have been removed. [1] Under the 2006 National Plan for Preparedness for Influenza Pandemics (also known as the National Pandemic Plan), the Ministry of Health is obligated to publish official government surveillance data on disease outbreaks on its website, based on compiled de-identified data collected at the national and regional levels. [2] The reports, which are published on a government website, cover seven-day periods at a time and include the total number of registered cases of infectious or parasitic diseases, together with more detailed breakdowns for three distinct categories of infections (gastrointestinal infections, airborne infections and transmissible infections). [3]

[1] Ministry of Health. 2020. "Health Act (Закон за здравето)". [https://www.lex.bg/laws/ldoc%20/2135489147]. Accessed 11 October 2020.
[2] Ministry of Health. 2006. "National Plan for Preparedness for Influenza Pandemic (Национален план на Република България за готовност за грипна пандемия)". [http://www.strategy.bg/StrategicDocuments/View.aspx?lang=bg-BG&Id=366]. Accessed 11 October 2020.
[3] Ministry of Health. 2020. "Information on the epidemic situation in the country (Справка за епидемичната обстановка в страната)". [https://www.mh.government.bg/bg/novini/epidemichna-obstanovka/spravka-za-epidemichnata-obstanovka-v-stran-39-20/]. Accessed 11 October 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

The Bulgarian government makes de-identified COVID-19 surveillance data publicly available via daily updates published on a single-gateway platform created in spring 2020. The Ministry of Health issued an order on 6 April 2020 for the launch of the

National Information System for Combating COVID-19, which stipulates that an information web portal will be operational and available to the public with immediate effect. [1] Coronovirus.bg contains all relevant information on the progression and spread of COVID-19 in Bulgaria, including daily reports on the daily data for registered cases, daily deaths/mortality rate, daily number of conducted PCR tests, number of hospitalized individuals and the number of daily recoveries recorded over the preceding 24-hour period. Publicly available on the gateway is also geographically presented information for COVID-19 patients and individuals under a compulsory quarantine, graphically displayed for all of Bulgaria's 28 provinces. [2]

In addition to this centralized web portal, the Governmental Information Service has also developed a mobile application for COVID-19, called ViruSafe, where any member of the public can voluntarily insert daily updates on their personal health status to assist with tracking the spread of the diseases. Another alternative to the Coronovirus.bg platform as a source of daily, real-time information on COVID-19 related data is the official chatbot of the Council of Ministers, available through a subscription on the mobile application Viber. [2]

[1] Ministry of Health. 2020. "Order 01-184/06.04.2020 (Заповед 01-184/06.04.2020)". [https://www.mh.government.bg/media/filer_public/2020/04/06/rd-01-184.pdf]. Accessed 11 October 2020.
[2] Coronavirus.bg. 2020. "Home". [https://coronavirus.bg/]. Accessed 11 October 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

Bulgaria has legislation that safeguards the confidentiality of identifiable health information for individuals, including data generated through health surveillance. The 2005 Health Act (last amended July 2020) contains provisions for the protection of personal patient data, including health status, physical and psychological development, as well as any other identifiable information contained in medical prescriptions, protocols and certificates, among others. The Act elaborates on eight scenarios for which health information may be shared with third parties, explicitly stating that any collection and disclosure of identifiable information for the purposes of medical statistical analysis must ensure personal patient data has been duly removed. [1]

Further to the Act, the existing legal framework has additional mechanisms in place to protect the confidentiality of individual identifiable health information, including both European Union (EU) directives extending to all EU member states and laws and regulations passed by the Bulgarian parliament. All relevant European and domestic legislation with significance on the matter can be accessed on the website of the Commission for Personal Data Protection, the body monitoring for compliance with all legal provisions on data protection. [2]

[1] Ministry of Health. 2020. "Health Act (Закон за здравето)". [https://www.lex.bg/laws/ldoc%20/2135489147]. Accessed 11 October 2020.
[2] Commission for Personal Data Protection. "Legislation". [https://www.cpdp.bg/en/index.php?p=rubric&aid=2]. Accessed 11 October 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

The legislation safeguarding the confidentiality of identifiable health information extends to the protection of data from cyber-attacks. As a member of the European Union (EU), Bulgaria is subject to the EU's General Data Protection Regulation (GDPR) and is obligated to safeguard personal data, including identifiable health information in accordance with all provisions set out by GDPR, as it became effective in May 2018. With regards to cyber-security, GDPR stipulates that all data held by public authorities must be overseen by a data protection officer who is competent to respond to cyber-threats and follow a strict notification procedure, informing all affected individuals of data breaches within 72 hours of their occurrence. [1]

Further cybersecurity requirements for public institutions processing personal data, including identifiable health information, are laid out by the 2018 Cybersecurity Act (last amended in 2020), to ensure all national authorities cooperate promptly with the Commission for Personal Data Collection in case of data breaches. [2]

[1] Commission for Personal Data Protection. 2016. "Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)". [https://www.cpdp.bg/userfiles/file/New_legislation/Regulation_EU_2016_679_En%20-%20consolidated.pdf]. Accessed 11 October 2020.
[2] Council of Ministers. 2018. "Cybersecurity Act (Закон за киберсигурност)". [https://www.lex.bg/bg/laws/ldoc/2137188253]. Accessed 11 October 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: 2

The government has made public statements, legislation and cooperative agreements to share surveillance data during a public health emergency with other countries in the region and these commitments pertain to data for more than one disease. At the level of the European Union, member states including Bulgaria take part in the Early Warning and Response System (EWRS), managed by the European Center for Disease Prevention and Control, as detailed in Decision No. 1082/2013/EU on Serious Cross-border Threats to Health. The EWRS is described as a permanent communication network between the European Commission and the competent public health authorities dealing with serious cross-border threats to human health and serving as a notification system regarding potential outbreaks of communicable diseases. [1]

The cross-border exchange of data during public health emergencies is also covered by the Ministry of Health's National Health Strategy 2020 and the 2020 Administrative Goals, both highlighting the importance of data-sharing in order to avoid

personnel and financial shortages within the health system when facing epidemiological emergencies. [2] [3]

[1] European Parliament. 2013. "Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health". [https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32013D1082]. Accessed 11 October 2020.
[2] Ministry of Health. 2015. "National Health Strategy (Национална здравна стратегия 2020)". [https://www.mh.government.bg/media/filer_public/2016/09/12/nzs_2020.pdf]. Accessed 11 October 2020.
[3] Ministry of Health. 2020. "Administrative Goals (Цели на администрацията за 2020г.)". [https://www.mh.government.bg/media/filer_public/2020/02/28/utvrdeni_tseli_2020.pdf]. Accessed 11 October 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: 2

There is a national system in place providing support to both central (national) and regional health authorities to conduct contact tracing in the context of active and future public health emergencies. Contact tracing procedures in cases of epidemiological emergencies are detailed in the 2005 Health Act (last updated in July 2020), the 2006 National Plan for Preparedness for Influenza Pandemics (also known as the National Pandemic Plan) and the 2019 Ordinance №6 on the Order and Conditions for Carrying Out Diagnostics, Prophylaxis and Control of Individual Infectious Diseases of the Respiratory System. According to the aforementioned documents, Regional Health Inspections, together with the Ministry of Health and in part the National Center of Infectious and Parasitic Diseases, are the health authorities responsible for conducting contact tracing in public health crises. Nationwide, uniform rules are applied and funding for compulsory testing of traced contacts is provided through the central health system. [1] [2] [3]

[1] Ministry of Health. 2020. "Health Act (Закон за здравето)". [https://www.lex.bg/laws/ldoc%20/2135489147]. Accessed 11 October 2020.
[2] Ministry of Health. 2006. "National Plan for Preparedness for Influenza Pandemic (Национален план на Република България за готовност за грипна пандемия)". [http://www.strategy.bg/StrategicDocuments/View.aspx?lang=bg-BG&Id=366]. Accessed 11 October 2020.
[3] Ministry of Health. 2019. "Ordinance №6 on the Order and Conditions for Carrying Out Diagnostics, Prophylaxis and Control of Individual Infectious Diseases of the Respiratory System (Наредба № 6 от 9 юли 2019 г. за реда и условията за провеждане на диагностика, профилактика и контрол на отделни заразни болести на дихателната система)". [https://www.mh.government.bg/media/filer_public/2019/07/17/naredba__6_ot_9_iuli_2019_g.pdf]. Accessed 11 October 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

Bulgaria provides wraparound services in the form of both economic support and medical attention to enable infected people and their contacts to self-isolate or quarantine as recommended. As mandated by the 2005 Health Act (last updated in July 2020), self-isolation and quarantine rules are set out by the Minister of Health for any individual communicable disease considered as an epidemiological threat, while on-the-ground implementation and control are carried out by Regional Health Inspections (RHI) and the network of general practitioners. Laboratory testing and related health services for suspected cases and their contacts are paid in full by the responsible RHI. [1] As a first point of contact, all confirmed and suspected cases are encouraged to inform their general practitioner of any developments and changes in their health status or call the hotlines of their RHI for medical advice. [2]

The economic support (both paycheck and job security) received by confirmed and suspected cases of infectious diseases is covered under the 2000 Social Security Code (last revised in August 2020), which contains provisions for the financial compensation paid out to individuals in the event of self-isolation. Compensation is paid out for temporary inability to work due to self-isolation or other compulsory removal from the workplace as prescribed by the health authorities by the National Social Security Institute. The cash benefits cover either the duration of the quarantine, or 90 calendar days in any given year if the recipient is prevented from returning to his old job and another suitable position is not provided by the employer. [3]

[1] Ministry of Health. 2020. “Health Act (Закон за здравето)”. [https://www.lex.bg/laws/ldoc%20/2135489147]. Accessed 11 October 2020.
[2] Regional Health Inspection – Plovdiv. 2020. “Instructions for Issuance of Certificates for Quarantine (Указание за издаване на болничен лист)”. [http://riokozpd.com/%D1%83%D0%BA%D0%B0%D0%B7%D0%B0%D0%BD%D0%B8%D0%B5-%D0%B7%D0%B0-%D0%B8%D0%B7%D0%B4%D0%B0%D0%B2%D0%B0%D0%BD%D0%B5-%D0%BD%D0%B0-%D0%B1%D0%BE%D0%BB%D0%BD%D0%B8%D1%87%D0%B5%D0%BD-%D0%BB%D0%B8%D1%81%D1%82-%D0%BF%D1%80%D0%B8-%D0%BA%D0%B0%D1%80%D0%B0%D0%BD%D1%82%D0%B8%D0%BD%D0%B0]. Accessed 11 October 2020.
[3] National Social Security Institute. “Compensations in case of temporary incapacity to work (Парични обезщетения при временна неработоспособност)”. [https://www.noi.bg/benefits/benefits/100-nerabotosposobnost/1861-povn13]. Accessed 11 October 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

There is no publicly available evidence to confirm that Bulgaria is disseminating de-identified data on contact tracing efforts for COVID-19 including the percentage of new cases from identified contacts in the form of daily reports or other

governmental communication. The official governmental information portal for COVID-19 was launched in April 2020 at Coronavirus.bg. It contains detailed statistical information and dynamic dashboard data on the following: new daily cases, active cases, total of confirmed cases, number of recoveries, mortality rate, number of PCR tests conducted and number of people in self-isolation. While COVID-19 can also be visually displayed and traced in all of Bulgaria's 28 regions, no information was found regarding de-identified data on contact tracing efforts or a percentage breakdown of new cases traced to confirmed ones. [1]

The National Statistical Institute has also introduced a COVID-19 rubric to its website, however, with a focus on economic and social data. [2] The Ministry of Health and associated agencies contain no relevant information. [3]

[1] Coronavirus.bg. 2020. "Information (Актуална информация)". [https://coronavirus.bg/arcgis/apps/opsdashboard/index.html#/ecacd239ee7e4fba956f7948f586af93]. Accessed 11 October 2020.
[2] National Statistical Institute. 2020. "COVID-19". [https://www.nsi.bg/bg/content/18120/basic-page/covid-19]. Accessed 11 October 2020.
[3] Ministry of Health. "Home". [https://www.mh.government.bg/bg/]. Accessed 11 October 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: 2

Current legislation and regulations mandate and enforce the cooperation between border control authorities and the public health system on monitoring suspected and potential cases for international travellers and trace and quarantine their contacts in the context of both active and future health emergencies. The 2005 Health Act (last updated in July 2020) and the 2002 Ordinance for Border Checkpoints (last revised in July 2017) regulate border control activities and the appropriate code of conduct for accepting international travellers into Bulgaria in times of epidemiological emergencies. [1] [2]

According to the Health Act, all or some international travellers may be subject to compulsory self-isolation with immediate effect upon entering the country in order to prevent the spread of the following highly contagious diseases, should these be considered a public health threat by the Ministry of Health: cholera, plague, smallpox, yellow fever, viral haemorrhagic fevers, diphtheria, typhoid fever, polio, brucellosis, anthrax, malaria, severe acute respiratory syndrome, COVID-19 and tuberculosis. [1] In order to achieve the above, border control personnel have been authorized by the Ministry of Health to perform a list core tasks aimed at preventing the spread of diseases that pose an immediate danger to the public. The complete list of thirteen tasks is included in Chapter III, Article 18 of the Ordinance for Border Checkpoints. The list of tasks include: search for the contacts of patients and the persons, for whom there is a suspicion that they are ill. [2]

[1] Ministry of Health. 2020. "Health Act (Закон за здравето)". [https://www.lex.bg/laws/ldoc%20/2135489147]. Accessed 11 October 2020.
[2] Ministry of Interior. 2017. "Ordinance for Border Checkpoint (Наредба за граничните контролно-пропускателни

пунктове)". [https://www.lex.bg/laws/ldoc/-548901372]. Accessed 11 October 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

Bulgaria has an in-country training program in applied epidemiology and citizens are also sent abroad on dedicated training programs. Domestically, multiple Medical Universities offer training in applied epidemiology as part of their curricula. These include the Medical University of Sofia, the Medical University of Plovdiv and the Medical University of Varna. [1] [2] [3]

