ROMANIA

Confidence Building Measure Return
(covering data for 2021)

Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, 10 April 1972

Declaration form on Nothing to Declare or Nothing New to Declare for use in the information exchange

Measure	Nothing to declare	Nothing new to declare	Year of last declaration if nothing new to declare
A, part 1			
A, part 2 (i)	X		
A, part 2 (ii)			
A, part 2 (iii)	X		
B	X		
C			
E			
F	X		
G			

(Please mark the appropriate box(es) for each measure with a tick, and fill in the year of last declaration in the last column where applicable.)

Date: **30 May 2022**

State Party to the Convention: **ROMANIA**

Date of ratification/accession to the Convention: **25 July 1979**

National point of contact: **OSCE, Non-Proliferation and Arms Control Directorate**

Ministry of Foreign Affairs

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Active promotion of contacts

The Third Review Conference agreed that States parties continue to implement the following:

"Active promotion of contacts between scientists, other experts and facilities engaged in biological research directly related to the Convention, including exchanges and visits for joint research on a mutually agreed basis."

In order to actively promote professional contacts between scientists, joint research projects and other activities aimed at preventing or reducing the occurrence of ambiguities, doubts and suspicions and at improving international cooperation in the field of peaceful bacteriological (biological) activities, the Seventh Review Conference encouraged States parties to share forward looking information, to the extent possible,

- on planned international conferences, seminars, symposia and similar events dealing with biological research directly related to the Convention, and

- on other opportunities for exchange of scientists, joint research or other measures to promote contacts between scientists engaged in biological research directly related to the Convention,

including through the Implementation Support Unit (ISU) within the United Nations Office for Disarmament Affairs.

Confidence-Building Measure "A"

Part 1 Exchange of data on research centres and laboratories

At the Third Review Conference it was agreed that States Parties continue to implement the following:

"Exchange of data, including name, location, scope and general description of activities, on research centres and laboratories that meet very high national or international safety standards established for handling, for permitted purposes, biological materials that pose a high individual and community risk or specialize in permitted biological activities directly related to the Convention."

Modalities

The Third Review Conference agreed on the following, later amended by the Seventh Review Conference:

Data should be provided by States Parties on each facility, within their territory or under their jurisdiction or control anywhere, which has any maximum containment laboratories meeting those criteria for such maximum containment laboratories as specified in the latest edition of the WHO[1] Laboratory Biosafety Manual and/or OIE[2] Terrestrial Manual or other equivalent guidelines adopted by relevant international organisations, such as those designated as biosafety level 4 (BL4, BSL4 or P4) or equivalent standards.

States Parties that do not possess a facility meeting criteria for such maximum containment should continue to Form A, part 1 (ii).

Form A, part 1 (i)

Exchange of data on research centres and laboratories[3]

1. Name(s) of facility[4] _____
2. Responsible public or private _____
   organization or company _____
3. Location and postal address _____
   _____
   _____
   _____

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence

[1] World Health Organization
[2] World Organization for Animal Health
[3] The containment units which are fixed patient treatment modules, integrated with laboratories, should be identified separately.
[4] For facilities with maximum containment units participating in the national biological defence research and development programme, please fill in name of facility and mark "Declared in accordance with Form A, part 2 (iii)".

_____

5. Number of maximum containment units[5] within the research centre and/or laboratory, with an indication of their respective size (m^2)

_____

6. Scope and general description of activities, including type(s) of micro-organisms and/or toxins as appropriate

_____

_____

_____

[5] In accordance with the latest edition of the WHO Laboratory Biosafety Manual, or equivalent.

Form A, part 1 (ii)

If no BSL4 facility is declared in Form A, part 1 (i), indicate the highest biosafety level implemented in facilities handling biological agents[6] on a State Party's territory:

Biosafety level 3[7]	**No (under construction)**
Biosafety level 2[8] (if applicable)	**yes**

Any additional relevant information as appropriate:

The facility operating the BSL 2+ containment laboratory was the **Military Medical Research Center**, located in Bucharest. As a result of its reorganization (based on the Emergency Ordinance of the Government of Romania No. 125 from August 2020), the Military Medical Research Center was incorporated in the structure of The "Cantacuzino" National Medico-Military Institute for Research and Development ("Cantacuzino" NMMIRD) with all its staff, facilities and equipments. For details, see the corresponding section of "Cantacuzino" NMMIRD.

[6] Microorganisms pathogenic to humans and/or animals

[7] In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.

[8] In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.

Form A, part 1 (ii)

If no BSL4 facility is declared in Form A, part 1 (i), indicate the highest biosafety level implemented in facilities handling biological agents[9] on a State Party's territory:

Biosafety level 3[10]	**yes (requires validation)**
Biosafety level 2[11] (if applicable)	**yes**

Any additional relevant information as appropriate:

The National Institute for Infectious Diseases "Matei Balș" Bucharest (INBI MB) is the most important Romanian medical institution in charge with the management of patients with infectious diseases and consequently with victims of incidents involving biological agents. INBI MB is currently being charged by the Ministry of Health with the management of patients in case of out of the ordinary outbreaks (major, unusual, pandemic, such as the early stages of the Ebola epidemic in West Africa in 2014, when INBI MB was charged with the management of the would be Ebola infected patients on Romanian territory).

INBI MB was involved in managing patients infected with SARS-CoV-2 from the very first case in Romania and is the leading institution that coordinates the national strategy on management of COVID-19 cases. INBI MB provides scientific counselling regarding infectious diseases policies in Romania for the Ministry of Health and also performs tasks related to first response in unusual outbreaks (such as the ones triggered by SARS, MERS CoV, H7N9 or H5N1 influenza viruses etc.). INBI MB functions as the seat for the National Anti-AIDS Commission (www.cnlas.ro), managing the prevention and treatment of AIDS on national level.

INBI MB is also involved in medical research, having a very modern and state of the art equipped Centre for Biomolecular Applied Research in Infectious Diseases, **including BSL2 and BSL3 facilities**. This laboratory facility is located in a 4 floor (plus a 5th technical floor) building with over 3300 sqm and has several dedicated areas for virology, bacteriology, molecular biology, genetics, immunology, clinical biochemistry as well as imagistics (radiology, CT, MRI etc. for patient use). These laboratories are employed in diagnostic and applied research activities, including test validation, test development and microbiological surveys. The primary objectives of these facilities are to provide a capability allowing Romania to:

[9] Microorganisms pathogenic to humans and/or animals

[10] In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.

[11] In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.

- Survey human health status in relation with circulating pathogenic strains (microbiological surveillance);
- Identification of strains of certain micro-organisms not usually found in this country.

The **BSL3 facilities** are located at the second floor (areas dedicated to pathogenic fungi and Mycobacterium tuberculosis) but mainly at the 4th floor (540 sqm), with separated access from the ground level; it includes a HLCC (High Level of Containment Care) infected patient management area (unique in Romania, designed for managing at least 2 patients simultaneously, up to a maximum of 4) as well as a nearby BSL3+ laboratory (with both glove box and level A suit systems), suited for diagnostic activities involving highly dangerous pathogens, up to P4 (including some of the select agents that have the potential to pose a severe threat to public health and safety, such as the agents on Select Agent List or Australia Group List). However, this capability refers mainly to diagnostic procedures performed on human biological samples (environmental samples will need further actions toward methods and techniques validation).

INBI MB **has no operational BSL4** and is not involved in any national biological defence research and development program.

Form A, part 1 (ii)

If no BSL4 facility is declared in Form A, part 1 (i), indicate the highest biosafety level implemented in facilities handling biological agents[12] on a State Party's territory:

Biosafety level 3[13]	**yes (not operational)**
Biosafety level 2[14] (if applicable)	**yes**

Any additional relevant information as appropriate:

The "Cantacuzino" National Medico-Military Institute for Research and Development ("Cantacuzino" NMMIRD), located in Bucharest, operates several BSL2 containment laboratories (totalling 739.42 sqm / 826.42 sqm with new added Military Research Center) within the Department of Microbiology for Public Health (Viral Respiratory Infections Laboratory, Bacterial Respiratory Infections Laboratory, Viral Enteric Infections Laboratory, Vector Borne Diseases Laboratory, Sexually Transmitted Diseases Laboratory, Bacterial Enteric Infections Laboratory, Nosocomial Infections Laboratory, Anaerobical and Zoonosis Infections Laboratory, Parasitology, Molecular Epidemiology Laboratory) and the Department of Research and Development. These laboratories are used in diagnostic and applied research activities, including test validation, test development and microbiological surveys of bacterial, viral, parasitic and mycotic diseases.

The primary objectives of these facilities are to provide a capability allowing Romania to:
- Survey human health status in relation with circulating pathogenic strains (microbiological surveillance);
- Identification of strains of certain micro-organisms not usually found in Romania (as SARS-CoV-2 in 2020).

"Cantacuzino" NMMIRD has a BSL3 facility (totalling 175 sqm) within the Department of Microbiology for Public Health, intended for diagnostic and applied research activities. Currently the BSL3 facility is not operational, as there still are several validation procedures to be performed.

