Invitation Letter to BTSF National Contact Points seeking applications for BTSF training activities on

PREVENTION AND CONTROL OF ANTIMICROBIAL RESISTANCE (AMR) IN THE CONTEXT OF AN OVERALL "ONE HEALTH" APPROACH TO PREVENTION AND CONTROL OF INFECTIONS AND REDUCING ANTIMICROBIAL RESISTANCE

under the "Better Training for safer Food" Initiative

CONTRACT NUMBER 2016 96 07
2ND PHASE

Valid as of 08/07/2022

1. *Course objectives*

General objective

The present BTSF project covers the AMR issue from "One Health" holistic approach, being the overall objective of the training the dissemination of the information, training for best practices and upgrading national systems in relation to the surveillance and monitoring on antimicrobial resistance. The training also aims to provide training on the methods of prevention and control of AMR in the veterinary and public health sectors with a holistic approach to prevent the infections and reduce the bacterial resistance.

Specific objectives

The purpose of the training will be to spread the knowledge between the participants of the implementation of the "One Health" approach on the use of and resistance to antimicrobials, providing the best practices on the design, implementation, and management of National Action Plans against antimicrobial resistance. The Plans will have to be implemented under the responsibility of the competent authority of the Member States. Each Member State therefore has an important role to play in ensuring that these objectives are achieved. A key element of the training will be to not only make participants aware of best practices in the **veterinary/food and public health sectors**, but to emphasize how vital is that a common approach is adopted throughout the Union.

With this purpose on mind, the training will aim at achieving the following objectives:

- Spread the knowledge of the implementation of the "One Heath" approach on the use and resistance of the antimicrobials.
    - AMR occurrence factors and general concepts.
    - AMR as an EU policy priority. European Commission Action Plan against rising threats from AMR 2011-2016.
    - European One Health Action Plan against Antimicrobial Resistance (AMR).
    - International initiatives in relation to AMR: WHO, UN, FAO, OIE, Codex Alimentarius, GHSA, TAFTAR, etc.
    - Role of the EU Agencies in relation to the AMR: EMA, ECDC, EFSA.
- Provide the best practices regarding the design, implementation, and management of National Action Plans against antimicrobial resistance.
    - Source of data, measure units and categorisation. Harmonization of source of data and harmonization of measure units between the countries.
    - Joint interagency cooperation.
- Promote the use of common indicators, monitoring and surveillance systems of antimicrobials and AMR in both human and veterinary sectors.
    - Integrated surveillance systems: harmonisation and best practices of monitoring systems for both sectors.
    - Knowledge gaps in relation to the environment: environmental mechanisms of AMR selection and transmission.

- Ensure that the trainees have a solid understanding of ways to collaborate and coordinate among the different national authorities as well as EU agencies involved in the monitoring and surveillance of the use of antimicrobials and their resistance.

2. *Training dates and locations*

2 additional four-days-long Face-to-Face training courses will be delivered between in the last 2022 trimester, with approximately 35 people in each session.

An introductory session in the morning of the first day will be followed by 4 days of training. The course agenda is attached (Annex 3).

Table 1: Training dates and Locations

Year	Training session	Course title	Location	Proposed dates	Registration deadline
2022	Session 17	Antimicrobial Resistance II	Malaga (TBC) / Spain	17-20/10/2022	**12/09/2022**
	Session 18	Antimicrobial Resistance II	Budapest (TBC) / Hungary	14-17/11/2022	**10/10/2022**

For organisational purposes, names of participants should be communicated **at the latest 30 days before each workshop**. A reminder will be sent to NCPs before each event.

3. Selection criteria for participants

Participant must:	1. Fulfil the eligibility criteria
	2. Meet the minimum requirements
	3. Be selected using the evaluation criteria

1. Eligibility criteria for Course on the Prevention and control of Antimicrobial Resistance in the context of a "One Health" approach
The training program is opened to participants whose application form is submitted by the corresponding BTSF National Contact Points. Only eligible participants should be further assessed against the minimum requirements below. • Have the capacity to work and make interventions in English language. • Be committed to disseminating the knowledge gained (courses, workshops, articles, blogs) in the short medium term once the training ends. Guidance on how to disseminate the knowledge will be provided during the sessions, and a follow up questionnaire will be performed to participants attending.

Participants must meet the minimum requirements below to ensure they can follow and fully participate in this course. Participants who do not meet the minimum requirements should not be proposed for the training.