With regard to international training, Bulgarian citizens can receive practical experience at training cites across the European Union and the European Economic Area as part of the European Program for Intervention Epidemiology Training (EPIET), initiated by the European Center for Disease Prevention and Control (ECDC). EPIET was merged with a fellowship program on microbiology training in 2016 and is now known as the ECDC Fellowship Program. [4] Furthermore, applied epidemiological training is also facilitated through the Network for Communicable Diseases Control in Southern Europe and the Mediterranean Countries with funding from the EU budget. Although public information on the training itself is scarce, the National Center of Infectious and Parasitic Diseases is listed as a focal point on the matter. [5]

[1] Medical University Sofia. "Public Health Faculty". [https://www.mu-sofia.bg/obuchenie/specialnosti/fakultet-obstestveno-zdrave/]. Accessed 11 October 2020.
[2] Medical University Plovdiv. "Public Health Faculty". [https://mu-plovdiv.bg/fakulteti/obshtestveno-zdrave/katedri/sotsialna-meditsina-obshtestveno-zdrave/prilozhna-epidemiologiya-profesor-stefanov/]. Accessed 11 October 2020.
[3] Medical University of Varna – Prof. Dr. Paraskev Stoyanov. "Epidemiology". [http://mu-varna.bg/BG/AboutUs/PublicHealth/Pages/US_epidemiologiq.aspx]. Accessed 11 October 2020.
[4] European Center for Disease Prevention and Control. "At a glance". [https://www.ecdc.europa.eu/en/epiet-euphem/about/intro]. Accessed 11 October 2020.
[5] EpiSouth. 2010. "Training in Public Health and Applied Epidemiology in the Mediterranean Countries and Balkans". [http://www.episouth.org/outputs/wp5/2_EpiSouth%20Strategic%20document%20on%20Training%20Rev%20luglio%202010.pdf]. Accessed 11 October 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: 1

Available field epidemiology training programs are explicitly inclusive of animal health professionals. The EPIET (European Program for Intervention Epidemiology Training) Path of the Fellowship Program of the European Center for Disease Prevention and Control (ECDC) is suitable for veterinary medicine candidates, provided they meet the eligibility criteria of the program, namely a post-secondary education diploma in veterinary medicine coupled with at least one year of work experience in public health or applied epidemiology. [1]

[1] European Center for Disease Prevention and Control. "Administrative Decision on Rules governing the EU-track of the ECDC Fellowship Program, filed epidemiology path (EPIET) and public health microbiology path (EUPHEM)". [https://www.ecdc.europa.eu/sites/default/files/documents/ECDC-AD-2020-13%20Administrative%20Decision%20on%20EU-track%20Cohort%202021.pdf]. Accessed 11 October 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

Bulgaria has an overarching National Health Strategy 2020 which serves as a national public health emergency response plan that addresses planning for multiple communicable diseases with epidemic or pandemic potential. The 2005 Health Act (last

revised in July 2020), the National Health Strategy 2020 and the accompanying Action Plan for the Fulfilment of the National Health Strategy 2020 all refer to mechanisms, adopted to ensure a high-level of preparedness for the effective response in the face public health emergencies caused by the spread of communicable diseases. [1] [2] [3] Additional details are featured in the Action Plan, under activities aimed at improving planning mechanisms to prepare the system for disaster response at the institutional, regional and national levels, part of overarching policies on communicable diseases. [3]

Notably, a publicly accessible 2008–2010 National Program for Strengthening the Capacity for Preventing the Import of Infectious Diseases and Responding to Events Representing Public Health Treats attests further to the existence of emergency response mechanisms for the spread of communicable diseases. [4]

[1] Ministry of Health. 2020. “Health Act (Закон за здравето)”. [https://www.lex.bg/laws/ldoc%20/2135489147]. Accessed 11 October 2020.
[2] Ministry of Health. 2015. “National Health Strategy (Национална здравна стратегия 2020)”. [https://www.mh.government.bg/media/filer_public/2016/09/12/nzs_2020.pdf]. Accessed 11 October 2020.
[3] Ministry of Health. 2016. “Action Plan for the Fulfilment of the National Health Strategy 2020 (План за действие за изпълнение на Националната здравна стратегия 2020)”. [https://www.mh.government.bg/media/filer_public/2016/09/12/plan_za_deistvie-nzs_2020.pdf]. Accessed 11 October 2020.
[4] Council of Ministers. 2010. “2008-2010 National Program for Strengthening the Capacity for Preventing the Import of Infectious Diseases and Responding to Events Representing Public Health Threats (Национална програма за укрепване капацитета на Република България за опазването и от внос на заразни болести и реагиране при събития, представляващи заплаха за общественото здраве 2008 - 2010 г.)”. [http://www.strategy.bg/StrategicDocuments/View.aspx?lang=bg-BG&Id=419]. Accessed 11 October 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: 0

Bulgaria's overarching national public health emergency response plan has not been updated in the last three years. The National Health Strategy 2020, which contains Bulgaria's overarching national public health emergency response plan, was adopted in 2015 and has not been updated since. [1] The strategy's accompanying action plan was adopted in 2016 and has not been updated since. [2] The Health Act, which also contains important provisions on public health emergency response, was adopted in 2005 and last amended in July 2020. [3]

[1] Ministry of Health. 2015. "National Health Strategy (Национална здравна стратегия 2020)". [https://www.mh.government.bg/media/filer_public/2016/09/12/nzs_2020.pdf]. Accessed 11 October 2020.
[2] Ministry of Health. 2016. "Action Plan for the Fulfilment of the National Health Strategy 2020 (План за действие за изпълнение на Националната здравна стратегия 2020)". [https://www.mh.government.bg/media/filer_public/2016/09/12/plan_za_deistvie-nzs_2020.pdf]. Accessed 11 October 2020.
[3] Ministry of Health. 2020. "Health Act (Закон за здравето)". [https://www.lex.bg/laws/ldoc%20/2135489147]. Accessed 11 October 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

The National Health Strategy 2020, Bulgaria's overarching national public health emergency response plan, includes considerations for paediatric and other vulnerable populations. The National Health Strategy's Policy 1.2 and Policy 1.7 are dedicated to Health of Children and Adolescents and Health of Vulnerable Groups with both addressing emergency preparedness measures to tackle infectious diseases. [1] Furthermore, the Strategy and its accompanying Action Plan for the Fulfilment of the National Health Strategy 2020 mandate special measures to be taken in relation to tackling vaccine-preventable diseases among vulnerable and marginalized groups who do not necessarily benefit from the state health insurance rights to which they are entitled to due to ethnic, cultural or social reasons, and are thus considered particularly high-risk in the event of a public health emergency caused by a highly communicable disease. [1] [2]

In addition, the 2005 Health Act (last revised in July 2020) calls for an emergency epidemic situation to be declared if the National Health Inspector deems an outbreak of a communicable disease to put at risk vulnerable or at-risk groups of the population, which are named as including children, the elderly, refugees, people with immunodeficiency, and people with chronic diseases. [3]

[1] Ministry of Health. 2015. “National Health Strategy (Национална здравна стратегия 2020)”. [https://www.mh.government.bg/media/filer_public/2016/09/12/nzs_2020.pdf]. Accessed 11 October 2020.
[2] Ministry of Health. 2016. “Action Plan for the Fulfilment of the National Health Strategy 2020 (План за действие за изпълнение на Националната здравна стратегия 2020)”. [https://www.mh.government.bg/media/filer_public/2016/09/12/plan_za_deistvie-nzs_2020.pdf]. Accessed 11 October 2020.
[3] Ministry of Health. 2020. “Health Act (Закон за здравето)”. [https://www.lex.bg/laws/ldoc%20/2135489147]. Accessed 11 October 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: 0

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: 1

Bulgaria has specific mechanisms for engaging with the private sector in assisting with outbreak emergency preparedness and response. These have generally been laid out in Chapter Three, Section I, Articles 19 and 20 of the 2006 Disaster Protection Act (last amended July 2020), according to which there is a functioning national Uniform Rescue System. Activities under the Uniform Rescue System may be performed to protect the public from disasters and emergencies including efforts aimed at limiting the spread of emerging epidemic and pandemic outbreaks of infectious and parasitic diseases. As stipulated by the Act, the private sector is part of the structure of the Uniform Rescue System, along with governmental agencies, municipalities, health facilities, non-governmental and non-for-profit organizations and the army. [1]

More concrete mechanisms regulating public-private cooperation in the context of emergency preparedness and response can be found in the 2019 Ordinance №3 for Carrying Out Medical Activities Not Covered by the Compulsory Health Insurance and Subsidized by the Ministry of Health (revised in September 2020). This Ordinance specifies the criteria and procedure under which private health facilities can receive governmental funding for assisting emergency preparedness and response efforts. Notably, these privately-funded hospitals have to fund a dedicated clinic or ward for infectious diseases, secure a clinical laboratory providing 24-hour services, house a pharmacy and have a allow for 24/7 admissions of patients diagnosed or showing symptoms of infectious diseases. [2]

[1] Ministry of Interior. 2020. “Disaster Protection Act (Закон за защита при бедствия)”. [https://www.lex.bg/laws/ldoc/2135540282]. Accessed 11 October 2020.
[2] Ministry of Health. 2019. “Ordinance №3 for Carrying Out Medical Activities Not Covered by the Compulsory Health Insurance and Subsidized by the Ministry of Health (Наредба № 3 от 5 април 2019 г. За медицинските дейности извън обхвата на задължителното здравно осигуряване, за които министерството на здравеопазването субсидира лечебни заведения, и за критериите и реда за субсидиране на лечебни заведения)”. [https://www.mh.government.bg/media/filer_public/2020/09/29/naredba-3-2019-medicinski-dejnost-izvyn-obhvata-na-zzo.pdf]. Accessed 11 October 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: 2

The implementation of non-pharmaceutical interventions (NPIs) during an epidemic or pandemic is covered by the domestic legislative framework with guidelines covering more than one disease. According to the 2005 Health Act (as amended in July 2020), in the event of imminent threats to public health caused by the rapid epidemic spread of an infectious or parasitic disease, an Emergency Epidemic Situation may be declared, calling for the implementation of NPIs. Section V, Article 63 of the Act describes the assessments made prior to the declaration of an Emergency Epidemic Situation which triggers the implementation of NPIs. These include considerations for the level of threat posed to public health by the pathogen in question, the degree of epidemic potential of the disease, the level of immunization in the population, the spread and behaviour of the pathogen in the region and the threat posed to children, elderly and other vulnerable groups, among others. Depending on the gravity of the epidemiological situation as assessed by the Ministry of Health, the Chief Health

Inspector and Regional Health Inspections, NPIs may be implemented in varying forms both nationally and/or regionally. [1]

[1] Ministry of Health. 2020. "Health Act (Закон за здравето)". [https://www.lex.bg/laws/ldoc%20/2135489147]. Accessed 11 October 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: 1

In the past year Bulgaria has activated its national emergency response plan for an infectious disease outbreak, but there is no evidence that it has completed a national-level biological threat focused exercise over the past year. The national emergency response plan was formally activated on 26 February 2020, following an order from the Prime Minister, and in line with all provisions put forward by the 2006 Disaster Protection Act (last amended July 2020). [1] [2] A list of orders relating to the emergency response measures put forward by the Bulgarian government has been published on the website of the Ministry of Health, containing all relevant decrees from 8 March 2020 to date. These include instructions on precautionary hygiene measures, disinfections, travel restrictions, the compulsory wearing of masks, as well as guidance on the work-mode of hospitality businesses, gyms, schools and other educational institutions. [3] The World Health Organization does not have Bulgaria on its list for simulation exercises (SimEx), either as a country having already conducted a SimEx or as a country planning on completing one. [4]

[1] Coronavirus.bg. 2020. "Orders from State Bodies". [https://coronavirus.bg/bg/231]. Accessed 14 November 2020.
[2] Ministry of Interior. 2020. "Disaster Protection Act (Закон за защита при бедствия)". [https://www.lex.bg/laws/ldoc/2135540282]. Accessed 11 October 2020.
[3] Ministry of Health. 2020. "Information on COVID-19 for citizens and medical professionals (Информация за COVID-19 за граждани и медицински специалисти". [https://www.mh.government.bg/bg/informaciya-za-grazhdani/informaciya-otnosno-noviya-koronavirus-2019-ncov/]. Accessed 11 October 2020.
[4] World Health Organization. "Simulation Exercise". [https://extranet.who.int/sph/simulation-exercise]. Accessed 11 October 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 Bulgaria has identified a list of gaps and best practices in response (either through an infectious disease response of a biological-threat focused exercise) and developed a plan to improve response capabilities in the past year. The country has not conducted an After Action Review (AAR) as per information from the World Health Organization (WHO). [1] The WHO IHR and the WHO regional page for Bulgaria as well as the Ministry of Health and the State Agency for National Security have been reviewed and found to contain no evidence of either an AAR of a biological threat-focussed IHR exercise [2] [3] [4] [5]. The last simulation exercise in Bulgaria took place in 2015, through an EU-supported effort to help the Balkan countries bolster their capacities for responding to a possible outbreak of foot-and-mouth disease [6].