"Cantacuzino" NMMIRD has no operational BSL4.

"Cantacuzino" NMMIRD is not involved in any national biological defense research and development programme.

[12] Microorganisms pathogenic to humans and/or animals
[13] In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.
[14] In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.

Form A, part 1 (ii)

If no BSL4 facility is declared in Form A, part 1 (i), indicate the highest biosafety level implemented in facilities handling biological agents[15] on a State Party's territory:

Biosafety level 3[16]	**yes**
Biosafety level 2[17] (if applicable)	**yes**

Any additional relevant information as appropriate:

Romania's National Sanitary Veterinary and Food Safety Authority (NSVFSA) operates a BSL3 containment laboratory, component of the **Institute for Diagnosis and Animal Health/ IDAH** (located in Bucharest, Dr. N. Staicovici street, no. 63, sector 5, zip code 050557; Phone: +40/374.322.013, Fax: . +40/21.411.33.94, e-mail: office@idah.ro , web: www.idah.ro/).

The BSL3 containment laboratory is used for diagnostic in animal health and welfare; including test validation, and surveys, and participation to the international inter-comparison and proficiency tests. Primary objectives are to have a capability allowing Romania to:
- demonstrate its animal health status; and
- demonstrate strains of certain micro-organisms not found in this country.

The Institute for Diagnosis and Animal Health is a governmental institution with public financing and has no national biological defence research and development programme.

IDAH (through its National Reference laboratories for animal health and welfare) co-ordinates the diagnosis and surveillance work on animal health of the 40 County Sanitary Veterinary and Food Safety Laboratories. It is also the National Reference Laboratory for GMO in Food and Feed.

The Institute for Diagnosis and Animal Health provides technical guidance for County Sanitary Veterinary and Food Safety Laboratories and has the responsibility of performing confirmatory tests. It has also the responsibility to organize every County Sanitary Veterinary and Food Safety Laboratory, training and continuous training activities, in order to teach the specialists working in the County Sanitary veterinary and Food Safety Laboratories.

The Institute is accredited in accordance with ISO 17025 and ISO 17043 by RENAR, national accreditation body. It also received an attestation from the National Authority for

[15] Microorganisms pathogenic to humans and/or animals
[16] In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.
[17] In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.

Scientific Research, to initiate/participate/conduct research programs in area falling within their competence.

As the main activity of the Institute for Diagnosis and Animal Health is the laboratory diagnosis in the field of animal health, it has reference materials (bacterial and viruses strains, etc.) destined strictly for the laboratory diagnostic and stored, manipulated and used in biosafety and biosecurity conditions, only by the authorized personnel.

The Institute for Diagnosis and Animal Health maintains a High Containment Unit, designed to handle live foot-and-mouth disease virus (FMDV) for diagnosis purposes. IDAH is licensed to use FMDV by Commission Decision 2008/339/EC.

Form A, part 1 (ii)

If no BSL4 facility is declared in Form A, part 1 (i), indicate the highest biosafety level implemented in facilities handling biological agents[18] on a State Party's territory:

Biosafety level 3[19]	**no**
Biosafety level 2[20] (if applicable)	**yes**

Any additional relevant information as appropriate:

The Institute for Hygiene and Veterinary Public Health (IHVPH), located in Bucharest, Campul Mosilor street no. 5, sector 2, postal code 021201, operates several BSL2 containment laboratories. Its source of financing comes only from the National Sanitary Veterinary and Food Safety Authority.

The Institute is the national reference laboratory in the field of animal origin products, food and animal feeding stuffs. Some of the main duties include activities of guidance, proficiency tests, technical co-ordination and control of the county Sanitary Veterinary Food Safety laboratories, sanitary veterinary expertise for animal origin foodstuffs, caring out of results confirmation for laboratory testing, participation in the development of guidelines, instructions and technical details in the field of food safety and participation in the assessment proceedings for the authorization of veterinary microbiology laboratory.

The types of the micro-organisms used in daily activities are mentioned in the following table:

No.	Micro-organism	Reference
1.	Aspergillus brasiliensis	ATCC 16404
2.	Aspergillus caesiellus	ATCC 42693
3.	Bacillus cereus	ATTCC 11778
4.	Bacillus subtilis subsp. spizizenii	ATCC 6633
5.	Candida albicans	ATCC 10231
6.	Campylobacter coli	ATCC 43478
7.	Campylobacter jejuni	ATTC 33291
8.	Campylobacter jejuni	ATCC 29428
9.	Campylobacter lari	ATCC 35221
10.	Citrobacter freundii	ATCC 43864

[18] Microorganisms pathogenic to humans and/or animals

[19] In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.

[20] In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.

11.	Clostridium perfringens	ATCC 13124
12.	Clostridium botulinum TIP F	NCTC 10281
13.	Clostridium botulinum TIP B	NCTC 7273
14.	Clostridium botulinum TIP E	NCTC 11219
15.	Clostridium botulinum TIP A	NCTC 11199
16.	Clostridium butiricum	ATCC 19398
17.	Cronobacter sakazakii	ATCC 29544
18.	Cronobacter muytjensii	ATCC 51329
19.	Enterobacter cloacae subsp. cloacae	ATCC 13047
20.	Enterococcus faecalis	ATCC 19433
21.	Enterococcus faecalis	ATCC 29212
22.	Enterococcus faecium	ATCC 6057
23.	Escherichia coli	ATCC 8739
24.	Escherichia coli	NCTC 12900 (serotip O157:H7)
25.	Escherichia coli	NCTC 13216
26.	Escherichia coli	ATCC 25922
27.	Listeria innocua serotip 6a	ATCC 33090
28.	Listeria ivanovii subsp. ivanovii	ATCC 19119
29.	Listeria monocytogenes serotip 4b	ATCC 13932
30.	Listeria monocytogenes serotip 1a	ATCC 35152
31.	Proteus mirabilis	ATCC 29906
32.	Pseudomonas aeruginosa	ATCC 10145
33.	Pseudomonas aeruginosa	ATCC 27853
34.	Rhodococcus equi	ATCC 6939
35.	Saccharomyces cerevisiae	ATCC 9763
36.	Salmonella enterica subsp. enterica serovar Choleraesuis	ATCC 10708
37.	Salmonella enterica subsp. enterica serovar Choleraesuis	ATCC 7001
38.	Salmonella enterica subsp. enterica serovar Enteritidis	ATCC 13076
39.	Salmonella enterica subsp. enterica serovar Abaetetuba	ATCC 35640
40.	Salmonella enterica subsp. enterica serovar Typhimurium	ATCC 14028
41.	Staphylococcus aureus subsp. aureus	ATCC 6538
42.	Staphylococcus aureus subsp. aureus	ATCC 25923
43.	Staphylococcus epidermidis	ATCC 12228
44.	Vibrio cholerae	NCTC 11348
45.	Vibrio furnissii	NCTC 11218
46.	Vibrio parahaemolyticus	NCTC 10884
47.	Vibrio parahaemolyticus	NCTC 10885
48.	Vibrio parahaemolyticus	NCTC 10903
49.	Vibrio parahaemolyticus	NCTC 10885
50.	Vibrio parahaemolyticus	ATCC 17802
51.	Vibrio vulnificus	NCTC 13647
52.	Wallemia mellicola	ATCC 42694
53.	Yersinia enterocolitica subsp. enterocolitica	ATCC 23715
54.	Yersinia enterocolitica	NCTC 11174
55.	Yersinia enterocolitica	NCTC 10598
56.	Yersinia intermedia	NCTC 11469