2. Minimum requirements for Course on the Prevention and control of Antimicrobial Resistance in the context of a "One Health" approach	**Yes/No**
The training program is mainly addressed to officials from National Competent Authorities involved, preferably at central level, in the monitoring, surveillance, reporting and control activities for the correct use of antimicrobials and the resistance to them in public health and veterinary/ food safety sectors, such as: • Senior officers from Public Health competent authorities. • Senior officers from Primary production of animals intended to be food competent authorities. • Senior officers from Food safety competent authorities. **IMPORTANT NOTE** **To assure a One Health approach in the training, NCPs are kindly required to send 2 participants per session, 1 from the public health sector, and 1 from veterinary / food safety sector. In all cases, they will have to be involved in the control and surveillance of the use of antimicrobials or their resistance.**	

The evaluation criteria should be used as a tool to prioritise participation (higher score indicates higher priority), but there is no minimum score necessary.

3. Evaluation criteria for Course 2		Enter Score
a)	Officials from National Competent Authorities involved, preferably at central level, in the monitoring, surveillance, reporting and control activities for the correct use of antimicrobials and the resistance to them in public health and veterinary/ food safety sectors, such as: • Senior officers from Public Health competent authorities. • Senior officers from Primary production of animals intended to be food competent authorities. • Senior officers from Food safety competent authorities. <u>Scoring</u> less than 3 years = 0 points; ≥ 3 years = 5 points; 5 - 10 years = 10 points; > 10 years = 12.5 points	
b)	Experience in the monitoring, surveillance, reporting and control activities for the correct use of antimicrobials and the resistance to them in public health and veterinary/ food safety sectors. <u>Scoring</u> no experience = 0 points; < 2 years = 5 points; 2-5 years = 7.5 points; > 5 years = 10 points	
c)	Contribution towards monitoring, surveillance, reporting and control activities for the correct use of antimicrobials and the resistance to them in public health and veterinary/ food safety sectors. <u>Scoring</u> no experience = 0 points; < 2 years = 5 points; 2-4 years = 10 points; > 4 years = 12.5 points	
d)	During the course, participants will be provided with a training package to be used as support dissemination material. Commitment to disseminate the knowledge received is a prerequisite for course participation. <u>Scoring</u> 1. Commitment to distribute the training material among their colleagues = 5 points; 2. Point 1 plus preparing and giving presentations based on the training material for the staff of national Competent Authorities/uploading training material to national Competent Authorities' intranets/websites = 10 points 3. Points 1, 2 plus preparing informative articles in the professional national journals = 15 points 4. no commitment = 0 points	
	Maximum total score	**50**

4. Country allocations

A total of 612 seats will be allocated according to the tables below. Please note that the number of allocated seats for each country may vary.

Table 2: Distribution of seats among the countries invited

			2022	
			2022-10-17/20	2022-11-14/17
			Malaga (TBC)	Budapest (TBC)
	Country	**Total Places**	**S17 (additional)**	**S18 (additional)**
1	Austria	16		2
2	Belgium	18		2
3	Bulgaria	16	2	
4	Croatia	18	2	2
5	Cyprus	8		
6	Czech Republic	18	2	2
7	Denmark	16		
8	Estonia	16	2	
9	Finland	12		
10	France	36	2	2
11	Germany	36	2	2
12	Greece	16	2	
13	Hungary	18		2
14	Ireland	18		2
15	Italy	36	2	2
16	Latvia	18	2	
17	Lithuania	16	2	
18	Luxembourg	8	2	
19	Malta	8		2
20	Netherlands	18	2	
21	Poland	18		2
22	Portugal	18	2	
23	Romania	16		2
24	Slovakia	18		2
25	Slovenia	12		2
26	Spain	36	2	2
27	Sweden	16	2	
Member States		**500**	**30**	**30**
28	Albania	6		
29	The Republic of North Macedonia	6	2	
30	Montenegro	6		
31	Serbia	6		2
32	Turkey	6		
Candidate Countries		**34**	**2**	**2**
33	Iceland	10		2
34	Norway	4	2	
35	Switzerland	8		
36	Northern Ireland	8		

			2022	
			2022-10-17/20	2022-11-14/17
			Malaga (TBC)	Budapest (TBC)
	Country	**Total Places**	**S17 (additional)**	**S18 (additional)**
EFTA & EEA & Countries with special agreements		**34**	**2**	**2**
37	Bosnia-Herzegovina	4		
38	Kosovo	4		
Potential Candidate Countries		**8**	**0**	**0**
39	Egypt	4		
40	Moldova	4		2
41	Morocco	4	2	
42	Russia	4		
43	Tunisia	4		
44	Ukraine	4		
45	United Kingdom	8		
Third Countries		**36**	**2**	**2**
TOTAL PARTICIPANTS		**612**	**36**	**36**

You are welcome to nominate more participants for the reserve list than indicated in the table above. If seats will become available, you will be informed in due time.