[1] World Health Organisation. "After Action Review". [https://extranet.who.int/sph/after-action-review]. Accessed 17 October 2020.
[2] World Health Organisation. "International Health Regulations". [http://www.who.int/topics/international_health_regulations/en/]. Accessed 17 October 2020.
[3] World Health Organisation. "Bulgaria - News and Features". [https://www.who.int/countries/bgr/en/]. Accessed 17 October 2020.
[4] Ministry of Health Republic of Bulgaria. "News (Новини)". [http://www.mh.government.bg/bg/novini/aktualno/]. Accessed 17 October 2020.
[5] State Agency for National Security Republic of Bulgaria. "Legislation". [http://www.dans.bg/en/legislation-menu-en.]. Accessed 17 October 2020.
[6] Food and Agriculture Organisation of the United Nations. 2015. "Bulgaria undertakes animal disease outbreak simulation".[http://www.fao.org/europe/news/detail-news/en/c/296021/]. Accessed 17 October 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 Bulgaria has undergone a national-level biological threat-focused exercise that has included private sector representatives. No evidence was found on the World Health Organization (WHO) IHR page, the WHO regional page for Bulgaria, the WHO Simulation Exercise page, the websites of the Ministry of Health and associated agencies to suggest Bulgaria took part in a biological threat-focused exercise over the past year or that there are such plans for the near future. [1] [2] [3] [4] [5]

[1] World Health Organization. “After Action Review”. [https://extranet.who.int/sph/after-action-review]. Accessed 11 October 2020.
[2] World Health Organization. “Bulgaria”. [https://www.euro.who.int/en/countries/bulgaria/data-and-statistics]. Accessed 11 October 2020.
[3] World Health Organization. “Simulation Exercise”. [https://extranet.who.int/sph/simulation-exercise]. Accessed 11 October 2020.
[4] Ministry of Health. “Home”. [https://www.mh.government.bg/bg/]. Accessed 11 October 2020.
[5] National Center of Infectious and Parasitic Disease. “Home”. [https://www.ncipd.org/index.php?lang=en]. Accessed 11

October 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

Bulgaria has an emergency operations center (EOC). The National 112 System Directorate at the Ministry of Interior is the body funcition as an EOC, coordinating and supervising a total of six emergency units in the country, which cover and respond to health-related and other emergencies and coordinate the work of response teams. [1]

In addition, Bulgaria has a Uniform Rescue System, which contains specific coordination mechanisms regarding the activities required for public health protection in the event of disasters involving emerging epidemic and pandemic outbreaks of infectious and parasitic diseases, as well as any other public health threats related to incidents resulting from the release of hazardous chemical, nuclear and biological materials into the environment. The legislative and regulative framework on the work of the Uniform Rescue System related to public health issues is detailed in the 2006 Disaster Protection Act (amended in July 2020), the 2005 Health Act (revised in July 2020) and the 2014-2020 National Strategy for Reducing Disaster Risk. [2] [3] [4]

Depending on the nature of the public health emergency, the immediate response team is either managed by the Head of the Regional Health Inspectorate (subordinate to the Ministry of Health) for emergencies in cases of epidemics and epizootics, or by the Head of the Territorial Unit of the Directorate-General for Fire Safety and Civil Protection (subordinate to the Ministry of Interior). [4] [5]

[1] Ministry of Interior. “National 112 System Directorate (Дирекция НС 112)”. [https://mvr.bg/112]. Accessed 17 October 2020.
[2] Ministry of Interior. 2020. “Disaster Protection Act (Закон за защита при бедствия)”. [https://www.lex.bg/laws/ldoc/2135540282]. Accessed 11 October 2020.
[3] Ministry of Interior. 2014. “2014-2020 National Strategy for Reducing Disaster Risk (Стратегия за намаляване на риска от бедствия)”. [https://mvr.bg/docs/default-source/strategicheskidokumenti/9066EC19-07_Str_Risk_Bedstvia-pdf.pdf] Accessed 11 October 2020.
[4] Ministry of Health. 2020. “Health Act (Закон за здравето)”. [https://www.lex.bg/laws/ldoc%20/2135489147]. Accessed 11 October 2020.
[5] Ministry of Interior. 2013. “Management, coordination and control in case of disastes, fires and emergencies (Управление, координация и контрол при възникване на бедствия, пожари и извънредни ситуации)”. [https://www.mvr.bg/docs/librariesprovider5/newsdocs/%D0%B1%D1%80%D0%BE%D1%88%D1%83%D1%80%D0%B0.pdf?sfvrsn=76fc7859_0]. Accessed 11 October 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 publicly available 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 that they do so in practice. Existing drill exercises covered under the Uniform Rescue System's annual training on early-warning and notification of the population do not include separate scenarios for health-specific systemic exercises. The Ministry of Interior has published Guidelines for Safe Conduct and Early-warning Signals and Notifications of the Population, according to which training exercises for general emergency preparedness are conducted bi-annually. A National Threat Alarm is tested on the first workday of April and October each year. [1] As mandated by the 2009 Ordinance for the Early-warning and Notification of Disasters, the National Threat Alarm is a three-minute constant signal with four-second frequency changes ranging from 700 to 1000 Hertz and may include one of eleven voice-warnings, including a separate message on epidemic emergencies. [2]

The 2006 Disaster Protection Act (revised in July 2020), the 2014-2020 National Strategy for Reducing Disaster Risk, the 2014 Ordinance on the Implementation of Preventative Activities by the Fire Safety and Civil Protection Authorities of the Ministry of Internal Affairs and the 2005 Health Act (updated in July 2020) do not mention emergency response exercises. [3] [4] [5] [6] The Ministry of Health and the National 112 System Directorate at the Minstry of Interior have no evidence of the above on their websites either. [7] [8]

[1] Ministry of Interior." Guidelines for Safe Conduct and Early-warning Signals and Notifications of the Population (Правила за безопасно поведение и сигнали за ранно предупреждение и оповестяване на населението)". [https://www.mvr.bg/gdpbzn/footer/info-center/pravila-signali/signali]. Accessed 11 October 2020.
[2] Ministry of Interior. 2009. "Ordinance for the Early-warning and Notification of Disasters (Наредба за ранното предупреждение и оповестяването при бедствия)". [https://www.lse.ac.uk/GranthamInstitute/wp-content/uploads/laws/1105.pdf]. Accessed 11 October 2020.
[3] Ministry of Interior. 2020. "Disaster Protection Act (Закон за защита при бедствия)". [https://www.lex.bg/laws/ldoc/2135540282]. Accessed 11 October 2020.
[4] Ministry of Interior. 2014. "2014-2020 National Strategy for Reducing Disaster Risk (Стратегия за намаляване на риска от бедствия)". [https://mvr.bg/docs/default-source/strategicheskidokumenti/9066EC19-07_Str_Risk_Bedstvia-pdf.pdf]. Accessed 11 October 2020.
[5] Ministry of Interior. 2014. "Ordinance on the Implementation of Preventative Activities by the Fire Safety and Civil Protection Authorities (Наредба за осъществяване на превантивна дейност от органите за пожарна безопасност и защита на населениетО)". [https://www.lex.bg/laws/ldoc/2136360497]. Accessed 11 October 2020.
[6] Ministry of Health. 2020. "Health Act (Закон за здравето)". [https://www.lex.bg/laws/ldoc%20/2135489147]. Accessed 11 October 2020.
[7] Ministry of Health. "Home". [https://www.mh.government.bg/bg/]. Accessed 11 October 2020.
[8] Ministry of Interior. "National 112 System Directorate". [https://mvr.bg/112/%D0%BD%D0%B0%D1%87%D0%B0%D0%BB%D0%BE]. Accessed 17 October 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 evidence that Bulgaria's Emergency Operations Center (EOC) has conducted a coordinated emergency response exercise activated within 120 minutes of the indenfication of the public health emergeny. The 2006 Disaster Protection Act (revised in July 2020), the 2014-2020 National Strategy for Reducing Disaster Risk, the 2014 Ordinance on the Implementation of Preventative Activities by the Fire Safety and Civil Protection Authorities of the Ministry of Internal Affairs and the 2005 Health Act (updated in July 2020) do not mention responding to emergencies within 120 minutes, or to emergency response exercises. [1] [2] [3] [4] The Ministry of Health and the National 112 System Directorate at the Minstry of Interior have no evidence of the above on their websites either. [5] [6]

[1] Ministry of Interior. 2020. "Disaster Protection Act (Закон за защита при бедствия)". [https://www.lex.bg/laws/ldoc/2135540282]. Accessed 11 October 2020.
[2] Ministry of Interior. 2014. "2014-2020 National Strategy for Reducing Disaster Risk (Стратегия за намаляване на риска от бедствия)". [https://mvr.bg/docs/default-source/strategicheskidokumenti/9066EC19-07_Str_Risk_Bedstvia-pdf.pdf]. Accessed 11 October 2020.
[3] Ministry of Interior. 2014. "Ordinance on the Implementation of Preventative Activities by the Fire Safety and Civil Protection Authorities (Наредба за осъществяване на превантивна дейност от органите за пожарна безопасност и защита на населениетО)". [https://www.lex.bg/laws/ldoc/2136360497]. Accessed 11 October 2020.
[4] Ministry of Health. 2020. "Health Act (Закон за здравето)". [https://www.lex.bg/laws/ldoc%20/2135489147]. Accessed 11 October 2020.
[5] Ministry of Health. "Home". [https://www.mh.government.bg/bg/]. Accessed 11 October 2020.
[6] Ministry of Interior. "National 112 System Directorate". [https://mvr.bg/112/%D0%BD%D0%B0%D1%87%D0%B0%D0%BB%D0%BE]. Accessed 17 October 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

There are no provisions in existing legislation and regulations mandating the implementation of joint exercises and/or simulations responding to a potential deliberate biological event to be carried out by public health and national security authorities and no standard operating procedures, guidelines or other official agreements are publicly available to confirm the existence of collaborative actions on response mechanisms for potential deliberate biological events between public health and security authorities either. The 2006 Disaster Protection Act (amended July 2020), the 2014-2020 National Strategy for Reducing Disaster Risk, the 2014 Ordinance on the Implementation of Preventative Activities by the Fire Safety and Civil Protection Authorities of the Ministry of Internal Affairs and the 2005 Health Act (updated in July 2020) contain no mention of the above collaboration. [1] [2] [3] [4] The Ministry of Health and the Minstry of Interior have no evidence of the

above on their websites either. [5] [6]

[1] Ministry of Interior. 2020. “Disaster Protection Act (Закон за защита при бедствия)”. [https://www.lex.bg/laws/ldoc/2135540282]. Accessed 11 October 2020.
[2] Ministry of Interior. 2014. “2014-2020 National Strategy for Reducing Disaster Risk (Стратегия за намаляване на риска от бедствия)”. [https://mvr.bg/docs/default-source/strategicheskidokumenti/9066EC19-07_Str_Risk_Bedstvia-pdf.pdf] Accessed 11 October 2020.
[3] Ministry of Interior. 2014. “Ordinance on the Implementation of Preventative Activities by the Fire Safety and Civil Protection Authorities (Наредба за осъществяване на превантивна дейност от органите за пожарна безопасност и защита на населениетО)”. [https://www.lex.bg/laws/ldoc/2136360497]. Accessed 11 October 2020.
[4] Ministry of Health. 2020. “Health Act (Закон за здравето)”. [https://www.lex.bg/laws/ldoc%20/2135489147]. Accessed 11 October 2020.
[5] Ministry of Health. “Home”. [https://www.mh.government.bg/bg/]. Accessed 11 October 2020.
[6] Ministry of Interior. “Home”. [https://mvr.bg/%D0%BD%D0%B0%D1%87%D0%B0%D0%BB%D0%BE]. Accessed 17 October 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 no evidence that Bulgaria has in place a risk communication plan that is specifically intended for use during a public health emergency that outlines how messages will reach populations and sectors with different communication needs.

Nonetheless, the 2006 Disaster Protection Act explicitly mentions the inclusion of public health emergencies in its provisions and contains details on strategic risk communication activities to be undertaken by various executive authorities, regional administrations and municipalities to ensure key messages reach those sections of the population with distinct communication needs. On a national level, communication with the public on matters of disaster management and public health emergency response falls within the realm of responsibility of the dedicated expert National Operational Headquarters, specifically appointed by the prime minister as crisis managers. According to the Act, the National Operational Headquarters is responsible for transmitting all key messages to the public and must rely on media outlets to ensure trustworthy and accurate information is communicated promptly. [1] In practice, the state-funded Bulgarian National Television (BNT) and the Bulgarian National Radio (BNR) are the two most commonly-used channels, accessible even in the most remote areas of the country and reaching vulnerable populations, especially the elderly. BNT is the only media in the country with daily news broadcasting in Turkish (the major minority language spoken in Bulgaria), allowing for disaster and health emergency communication to effectively reach populations with distinct communication needs. [2] [3]

On a regional and municipal level, mayors are obliged to develop a municipal program for disaster risk reduction which is adapted according to the distinct urbanization features of the municipality. In addition, for disasters and public health emergencies localised to regional or municipal boundaries, communication activities and engagement activities are taken up

by either the responsible regional administration or the respective municipality. [1]

The Ministry of Health and the National 112 System Directorate at the Minstry of Interior have no evidence of the above on their websites either. [4] [5]

[1] Ministry of Interior. 2020. "Disaster Protection Act (Закон за защита при бедствия)". [https://www.lex.bg/laws/ldoc/2135540282]. Accessed 11 October 2020.
[2] Bulgarian National Radio. 2020. "News (Новини)". [https://bnr.bg/]. Accessed 11 October 2020.
[3] Bulgarian National Television. 2020. "News in Turkish (Новини на турски език)". [https://bnt.bg/bg/a/254292-novini-na-turski-ezik]. Accessed 11 October 2020.
[4] Ministry of Health. "Home". [https://www.mh.government.bg/bg/]. Accessed 11 October 2020.
[5] Ministry of Interior. "National 112 System Directorate". [https://mvr.bg/112/%D0%BD%D0%B0%D1%87%D0%B0%D0%BB%D0%BE]. Accessed 17 October 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: 0

There is no evidence that Bulgaria has in place a risk communication plan that is specifically intended for use during a public health emergency. The 2006 Disaster Protection Act (amended 2020) lists the communication mechanisms used in the implementation of policy on disasters in general, which are described as events that pose risks to the life and health of the population, to the environment and/or to property, but are not explicitly defined as including epidemics or other public health emergencies. The Act highlights the individual responsibilities of various executive authorities, regional administrations and municipalities. This general communication plan stipulates that communication with the public involves the establishment of an expert National Operational Headquarters to ensure the linear stream of information and prevent the dissemination of inaccuracies regarding the unfolding of the emergency. The act also states that communication activities rely on the media to transmit key message to society at large, with the aim of keeping the population up-to-date on the development of the disaster, the actions undertaken to control its consequences and necessary precautionary measures to be taken by the public. [1]

Bulgaria's handling of the coronavirus crisis suggests that in practice this risk communication plan is applied during public health emergencies. [2] [3] The Ministry of Health website contains no additional information on a risk communication plan intended for use during a public health emergency. [4]

[1] Ministry of Interior. 2020. "Disaster Protection Act (Закон за защита при бедствия)". [https://www.lex.bg/laws/ldoc/2135540282]. Accessed 11 October 2020.
[2] National Statistical Institute. 2020. "Data from the National Operational Headquarters". [https://www.nsi.bg/en/content/18163/basic-page/data-national-operational-headquarters]. Accessed 11 October 2020.
[3] Darik News. 2020. "COVID-19 briefings renewed (Брифингите на щаба за COVID-19 се възобновяват)". [https://dariknews.bg/novini/bylgariia/brifingite-na-shtaba-za-covid-19-se-vyzobnoviavat-2242500]. Accessed 11 October 2020.