57.	Yersinia pseudotuberculosis	NCTC 10275
58.	Yersinia enterocolitica palearctica O	NCTC 13769
59.	E. coli O103	ref. EURL E coli B07
60.	E. coli O111	ref. EURL E coli A07
61.	E. coli O157	ref. EURL E coli C07
62.	E. coli O145	ref. EURL E coli E07
63.	E. coli O26	ref. EURL E coli D07
64.	E. coli O104:K-H12	ref. EURL E coli H519
65.	E. coli O113:H21	ref. EURL E coli 6182-50
66.	E. coli O55:H-	ref. EURL E coli Su 3912-41
67.	E. coli O121:K-:H10	ref. EURL E coli 39w
68.	E. coli O128ab:H2	ref. EURL E coli Cigleris
69.	E. coli O146:K-:H21	ref. EURL E coli CDC2950-54
70.	E. coli O91:K-:H-	ref. EURL E coli H307B
71.	E. coli O104:H4	ref. EURL E coli D4116
72.	Salmonella Braenderup	ref. EURL E coli H9812
73.	E. coli	ref. EURL SSI-NN14
74.	E. coli	ref. EURL EA22
75.	E. coli	ref. EURL SSI-OO15
76.	E. coli	ref. EURL E coli D2653
77.	E. coli	ref. EURL E coli D3602
78.	E. coli	ref. EURL E coli D3522
79.	E. coli	ref. EURL E coli D3428
80.	E. coli	ref. EURL E coli D3648
81.	E. coli	ref. EURL E coli D3546
82.	E. coli	ref. EURL E coli D3509
83.	E. coli	ref. EURL E coli D3431
84.	E. coli	ref. EURL E coli D4134
85.	Staphylococcus aureus	ref. EURL CPS FRI 137
86.	Staphylococcus aureus	ref. EURL CPS FRI 361
87.	Staphylococcus aureus	ref. EURL CPS A900322
88.	Staphylococcus aureus	ref. EURL CPS FRI S6
89.	Staphylococcus aureus	ref. EURL CPS FRI 326
90.	Listeria monocytogenes	ref. Anses 00EB248LM ref. colectie Inst. Pasteur Clip74902
91.	Listeria monocytogenes	ref. Anses 00EB249LM ref. colectie Inst. Pasteur Clip74903
92.	Listeria monocytogenes	ref. Anses 00EB250LM .ref. colectie Inst. Pasteur Clip74904
93.	Listeria monocytogenes	ref. Anses 00EB254LM ref. colectie Inst. Pasteur Clip74908
94.	Listeria monocytogenes	ref. Anses 00EB256LM ref. colectie Inst. Pasteur Clip74910
95.	E. coli ESBL AmpC martor +	2005-10-96-1K99+ EURL AR
96.	E. coli ESBL AmpC martor -	OXA-30 EURL AR
97.	E. coli control CARBAPENEMAZE	TZ3638 EURL AR
98.	E. coli control CARBAPENEMAZE	TZ 116 EURL AR
99.	E. coli	ATCC 16874
100.	Enterococcus faecalis	ATCC 29212 ref. EURL-AR
101.	E. coli	ATCC 25922 ref. EURL-AR
102.	Staphylococcus aureus	ATCC 29213 ref. EURL-AR

103.	Salmonella infantis	ref. EURL Salmonella
104.	Campylobacter jejuni	ATCC 33560 ref. EURL-AR
105.	Bacillus cereus	NCTC 11143
106.	Norovirus G I	lenticule disc-Certified Reference Material from Public Health England and reference materials from European Union Reference Laboratory for foodborne viruses
107.	Norovirus G II	lenticule disc-Certified Reference Material from Public Health England and reference materials from European Union Reference Laboratory for foodborne viruses
108.	Hepatitis A virus	lenticule disc-Certified Reference Material from Public Health England and reference materials from European Union Reference Laboratory for foodborne viruses
109.	Clostridium botulinum type B	Strain isolated by IHVPH in food
110.	Clostridium botulinum type E	Strain isolated by IHVPH in food
111.	Clostridium botulinum TIP A	NCTC 11199
112.	Clostridium botulinum type B	NCTC 7273 Public Health England
113.	Clostridium botulinum type E	NCTC 7272 Public Health England
114.	Clostridium botulinum type F	NCTC 10281 Public Health England
115.	Vibrio vulnificus	NC 13647 Public Health England
116.	Vibrio cholerae	NC 11348 Public Health England
117.	Vibrio parahaemolyticus	NC 10885 Public Health England
118.	Vibrio parahaemolyticus	NC 10884 Public Health England
119.	Vibrio parahaemolyticus	NC 10903 Public Health England

Form A, part 1 (ii)

If no BSL4 facility is declared in Form A, part 1 (i), indicate the highest biosafety level implemented in facilities handling biological agents[21] on a State Party's territory:

Biosafety level 3[22]	**no**
Biosafety level 2[23] (if applicable)	**yes**

Any additional relevant information as appropriate:

The Institute for Control of Veterinary Biological Products and Medicines (ICVBPM), located in Bucharest, 39 Dudului Street, sector 6, Romania, is a unit with juridical status, functioning as a national reference institute, under the technical subordination of the National Sanitary Veterinary and Food Safety Authority. ICVBPM has competence in the field of veterinary medicinal products, biocides, feed additives, diagnosis sets, other veterinary products (vitamins, mineral supplements and cosmetics).

The main task with relevance on these issues is quality control of veterinary of live and inactivated vaccines for bacterial, viral, parasites:

- live vaccines against distemper, infectious hepatitis, infectious laryngotracheitis, parvovirosis and parainfluenza in dogs,
- inactivated vaccine for rabies,
- live and inactivated vaccines for panleucopenia, calicivirus and herpesvirus infection of cats,
- live and inactivated vaccines for IBR, BVD and SRB of bovine,
- rabies live vaccine for oral immunization in foxes,
- live vaccines against Aujeszky virus for pigs,
- live vaccine against myxomatosis and inactivated vaccines for Infectious Rabbit Hemorrhagic Disease,
- live vaccine against infectious bronchitis in poultry, infectious bursitis in poutry (Gumboro disease), Newcastle disease in poultry, inactivated vaccine against the egg drop syndrome, Inactivated vaccine against Newcastle disease and infectious bursitis in poultry,
- vaccine against porcine parvovirosis, inactivated,
- vaccine against leptospirosis in dogs and furry animals,
- inactivated vaccine against equine influenza and tetanus,
- inactivated vaccines against parvovirosis and swine erysipelas,
- live vaccine against antrax with B. Anthracis, attenuated strain 1190 R,
- live vaccines for Salmonella in poultry,
- vaccine inactivated against avian Cholerae.

[21] Microorganisms pathogenic to humans and/or animals

[22] In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.

[23] In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.

Quality control of veterinary pharmaceutical products (antimicrobial, anti-inflammatory, antiparasitics, etc.). To perform the quality control of pharmaceutical products is used the microorganisms test as bellow:

- Staphylococcus aureus ATCC 6538,
- Bacillus subtilis ATCC 6633, NCTC 2589,
- Pseudomonasaeruginosa ATCC 9027,
- Clostridium sporogenes ATCC 11437,
- Candida albicans ATCC 10231,
- Aspergillus Brasiliensis ATCC16404,
- Escherichia coli ATCC 8739, ATCC 10536, ATCC 1133,
- Salmonella enterica subsp. Enterica serovariant typhimurium ATCC 14028,
- Saccharomyces cerevisiae ATCC 2601,
- Micrococcus luteus ATCC 10240, ATCC 9341,
- Bordetella bronchiseptica ATCC 4617,
- Bacillus pumilus NCTC 8241, CIP 76.18,
- Staphylococcus epidermitis NCIMB 8853, CIP 68.21, ATCC 12228,
- Candida tropicalis CIP 1433-83, NCYC 1393,
- Bacillus spizizenii ATCC 4617,
- Streptococcus faecalis 8043.

Diagnostic test kits: for viral, bacterial and parasites disease by following tests: ELISA, immunodifusion test, complement bond reaction, slow and quick agglutination, immunofluorescent test, immunoperoxidase test.

Quality control of immunological veterinary medicinal products: Tuberculines avian and bovines (PPD) by using inactivated strains of Mycobacterium bovis and avium.

The laboratory's activities are organized and performed according to ISO 17025:2017 requirements and ISO 9001:2015 requirements.

Form A, part 1 (ii)

If no BSL4 facility is declared in Form A, part 1 (i), indicate the highest biosafety level implemented in facilities handling biological agents[24] on a State Party's territory:

Biosafety level 3[25]	**no**
Biosafety level 2[26] (if applicable)	**yes**

Any additional relevant information as appropriate:

The facility operating BSL2 containment laboratories is **Pasteur Filipesti Branch SA** - BUCHAREST WORKING POINT (Giulesti street no. 333, sector 6, Postal Code 060269, Bucharest). The source of financing of the reported activity is Pasteur Filipesti Branch SA.

The research activity regards animal viruses and bacteria (*Escherichia coli*, *Actinobacillus pleuropenumoniae*, *Erysipelothrix rhusiopathiae*, Aujeszky virus, avian laringotracheitis virus, avian coronavirus, avipox viruses, avian bursitis virus, avian paramyxoviruses, *Mycoplasma agalactiae*, *Clostridium perfringens, Clostridium septicum, Clostridium novyi, Clostridium chauvoei, Leptospira* spp.). Veterinary immunoprophylactic and pharmaceutical products, but also *in vivo* and *in vitro* diagnostic products are also provided.

The laboratories activities are organized in accordance to ISO 9001:2018 and for some of their methods to ISO 17025:2017 requirements.

[24] Microorganisms pathogenic to humans and/or animals

[25] In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.

[26] In accordance with the latest edition of the WHO Laboratory Biosafety Manual and/or the OIE Terrestrial Manual or other equivalent internationally accepted guidelines.

Part 2 Exchange of information on national biological defence research and development programmes

At the Third Review Conference it was agreed that States Parties are to implement the following:

In the interest of increasing the transparency of national research and development programmes on biological defence, the States Parties will declare whether or not they conduct such programmes. States Parties agreed to provide, annually, detailed information on their biological defence research and development programmes including summaries of the objectives and costs of effort performed by contractors and in other facilities. If no biological defence research and development programme is being conducted, a null report will be provided.