5. Face-to-face logistical arrangements

In the case of face-to-face training sessions, the European Commission will fund in full the visa, travel, accommodation, meals, and field visit costs for all training participants. No daily allowance will be paid on top of this. Any other costs are to be paid by the participants themselves.

Participants will arrive at the training venues on Day 1 afternoon and training will commence on Day 1 afternoon (depending on travel connections, participants may be requested to arrive at the training venues on Day-1 evening). Return travel will be on Day 4 afternoon (or Day 5 morning according to flight connections).

AENOR team will liaise further with the nominated participants for all logistics and practical aspects.

6. Virtual Classrooms

The VC sessions will be organised with the use of the Zoom web conferencing tool. To avoid delays, participants will be invited take part in a short technical test of their equipment a few days before the training sessions. This will allow participants to test their equipment and view the main features of the VC application platform.

During this brief test, participants will have the chance to learn all the tools of the VC platform. During this meeting, the Event Manager and Assistant Event Manager will also go through the main aspects of the agenda and different sessions that are foreseen. Additionally, in the morning of Day 1 of the VC, time will be dedicated to a technical session to refresh participants on the main features of the platform, and ensure connections are working properly.

The participants should have *a computer with a working camera and audio system (speaker and microphone) as well as a good internet connection.*

Annex 1: Background and main topics covered in training

Background

The spreading of antimicrobial resistance is a natural biological phenomenon, but lately a variety of factors have contributed to accelerate this dissemination. In Europe it is estimated that around 33.000 patients die annually as a result of infections caused by antibiotic-resistant bacteria meaning an estimated cost of EUR 1.5 billion per year in healthcare costs and productivity losses. Combating antimicrobial resistance has become a global public health challenge.

In 2008, the European Council, through his own conclusions on antimicrobial resistance, called upon the Member States to strengthen surveillance systems and improve data quality on antimicrobial resistance and on consumption of antimicrobial agents within both the human and veterinary sectors.

The evaluation of the first EC Action Plan on antimicrobial resistance 2011-2016, published in October 2016 by the Commission, showed that it had a clear added value acting as a symbol of political commitment, stimulating several actions within Member States, and had served to strengthen international cooperation.

One of the areas being developed has been the improvement of the surveillance of antimicrobials and monitoring of antimicrobials consumption. Further assistance will be needed to support EU Member States as there are still, today, big differences between them, and the "One Health" approach will have to be reinforced, giving a bigger role to environmental issues.

Therefore, in June 2017 the Commission adopted the EU One Health Action Plan against AMR, as requested by the Member States, based on key objectives built on three main pillars: 1. Making the EU a best practice region, 2. Boosting research, development and innovation, and 3. Shaping the global agenda.

In 2014 a BTSF initiative was launched, focused on monitoring and controlling zoonoses and zoonotic agents related with antimicrobial resistance and the prevention of this resistance.

In 2017, a new training programme covering AMR issue from a "One Health" approach was launched, covering veterinary sector, public health sector and environment. A second phase, from mid-2019 till mid-2021, will continue disseminating the most updated information related to AMR for both the prevention and control of the use and the resistance monitoring of antimicrobials.

Main topics covered in the training

The following topics will be addressed:

- Occurrence factors of AMR and general concepts related to AMR.
- 2011-2016 EC Action Plan against the rising threats from AMR with focus on its multi-sectorial approach and presentation of the results of the external evaluation of this Plan.
- EU strategy 2017-2022 against AMR.
- Overview of the EU legal framework applicable to AMR and the use of antimicrobials.
- Relevant international initiatives in the field of AMR (e.g. Codex Alimentarius, WHO, OIE and FAO initiatives, UN, TATFAR, GHSA initiative).

- Relevant EU rules and initiatives for monitoring and reporting of AMR in veterinary and human medicine, including bacterial species/food/animal combinations, sampling rules, rules for analysis, antimicrobial susceptibility testing and interpretation of results.
- Specific case of Methicillin-resistant Staphylococcus aureus (MRSA) and of bacterial resistance to certain last-resort antibiotics for humans (colistin and carbapenems).
- Work of the EU agencies EMA, EFSA and ECDC to tackle AMR, including joint interagency cooperation.
- The role of environment in emergence and spread of AMR - how does the introduction of antimicrobials and resistant microorganisms from both human and animal sources contribute to AMR.
- Relevant EU initiatives for monitoring the use of antimicrobials in veterinary and human medicine and practical application of those rules:
- Methods for the collection of data on the use of antimicrobials at different levels.
- Collection of data by animal species (veterinary sector) and by patients' categories (human sector).
- Units of measurement of consumption.
- Commission guidance documents on prudent use of antimicrobials in veterinary and human medicine.
- Examples of “One Health” approach and good practices for strategies and actions aimed at promoting and strengthening the sensible use of antimicrobials in veterinary and human medicine.
- Communication practices and resources used to develop campaigns on prevention and use of antimicrobials

In this sense, participants will be invited to participate actively in discussions, debriefings and working groups. They will be given preparation tasks prior to the attendance to the session and asked to update their knowledge of EU legislation in their sector and to bring examples of their national practices and communication materials in their given sector.