[4] Ministry of Health. “Home”. [https://www.mh.government.bg/bg/]. Accessed 11 October 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

There is insufficient evidence that Bulgaria has in place a risk communication plan that is specifically intended for use during a public health emergency that designates a specific position within the government to serve as primary spokesperson during public health emergencies.

The 2006 Disaster Protection Act, which explicitly covers public health emergencies, states that a National Operational Headquarters is set up to act as a crisis management board, following a direct order from the prime minister. According to the Act, the National Operational Headquarters and its head report to the prime minsiter, the president and the speaker of the National Assembly, also disseminating information to the public via media outlets on the course of the public health emergency or any other national emergency for that matter. The first and primary figure to speak at briefings is the prime minister, while technical information on the course of the pandemic is presented by the Headquarters. Further clarifications in the Act establish that for smaller scale emergencies, contained to a single administrative region or municipality, the role of spokesperson is then taken up by the responsible governor or mayor. [1]

The Ministry of Health and the National 112 System Directorate at the Minstry of Interior have no further relevant information on their websites. [2] [3]

[1] Ministry of Interior. 2020. “Disaster Protection Act (Закон за защита при бедствия)”.
[https://www.lex.bg/laws/ldoc/2135540282]. Accessed 11 October 2020.
[2] Ministry of Health. “Home”. [https://www.mh.government.bg/bg/]. Accessed 11 October 2020.
[3] Ministry of Interior. “National 112 System Directorate”.
[https://mvr.bg/112/%D0%BD%D0%B0%D1%87%D0%B0%D0%BB%D0%BE]. Accessed 17 October 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: 2

In the past year, Bulgaria's public health system has actively shared messages about ongoing health concerns via online media platforms, including to dispel misinformation. The Ministry of Health has a dedicated news section on its website, where it posts daily on matters of public health concern, ranging from stories related to COVID-19 to donor and disability

regulations. Publications dispelling misinformation and outright malicious fake news are also regularly featured, dating back to as early as 2017. Most recently, the Ministry warned against disinformation on disability compensation schemes. [1] [2]

The Ministry is also active on social network Facebook, with a page dating back to 2015, which currently has over 82,000 followers. Like the Ministry's website, the platform is used to both inform the public about current health matters of high importance and to dispel rumours and disinformation. [3]

[1] Ministry of Health. "Fake news (Фалшиви новини)". [https://www.mh.government.bg/bg/search/?q=%D1%84%D0%B0%D0%BB%D1%88%D0%B8%D0%B2%D0%B8+%D0%BD%D0%BE%D0%B2%D0%B8%D0%BD%D0%B8]. Accessed 11 October 2020.
[2] Ministry of Health. 2020. "MH: An absurd statement about a new TELK Law is spreading on social media (МЗ: В социалните мрежи се разпространява абсурдно твърдение за "нов Закон за ТЕЛК")". [https://www.mh.government.bg/bg/novini/aktualno/mz-v-socialnite-mrezhi-se-razprostranyava-absurdno/]. Accessed 11 October 2020.
[3] Facebook. "Ministry of Health (Министерство на здравеопазването)". [https://www.facebook.com/%D0%9C%D0%B8%D0%BD%D0%B8%D1%81%D1%82%D0%B5%D1%80%D1%81%D1%82%D0%B2%D0%BE-%D0%BD%D0%B0-%D0%B7%D0%B4%D1%80%D0%B0%D0%B2%D0%B5%D0%BE%D0%BF%D0%B0%D0%B7%D0%B2%D0%B0%D0%BD%D0%B5%D1%82%D0%BE-1622143941376548]. Accessed 11 October 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 is no publicly available evidence to suggest that the prime minister, the president or other senior figures in government have made claims based on misinformation/disinformation on infectious diseases over the past two years. There is no evidence of such claims on any of Bulgaria's main news websites (Bulgarian National Television, Nova News, BTV News, Capital, Dnevnik, Vesti.bg and Dnes.bg). [1][2][3][4][5][6][7]

[1] Bulgarian National Television. 2020. [https://bntnews.bg/latest.html]. Accessed 11 October 2020.
[2] Nova News. 2020. [https://nova.bg/news]. Accessed 11 October 2020.
[3] BTV News. 2020. [https://btvnovinite.bg/]. Accessed 11 October 2020.
[4] Capital. 2020. [https://www.capital.bg/]. Accessed 11 October 2020.
[5] Dnevnik. 2020. [https://www.dnevnik.bg/]. Accessed 11 October 2020.
[6] Vesti.bg. 2020. [https://www.vesti.bg/]. Accessed 11 October 2020.
[7] Dnes.bg. 2020. [https://www.dnes.bg/]. Accessed 11 October 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: 67.95

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: 116.21

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: 0

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: 0

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: 0

In the past year, Bulgaria has issued restrictions, without international/bilateral support, on the export of medical goods. Due to the spread of COVID-19, in March and April 2020 the Council of Ministers issued Decisions №159, 189 and 204, which introduced temporary export bans on medical goods, including approved disinfectants and their derivatives, and personal protective equipment (disposable overalls, disposable medical and surgical masks, goggles, latex/nitrile gloves and socks). [1] [2] The export of key medicine was also banned in late April for illnesses (including chronic ones) of a socially important nature, such as diabetes, schizophrenia and malignant diseases. The duration of the restrictions was linked to the duration of the state of emergency, declared in the country on 13 March 2020. [3]

[1] Bulgarian National Radio. 2020. "Medical Protective Devices included in export ban (Забраната за износ обхвана още медицински защитни изделия)." [https://bnr.bg/post/101263133/ms-razshiri-obhvata-na-zabranata-za-iznosa-na-dezinfektanti-i-predpazni-sredstva]. Accessed 11 October 2020.
[2] Ministry of Health. 2020. "RMS № 159 on measures taken in relation to COVID-19 amended (Изменя се РМС № 159 относно предприети мерки във връзка със заболяването COVID-19)".
[https://www.mh.government.bg/bg/novini/ministerski-savet/izmenya-se-rms-159-otnosno-predprieti-merki-vv-vrz/]. Accessed 11 October 2020.
[3] Ministry of Health. 2020. "The export of medicinal products is prohibited (Забранява се износът на лекарствени продукти)". [https://www.mh.government.bg/bg/novini/aktualno/zabranyava-se-iznost-na-lekarstveni-produkti/]. Accessed 11 October 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: 0

In the past year, Bulgaria has issued restrictions, without international/bilateral support, on the export of non-medical goods. In March 2020, due to the public health emergency linked to the spread of COVID-19, the export of textiles was banned short-term to allow the country to produce a sufficient amounts of personal protective equipment for the needs of front-line workers such as medical personnel and border control staff. [1] Despite border closures and export restrictions on both medical and certain non-medical goods, the Bulgarian government stated a firm position against restrictions on food exports to support the producers and the sector at large and diminish the adverse economical effects of the pandemic. [2]

[1] Mediapool.bg. 2020. "Textile factories have a patriotic task to secure masks and PPE (Текстилните фабрики с патриотична задача да осигурят маски и защитни облекла срещу COVID-19)", [https://www.mediapool.bg/tekstilnite-fabriki-s-patriotichna-zadacha-da-osiguryat-maski-i-zashtitni-oblekla-sreshtu-covid-19-news304328.html]. Accessed 11

October 2020.
[2] Agroclub.bg. 2020. “Even with closed borders because of COVID-19 we will not be left without food (Дори при затворени граници заради COVID-19, няма да останем без хранителни стоки)”. [https://agroclub.bg/news/%D0%B4%D0%BE%D1%80%D0%B8-%D0%BF%D1%80%D0%B8-%D0%B7%D0%B0%D1%82%D0%B2%D0%BE%D1%80%D0%B5%D0%BD%D0%B8-%D0%B3%D1%80%D0%B0%D0%BD%D0%B8%D1%86%D0%B8-%D0%B7%D0%B0%D1%80%D0%B0%D0%B4%D0%B8-covid-19-%D0%BD%D1%8F%D0%BC%D0%B0-%D0%B4%D0%B0-%D0%BE%D1%81%D1%82%D0%B0%D0%BD%D0%B5%D0%BC-%D0%B1%D0%B5%D0%B7-%D1%85%D1%80%D0%B0%D0%BD%D0%B8%D1%82%D0%B5%D0%BB%D0%BD%D0%B8-%D1%81%D1%82%D0%BE%D0%BA%D0%B8-1-2285]. Accessed 11 October 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, Bulgaria has implemented bans, without international/bilateral support, on travelers arriving from specific countries. Due to the global COVID-19 pandemic, from 13 March 2020 to 14 June 2020 foreign citizens (including European Union citizens) were not permitted to enter Bulgaria. This ban coincided with a national state of emergency. [1] Since then, restrictions have been placed on arrivals from various places, with the list updated on an ongoing basis to reflect the rise of cases in different parts of the world. All restrictions have featured a list of exceptions that include Bulgarian citizens and foreigners with permanent residency rights in the country, medical specialists and transport personnel involved in the supply and delivery of medical goods, diplomats and others. [2]

[1] Dnevnik. 2020. “The Ban on entering Bulgaria already covers EU citizens (Забраната за влизане в България вече обхваща и граждани на ЕС)”. [https://www.dnevnik.bg/bulgaria/2020/05/14/4066687_zabranata_za_vlizane_v_bulgariia_veche_obhvashta_i/]. Accessed 11 October 2020.
[2] Ministry of Health. 2020. “Order 01-448/31.07.2020 (Заповед 01-448/31.07.2020г.)”. [https://www.mh.government.bg/media/filer_public/2020/07/31/rd-01-448.pdf]. Accessed 11 October 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: 403.32

2015

WHO; national sources

4.1.1b

Nurses and midwives per 100,000 people

Input number

Current Year Score: 481.56

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: 1

Bulgaria has a health workforce strategy that has been updated in the past five years. Bulgaria's health workforce strategy is included in the National Health Strategy 2020 and the accompanying Action Plan for the Fulfilment of the National Health Strategy 2020, both of which were adopted in 2015. These documents detail the Ministry of Health's stance on workforce issues and the actions foreseen to address them. Human capital development and management for healthcare workers is covered by Policy 2.7. "Development of Human Capital in the Healthcare System". in both the Strategy and the Plan, addressing issues such as the uneven distribution of qualified specialist healthcare workers across Bulgaria's regions, the challenges posed by the ageing population and workforce migrations, and the absence of sustainable mechanisms for equal career development and further training. Apart from identifying workforce shortages, the Strategy and the Plan propose eleven concrete measures to address shortfalls in the system including measures for increasing economic stimuli, developing a single electronic system for monitoring workforce distributions across the regions, establishing links between university

admissions for medical disciplines and current imbalances in the system and others. The Strategy also documents the size of the healthcare workforce and other statistical data on medical coverage and comparisons between present-day numbers and the early 1990s. [1] [2]

[1] Ministry of Health. 2015. "National Health Strategy (Национална здравна стратегия 2020)". [https://www.mh.government.bg/media/filer_public/2016/09/12/nzs_2020.pdf]. Accessed 11 October 2020.
[2] Ministry of Health. 2016. "Action Plan for the Fulfilment of the National Health Strategy 2020 (План за действие за изпълнение на Националната здравна стратегия 2020)". [https://www.mh.government.bg/media/filer_public/2016/09/12/plan_za_deistvie-nzs_2020.pdf]. Accessed 11 October 2020.

4.1.2 Facilities capacity

4.1.2a

Hospital beds per 100,000 people

Input number

Current Year Score: 745

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

There are medical facilities in Bulgaria with the capacity to isolate patients with highly communicable diseases in special patient isolation units within specialist clinics/wards for infectious diseases. 2013's Ordinance №3 for the Approval of the Medical Standard for the Prevention and Control of Nosocomial Infections mandates the establishment of isolators for patients infected with highly communicable diseases as part of the standardized architectural zoning for all public and private hospitals housing an infectious diseases ward. The Ordinance also stipulates that approved procedures for disinfecting airflows and surfaces must be followed when there is an infection risk associated with a highly pathogenic or otherwise unusual infectious agent with possible different routes of transmission. [1]

In addition, the Ministry of Health published an official guide on the Basic Steps and Behaviour for the Identification of COVID-19 Patients in March 2020 which further detailing the appropriate use of isolation units within public and private medical facilities need. [2] On its website, the Military Medical Academy in the capital Sofia has described its own isolation infrastructure and biosafety procedures for treating patients with highly communicable diseases, considered to be among the most advanced in the whole country. It provides evidence of the existence of advanced isolation rooms with features such as negative pressure, entry / exit lock system, and separate lavatories. [3]

[1] Ministry of Health. 2013. "Ordinance №3 for the Approval of the Medical Standard for the Prevention and Control of Nosocomial Infections (Наредба № 3 от 8.05.2013 г. за утвърждаването на медицински стандарт по превенция и

контрол на вътреболничните инфекции)". [https://www.mh.government.bg/media/filer_public/2015/11/18/prevenciq-control-vutrebolnichni-infekcii.pdf]. Accessed 11 October 2020.
[2] Ministry of Health. 2020. "Basic Steps and Behaviour for the Identification of COVID-19 Patients (Основни стъпки и поведение при идентифициране на пациенти със съмнение за COVID-19)".
[https://www.mh.government.bg/media/filer_public/2020/03/25/covid19instruction-1_dobavjane_za_med_sp.pdf]. Accessed 11 October 2020.
[3] Military Medical Academy. "Infectious diseases (Инфекциозни болести)".
[https://vma.bg/%D0%9F%D1%8A%D1%80%D0%B2%D0%B0-%D0%BA%D0%BB%D0%B8%D0%BD%D0%B8%D0%BA%D0%B0-%D0%BF%D0%BE-%D0%B8%D0%BD%D1%84%D0%B5%D0%BA%D1%86%D0%B8%D0%BE%D0%B7%D0%BD%D0%B8-%D0%B1%D0%BE%D0%BB%D0%B5%D1%81%D1%82%D0%B8.html]. Accessed 11 October 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: 1