States Parties will make declarations in accordance with the attached forms, which require the following information:

(1) The objective and summary of the research and development activities under way indicating whether work is conducted in the following areas: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination and other related research;

(2) Whether contractor or other non-defence facilities are utilized and the total funding provided to that portion of the programme;

(3) The organizational structure of the programme and its reporting relationships; and

(4) The following information concerning the defence and other governmental facilities in which the biological defence research and development programme is concentrated;

(a) location;

(b) the floor areas (sqM) of the facilities including that dedicated to each of BL2, BL3 and BL4 level laboratories;

(c) the total number of staff employed, including those contracted full time for more than six months;

(d) numbers of staff reported in (c) by the following categories: civilian, military, scientists, technicians, engineers, support and administrative staff;

(e) a list of the scientific disciplines of the scientific/engineering staff;

(f) the source and funding levels in the following three areas: research, development, and test and evaluation; and

(g) the policy regarding publication and a list of publicly-available papers and reports.

Form A, part 2 (i)

National biological defence research and development programmes Declaration

Are there any national programmes to conduct biological defence research and development within the territory of the State Party, under its jurisdiction or control anywhere? Activities of such programmes would include prophylaxis, studies on

pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination and other related research.

Yes/No

If the answer is Yes, complete Form A, part 2 (ii) which will provide a description of each programme.

Form A, part 2 (ii)

National biological defence research and development programmes

Description

1. State the objectives and funding of each programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination and other related research.

2. State the total funding for each programme and its source.

3. Are aspects of these programmes conducted under contract with industry, academic institutions, or in other non-defence facilities?

Yes/No

4. If yes, what proportion of the total funds for each programme is expended in these contracted or other facilities?

5. Summarize the objectives and research areas of each programme performed by contractors and in other facilities with the funds identified under paragraph 4.

6. Provide a diagram of the organizational structure of each programme and the reporting relationships (include individual facilities participating in the programme).

7. Provide a declaration in accordance with Form A, part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to each national biological defence research and development programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

Form A, part 2 (iii)

National biological defence research and development programmes

Facilities

Complete a form for each facility declared in accordance with paragraph 7 in Form A, part 2 (ii).

In shared facilities, provide the following information for the biological defence research and development portion only.

1. What is the name of the facility?

2. Where is it located (include both address and geographical location)?

3. Floor area of laboratory areas by containment level:

BL2 _____ (sqM)

BL3 _____ (sqM)

BL4 _____ (sqM)

Total laboratory floor area _____ (sqM)

4. The organizational structure of each facility.

(i) Total number of personnel _____

(ii) Division of personnel:

Military _____

Civilian _____

(iii) Division of personnel by category:

Scientists _____

Engineers _____

Technicians _____

Administrative and support staff _____

(iv) List the scientific disciplines represented in the scientific/engineering staff.

(v) Are contractor staff working in the facility? If so, provide an approximate number.

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

(vii) What are the funding levels for the following programme areas:

Research _____

Development _____

Test and evaluation _____

(viii) Briefly describe the publication policy of the facility:

(ix) Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months. (To include authors, titles and full references.)

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms[27] and/or toxins studied, as well as outdoor studies of biological aerosols.

[27] Including viruses and prions.

Confidence-Building Measure "B"

Exchange of information on outbreaks of infectious diseases and similar occurrences caused by toxins

At the Third Review Conference it was agreed that States Parties continue to implement the following:

> Exchange of information on outbreaks of infectious diseases and similar occurrences caused by toxins, and on all such events that seem to deviate from the normal pattern as regards type, development, place, or time of occurrence. The information provided on events that deviate from the norm will include, as soon as it is available, data on the type of disease, approximate area affected, and number of cases.

The Seventh Review Conference agreed the following:

> No universal standards exist for what might constitute a deviation from the normal pattern.

Modalities

The Third Review Conference agreed on the following, later amended by the Seventh Review Conference:

1. Exchange of data on outbreaks that seem to deviate from the normal pattern is considered particularly important in the following cases:

- When the cause of the outbreak cannot be readily determined or the causative agent[28] is difficult to diagnose,

- When the disease may be caused by organisms which meet the criteria for risk groups III or IV, according to the classification in the latest edition of the WHO Laboratory Biosafety Manual,

- When the causative agent is exotic to a given geographical region,

- When the disease follows an unusual pattern of development,

- When the disease occurs in the vicinity of research centres and laboratories subject to exchange of data under item A,

- When suspicions arise of the possible occurrence of a new disease.

2. In order to enhance confidence, an initial report of an outbreak of an infectious disease or a similar occurrence that seems to deviate from the normal pattern should be given promptly after cognizance of the outbreak and should be followed up by annual reports. To enable States Parties to follow a standardized procedure, the Conference has agreed that Form B should be used, to the extent information is known and/or applicable, for the exchange of annual information.

3. The declaration of electronic links to national websites or to websites of international, regional or other organizations which provide information on disease outbreaks (notably outbreaks of infectious diseases and similar occurrences caused by

[28] It is understood that this may include organisms made pathogenic by molecular biology techniques, such as genetic engineering.

toxins that seem to deviate from the normal pattern) may also satisfy the declaration requirement under Form B.

4. In order to improve international cooperation in the field of peaceful bacteriological (biological) activities and in order to prevent or reduce the occurrence of ambiguities, doubts and suspicions, States Parties are encouraged to invite experts from other States Parties to assist in the handling of an outbreak, and to respond favourably to such invitations, respecting applicable national legislation and relevant international instruments.

Form B

Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern[29]

1. Time of cognizance of the outbreak _____
2. Location and approximate area affected _____
3. Type of disease/intoxication _____
4. Suspected source of disease/intoxication _____
5. Possible causative agent(s) _____
6. Main characteristics of systems _____
7. Detailed symptoms, when applicable _____
- respiratory _____
- circulatory _____
- neurological/behavioural _____
- intestinal _____
- dermatological _____
- nephrological _____
- other _____
8. Deviation(s) from the normal pattern as regards
- type _____
- development _____
- place of occurrence _____
- time of occurrence _____
- symptoms _____
- virulence pattern _____
- drug resistance pattern _____
- agent(s) difficult to diagnose _____
- presence of unusual vectors _____
- other _____
9. Approximate number of primary cases _____
10. Approximate number of total cases _____
11. Number of deaths _____
12. Development of the outbreak _____
13. Measures taken _____

[29] See paragraph 2 of the chapeau to Confidence-Building Measure B.

Confidence-Building Measure "C"

Encouragement of publication of results and promotion of use of knowledge

At the Third Review Conference it was agreed that States parties continue to implement the following:

> Encouragement of publication of results of biological research directly related to the Convention, in scientific journals generally available to States parties, as well as promotion of use for permitted purposes of knowledge gained in this research.

Modalities

The Third Review Conference agreed on the following:

1. It is recommended that basic research in biosciences, and particularly that directly related to the Convention should generally be unclassified and that applied research to the extent possible, without infringing on national and commercial interests, should also be unclassified.

2. States parties are encouraged to provide information on their policy as regards publication of results of biological research, indicating, *inter alia*, their policies as regards publication of results of research carried out in research centres and laboratories subject to exchange of information under item A and publication of research on outbreaks of diseases covered by item B, and to provide information on relevant scientific journals and other relevant scientific publications generally available to States parties.

3. The Third Review Conference discussed the question of cooperation and assistance as regards the safe handling of biological material covered by the Convention. It concluded that other international forums were engaged in this field and expressed its support for efforts aimed at enhancing such cooperation.

Romania encourages publication of results of biological research directly related to the Convention provided it is in compliance with good biosecurity practices.

- **Published papers generated through research and development activities performed within "Cantacuzino" NMMIRD in 2021**

No.	Title of the published scientific paper	Name of the Scientific Journal	Authors	Additional information
1	The extraction procedure and cyclic voltammetry assay using screen printed electrodes for detection of monosodium glutamate from different processed food sources	Revista de Chimie	Dora Domnica Baciu, Aurora Sălăgeanu, Teodor Vișan	https://doi.org/10.37358/RC.20.2.7947
2	Generation of a 3D melanoma model and visualization of doxorubicin uptake by fluorescence imaging	Analytical Biochemistry: Methods in the Biological Sciences	Baciu, D.D, Dumitrașcu, A.M, Vasile,V., Palade, B, Sălăgeanu, A	Under peer review