With this programme, the Commission wants to ensure a real holistic “One Heath” approach where the veterinary and public health elements are both present in the Action Plan and able to interact. Therefore, **the programme is addressed to both public health and veterinary sectors’ representatives.**

The distribution of participants will ensure the creation of national networks between the two sectors that can further promote and strengthen the collaboration and coordination of activities on AMR at national level.

Annex 2: Legislation and guidance

The level of development of harmonised legislation for each sector is different, being more developed in the veterinary field that in the human sector. In addition, non-binding documents exist e.g. guidelines and are recommended to be used by Member States.

The EU legislative framework in the human sector includes:

- Directive 2001/83/EC of the EP and Council (6 November 2001) on medicinal products for human use.
- Regulation (EC) No 726/2004 of the EP and Council (31 March 2004) laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (revision on-going, provisions on vet. medicines proposed to be moved to a new Regulation).
- Decision No 1082/2013/EU of the EP and Council (22 Oct 2013) on serious cross-border threats to health.

EU legislation in the veterinary sector

The current legal framework for veterinary medicinal products and medicated feed (Directive 2001/82/EC, Regulation, (EC) No 726/2004 and Directive 90/167/EEC have been replaced by Regulation (EU) 2019/6 on veterinary medicinal products and Regulation (EU) 2019/4 on medicated feed. The new regulations will apply from 28 January 2022.

As part of their implementation, the two Regulations require the European Commission to adopt delegated and implementing acts. This new legislation contains a comprehensive set of concrete provisions addressing the public and animal health risk of AMR. These provisions include a reinforced ban on the use of antimicrobials to promote growth or increase yield in animals; a ban on the preventive use of antibiotics in groups of animals; a ban on the preventive use of antimicrobials via medicated feed; the possibility to reserve certain antimicrobials for humans only; restrictions on metaphylactic use and compulsory collection of data on sales and use of antimicrobials. In addition, given the international dimension of AMR, the ban on using antimicrobials as growth promoters and the restrictions in using those antimicrobials designated in the EU as reserved for human use will also apply to animals or products of animal origin intended for import from Third Countries to the EU.

Other Regulations

- Regulation (EC) No 470/2009 on Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin

Food – Zoonotic Agents

- Directive 2003/99/EC on the monitoring of zoonoses and zoonotic agents
- Commission Implementing Decision 2020/1729 on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria and repealing Implementing Decision 2013/652/EU

The new legal framework on Animal Health is based on “Prevention is better than cure”

- Animal Health Law: Regulation (EU) 2016/429 of the EP and the Council (9 March 2016) on transmissible animal diseases in its delegated and implementing acts

It has a preventive driven approach by the improvement animal health and biosecurity measures, good farming

practices, by establishing clear responsibility for all players for animal health, between the operators, that have to ensure the level of animal health and biosecurity, the veterinarians, by preventing the spreading of pathogens and raising awareness, and the Competent Authorities, by protecting the animal health, human health, and environment.

The new legislation also prioritises the EU intervention, by identifying the resistant pathogens: “disease agents”, by establishing disease preventive and control measures may apply (surveillance, eradication…), and implementing legal basis to monitor AMR in animal pathogens.

The use of antimicrobials in animals needs to conform to EU and national rules and, in particular, must follow the authorised Summary of Product Characteristics (SPC).

The SPC contains information on the conditions for using a veterinary medicinal product as developed during the risk assessment process. In accordance with Article 14 of Directive 2001/82/EC and Article 31 of Regulation (EC) No 726/2004, any application for a marketing authorisation must be accompanied by the SPC which is proposed by the applicant, and assessed and, if necessary, amended by the competent authority.