There is evidence that Bulgaria has demonstrated capacity to expand isolation capacity in response to an infectious disease outbreak in the past two years and that the country has developed and tested a plan to expand isolation capacity. This was confirmed by now former Defence Minister Krasimir Karakachanov via a public statement on 27 October 2020. Isolation capacity was first expanded in the spring of 2020, when large buildings such as Bulgaria's largest indoor sport hall Armeec Arena were converted into isolation units where COVID-19 patients could be isolated and given treatment. Although they were never used, Karakachanov confirmed that plans were in place for their subsequent conversion into isolators, pending a decision by the National Operational Headquarters. This information was confirmed in official communication from the Ministry of Defence with information disseminated via the official ministerial YouTube channel. [1] [2]

[1] Dnes.bg. 27 October 2020. "Karakachanov: We are ready to set up field hospitals (Каракачанов: Имаме готовност за създаване на полеви болници)". [https://www.dnes.bg/obrazovanie/2020/10/27/karakachanov-imame-gotovnost-za-syzdavane-na-polevi-bolnici.467377]. Accessed 30 April 2021.
[2] Ministry of Defence – YouTube Channel. 23 March 2020. "Military Field Hospital in Armeec Arena (exercise)".
[https://www.youtube.com/watch?v=lt6XEjK2Hn0]. Accessed 30 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

Bulgaria has a national procurement protocol in place which can be utilized by the Ministry of Health and the Ministry of Agriculture, Food and Forestry for the acquisition of laboratory supplies and also medical supplies. The 2016 Public Procurement Act (amended 2020) provides national standardized guidelines on procurement procedures to be used by all public institutions, including the Ministry of Health and the Ministry of Agriculture, Food and Forestry. The acquisition of laboratory supplies must follow all relevant provisions covered by the Act. The document, however, specifically mentions medical supplies among the list of possible exceptions, stating that the protocol does not have to apply to the procurement by contracting authorities for certain medicine, medical goods and PPE, "necessary to ensure the anti-epidemic measures introduced by an Order from the Minister of Health or the Head of a Regional Health Inspection, in the event of a state of emergency." [1]

The databases of the Public Procurement Agency reveal that procurement procedures for laboratory and medical supplies do follow the national procurement protocol and are frequently published by publicly-funded hospitals, with over ten announced since the beginning of September 2020. [2] The Ministry of Health also publishes procurements for both medical and laboratory supplies in line with the aforementioned Act on its own website. [3] The Ministry of Agriculture, Food and Forestry also has a dedicated page for procurement, but there has been no procurement of medical and laboratory supplies in the last four years. [4]

[1] Council of Ministers. 2020. Public Procurement Act (Закон за обществените поръчки)". [https://www.lex.bg/laws/ldoc/2136735703]. Accessed 11 October 2020.
[2] Public Procurement Agency. "Procurement Procedures". [https://app.eop.bg/today/reporting/search]. Accessed 11 October 2020.
[3] Ministry of Health. 2021. "Procurement". [https://www.mh.government.bg/bg/profil-na-kupuvacha/]. Accessed 30 April 2021.
[4] Ministry of Agriculture, Food and Forestry. 2021. "Procurement". [https://www.mzh.government.bg/bg/profil-na-kupuvacha/obyavi/]. Accessed 30 April 2021.

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: 1

Bulgaria has a stockpile of medical supplies, including equipment and PPE, vaccines, medicines, therapeutics and diagnostics, reserved for national use during a public health emergency but there is insufficient evidence of what it contains. In March 2020, Bulgaria ratified the Framework Agreement on Joint Procurement Agreement to Procure Medical Countermeasures as a Member State of the European Union, and so it is now entitled to use the Framework Agreement in order to participate in new procurement procedures for the acquisition of medical countermeasures for the purposes of addressing public health emergencies. [1] [2] As an additional safety net, Bulgaria can rely on the recently created strategic rescEU medical stockpile and distribution mechanism, managed by the EU Civil Protection Mechanisms and covering the delivery of items such as ventilators, PPE, vaccines, therapeutics and laboratory supplies. [3]

Domestically, a stockpile of medical supplies is also kept at the State Agency for State Reserve and Wartime Stocks but there

is no further evidence available. [4]

[1] European Commission. “Joint Procurement of medical countermeasures”. [https://ec.europa.eu/health/preparedness_response/joint_procurement_en#:~:text=The%20aim%20of%20the%20joint,for%20the%20participating%20EU%20countries.&text=Medical%20countermeasures%20for%20serious%20cross%2Dborder%20threats%20to%20health]. Accessed 11 October 2020.
[2] Ministry of Health. 2020. “Framework Agreement on Joint Procurement Agreement to Procure Medical Countermeasures (Рамково споразумение за съвместно възлагане на обществени поръчки при мерки за медицинско противодействие)”. [https://www.lex.bg/bg/laws/ldoc/2137202064]. Accessed 11 October 2020.
[3] European Commission. “rescEU”. [https://ec.europa.eu/echo/what/civil-protection/resceu_en]. Accessed 11 October 2020.
[4] State Agency for State Reserve and Wartime Stocks. “Procedures”. [https://www.statereserve.bg/bg/profil-na-kupuvacha/obshhestveni-porchki/pp13-op-2015-dostavka-na-vaksini-i-serumi/]. Accessed 11 October 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 insufficient evidence that Bulgaria has a stockpile of laboratory supplies intended for national use during a public health emergency. Domestically, a stockpile of supplies is kept at the State Agency for State Reserve and Wartime Stocks although there is no further evidence provided on what is included and whether laboratory supplies are included. [1]

[1] State Agency for State Reserve and Wartime Stocks. “Procedures”. [https://www.statereserve.bg/bg/profil-na-kupuvacha/obshhestveni-porchki/pp13-op-2015-dostavka-na-vaksini-i-serumi/]. Accessed 11 October 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: 1

Bulgaria conducts annual reviews of the national stockpile to ensure supply is sufficient for a public health emergency. Annual reviews are required under the 2003 Ordinance on the Conditions and Procedures for Organizing the Activities of the State Reserve and Wartime Stocks, which states that the director of the governmental State Reserve approves annual plans that include provisions for the creation, expansion, renewal or modernization of all relevant stockpiles. Activities related to the review and the maintenance of the national stockpile are funded by the state budget. [1] The reviews are published by the Directorate General “State reserves, wartime and mandatory stocks” as mandated by the Rules of Procedure of the agency. [2]

[1] Council of Ministers. 2003. “Ordinance on the Conditions and Procedures for Organizing the Activities of the State Reserve and Wartime Stocks (Наредба за условията и реда за организиране на дейностите по държавните резерви и военновременните запаси)”.
[http://micmrc.government.bg/files/normativna_uredba/NAREDBA_za_usloviqta_i_reda_za_organizirane_na_dejnostite_po

_dyrjavnite_rezervi_i_voennovremennite_z.pdf]. Accessed 30 April 2021.
[2] State Reserve. 2021. "Directorate General "State reserves, wartime and mandatory stocks" (Главна Дирекция "Държавни резерви, военновременни и задължителни запаси")."
[https://www.statereserve.bg/bg/struktura/%D1%81%D0%BF%D0%B5%D1%86%D0%B8%D0%B0%D0%BB%D0%B8%D0%B7%D0%B8%D1%80%D0%B0%D0%BD%D0%B0-%D0%B0%D0%B4%D0%BC%D0%B8%D0%BD%D0%B8%D1%81%D1%82%D1%80%D0%B0%D1%86%D0%B8%D1%8F/glavna-direkcziya-drzhavni-rezervi,-voennovremenni-i-zadlzhitelni-zapasi.html]. Accessed 30 April 2021.

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

The Bulgarian government has leveraged domestic manufacturing capacity to produce medical supplies through an agreement with the private sector and procured medical goods via established mechanisms during a public health emergency. The Ministry of Economy first announced plans to leverage manufacturing capacity of medical supplies such as face masks, shields and goggles in March 2020 as a governmental initiative to combat the impending COVID-19 crisis. It was announced that during a series of meetings with representatives from the Ministry, businesses and science, an agreement was reached for the testing and development of multi-use face coverings, and daily production targets were set at 30-40,000 face masks and 3000 shields and goggles until initial demand was met. [1] The complete list of producers involved in the production of face coverings and other PPE is published by the Ministry of Health. [2] With regards to plans and procedures relating to the production of medical countermeasures and vaccines, the databases of the Ministry of Health and the Bulgarian Drug Agency contain no relevant provisions. [3] [4]

Furthermore, in order to secure sufficient quantities of medical countermeasures to ensure local needs are adequately met in the event of a public health emergency, Bulgaria can benefit from relevant procurement mechanisms using the Framework Agreement on Joint Procurement Agreement to Procure Medical Countermeasures. [5]

[1] Ministry of Economy. 2020. "Production starts of Bulgarian masks, face shields and goggles (Стартира производство на български маски, шлемове и очила)". [https://mi.government.bg/bg/news/startira-proizvodstvo-na-balgarski-maski-shlemove-i-ochila-3891.html]. Accessed 11 October 2020.
[2] Ministry of Health. " List of Bulgarian manufacturers of PPE (Списък на български производители, предлагащи предпазни средства)".
[https://www.mh.government.bg/media/filer_public/2020/08/21/blgarski_proizvoditeli_na_predpazni_sredstva__21082020g_.pdf]. Accessed 11 October 2020.
[3] Ministry of Health. "News".
[https://www.mh.government.bg/bg/search/?q=%D0%BF%D1%80%D0%BE%D0%B8%D0%B7%D0%B2%D0%BE%D0%B4%D1%81%D1%82%D0%B2%D0%BE+%D0%BD%D0%B0+%D0%BB%D0%B5%D0%BA%D0%B0%D1%80%D1%81%D1%82%D0%B2%D0%B0]. Accessed 11 October 2020.
[4] Bulgarian Drug Agency. "Normative Acts (Нормативни актове)".

[https://www.bda.bg/bg/%D0%BD%D0%BE%D1%80%D0%BC%D0%B0%D1%82%D0%B8%D0%B2%D0%BD%D0%B8-%D0%B0%D0%BA%D1%82%D0%BE%D0%B2%D0%B5]. Accessed 11 October 2020.
[5] European Commission. "Joint Procurement of medical countermeasures". [https://ec.europa.eu/health/preparedness_response/joint_procurement_en#:~:text=The%20aim%20of%20the%20joint,for%20the%20participating%20EU%20countries.&text=Medical%20countermeasures%20for%20serious%20cross%2Dborder%20threats%20to%20health]. Accessed 11 October 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 insufficient evidence that Bulgaria has a plan or agreement to leverage domestic manufacturing capacity to produce or produce leboratory supplies. Statements from leading experts, quoted in the media, suggest that Bulgaria does not have large-scale production capabilities for reagents used in identifying COVID-19 cases, as these appear to be mostly imported. [1] [2] [3] Bulgaria however is party to the Framework Agreement on Joint Procurement Agreement to Procure Medical Countermeasures [4] There is no further evidence on the website of the Ministry of Health [4]

[1] Free Europe. 2020. â€œReagents. The answer as to why there are not enough tests in the world (ÐÐµÐ°Ð3ÐµÐ1/2Ñ‚Ð¸Ñ‚Ðµ. ÐÑ‚Ð3Ð3/4Ð²Ð3/4Ñ€ÑŠÑ‚ Ð1/2Ð° Ð²ÑŠÐ¿Ñ€Ð3/4ÑÐ° Ð·Ð°Ñ‰Ð3/4 Ð¿Ð3/4 ÑÐ²ÐµÑ‚Ð° Ð1/2ÑÐ¼Ð° Ð´Ð3/4Ñ‚Ð°Ñ‚ÑŠÑ‡Ð1/2Ð3/4 Ñ‚ÐµÑ‚Ð3/4Ð²Ðµ)â€. [https://www.svobodnaevropa.bg/a/30565385.html]. Accessed 11 October 2020.
[2] Monitor. 2020. â€œA COVID-19 vaccines will be available next fall (Ð'Ð°ÐºÑÐ¸Ð1/2Ð° Ñ€Ñ€ÐµÑ‰Ñƒ COVID-19 Ñ‰Ðµ Ð¸Ð¼Ð° Ð1/2Ð° Ð¿Ð°Ð·Ð°Ñ€Ð° ÑÐ»ÐµÐ´Ð²Ð°Ñ‰Ð°Ñ‚Ð° ÐµÑÐµÐ1/2)â€. [https://www.monitor.bg/bg/a/view/doc-chorbanov-vaksina-sreshtu-covid-19-shte-ima-na-pazara-sledvashtata-esen-227302]. Accessed 11 October 2020.
[3] Bulgarian National Television. 2020. â€œBulgaria does not have reagents for testing the Chinese coronavirus (Ð'ÑŠÐ»Ð3Ð°Ñ€Ð¸Ñ Ð1/2ÑÐ¼Ð° Ñ€ÐµÐ°ÐºÑ‚Ð¸Ð²Ð¸ Ð·Ð° Ð¸Ð·ÑÐ»ÐµÐ´Ð²Ð°Ð1/2Ðµ Ð1/2Ð° ÐºÐ¸Ñ‚Ð°Ð¹ÑÐºÐ¸Ñ ÐºÐ3/4Ñ€Ð3/4Ð1/2Ð°Ð²Ð¸Ñ€ÑƒÑ)â€. [https://bntnews.bg/bg/a/blgariya-nyama-reaktivi-za-izsledvane-na-kitayskiya-koronavirus]. Accessed 11 October 2020.
[4] European Commission. â€œJoint Procurement of medical countermeasuresâ€.