3	*Saccharomyces cerevisiae* cells lacking transcription factors Skn7 or Yap1 exhibit different susceptibility to cyanidin	Heliyon	Ruta, L.L., Oprea, E., Popa, C.V., Farcasanu, I.C.	https://doi.org/10.1016/j.heliyon.2020.e05352
4	Edible and functionalized films/coatings-performances and perspectives	Coatings	Avramescu, S.M., Butean, C., Popa, C.V., Ortan A., Moraru, I., Temocico, G.	https://doi.org/10.3390/coatings10070687
5	Resistance and features of Bacteroides spp. isolated from abdominal infections in romanian patients	Pathogens, vol.9, Nr.11/2020.	Pricop R.G., Gheorghe I., Pircalabioru G., Cristea C.V., Popa M., Marutescu L., Chifiriuc M.C., Mihăescu G	-
6	Antibiotherapy: latest current affairs – state of the art 2019	Vol. CXXIII • No. 2/2020 • May • Romanian Journal of Military Medicine	Viorel Ordeanu, Lucia E. Ionescu, Victoria G. Dumitrescu, Roxana G. Pricop, Răzvan Neagu, Diana M. Popescu	-
7	The strategic need for the implementation of a technological platform for the microproduction of antidotes for the CBRN medical protection	Vol. CXXIII • No. 3/2020 • August • Romanian Journal of Military Medicine	Viorel Ordeanu , Adrian A. Andrieș, Lucia E. Ionescu, Marius Necșulescu , Diana M. Popescu	-
8	Medical devices in current medicine	Vol. CXXIII • No. 4/2020 • November • Romanian Journal of Military Medicine	Viorel Ordeanu, Lucia E. Ionescu, Victoria G. Dumitrescu, Roxana G. Pricop, Răzvan Neagu, Diana M. Popescu	-
9	Effect of Different Antioxidants on X-ray Induced DNA Double-strand Breaks Using γ-H2AX in Human Blood Lymphocytes	Health Physiscs	Nicoleta Simona Bicheru, Cerasela Haidoiu, Octavian Călborean, Adrian Popa, Ioana Porosnicu, Radu Hertzog	10.1097/HP.0000000000001267
10	Hypoxic preconditioning - a non-pharmacological approach in COVID-19 prevention	International Journal of Infectious Diseases	Radu Gabriel Hertzog, Nicoleta Simona Bicheru, Diana Mihaela Popescu, Octavian Călborean, Ana-Maria Catrina	10.1016/j.ijid.2020.11.181
11	Radiotherapy in the fight against pneumonia associated with SARS-CoV-2	International Journal of Radiation Biology	Radu Gabriel Hertzog, Nicoleta Simona Bicheru	10.1080/09553002.2020.1822560
12	The Synthesis and Toxicological Characterization of Neurotoxic Chemical Agents Simulants ..	Revista de Chimie vol 70 no.11.nov.2019	Mihai Silviu Tudosie, Cristina Anca Secară, Cătălin-Gabriel Smarandache, Simona Bicheru, Constantin Drăghici	https://doi.org/10.37358/RC.70.19.11.7664
13	The synthesis and in vitro testing of symmetric bispiridinium compounds active in the exposure to neurotoxic chemical agents	Vol. CXXIII • No. 2/2020 • May •• Romanian Journal of Military Medicine	Cristina Anca Secară, Bogdan Patrinichi, Simona Bicheru, Mihai Tudosie	http://www.revistamedicinamilitara.ro/

14	Differential diagnosis in case of overdose of antiepileptic treatment. Clinical case,	Vol. CXXIII • No. 1/2020 • May Romanian Journal of Military Medicine	Mihail S. Tudosie, Genica Caragea, Ana D. Radu, Ilenuța L. Dănescu,	http://www.revistamedicinamilitara.ro/
15	Study regarding the determination of valproic acid serum levels by EMIT	Revista Farmacia, nr. 5, 2020	Mihail S. Tudosie, Genica Caragea, Ileana Dănescu, Radu Macovei	www.FarmaciaJournal.com http://doi.org.//1031925/farmacia.2020.5.17
16	Comprehensive characterization of silica-modified silicon rubbers	Journal of the Mechanical Behavior of Biomedical Materials	Chiulan, Ioana; Panaitescu, Denis Mihaela; Radu, Elena-Ruxandra; Frone, Adriana Nicoleta; Gabor, Raluca Augusta; Nicolae, Cristian Andi; Jinescu, George; Tofan, Vlad; Chinga-Carrasco, Gary	10.1016/J.JMBBM.2019.103427
17	Relationship between chemokines and T lymphocytes in the context of respiratory allergies (Review)	Experimental and Therapeutic Medicine	Nicolae Ovidiu Berghi, Mihai Dumitru, Daniela Vrînceanu, Radu Constantin Ciuluvica, Anca Simioniuc-Petrescu *Ramona Caragheorgheopol, ,Catalin Tucureanu* Roxana Sfrent Cornateanu, Călin Giurcaneanu	10.3892/etm.2020.8961
18	Bacterial cellulose sponges obtained with green cross-linkers for tissue engineering	Materials Science and Engineering: C Volume 110, May 2020, 110740	Frone, A.N., Panaitescu, D.M, Nicolae, C.A., Gabor, A.R., Trusca, R., Casarica, A., Stănescu, P.O., *Baciu, D.D., Saălăgeanu, A*	10.1016/j.msec.2020.110740
19	In vitro Evaluation of the Antiproliferative Effect, Cytotoxicity and Proinflammatory Activity of the Food Additive Monosodium Glutamate on RAW 264.7 Cell Line	Revista de Chimie, March 2020, Volume 71, Issue 2, 443-448	Dora Domnica Baciu, Aurora Sălăgeanu, Teodor Vișan	10.37358/RC.20.2.7947
20	Factorial design optimization of polystyrene microspheres obtained by aqueous dispersion polymerization in the presence of poly(2-ethyl-2-oxazoline) reactive stabilizer	Polymer International	Tanța - Verona Iordache, Nicoleta D Banu, Elena D Giol, Dumitru M Vuluga, Florica A Jerca, Valentin V Jerca	https://doi.org/10.1002/pi.5974
21	Fever temperatures abolish bacterial hemolysis: a microcalorimetry investigation	Archives of Biochemistry and Biophysics	Mihaela Palela, Elena-Diana Giol, Andreia Anzuța, Oxana G Ologu, Razvan C Stan	in press
22	Fever temperatures abolish bacterial hemolysis: a microcalorimetry investigation	bioRxiv- The preprint server for biology	Mihaela Palela, Elena-Diana Giol, Andreia Amzuța, Oxana G Ologu, Razvan C Stan	https://doi.org/10.1101/2020.11.23.393553

23	The Beneficial Mechanical and Biological Outcomes of Thin Copper-Gallium Doped Silica-Rich Bio-Active Glass Implant-Type Coatings	Coatings	George E. Stan,Teddy Tite, Adrian-Claudiu Popa, Iuliana Maria Chirica, Cătălin C. Negrilă, Cristina Beșleagă , Irina Zgura, Any Cristina Sergentu, Gianina Popescu-Pelin, Daniel Cristea, Lucia E. Ionescu , Marius Necsulescu, Hugo R. Fernandes and José M. F. Ferreira	doi:10.3390/coatings10111119
24	Composite nanogels based on zeolite - poly(ethylene glycol) diacrylate for controlled drug delivery	Nanomaterials	Cătălina Paula Spătărelu, Anita-Laura (Radu) Chiriac, Bogdan Cursaru, Tanța-Verona Iordache, Ana-Mihaela Gavrilă, Crina-Thea Cojocaru, Razvan-Edward Botez, Bogdan Trica, Andrei Sârbu, Mircea Teodorescu, Vlad Tofan, Francois-Xavier Perrin, Anamaria Zaharia	10.3390/nano10020195
25	Antibiotherapy: latest current affairs – state of the art 2019	Vol. CXXIII • No. 2/2020 • May • Romanian Journal of Military Medicine	Viorel Ordeanu, Lucia E. Ionescu, Victoria G. Dumitrescu, Roxana G. Pricop, Răzvan Neagu, Diana M. Popescu	-
26	The strategic need for the implementation of a technological platform for the microproduction of antidotes for the CBRN medical protection	Vol. CXXIII • No. 3/2020 • August • Romanian Journal of Military Medicine	Viorel Ordeanu , Adrian A. Andrieș, Lucia E. Ionescu, Marius Necșulescu , Diana M. Popescu	-
27	Diabetic nephropathy associates with deregulation of enzymes involved in kidney sulphur metabolism	Journal of cellular and molecular medicine,24 (20), 12131-12140	Elena Uyy, Viorel Iulian Suica, Raluca Maria Boteanu, Florentina Safciuc, Aurel Cerveanu ‐ Hogas, Luminita Ivan, Crina Stavaru, Maya Simionescu, Felicia Antohe	Online ISSN:1582-4934
28	Implications of the one health concept in agriculture	Scientific Works. Series C. Veterinary Medicine. Vol. LXVI (1), 2020 ISSN 2065-1295; ISSN 2343-9394 (CD-ROM); ISSN 2067-3663 (Online); ISSN-L 2065-1295	Viorel Ordeanu, Marius Necșulescu, Diana M. Popescu, Lucia E. Ionescu	-