Some examples of CVMP referrals and positive opinions can be found in the following articles:
Article 35

- Lincomycin & spectinomycin combinations administered orally to pigs and poultry / indications, dosing regimens, WPs, adopted at May meeting
- Colistin in combination with other antimicrobials for oral administration / follow up to AMEG advice on colistin (2013), adopted at April meeting

Article 34

- Denagard 45% oral granules (tiamulin)
- Girolan-Apralan (Apramycin)

Annex 3: Agenda

Table 1 – Agenda Virtual Course

Day 1	Welcome of participants
	General introduction on BTSF
	Introduction on the course programme
	Knowledge test
	Overview of the general concepts and the history of ANTIMICTOBIAL RESISTANCE
	EU Legislative framework: EU legislation
	GROUP BRAINSTORMING about the NVR, the EU Action Plan and the international initiatives
Day 2	EU Legislative framework Monitoring and Reporting Use of Antimicrobials
	EU Guidelines on AMR GROUP ACTIVITY on the Implementation of the EU rules and Guidelines
Day 3	Monitoring and Reporting of Antimicrobial Resistance Case Study of MRSA
Day 4	The role of environment in spreading AMR BRAINSORMING on Environmental sources contributing to AMR GROUP ACTIVITY on knowledges gaps TRANSFORMATION session
Day 5	GROUP ACTIVITY on communication practices JIACRA Report Summary
	Q&A session
	Knowledge test
	Final speeches

Table 2 – Agenda F2F

Day 1	Welcome of participants
	General introduction on BTSF
	Introduction on the course programme
	Knowledge test
	Overview of the general concepts and the history of ANTIMICTOBIAL RESISTANCE
Day 2	EU Legislative framework: EU legislation
	GROUP BRAINSTORMING about the NVR, the EU Action Plan and the international initiatives
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	EU Guidelines on AMR GROUP ACTIVITY on the Implementation of the EU rules and Guidelines
Day 3	Monitoring and Reporting of Antimicrobial Resistance Case Study of MRSA
	The role of environment in spreading AMR
	BRAINSORMING on Environmental sources contributing to AMR
	GROUP ACTIVITY on knowledges gaps
	TRANSFORMATION session
Day 4	JIACRA Report GROUP ACTIVITY on communication practices Summary
	Q&A session
	Knowledge test
	Online evaluation
	Certificates and Final speeches

Annex 4: Training material, outcomes and dissemination activities

Participants will receive an email prior to the course with the link to the BTSF Academy and their password to access it provided by the team at BTSF Academy platform.

All the presentations and hands-out will be available for download from the BTSF Academy, as well as background information on the tutors' team and IT guidance documents.

At the end of the course, participants will be provided with a syllabus to facilitate the dissemination of the contents.

Additionally, after the end of the training, pending their mandatory attendance to each day of the training, participants will be granted with their certificate of attendance.

Training material

All participants will receive a Dissemination Kit electronically to enable them to actively disseminate course knowledge upon their return from BTSF training. Participants attending face-to-face courses will receive the information on the USB key.

Dissemination Kit

This contains the following training materials:

- All course presentations
- Study notes on field trips and group activities/discussions and conclusions thereof
- The course syllabus
- The training information sheet
- Glossary of terms and abbreviations used in the course
- Additional references for further study
- Written guidance on how to actively disseminate course knowledge to colleagues upon participants' return to their home countries, different methodologies/examples/best practice
- Other information and material delivered at the course such as quizzes, FAQs etc.

Dissemination questionnaire

Two to three months after the respective training session, participants will receive a standard questionnaire requesting information on the dissemination activities of the participant after the training, and details on differences in the approach adopted in day-to-day work following the training.

Self-assessment test

Furthermore, the programme will include an anonymous knowledge test to be carried out at the beginning and at the end of each training session in order to measure the impact of the training on the understanding of the participants of the subjects taught.

Participants are expected to agree to carry out the above tests and to reply to the surveys and questionnaires.

For Virtual Classrooms

Participant agree to be registered in the BTSF Academy and agree to be recorded during VC training sessions and to take a group photo of the participants and tutors at the end of the training. Videos and photo will be published in the BTSF Academy in the corresponding training course section and will be visible only to registered users of the BTSF ACADEMY.

Please find more information regarding data protection here:

https://btsfacademy.eu/training/mod/page/view.php?id=417

Annex 5: Contractor contact details

The Project is managed by: AENOR

Project Manager: Mónica ZABALA

Training Coordinator for Course 17: Antonio LOPEZ

Training Coordinator for Course 18: Cristina MUÑOZ

Separate notifications will be sent to National Contact Points for each course and will contain the names and contact details of the Event Manager and Assistant Event Manager as well as logistical details on the event.

All official communication between National Contact Points and the project will be maintained through the functional e-mail address 20169607_amr@aenor.com or by phone to +34 676 172 096.

All information on BTSF training can be found at the BTSF Academy website and at http://btsf-aenor.com/. These websites will be regularly updated with details of forthcoming courses.