[https://ec.europa.eu/health/preparedness_response/joint_procurement_en#:~:text=The%20aim%20of%20the%20joint,for%20the%20participating%20EU%20countries.&text=Medical%20countermeasures%20for%20serious%20cross%2Dborder%20threats%20to%20health]. Accessed 11 October 2020.
[5] Ministry of Health. â€œHomeâ€. [https://www.mh.government.bg/bg/]. Accessed 11 October 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: 1

The Bulgarian government has developed a plan for the dispensing of medical countermeasures for national use during a public health emergency. According to the 2005 Health Act (last updated in July 2020), the minister of health develops plans for the dispensing of medical countermeasures at times of disasters and catastrophes, including possible epidemic outbreaks. The plans are approved by the Council of Ministers and contain provisions for the organization of stockpiling and distribution of all necessary medical resources, including countermeasures, needed for domestic medical needs. [1] The 2003 State Reserves and Wartime Stocks Act (revised in July 2020) explicitly confirms that existing reserves of medical countermeasures for use during public health emergencies and other disasters are decided on by the Council of Ministers. [2] In addition, the 2006 National Plan for Preparedness for Influenza Pandemics (also known as the National Pandemic Plan) details the concrete plan for dispensing medical countermeasures for health emergencies caused by the spread of influenza or other unknown pathogens with an epidemic or pandemic potential. According to the Plan, a step-by-step approach has been developed for the distribution of vaccines, antiviral medicines, therapeutics and diagnostics, using a social segmentation approach aimed at ensuring that those most at risk are allocated a proportionate part of the existing medical countermeasures reserves. A centralised dispensation plan is developed by the Ministry of Health, with regional logistical matters managed by the relevant Regional Health Inspection. The plan outlines that the Regional Inspectorate for Protection and Control of Public Health and the Regional Health Centres are responsible for distribution of the vaccine and that plans will be made to organize immunization points for dispensing, including for schools, in hospitals and through general practicitioners. [3]

[1] Ministry of Health. 2020. â€œHealth Act (Ð—Ð°ÐºÐ3/4Ð1/2 Ð·Ð° Ð·Ð´Ñ€Ð°Ð²ÐµÑ‚Ð3/4)â€. [https://www.lex.bg/laws/ldoc%20/2135489147]. Accessed 11 October 2020.
[2] Council of Ministers. 2020. â€œState Reserves and Wartime Stocks Act (Ð—Ð°ÐºÐ3/4Ð1/2 Ð·Ð° Ð´ÑŠÑ€Ð Ð°Ð²Ð1/2Ð¸Ñ‚Ðµ Ñ€ÐµÐ·ÐµÑ€Ð²Ð¸ Ð¸ Ð²Ð3/4ÐµÐ1/2Ð1/2Ð3/4Ð²Ñ€ÐµÐ¼ÐµÐ1/2Ð1/2Ð¸Ñ‚Ðµ Ð·Ð°Ð¿Ð°ÑÐ¸)â€. [https://www.lex.bg/laws/ldoc/2135462883]. Accessed 11 October 2020.
[3] Ministry of Health. 2006. â€œNational Plan for Preparedness for Influenza Pandemic (ÐÐ°Ñ†Ð¸Ð3/4Ð1/2Ð°Ð»ÐµÐ1/2

Ð¿Ð»Ð°Ð1/2 Ð1/2Ð° Ð
ÐµÐ¿ÑƒÐ±Ð»Ð¸ÐºÐ°
Ð'ÑŠÐ»Ð3Ð°Ñ€Ð¸Ñ&#65533; Ð·Ð°
Ð3Ð3/4Ñ‚Ð3/4Ð²Ð1/2Ð3/4Ñ&#65533;Ñ‚ Ð·Ð°
Ð3Ñ€Ð¸Ð¿Ð1/2Ð°
Ð¿Ð°Ð1/2Ð´ÐµÐ¼Ð¸Ñ&#65533;)â€&#65533;.
[http://www.strategy.bg/StrategicDocuments/View.aspx?lang=bg-BG&Id=366]. Accessed 11 October 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 public evidence that the Bulgarian government has developed concrete plans to receive health personnel from other countries to respond to public health emergencies. Existing regulations suggest that standardized procedures on migration and employment mechanisms would be applied. As a member of the European Union (EU), Bulgaria must follow the provisions Council Directive 2009/50/EC of 25 May 2009 on the Conditions of Entry and Residence of Third-country Nationals for the Purposes of Highly Qualified Employment which requires the observance of ethical recruitment policies and principals for the health sector, given critical shortages of health workers in developing countries. [1] Domestically, the Labor Migration and Labor Mobility Act defines the conditions for the appropriate labor processes followed in the employment of EU and third-country citizens, including the concrete policy for the employment of highly skilled personnel such as doctors and other health workers. [2] In practice, the specific rules for the employment of foreign nationals are covered by the Employment Agency, associated with the Ministry of Labor and Social Policy, and its normative framework. [3]

[1] European Commission. 2009. â€œCouncil Directive 2009/50/EC of 25 May 2009 on the conditions of entry and residence of third-country nationals for the purposes of highly qualified employmentâ€&#65533;. [https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32009L0050]. Accessed 11 October 2020.
[2] Ministry of Labor and Social Policy. 2019. â€œLabor Migration and labor Mobility Act (Ð—
Ð°ÐºÐ3/4Ð1/2 Ð·Ð°
Ñ‚Ñ€ÑƒÐ´Ð3/4Ð²Ð°Ñ‚Ð°
Ð¼Ð¸Ð3Ñ€Ð°Ñ†Ð¸Ñ&#65533; Ð¸
Ñ‚Ñ€ÑƒÐ´Ð3/4Ð²Ð°Ñ‚Ð°
Ð¼Ð3/4Ð±Ð¸Ð»Ð1/2Ð3/4Ñ&#65533;Ñ‚)â€&#65533;.
[https://www.lex.bg/bg/laws/ldoc/2136803084]. Accessed 11 October 2020.
[3] Employment Agency. â€œEmployment of foreign nationals â€" normative framework (Ð—
Ð°ÐµÑ‚Ð3/4Ñ&#65533;Ñ‚ Ð1/2Ð° Ñ‡ÑƒÐ
Ð´ÐµÐ1/2Ñ†Ð¸ â€"
Ð1/2Ð3/4Ñ€Ð¼Ð°Ñ‚Ð¸Ð²Ð1/2Ð°
ÑƒÑ€ÐµÐ´Ð±Ð°)â€&#65533;. [https://www.az.government.bg/pages/zaetost-na-chuzhdenci-normativna-uredba/]. Accessed 11 October 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: 4

2020

World Policy Analysis Center

4.4.1b

Access to skilled birth attendants (% of population)

Input number

Current Year Score: 99.8

2015

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: 786.59

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

World Policy Analysis Center

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 legislation, policy or public statement committing to the provision of prioritized healthcare services to healthcare workers who become sick as a result of responding to a public health emergency. No relevant provisions were found under the 2005 Health Act (last updated in July 2020), the 2006 National Plan for Preparedness for Influenza Pandemics (also known as the National Pandemic Plan) or the 2000 Social Security Code (last revised in August 2020). [1] [2] [3] The Ministry of Health's National Health Strategy 2020 and other relevant orders contain no evidence of such provisions either. [4]

[1] Ministry of Health. 2020. "Health Act (Закон за здравето)". [https://www.lex.bg/laws/ldoc%20/2135489147]. Accessed 11 October 2020.
[2] Ministry of Health. 2006. "National Plan for Preparedness for Influenza Pandemic (Национален план на Република България за готовност за грипна пандемия)". [http://www.strategy.bg/StrategicDocuments/View.aspx?lang=bg-BG&Id=366]. Accessed 11 October 2020.
[3] Ministry of Labor and Social Policy. 2020. "Social Security Code (Кодекс за социално осигуряване)". [https://www.lex.bg/laws/ldoc/1597824512]. Accessed 11 October 2020.
[4] Ministry of Health. 2015. "National Health Strategy (Национална здравна стратегия 2020)". [https://www.mh.government.bg/media/filer_public/2016/09/12/nzs_2020.pdf]. Accessed 11 October 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: 0

There is insufficient evidence that a working two-way communication system has been set-up for public health officials and healthcare workers to communicate during a public health emergency. According to the 2019 Ministry of Health's Rules of Procedure, there is a communication-information system for crisis management in the event of public health emergencies or other disasters, situated within the Medical Activities Directorate, but the document does not provide more specifics on its functionalities. For day-to-day operations, the Electronic Healthcare Directorate maintains an interoperable internal communication system between the Ministry, associated agencies, the National Health Insurance Fund and medical establishments (both public and private). [1]

Furthermore, healthcare workers communicate with the public healthcare administration via communication systems managed by the National Center for Public Health and Analysis (NSPHA) which confirms the existence of a two-way stream of information flows, nonetheless, it is unclear if special communication channels have been set in place to address

communication during public health emergencies. [2]

Notably, the 2006 National Plan for Preparedness for Influenza Pandemics (also known as the National Pandemic Plan) does mention the existence of communication mechanisms for emergency and routine daily communication between health authorities, the state administration, medical facilities and other institutions relevant for pandemic-related activities, as well as doctors and other medical practitioners across the county, but these appear to follow a predominantly top-down approach. [3]

[1] Ministry of Health. 2019. Ministry of Health's Rules of Procedure (Устройствен правилник на Министерство на здравеопазването)". [https://www.mh.government.bg/media/filer_public/2019/03/29/ustroistven_pravilnik_na_ministerstvoto_na_zdraveopazvaneto.pdf]. Accessed 11 October 2020.
[2] National Center on Public Health and Analyses. 2020. "Annual Report (Годишен доклад)". [https://ncpha.government.bg/images/___NCPHA/__MainActivities/_AnnualReports/NCPHA_AnnualReport_2019.pdf]. Accessed 11 October 2020.
[3] Ministry of Health. 2006. "National Plan for Preparedness for Influenza Pandemic (Национален план на Република България за готовност за грипна пандемия)". [http://www.strategy.bg/StrategicDocuments/View.aspx?lang=bg-BG&Id=366]. Accessed 11 October 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

There is insufficient evidence that a working two-way communication system has been set up for public health officials and healthcare workers to communicate during a public health emergency. As such, it cannot be concluded with certainty whether healthcare workers in both the public and private sectors would be encompassed. Ministry of Health resources contain no further evidence. [1] [2] [3]

[1] Ministry of Health. 2019. Ministry of Health's Rules of Procedure (Устройствен правилник на Министерство на здравеопазването)". [https://www.mh.government.bg/media/filer_public/2019/03/29/ustroistven_pravilnik_na_ministerstvoto_na_zdraveopazvaneto.pdf]. Accessed 11 October 2020.
[2] National Center on Public Health and Analyses. 2020. "Annual Report (Годишен доклад)". [https://ncpha.government.bg/images/___NCPHA/__MainActivities/_AnnualReports/NCPHA_AnnualReport_2019.pdf]. Accessed 11 October 2020.
[3] Ministry of Health. 2006. "National Plan for Preparedness for Influenza Pandemic (Национален план на Република България за готовност за грипна пандемия)". [http://www.strategy.bg/StrategicDocuments/View.aspx?lang=bg-BG&Id=366]. Accessed 11 October 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: 1

Bulgaria's national public health system is monitoring for and tracking the number of healthcare associated infections (HCAI) that take place in healthcare facilities. The control and reporting of HCAIs is covered under the 2005 Health Act (last updated in July 2020), 2005's Ordinance №2 for the Organization of Prevention and Control of Hospital Associated Infections (revised in 2010) and the 2013 Ordinance №3 for the Approval of the Medical Standard for the Prevention and Control of Nosocomial Infections. [1] [2] [3] According to these, the Ministry of Health has an internal expert advisory board which analyses incoming data on HCAI and works directly with healthcare facilities on recommending measures to reduce HCAIs in line with policy guidelines. HCAI data is sent to the Ministry by specialist HCAI committees within each medical facility, responsible for registering HCAIs and conducting internal investigations and assessments. [4] Data assessments and methodological control over the performance of these committees are exercised by the responsible Regional Health Inspectorate. HCAI data is also received and reviewed by the National Center of Infectious and Parasitic Diseases and medical universities for the purposes of systemic research on the problems of prevention of HCAIs. [2]

[1] Ministry of Health. 2020. "Health Act (Закон за здравето)". [https://www.lex.bg/laws/ldoc%20/2135489147]. Accessed 11 October 2020.
[2] Ministry of Health. 2010. "Ordinance №2 for the Organization of Prevention and Control of Hospital Associated Infections (Наредба № 2 от 10 януари 2005 г. За организацията на профилактиката и контрола на вътреболничните инфекции)". https://www.lex.bg/laws/ldoc/2135497798]. Accessed 11 October 2020.
[3] Ministry of Health. 2013. "Ordinance №3 for the Approval of the Medical Standard for the Prevention and Control of Nosocomial Infections (Наредба № 3 от 8.05.2013 г. за утвърждаването на медицински стандарт по превенция и контрол на вътреболничните инфекции)". [https://www.mh.government.bg/media/filer_public/2015/11/18/prevenciq-control-vutrebolnichni-infekcii.pdf]. Accessed 11 October 2020.
[4] Pirogov. Committee on Hospital Associated Infections (Комисия за борба с вътреболничните инфекции)". [https://pirogov.eu/bg/komisiia-za-borba-s-vtrebolnichnite-infektsii_p556.html]. Accessed 11 October 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

Bulgaria requires ethical reviews prior to the beginning of a clinical trial. Under the 2007 Medicinal Products in Human Medicine Act, last updated in August 2019, all clinical trials are subject to independent ethical reviews, conducted on-site at the facilities where trials are taking place. [1] A centralized Ethical Commission on Clinical Trials set up by the Minister of Health is responsible for the oversight of ethical standards during clinical trials and for issuing approvals. [2] [3] All normative requirements necessary for the successful completion of the compulsory ethical review process during clinical trials are published by the Bulgarian Drug Agency on a dedicate page of its website. [4]

[1] Ministry of Health. 2020. "Medicinal Products in Human Medicine Act (Закон за лекарствените продукти в хуманната медицина)". [https://www.bda.bg/images/stories/documents/regulations/zakoni/ZLPHM_NEW.pdf]. Accessed 11 October 2020.
[2] Ministry of Health. 2019. "Rules of Procedure (Правилник)".
"https://www.mh.government.bg/media/filer_public/2019/05/07/pravilnik-ekki-zlphm.pdf]. Accessed 11 October 2020.
[3] Ministry of Health. "Ethical Commission on Clinical Trials (Етична комисия за клинични изпитвания)".
[https://www.mh.government.bg/bg/ministerstvo/komisii/etichnata-komisiya-za-klinichni-izpitvaniya/]. Accessed 11 October 2020.
[4] Bulgarian Drug Agency. "Ethical Commission (Етична комисия)".
[https://www.bda.bg/bg/%D0%B8%D0%BD%D1%84%D0%BE%D1%80%D0%BC%D0%B0%D1%86%D0%B8%D1%8F-%D0%B7%D0%B0-%D1%84%D0%B8%D1%80%D0%BC%D0%B8%D1%82%D0%B5/66-ethics-commission]. Accessed 11 October 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

No publicly available evidence was found to confirm that there is an expedited process for approving clinical trials for unregistered medical countermeasures to treat ongoing epidemics. Existing legislation and relevant regulations such as the 2007 Medicinal Products in Human Medicine Act (last amended in August 2019), and the 2019 Rulebook on the Terms and Conditions of the Work of the Ethical Commission for Clinical Trials under the Medicinal Products in Human Medicine Act, contain no reference to the aforementioned processing changes in the execution of clinical trials and standardized approval procedures. [1] [2] The websites of the Ministry of Health and the Bulgarian Drug Agency do not contain any information on the matter. [3][4]

[1] Ministry of Health. 2020. "Medicinal Products in Human Medicine Act (Закон за лекарствените продукти в хуманната медицина)". [https://www.bda.bg/images/stories/documents/regulations/zakoni/ZLPHM_NEW.pdf]. Accessed 11 October 2020.
[2] Ministry of Health. 2019. "Rules of Procedure (Правилник)".
"https://www.mh.government.bg/media/filer_public/2019/05/07/pravilnik-ekki-zlphm.pdf]. Accessed 11 October 2020.
[3] Ministry of Health. "Ethical Commission on Clinical Trials (Етична комисия за клинични изпитвания)".
[https://www.mh.government.bg/bg/ministerstvo/komisii/etichnata-komisiya-za-klinichni-izpitvaniya/]. Accessed 11 October 2020.
[4] Bulgarian Drug Agency. "Ethical Commission (Етична комисия)".