29	"To be or not to be" Cat de real este diagnosticul infectiei COVID-19	Romanian Journal of Infectious Diseases 2020 23(2)	Sorin Bivolaru, Oana Cristina Voinea, Manuela Arbune	http://10.3789 7/RJID.2.16
30	Analysis of blood parameters in a study of metabolic syndromes induction by purified diets in mice	Romanian Archives of Microbiology and Immunology	Simona Popoiu, Ana-Maria Teodoru, Nicolae Levandovschi, Cristin Coman	-
31	The relationship between chemokine ligand 3 and allergic rhinitis	CureusApril 22, 2020, 12(4): e7783. doi:10.7759/cureus. 7783	Berghi O, Dumitru M, *Caragheorgheopol Ramona, Tucureanu Catalin*, Simioniuc-Petrescu A, Sfrent-Cornateanu R, Giurcaneanu C.	10.7759/cureu s.7783
32	Diferențierea genotipică a unor tulpini de S. intermedius și S. pseudintermedius izolate de la câini și pisici	Revista Romana de Medicina Veterinara, 30, 3: 81-84	Iulia Bucur, N. Cătana, M. Necșulescu, K. Imre, V. Herman, Ileana Nichita, E. Tîrziu	-
33	The antibacterial and antibiofilm effects of humulus lupulus l. esential oil	Social Science Research Network SSRN	Gabriela Costache, Mona Luciana Gălăţanu, Mariana Popescu, Lucia Elena Ionescu, Roxana Pricop, Răzvan Neagu, Viorel Ordeanu.	-
34	The impact of the covid-19 pandemic on national and international security	Proceedings	Viorel Ordeanu, Lucia E. Ionescu	-
35	Concepția de realizare a unei platforme tehnologice pentru antidoturi specifice de protecție medicală cbrn	Revista de Ştiinţe Militare	Viorel Ordeanu, Constantin Mircioiu	-
36	What do we owe to Henrietta Lacks? Considerations on the ethics of biobanking"	Romanian Archives of Microbiology and Immunology, 79(1): 54-67	Alexandra-Maria Născuțiu, Andreea-Roxana Lupu,	-
37	Predominance of influenza virus A(H3N2) 3C.2a1b and A(H1N1)pdm096B.1A5A genetic subclades in the WHO European Region, 2018–2019	Vaccine, Volume 38, Issue 35, 31 July 2020 (pg 5707-5717)	Angeliki Melidou, Olav Hungnes, Dmitriy Pereyaslov, Cornelia Adlhoch, Hannah Segaloff, Emmanuel Robesyn, Pasi Penttinen, Sonja J. Olsen, European Region influenza surveillance network (Romania: Lazăr M, Cherciu C.)	
38	Surveillance of medically-attended influenza in elderly patients from Romania – data from three consecutive influenza seasons (2015/16, 2016/17 and 2017/18)	Influenza and Other Respiratory Viruses, 15 May 2020	Pițigoi D, Streinu-Cercel A, Ivanciuc A E, Lazăr M. Cherciu C M, Mihai M.E., Nițescu M, Aramă V, Crăciun M D, Streinu-Cercel A, Săndulescu O.	

- **Other scientific papers published in 2021 as a collaborative work of "Cantacuzino" NMMIRD with local and foreign institutions**

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2. Georgiana V. Tiron, Ioana G. Stancu, Sorin Dinu, Florian L. Prioteasa, Elena Fălcuță, Cornelia S. Ceianu, Ani I. Cotar. Characterization and host-feeding patterns of Culex pipiens s.l. taxa in an endemic West Nile virus area in southeastern Romania. Vector Borne and Zoonotic Diseases.

3. Corneliu P Popescu, Ani I Cotar , Sorin Dinu, Mihaela Zaharia, Grațiela Tardei, Emanoil Ceaușu, Daniela Bădescu, Simona Ruță, Cornelia S. Ceianu, Symin Aysel Florescu. Emergence of Toscana virus in Romania. Emerging Infectious Diseases. (IF 6.259)

4. Georgeta Cristina Oprea, Sorin Dinu, Maria Damian, Veronica Lazar. Methods use for direct detection of Bordetella pertussis infections in Romania. Rom Biotechnol Lett 25 (4): 1696-1700, 2020

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7. Oprea M, Njamkepo, E, Cristea D. et al. The seventh pandemic of cholera in Europe revisited by microbial genomics. Nat Commun 11, 5347 (2020) https://doi.org/10.1038/s41467-020-19185-y

8. Elena Fălcuță, Liviu Florian Prioteasa, Cintia Horváth, Ioana Raluca Păstrav, Francis Schaffner, Andrei Daniel Mihalca. The invasive Asian tiger mosquito Aedes albopictus in Romania: towards a country-wide colonization? Parasitology Research (2020) 119:841–845

9. Romeo Bellinia, Antonios Michaelakisb, Dušan Petrićc, Francis Schaffnerd, Bulent Alten, Paola Angelinif, Carles Arandag, Norbert Beckeri, Marco Carrieria, Marco Di Lucaj, Elena Fălcuță et al., Practical management plan for invasive mosquito species in Europe: I. Asian tiger mosquito (Aedes albopictus), April 2020, Travel Medicine and Infectious Disease 35, DOI: 10.1016/j.tmaid.2020.101691.

10. Dragomirescu CC, Lixandru BE, Coldea IL, Corneli ON, Pană M, Palade AM, Cristea CV, Suciu I, Suciu G, Manolescu LSC, Popa GL, Popa MI. Antimicrobial susceptibility testing for Corynebacterium species isolated from clinical samples in Romania. Antibiotics. 2020;9(1):31 doi:10.3390/antibiotics9010031 CA .

11. Leopold Tie, Mina Răileanu, Mihaela Bacalum, Irina Codita, Ștefania Mădălina Negrea, Costin Ștefan Caracoti, Elena-Carmina Drăgulescu, Andreea Campu, Simion Astilean, Monica Focsan. Versatile Polypeptide-Functionalized Plasmonic Paper as

Synergistic Biocompatible and Antimicrobial Nanoplatform. Molecules. 2020 Jul; 25(14): 3182, doi: 10.3390/molecules25143182.

12. Felix Lötsch, Barbara Albiger, Dominique L. Monnet, Marc J. Struelens, Harald Seifert , Anke Kohlenberg, European Antimicrobial Resistance Genes Surveillance Network (EURGen-Net) carbapenem-resistant *Acinetobacter baumannii* capacity survey group (....Romania – Irina Codiță....). Epidemiological situation, laboratory capacity and preparedness for carbapenem-resistant Acinetobacter baumannii in Europe, 2019. . Euro Surveill. 2020;25(45):pii=2001735.

13. Davies K, Lawrence J, Berry C, Davis G, Yu H, Cai B, Gonzalez E, Prantner I, Kurcz A, Macovei I, Pituch H, Nováková E, Nyc O, Gärtner B, Berger FK, Oleastro M, Cornely OA, Vehreschild MJGT, Pedneault L and Wilcox M, 2020. Risk factors for primary *Clostridium difficile* infection; results from the observational study of risk factors for *Clostridium difficile* infection in hospitalized patients with infective diarrhea (ORCHID). *Frontiers in Public Health*, 8: 293. https://doi.org/10.3389/fpubh.2020.00293.

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15. Georgeta Cristina Oprea- „The virulence factors involved in Bordetella pertussis pathogenesis and their genetic regulation”- articol acceptat spre publicare in revista Romanian Archives for Microbiology and Immunology nr. 2/2020.

- **Published papers generated through research and development activities performed within The National Institute for Infectious Diseases "Matei Balș" (INBI MB) in 2021**

1. Leuștean A, Popescu C, Nichita L, Tilișcan C, Aramă V. Dynamics of APRI and FIB-4 in HCV cirrhotic patients who achieved SVR after DAA therapy. Exp Ther Med. 2021 Jan;21(1):99. Print ISSN: 1792-0981, Online ISSN:1792-1015 (Published online on November 26, 2020). IF=1.785

2. Molagic V, Popescu C, Tilișcan C, Aramă V, Aramă SS. Rapid loss of HBs antigen in patients with HBV reactivation and high level of transaminases during immunosuppressive therapy - case series. Revista Română de Medicina de Laborator. Nr. 29(1)/2021 DOI:10.2478/rrlm-2020-0039. IF 2020= 1.027

3. Stratan L, Tilișcan C, Aramă V, Lazăr M, Vișan A, Ganea O, Trifonescu MI, Aramă SS, Ion D. COVID-19 associated coagulopathy is correlated with increased age and markers of inflammation response. Revista Română de Medicina de Laborator. Nr. October 2021. DOI:10.2478/rrlm-2021-0031. IF 2020= 1.027

4. Stuurman AL, Biccler J, Carmona A, Descamps A, Díez-Domingo J, Muñoz Quiles C, Nohynek H, Rizzo C, Riera-Montes M; DRIVE Public Partners (Chironna M, Napoli C, Manini I, Pandolfi E, Icardi G, Panatto D, Mosca S, Lai PL, Orsi A, Mira-Iglesias A, Lópex-Obrador FX, Auvinen R, Skogberg K, Loginov R, Bellino S, Punzo O, Bella A, Redberger-Fritz M, Drăgănescu AC, Săndulescu O, Pițigoi D, Florea D, Vlaicu O, Oțelea D, Bilașco A, Streinu-Cercel A, Luminos MD, Aramă V, Streinu-Cercel A, De Smedt T, De Smedt N, de Lusignan S, Hoang U, Liyanage H, Baum U, Syrjänen RK, Ikonen N, Bonanni P, Ravaldi C, Vannacci A, Bonaiuti R, Levi M, del Amo Morán E, Rodrigo-Pendás JA, Antón A, Andrés C, Uriona-Tuma S.): Brand-specific influenza vaccine effectiveness estimates during 2019/20 season in Europe - Results from the DRIVE EU study platform. Vaccine. 2021 Jun 29;39(29):3964-3973. Impact factor (2020): 3.641