[https://www.bda.bg/bg/%D0%B8%D0%BD%D1%84%D0%BE%D1%80%D0%BC%D0%B0%D1%86%D0%B8%D1%8F-%D0%B7%D0%B0-%D1%84%D0%B8%D1%80%D0%BC%D0%B8%D1%82%D0%B5/66-ethics-commission]. Accessed 11 October 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 Bulgarian Drug Agency (BDA) is the governmental agency responsible for approving new medical countermeasures for humans. The Authorization of Medicinal Products Directorate within the BDA is tasked with overseeing the approval processes of new medical countermeasures for humans. [2] The work of the BDA and its relevant internal structures is regulated by the 2007 Medicinal Products in Human Medicine Act (last updated in August 2019), 2007's Ordinance №27 on the Data and Documentation Requirements for the Authorization for Use and Registration of Medicinal Products (revised in 2018) and the 2019 Rulebook on the Terms and Conditions of the Work of the Ethical Commission for Clinical Trials under the Medicinal Products in Human Medicine Act. According to the above, the BDA abides by the Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 when approving new medical countermeasures for humans, including any procedures involving the issuance, renewal and/or extension of permits, registrations and any other related authorizations. [2] [3] [4]

[1] Bulgarian Drug Agency. "About (За ИАЛ)". [https://www.bda.bg/bg/%D0%B7%D0%B0-%D0%B8%D0%B0%D0%BB]. Accessed 11 October 2020.
[2] Ministry of Health. 2020. "Medicinal Products in Human Medicine Act (Закон за лекарствените продукти в хуманната медицина)". [https://www.bda.bg/images/stories/documents/regulations/zakoni/ZLPHM_NEW.pdf]. Accessed 11 October 2020.
[3] Bulgarian Drug Agency. 2018. "Ordinance №27 on the Data and Documentation Requirements for the Authorization for Use and Registration of Medicinal Products (Наредба № 27 от 15 юни 2007 г. За изискванията към данните и документацията за разрешаване за употреба и регистрация на лекарствени продукти)". [https://www.bda.bg/images/stories/documents/regulations/naredbi/201910_%D0%9D%D0%B0%D1%80%D0%B5%D0%B4%D0%B1%D0%B0%2027.pdf]. Accessed 11 October 2020.
[4] Bulgarian Drug Agency. "Rules of Procedure (Устройствен правилник)". [https://www.bda.bg/images/stories/documents/regulations/up_ial.pdf]. Accessed 11 October 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

The process of approving new medical countermeasures is expedited at times of public health emergencies. The 2007 Medicinal Products in Human Medicine Act, last updated in August 2019, governs the procedures and conditions tha allow for an expedited processes for approving the use of new medical products and treatments to address epidemic and pandemic outbreaks, or any other disasters posing a threat to public health. As stipulated by the Act, the Minister of Health

may order the authorization of medical countermeasures for a set period of time for medical products not approved under standard procedures, subject to consultations with the National Health Inspector and the Director General of the Bulgarian Drug Agency. The above procedure applies for medical countermeasures that do not have a suitable approved alternative at the time of confirming a state of public health emergency. [1]

[1] Ministry of Health. 2020. "Medicinal Products in Human Medicine Act (Закон за лекарствените продукти в хуманната медицина)". [https://www.bda.bg/images/stories/documents/regulations/zakoni/ZLPHM_NEW.pdf]. Accessed 11 October 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

Epidemic and pandemic outbreaks are integrated into Bulgaria's natural risk reduction strategy. Provisions of mitigation measures for combatting epidemic and/or pandemic public health emergencies are featured in the 2006 Disaster Protection Act (amended in July 2020), the 2014-2020 Disaster Risk Reduction Strategy and the 2018 National Security Strategy. As stipulated by the existing legislative and regulative frameworks, current national priority efforts aim at reducing risks associated with the outbreak of epidemics through the improvement of systemic monitoring and control measures, preventing the import of highly-infectious diseases with a known epidemic potential and equipping the healthcare system

with adequate mechanisms for the prompt eradication of confirmed outbreaks. [1] [2] [3]

[1] Ministry of Interior. 2020. “Disaster Protection Act (Закон за защита при бедствия)”. [https://www.lex.bg/laws/ldoc/2135540282]. Accessed 11 October 2020.
[2] Council of Ministers. 2014. “2014-2020 Disaster Risk Reduction Strategy (Стратегия за намаляване на риска от бедствия 2014-2020г.)”. [http://www.strategy.bg/StrategicDocuments/View.aspx?lang=bg-BG&Id=894]. Accessed 11 October 2020.
[3] Ministry of Defense. 2018. “National Security Strategy (Стратегия за национална сигурност на Република България)”. [https://www.mod.bg/bg/doc/cooperation/20181005_Akt_strateg_NS_RB.pdf]. Accessed 11 October 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

Bulgaria has cross-border agreements with neighboring countries, and as part of a regional group, with regards to public health emergencies, and there is no evidence of gaps in implementation. There is an overarching European Union (EU) authority, the European Center for Disease Prevention and Control, which offers EU member states support at times of health emergencies. [1] The Health Security Committee is a further platform that enlists health ministers across the bloc in efforts to coordinate responses to multi-country public health emergencies. [2] Together with nine other countries, Bulgaria is also a member of the South-Eastern Europe Health Network, which promotes an integrated regional "one health" approach to the surveillance and monitoring of communicable diseases and is another source of support in the event of a public health emergency. [3] In addition, Bulgaria has bilateral agreements with two of its neighbours, Serbia and North Macedonia, which deal with cross-border cooperation and assistance in the event of any natural or man-made disaster. [4] [5]

[1] European Center for Disease Prevention and Control. “Public Health Functions”. [https://www.ecdc.europa.eu/en/about-us/who-we-are/units/public-health-functions]. Accessed 11 October 2020.
[2] European Commission. “Health Security Committee members”. [https://ec.europa.eu/health/preparedness_response/risk_management/hsc/members_en]. Accessed 11 October 2020.
[3] South-Eastern Europe Health Network. “Home”. [http://seehn.org/]. Accessed 11 October 2020.
[4] Focus. 2020. “Agreement with Serbia on cooperation in the field of disaster protection approved (Утвърдено е споразумението със Сърбия за сътрудничество в областта на защитата от природни бедствия)”. [http://m.focus-news.net/?action=news&id=2767778]. Accessed 11 October 2020.
[5] Bulgarian National Television. 2017.”Bulgaria and Macedonia agree on disaster protection cooperation (България и Македония се споразумяха за сътрудничество при защита от бедствия)“. [https://bntnews.bg/bg/a/blgariya-i-makedoniya-se-sporazumyakha-za-strudnichestvo-pri-zashchitata-ot-bedstviya]. Accessed 11 October 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: 2

Bulgaria has cross-border agreements in place and is part of a regional group on animal health emergencies, and there is no evidence of gaps in their implementation. The European Union (EU) Veterinary Emergency Team offers expert support in situations affected by animal epidemics and assists member states, including Bulgaria, with serious animal diseases outbreaks. The EU Veterinary Emergency Team was established by Commission Decision 2007/142/EC and its experts stay on stand-by, ready to respond to animal health situations in both EU countries and certain non-EU ones. [1]

In addition to European support, Bulgaria can also call upon bilateral agreements signed with its neighbours the Serbia and North Macedonia. An official agreement was signed between the Bulgarian Veterinary Union and the Veterinary Chamber of the Republic of North Macedonia in February 2018, which calls for joint annual plans involving the prevention of animal epidemics. [2] A single-gateway information system on the surveillance, control and eradication of especially dangerous animal diseases between Bulgaria and Serbia has also been in place since 2014. [3]

[1] European Commission. “Veterinary Emergency Team”. [https://ec.europa.eu/food/animals/animal-diseases/emergency-team_en]. Accessed 11 October 2020.
[2] Sinor.bg. 2018. “Bulgaria and Macedonia to tackle animal diseases together (България и Македония ще борят заедно болестите по животните)”. [https://sinor.bg/51872-balgariya-i-makedoniya-ste-boryat-zaedno-bolestite-po-zhivotnite]. Accessed 11 October 2020.
[3] Darik News. 2014. “A single information system on animal diseases in Bulgaria and Serbia (Единна информационна система за заразните болести в България и Сърбия)”. [https://dariknews.bg/regioni/kiustendil/edinna-informacionna-sistema-za-zaraznite-bolesti-v-bylgariq-i-syrbiq-1348182]. Accessed 11 October 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: 1

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: 4

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: 1

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: 0

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: 1

There is publicly available evidence that Bulgaria has allocated national funds to improve its national capacity to address epidemic threats within the past three years. According to the 2020 Ministry of Health budget, the Bulgarian government allocated a grand total of BGN 73,371,500 BGN (USD 44.36 million) to the budget program on Prevention and Control of Infectious Diseases. [1] More concretely, Resolution №198 of 6 August 2020 for the Approval of Additional Expenditure in the Budget of the Ministry of Health for 2020 confirms that the Bulgarian government committed additional national funds to improving national capacity to address the epidemic threat posed by the COVID-19 outbreak. With the Regulation, the Council of Ministers approved additional expenses for the subsidizing of state and municipal medical facilities to keep their infectious disease clinics and wards prepared to perform medical activities in the event of an epidemic outbreak, caused by an infectious disease. [2]

[1] Ministry of Health. 2020. “Budget for 2020 (Бюджет за 2020 г.)”. [https://www.mh.government.bg/media/filer_public/2020/01/16/biudzhet_na_ministerstvo_na_zdraveopazvaneto_za_2020_g.pdf]. Accessed 11 October 2020.
[2] Council of Ministers. 2020. “Resolution №198 of 6 August 2020 for the Approval of Additional Expenditure in the Budget of the Ministry of Health for 2020 (Постановление № 198 от 6 август 2020 Г. за одобряване на допълнителни разходи по бюджета на Министерството на здравеопазването за 2020 г.)”. [https://dv.parliament.bg/DVWeb/showMaterialDV.jsp;jsessionid=E93F872474BD7369E0062D448FAA8040?idMat=150747]. Accessed 11 October 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 available evidence that Bulgaria has identified a special emergency public funding mechanism and funds that can be accessed at times of public health emergency. The World Bank Pandemic Financing Facility, the Ministry of Health (and associate agencies), the 2006 Disaster Protection Act (last amended in July 2020), and the 2014-2020 National Strategy for Reducing Disaster Risk contain no information on the existence of such funding mechanisms. [1] [2] [3] [4]

Notably, as a member state of the European Union, Bulgaria was able to benefit from the Coronavirus Response Investment Initiative (CRII) and use unspent resources from the European Regional Development Fund under the 2014–2020 Operational Program Regions In Growth to address the aftermath of the public health emergency caused by COVID-19. Through this program, Bulgaria was able to redirect funds towards improving the crisis response capacity of the healthcare system and make it more resilient to similar crises. [5] In addition, the Bulgarian government developed eight financial mechanisms with public funding in April 2020 to respond to the challenges caused by the uncertainty of the coronavirus pandemic. [6]

[1] World Bank. 2017. “Pandemic Emergency Financing Facility (PEF)”. [http://pubdocs.worldbank.org/en/119961516647620597/PEF-Operational-Brief-Dec-2017.pdf]. Accessed 11 October 2020.
[2] Ministry of Health. “Home”. [https://www.mh.government.bg/bg/]. Accessed 11 October 2020.
[3] Ministry of Interior. 2020. “Disaster Protection Act (Закон за защита при бедствия)”. [https://www.lex.bg/laws/ldoc/2135540282]. Accessed 11 October 2020.
[4] Ministry of Interior. 2014. “2014-2020 National Strategy for Reducing Disaster Risk (Стратегия за намаляване на риска от бедствия)”. [https://mvr.bg/docs/default-source/strategicheskidokumenti/9066EC19-07_Str_Risk_Bedstvia-pdf.pdf] Accessed 11 October 2020.

[5] European Commission. 2020. “Coronavirus: Commission approves more than EUR 20 million in cohesion policy support to deal with the health emergency in Bulgaria”. [https://ec.europa.eu/regional_policy/en/newsroom/news/2020/06/25-06-2020-coronavirus-commission-approves-more-than-eur20-million-in-cohesion-policy-support-to-deal-with-the-health-emergency-in-bulgaria]. Accessed 11 October 2020.
[6] Bulgarian National Radio. 2020. “Eight financial instruments in support of businesses and citizens in Bulgaria (Осем финансови инструмента ще подкрепят бизнеса и гражданите в България)”. [https://bnr.bg/radiobulgaria/post/101262405/8-finansovi-instrumenta-shte-podkrepat-biznesa-i-grajdanite-v-balgaria]. Accessed 11 October 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: 1

There is insufficient evidence that senior leaders have made public commitments to support other countries to improve their capacity to address epidemic threats by providing state support in the past three years, but there is evidence that Bulgaria has supported improvements in domestic capacity to address epidemics. In 2018, the then Minister of Health Kiril Ananiev made a commitment to support all elements of healthcare reform in North Macedonia, including epidemic threats' preparedness with a focus on capacity-building and training measures for healthcare providers and improving medicine effectiveness. [1]

While there is insufficient evidence of support for capacity development of other countries, there is evidence of support for response efforts. In addition, in May 2020, Bulgaria's minister of foreign affairs, Ekaterina Zaharieva initiated the provision of aid to countries in the Western Balkans, the Eastern Partnership and the Southern Neighborhood, funded through official development aid money as allocated in the official budget of the Ministry of Foreign Affairs as part of a coronavirus relief and support program. Under the initiative, Bulgaria provided personal protective equipment and food packages to North Macedonia, Albania, Serbia, Bosnia, Montenegro, Armenia, Georgia, Moldova, Ukraine, Belarus and Iraq. [2][3]

[1] Bulgarian National Television. 2018. "Bulgaria will give expert support to North Macedonia for its healthcare (България ще окаже експертна помощ на Македония в сектор "Здравеопазване")". [https://bntnews.bg/bg/a/blgariya-shche-okazhe-ekspertna-pomoshch-na-makedoniya-v-sektor-zdraveopazvane]. Accessed 03 December 2020.
[2] Bulgarian National Television. 2020. “Bulgaria donated PPE to North Macedonia and Albania (България дари защитни облекла срещу коронавируса на Република Северна Македония и Албания)”. [https://bntnews.bg/news/balgariya-dari-zashtitni-oblekla-sreshtu-koronavirusa-na-republika-severna-makedoniya-i-albaniya-1056037news.html]. Accessed 11 October 2020.
[3] Vesti.bg. 2020. “Bulgaria will help Skopje with COVID-19 efforts (България ще помогне на Скопие в борбата с COVID-19)”. [https://www.vesti.bg/temi-v-razvitie/tema-koronavirus/bylgariia-shte-pomogne-na-skopie-v-borbata-s-covid-19-610854]. Accessed 11 October 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 Bulgaria has invested finances to improve domestic capacity to address epidemic threats over the past three years, but the country has not offered support to other countries to improve their capacity in addressing epidemic emergencies. In June 2020, it was announced that the European Commission approved the reallocation of EUR 20,000,000 (USD 23,661,700) of cohesion policy funding for the Bulgarian Ministry of Health to use to purchase new top-class medical equipment, life-saving medication and medical supplies to strengthen the domestic healthcare sector's preparedness to tackle the public health-related challenges of the COVID-19 emergency and strengthen capacity for future epidemic threats by upgrading and replacing outdated medical equipment across the country. [1] A new National Plan for Pandemic Preparedness, not directly related to the ongoing COVID-19 crisis, was approved by the Bulgarian government in December 2020, featuring planning and financing measures for future pandemics. [2]

Bulgaria was able to benefit from the Coronavirus Response Investment Initiative (CRII) and use unspent resources from the European Regional Development Fund under the 2014-2020 Operational Program Regions In Growth to address the aftermath of the public health emergency caused by COVID-19. Through this program, Bulgaria was able to redirect funds towards improving the crisis response capacity of the healthcare system and make it more resilient to similar crises in the future. [1] In addition, the Bulgarian government developed eight financial mechanisms with public funding in April 2020 to respond to the challenges caused by the uncertainty of the coronavirus pandemic. [3]

In addition, Bulgaria provided aid to countries in the Western Balkans, the Eastern Partnership and the Southern Neighborhood, funded through official development aid money as allocated in the official budget of the Ministry of Foreign Affairs as part of a coronavirus relief and support program in May 2020. Under the initiative, Bulgaria provided personal protective equipment and food packages to North Macedonia, Albania, Serbia, Bosnia, Montenegro, Armenia, Georgia, Moldova, Ukraine, Belarus and Iraq. [4] [5] Furtheremore, Bulgaria also received funds from the World Health Organisation and the Global Fund over the past three years to projects related to capacity building measures for addressing epidemic threats. According to the Global Health Security Funding Tracking Dashboard, the two organisations have disbursed funds for developing, among others, legislation and workforce development, and fighting antimicrobial resistance. [6] [7]

[1] European Commission. 2020. "Coronavirus: Commission approves more than EUR 20 million in cohesion policy support to deal with the health emergency in Bulgaria". [https://ec.europa.eu/regional_policy/en/newsroom/news/2020/06/25-06-2020-coronavirus-commission-approves-more-than-eur20-million-in-cohesion-policy-support-to-deal-with-the-health-emergency-in-bulgaria]. Accessed 11 October 2020.
[2] Dnevnik.bg. 2020. "The government has a new preparedness plan for a future pandemic (Правителството има нов план за готовност за следваща пандемия)".
[https://www.dnevnik.bg/bulgaria/2020/12/02/4146544_pravitelstvoto_ima_obsht_plan_za_gotovnost_za/]. Accessed 03 December 2020.
[3] Bulgarian National Radio. 2020. "Eight financial instruments in support of businesses and citizens in Bulgaria (Осем финансови инструмента ще подкрепят бизнеса и гражданите в България)".
[https://bnr.bg/radiobulgaria/post/101262405/8-finansovi-instrumenta-shte-podkrepat-biznesa-i-grajdanite-v-balgaria].
Accessed 11 October 2020.

[4] Bulgarian National Television. 2020. “Bulgaria donated PPE to North Macedonia and Albania (България дари защитни облекла срещу коронавируса на Република Северна Македония и Албания)”. [https://bntnews.bg/news/balgariya-dari-zashtitni-oblekla-sreshtu-koronavirusa-na-republika-severna-makedoniya-i-albaniya-1056037news.html]. Accessed 11 October 2020.
[5] Vesti.bg. 2020. “Bulgaria will help Skopje with COVID-19 efforts (България ще помогне на Скопие в борбата с COVID-19)”. [https://www.vesti.bg/temi-v-razvitie/tema-koronavirus/bylgariia-shte-pomogne-na-skopie-v-borbata-s-covid-19-610854]. Accessed 11 October 2020.
[6] World Health Organisation. "Humanitarian Health Action". [http://www.who.int/hac/en/]. Accessed 17 October 2020.
[7] Global Health Security Tracking Dashboard. [https://tracking.ghscosting.org/#analysis/BG/r]. Accessed 17 October 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: 1

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 evidence of a publicly available plan or policy for sharing genetic data, clinical specimens or isolated specimen, along with epidemiological data with international organizations or other countries. No evidence of such a policy was found on the websites of the Ministry of Health or the Ministry of Agriculture, Food and Forestry and their associated agencies. [1][2] However, as a member of the European Union, Bulgaria contributes to the recently launched COVID-19 Data Exchange, developed in an effort to facilitate access to relevant data for researchers, scientists, doctors and Member State governments. [3][4]

[1] Ministry of Health. “Data exchange”. [https://www.mh.government.bg/bg/search/?q=%D0%BF%D0%BB%D0%B0%D1%82%D1%84%D0%BE%D1%80%D0%BC%D0%B0+%D0%B7%D0%B0+%D0%BE%D0%B1%D0%BC%D0%B5%D0%BD+%D0%BD%D0%B0+%D0%B4%D0%B0%D0%BD%D0%BD%D0%B8]. Accessed 11 October 2020.
[2] Ministry of Agriculture, Food and Forestry. “Data exchange”.

[https://www.mzh.government.bg/bg/search/?q=%D0%BF%D0%BB%D0%B0%D1%82%D1%84%D0%BE%D1%80%D0%BC%D0%B0+%D0%B7%D0%B0+%D0%BE%D0%B1%D0%BC%D0%B5%D0%BD+%D0%BD%D0%B0+%D0%B4%D0%B0%D0%BD%D0%BD%D0%B8]. Accessed 11 October 2020.
[3] European Commisison. 2020. “EC launches a data exchange platform”. [https://ec.europa.eu/bulgaria/news/ec-launches-data-sharing-platform-for-researchers_bg]. Accessed 11 October 2020.
[4] Big Data Value Association. 2020. “COVID-19 Data Exchange”. [https://www.bdva.eu/node/1451]. Accessed 11 October 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

There is no publicly available evidence that Bulgaria has failed to share samples in accordance with the Pandemic Influenza Preparedness (PIP) framework in the past two years. The World Health Organization's website does not feature any evidence that Bulgaria has failed to share samples in accordance with the PIP framework [1]. No news articles addressing the issue could be found in international or local media. The National Laboratory "Influenza and ARD", subordinated to the National Centre of Infectious and Parasitic Diseases, is listed as one of the National Influenza Centres by the WHO [2]. The laboratory is also part of the European Influenza Surveillance Network (EISN) as well as of the European Centre for Disease Prevention and Control (ECDC) [3]. Since 2009, the laboratory has also participated in the European and international network for information sharing with regard to influenza epidemics [3].

[1] World Health Organisation. "Bulgaria - News and Features". [https://www.who.int/countries/bgr/]. Accessed 11 October 2020.
[2] World Health Organisation. "National Influenza Centres". [https://www.who.int/influenza/gisrs_laboratory/national_influenza_centres/list/en/index3.html]. Accessed 11 October 2020.
[3] National Centre of Infectious and Parasitic Diseases. "National Reference Laboratory for Infectious and Parasitic Diseases". [https://www.ncipd.org/index.php?option=com_k2&view=item&id=72:nrl-grip-i-orz&Itemid=1095&lang=bg]. Accessed 11 October 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

There is no evidence that Bulgaria has failed to share pandemic pathogen samples, including COVID-19 samples, during an outbreak in the past two years. The World Health Organisation and the Ministry of Health were consulted and found to have no reference of such practice. [1] [2]. No news articles on the subject were found in international or local media, either.

[1] World Health Organisation. "Bulgaria - News and Features". [https://www.who.int/countries/bgr/]. Accessed 11 October 2020.

[2]] Ministry of Health. 2020. https://www.mh.government.bg/bg/]. Accessed 11 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: 2

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: 44

2020

Transparency International

6.1.1f

Accountability of public officials (Economist Intelligence score; 0-4, where 4=best)

Input number

Current Year Score: 2

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: 3

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: 1

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: 3

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: 4

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: 1

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: 3

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: 98.4

2011

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: 0.78

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: 0.4

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

The latest available figures indicate that less than 25% of Bulgaria's employment is in the informal sector. While the National Statistical Institute does not include data on informal employment in its comprehensive annual statistical reports on the workforce and employment, officially verified figures were most recently shared by the Confederation of Independent Trade Unions in Bulgaria (CITUB) in September 2019. [1] [2] According to CITUB's national secretary, the exact percentage of employment in the informal sector is 15.9%, putting Bulgaria among the five countries in the European Union with the highest share of informal employment. [2] Other sources suggest that this percentage might actually be higher, and closer to 21%. [3]

[1] National Statistical Institute. 2020. “Surveillance of the Workforce: Employed Persons and Employment Rates – National Level; Statistical Regions: Areas”. [https://www.nsi.bg/bg/content/4009/%D0%B7%D0%B0%D0%B5%D1%82%D0%B8-%D0%BB%D0%B8%D1%86%D0%B0-%D0%B8-%D0%BA%D0%BE%D0%B5%D1%84%D0%B8%D1%86%D0%B8%D0%B5%D0%BD%D1%82%D0%B8-%D0%BD%D0%B0-%D0%B7%D0%B0%D0%B5%D1%82%D0%BE%D1%81%D1%82-%D0%BD%D0%B0%D1%86%D0%B8%D0%BE%D0%BD%D0%B0%D0%BB%D0%BD%D0%BE-%D0%BD%D0%B8%D0%B2%D0%BE-%D1%81%D1%82%D0%B0%D1%82%D0%B8%D1%81%D1%82%D0%B8%D1%87%D0%B5%D1%81%D0%BA%D0%B8-%D1%80%D0%B0%D0%B9%D0%BE%D0%BD%D0%B8-%D0%BE%D0%B1%D0%BB%D0%B0%D1%81%D1%82%D0%B8?page=1]. Accessed 11 October 2020.
[2] Federation of Independent Construction Unions. 2019. “News (Новини)”. [http://www.fnss-bg.org/%D0%B1%D1%8A%D0%BB%D0%B3%D0%B0%D1%80%D0%B8%D1%8F-%D0%B5-%D0%B2-%D1%82%D0%BE%D0%BF-%D0%BF%D0%B5%D1%82-%D0%BD%D0%B0-%D1%81%D1%82%D1%80%D0%B0%D0%BD%D0%B8%D1%82%D0%B5-%D0%BE%D1%82-%D0%B8%D0%B7%D1%82%D0%BE/]. Accessed 11 October 2020.
[3] Pariteni. 2019. “Gray sector in the economy reaches 21% (Сивият сектор в икономиката ни достига 21%)”. [https://www.pariteni.bg/novini/osigurjavane/siviiat-sektor-v-ikonomikata-ni-dostiga-21-232497]. Accessed 11 October 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: 0

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: 0.41

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: 3

2021

Economist Intelligence

6.4 ENVIRONMENTAL RISKS

6.4.1 Urbanization

6.4.1a

Urban population (% of total population)

Input number

Current Year Score: 75.35

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: 1.88

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: 3

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: 74.96

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: 616.5

2019

WHO

6.5.1c

Population ages 65 and above (% of total population)

Input number

Current Year Score: 21.25

2019

World Bank

6.5.1d

Prevalence of current tobacco use (% of adults)

Input number

Current Year Score: 38.9

2018

World Bank

6.5.1e

Prevalence of obesity among adults

Input number

Current Year Score: 25

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: 99

2017

UNICEF; Economist Impact

6.5.2b

Percentage of homes with access to at least basic sanitation facilities

Input number

Current Year Score: 86.0

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: 941.67

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