5. Florin Căruntu. Residual low HDV viraemia is associated HDV RNA relapse after PEG-IFNa-based antiviral treatment of hepatitis delta: Results from the HIDIT-II study By: Bremer, Birgit; Anastasiou, Olympia E.; Hardtke, Svenja; et al.Liver International, Volume: 41 Issue: 2 Pages: 295-299 Published: FEB 2021 Early Access: DEC 2020

6. Florin Căruntu. A transient early HBV-DNA increase during PEG-IFN alpha therapy of hepatitis D indicates loss of infected cells and is associated with HDV-RNA and HBsAg reduction By: Anastasiou, Olympia E.; Yurdaydin, Cihan; Maasoumy, Benjamin; et al.Journal of Viral hepatitis, Volume: 28 Issue: 2 Pages: 410-419 Published: FEB 2021 Early Access: DEC 2020

7. Cost-Efficacy of Antiretroviral Regimens Recommended in Treatment-Naive HIV-Infected Adults. A Single Center Experience Raluca Jipa, Iulia Nedelcu, Eliza Manea, Anca Damalan, Adriana Hristea 1, Processes 2021, 9, 956. ISI IF 2,84 https://doi.org/10.3390/pr9060956

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Irina Stoica, Madalina Stoica, Adriana Hristea Viruses 2021, 13, 1244. https://doi.org/10.3390/v13071244 ISI IF 5,04 ISI IF 5,08

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- **Research projects performed in INBI MB during 2021 with topics related to the BWTC**

1. International research project: ***Monitoring of immune status after vaccination against COVID-19 – longitudinal/observational study***. Sponsored by Roche Diagnostic. December 2020 – December 2021. Principal investigator (Romania):Prof. Dr. Victoria Aramă.

2. International multicentric clinical study: **V590-003 - *Safety. Efficacy and Immunogenicity of V590 (rVSVΔG-SARS-CoV-2 Vaccine) in Adults. Phase III***.

October 2020 – October 2021. Sponsored by Merck & Co. Principal investigator (Romania):Prof. Dr. Victoria Aramă.

3. International clinical study: **V591-002 - *A phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Safety and tolerability. Efficacy, and Immunogenicity of V591 (MV SARS-CoV-2, Live, Recombinant) in Healthy Adults***. September 2020 – September 2021. Sponsored by Merck & Co. Principal investigator (Romania):Prof. Dr. Victoria Aramă.

4. ***Exploration of the influence of the gut microbiota and the preexisting immune status to respiratory pathogenic agents on SARS-CoV-2 infection outcome***. June 2021-July 2022.

Project coordinator: Prof. Univ. Dr. Veronica Lazăr, Faculty of Biology, Bucharest University.

Partner institutions: University of Montreal, Canada; National Institute of Infectious Diseases Prof. Dr. Matei Balș, Virology Institute St. Nicolau (I.V.N); Colțea Clinical Hospital; Ploiești County Emergency Hospital;

5. **MYR 204** - "A Multicenter, Open-label, Randomized Phase 2b Clinical Study to Assess Efficacy and Safety of Bulevirtide in Combination with Pegylated Interferon alfa-2a in Patients with Chronic Hepatitis Delta". Sponsored by MYR GmbH, Hessenring 89, 61348 Bad Homburg, Germany. EudraCT number: 2019-001485-15. 2019-2021. Principal investigator (Romania):Prof. Dr. Victoria Aramă.

6. **WHO-SOLIDARITY** – International randomized clinical study on several additional treatments for COVID-19 in hospitalized patients with local standard of care treatment. Nr EudraCT: 2020-001366-11. Project coordinator: Prof. Dr.Victoria Arama; Principal Investigator: Dr. Simin Aysel Florescu;Sponsored by: Romanian Ministry of Health and WHO; 2020-2021.

7. Strenghtening of institutional capacity for medical care asociated infections control and management of antibiotic use in Romania – part of "Health care challenges at european level" financed through SEE 2014 – 2021. Project promoter: National Institute of Infectious Diseases Prof. Dr. Matei Balș in partnership with Norway National Institute of Public Health. 01.02.2020 – 31.01.2022.

8. A Phase 3 Randomized, Double-Blind Trial to Evaluate The Safety and Immunogencity of A 20-Valent Pneumococcal Conjugate Vaccine Given as a Series of 2 Infant Doses and 1 Toddler Dose in Healthy Infants – ongoing clinical study. Investigational Product Number: PF-06482077. Protocol Number: B7471012. European Clinical Trials Database (EudraCT) Number: 2019-003306-27

9. A phase 2b, Open-Label Trial to Assess the Safety, Tolerability and Immunogenicity of MenABCWY in Healty Infants 2 and 6 Months of Age – ongoing clinical study. Study Intervention Number: PF-06886992. EudraCT Number: 2020-000948-60. Protocol Number: C3511002, Phase: 2b.

10. "Development of Robust and Innovative Vaccine Effectiveness (DRIVE)", finanțat prin Innovative Medicines Initiative (IMI) 2 Grant Agreement No. 777363. Octomber 2021 – June 2022. Project Partener: Institutul Național de Boli Infecțioase "Prof. Dr. Matei Balș". Project Coordinator: Fundación Para el Fomento de Investigación Sanitaria y Biomédica de la Comunitat Valenciana (FISABIO), Valencia, Spain.

11. "GIHSN prospective epidemiological active surveillance study in Romania". Global Influenza Hospital Surveillance Network (GIHSN) 2021-2022. Financed by Foundation for influenza epidemiology, Fondation de France, Sanofi Pasteur.

12. “Development of Robust and Innovative Vaccine Effectiveness (DRIVE)”, finanțat prin Innovative Medicines Initiative (IMI) 2 Grant Agreement No. 777363. 2020 – 2021. Proiect Partener: Institutul Național de Boli Infecțioase “Prof. Dr. Matei Balș”. Project Coordinator: Fundación Para el Fomento de Investigación Sanitaria y Biomédica de la Comunitat Valenciana (FISABIO), Valencia, Spain.

13. University Medical Center Utrecht. Multi-centre EuRopean study of MAjor Infectious Disease Syndromes (MERMAIDS) – Acute Respiratory Infections (MERMAIDS ARI) 2.0. Funded from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 101003589.

14. “Surveillance of Hepatitis C Antiviral Resistance, Epidemiology and MethoDologies” (SHARED), part of international research project “Development, Validation and Worldwide Dissemination of a Standard and Next Generation Deep Sequence Assay of HCV, and Application to a Longitudinal Analysis in a Very Well Characterized PWID Cohort” financed by Genome BC. Coordinated by d Dr. Anita Howe, British Columbia Center for Excellence in HIV/AIDS, Vancouver, British Columbia, Canada. Proiect Partner: National Institute Național for Infectious Diseases “Prof. Dr. Matei Balș”. Nr. 3113/25.04.2018.

15. “Evaluation of an antigen detection based diagnostic algorithm for HCV infection in a reference infectious diseases institute in Romania” Nr. 2790/27.02.2018. Financed by Abbott GmbH & Co & Co KG. ARCHITECT HCV-Ag.

16. “Hepatitis C antiviral therapy failure registry” (HepCaRe), implemented by European Society for Translational Antiviral Research (ESAR), University Medical Centre Utrecht, Utrecht, Olanda. Project Partener: National Institute Național for Infectious Diseases “Prof. Dr. Matei Balș”. c/8165/15.11.2017.

17. **Protocol AI438047/205888** A Multi-arm, Phase 3, Randomized, Placebo Controlled, Double Blind Clinical Trial to Investigate the Efficacy and Safety of BMS-A randomized, double-blind, 104-weeks treatment study to evaluate the efficacy, safety, tolerability and pharmacokinetics of telbivudine oral solution and tablets in children and adolescents with compensated HBeAg-positive and negative chronic hepatitis B virus infection 663068/GSK3684934 in Heavily Treatment Experienced Subjects Infected with Multi-drug Resistant HIV-1 (2015- ongoing)

18. **Protocol GSK 200304** A Phase 3b, randomised, open labelstudy of the antiviral activity and safety of dolutegravir compared to lopinavir/ritonavir both administered with dual nucleoside reverse transcriptase inhibitor therapy in HIV-1 infected adult subjects with treatment failure on first line therapy. (2015-2021)

19. **Protocol Aramchol 005 ARREST** A Phase IIb, double blind, randomized controlled clinical trial to evaluate the efficacy and safety of two Aramchol doses versus placebo in patients with Non-Alcoholic- Steatohepatitis (NASH). (2016-2019)

20. **Protocol GFT505-315-1** A Multicenter, Randomized, Double-Blind, Placebo-Controlled Phase III Study to Evaluate the Efficacy and Safety of Elafibranor in Patients with Nonalcoholic Steatohepatitis (NASH) and fibrosis (2016-2021).

21. **Protocol GSK 205543** A Phase III, randomised, double-blind, multicentre, parallel-group, non-inferiority study evaluating the efficacy, safety, and tolerability of dolutegravir plus lamivudine compared to dolutegravir plus tenofovir/emitricitabine in HIV-1-infected treatment-naive adults. (2016-2021)

22. **Protocol SANOFY POSY-TEICO OBS13842** Prospective, observational cohort, evaluating the incidence of nephrotoxicity and other adverse events of interest in patients

treated with the higher recommended teicoplanin loading dose (12 mg/kg twice a day), and comparison with external historical comparator data. (2017-2020)

23. **Protocol AMGEN (AMG145/Evolocumab) 20130286** A Double Blind, Randomized, Placebo-Controlled, Multicenter Study to Evaluate Safety, Tolerability, and Efficacy on LDL-C of Evolocumab (AMG 145) in Subjects With HIV and With Hyperlipidemia and/or Mixed Dyslipidemia. (2017-2020)

24. **AC-061A302** A multi-center, randomized, double-blind study to compare the efficacy and safety of cadazolid versus vancomycin in subjects with Clostridium difficile-associated diarrhea (CDAD).

25. **CP40617** A phase III, randomized, double-blind placebo-controlled, multicenter study to evaluate the efficacy and safety of baloxavir marboxil in combination with standard-of-care neuraminidase inhibitor in hospitalized patients with severe influenza. (2019-2020)

26. **MK-8558-022** A Single-Dose Clinical Trial to Study the Saftey, Tolerability, Pharmacokinetics and Anti-RetroviralActivity of MK-8558 Monotherapy in Anti-retroviralTherapy (ART)-Naïve, HIV-1 Infected Participants 2019-2020

27. **Educationaql project**: Tick-borne diseases and their prevention ID: 62051309, **Global Medical Grants, Pfizer 2020**.

28. **Observational study on incidence and seroprevalenece of tick- borne encephalitis virus infection in Romania, 2020-2022 Global Medical Grants, Pfizer 2020, ID: 57519415**.

29. **Proiect**: *Single-dose clinical trials to study the safety, tolerability, pharmacokinetics, and anti-retroviral activity of MK-8527 monotherapy in anti retroviral therapy (ART)-nive, HIV-1infected patients*. (Arensia Exploratory Medicine GmbH)

30. **2019-2021** Erasmus+ Programme 2014-2020 : ***"Let's produce new functional bakery products for people with digestive disorders"*** 2019-1-RO01-KA202-063170

31. **ATLAS** - Antimicrobial Testing Leadership and Surveillance. Coordinated by Pfizer. Project Partner: National Institute Național for Infectious Diseases "Prof. Dr. Matei Balș".

Confidence-Building Measure "D"

(Deleted)

Confidence-Building Measure "E"

Declaration of legislation, regulations and other measures

At the Third Review Conference the States parties agreed to implement the following, later amended by the Seventh Review Conference:

As an indication of the measures which they have taken to implement the Convention, States parties shall declare whether they have legislation, regulations or other measures:

(a) To prohibit and prevent the development, production, stockpiling, acquisition or retention of the agents, toxins, weapons, equipment and means of delivery specified in Article I of the Convention, within their territory or anywhere under their jurisdiction or under their control anywhere;

(b) In relation to the export or import of micro-organisms pathogenic to man, animals and plants or of toxins in accordance with the Convention;

(c) In relation to biosafety and biosecurity.

States parties shall complete the attached form (Form E) and shall be prepared to submit copies of the legislation or regulations, or written details of other measures on request to the Implementation Support Unit (ISU) within the United Nations Office for Disarmament Affairs or to an individual State party. On an annual basis States parties shall indicate, also on the attached form, whether or not there has been any amendment to their legislation, regulations or other measures.

Form E

Declaration of legislation, regulations and other measures

Relating to	Legislation	Regulations	Other measures[30]	Amended since last year
(a) Development, production stockpiling, acquisition or retention of microbial or other biological agents, or toxins, weapons, equipment and means of delivery specified in Article I	**Yes**	**Yes**	**Yes**	**No**
(b) Exports of micro-organisms[31] and toxins	**Yes**	**Yes**	**No**	**Yes**

[30] Including guidelines.

(c) Imports of micro-organisms[11] and toxins	**Yes**	**Yes**	**No**	**No**
(d) Biosafety[32] and biosecurity[33]	**Yes**	**Yes**	**Yes**	**No**

Name of legislation, regulations and other measures

No	Specification	No	Year	Topic
1	Regulation (EU) 2021/821 of the European Parliament and of the Council	821	2021	Setting up a Union regime for the control of exports, brokering, technical assistance, transit and transfer of dual-use items
2	Commission Delegated Regulation (EU) 2022/1	1	2022	Amending Regulation (EU) 2021/821 of the European Parliament and of the Council as regards the list of dual-use items
3	Council Regulation (EU) 2015/1861	1861	2015	Modifying Council Regulation (EU) 267/2012 regarding restrictive measures against Iran
4	Government Ordinance	119	2010	Regarding the control regime of dual use items operations
5	Law	197	2011	Approving Government Ordinance No 119/2010
6	Government Ordinance	12	2012	Modifying Government Ordinance No 119/2010
7	Law	35	2013	Approving Government Ordinance No 12/2012
8	Order of the Minister of Foreign Affairs	914	2012	Approving the regulation for implementing the provisions of Government Ordinance No 119/2010 regarding the control regime of dual-use items operations
9	Order of the Minister of Foreign Affairs	358	2016	Approving the methodological norms for applying the provisions of Council Regulation (EU) 2015/1861 modifying Reg. (EU) 267/2012 regarding restrictive measures against Iran

[31] Micro-organisms pathogenic to man, animals and plants in accordance with the Convention.

[32] In accordance with the latest version of the WHO Laboratory Biosafety Manual or equivalent national or international guidance.

[33] In accordance with the latest version of the WHO Laboratory Biosecurity Guidance or equivalent national or international guidance.

Confidence-Building Measure "F"

Declaration of past activities in offensive and/or defensive biological research and development programmes

In the interest of increasing transparency and openness, States parties shall declare whether or not they conducted any offensive and/or defensive biological research and development programmes since 1 January 1946.

If so, States parties shall provide information on such programmes, in accordance with Form F.

Form F

Declaration of past activities in offensive and/or defensive biological research and development programmes

1. Date of entry into force of the Convention for the State Party.

2. Past offensive biological research and development programmes:

- Yes/No

- Period(s) of activities

- Summary of the research and development activities indicating whether work was performed concerning production, test and evaluation, weaponization, stockpiling of biological agents, the destruction programme of such agents and weapons, and other related research.

3. Past defensive biological research and development programmes:

- Yes/No

- Period(s) of activities

- Summary of the research and development activities indicating whether or not work was conducted in the following areas: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination, and other related research, with location if possible.

Confidence-Building Measure "G"

Declaration of vaccine production facilities

To further increase the transparency of biological research and development related to the Convention and to broaden scientific and technical knowledge as agreed in Article X, each State party will declare all facilities, both governmental and non-governmental, within its territory or under its jurisdiction or control anywhere, producing vaccines licensed by the State party for the protection of humans. Information shall be provided on Form G attached.

Form G

Declaration of vaccine production facilities

1. Name of facility: The "Cantacuzino" National Medico-Military Institute for Research and Development, Bucharest

2. Location (mailing address): Splaiul Independentei 103 – 105, 050096, Sector 5, Bucharest, Romania

3. General description of the types of diseases covered:

While the "Cantacuzino" NMMIRD has a production facility and has, in the past, produced several vaccines, the facility is not currently operational. A Trivalent Northern Hemisphere Influenza Vaccine (egg-adapted influenza virus) was manufactured at this facility, as was a monovalent vaccine for the pandemic A/H1N1v strain. A BCG vaccine was also manufactured at the facility.

Form G

Declaration of vaccine production facilities

1. Name of facility: SC Pasteur – Filiala Filipesti Srl, working point Bucharest

2. Location (mailing address): 333 Giulesti Str., 060269 Bucharest, sector 6, Romania;

Phone: +40212209909; fax: +40212206915; email: office@pasteur.ro

3. General description of the types of diseases covered: animal diseases (viral, bacterial diseases). Antravac – live antrax vaccine for animals: cattle, horses, sheep, goats and swine

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Form G

Declaration of vaccine production facilities

1. Name of facility: ROMVAC COMPANY S.A.

2. Location (mailing address): Soseaua Centurii (Centurii Drive) No. 7, Voluntari, IF-077109, Romania; email: romvac@romvac.ro;

3. General description of the types of diseases covered: animal diseases (viral, bacterial diseases). Carboromvac – live antrax vaccine for animals: cattle, sheep, goats, horses and swine

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