

KEY ISSUES

Objective of the Communication: Efforts to combat the spread of antimicrobial resistance are to be intensified.

Affected parties: Citizens and companies, employed people and authorities connected to healthcare, veterinary care, animal husbandry, food production and retailing and the environmental sector.



Pro: (1) Efforts to combat AMR are advisable both EU wide and globally because resistant pathogens spread across borders.

(2) Reducing the use of antimicrobials is essential for combating AMR.

(3) EU aid for the development of new antimicrobials will help to cover future needs. It is unproblematic in ordopolitical terms insofar as it is restricted to basic research.

The most important passages in the text are indicated by a line in the margin.

CONTENT

Title

Communication COM(2017) 339 of 29 June 2017: **A European One Health Action Plan against Antimicrobial Resistance (AMR)**

Brief Summary

► Context and objectives

- Antimicrobial resistance (AMR) is (p. 2)
 - the acquired resistance of pathogenic micro-organisms – such as bacteria, viruses and fungi – (hereinafter pathogens)
 - to antimicrobials – such as antibiotics, antivirals and anti-fungals – against which there was previously no resistance.
- AMR impedes the ability to combat pathogens in the healthcare and animal husbandry sectors. AMR is increasing. In the EU, AMR is responsible for an estimated 25,000 deaths each year and € 1.5 billion in healthcare costs and diminished productivity due to illness (p. 2–3).
- The main cause of AMR is the excessive and inappropriate use of antimicrobials (p. 2). In addition, according to the Commission, the development of new antibiotics has slowed in the last 20 years (p. 4).
- In combating AMR, the EU is pursuing the concept of “One Health” which refers to the fact that, due to interdependence, measures must be taken not only in the area of human health but also in those of animal health and the environment (p. 3).
 - Resistant pathogens can also be passed from animals to humans – such as through the environment via contaminated water (p. 3).
 - An environment over-loaded by antimicrobials can give rise to AMR (p. 3).
- The Communication contains an Action Plan which will continue with the current EU measures and place greater emphasis on the environment. The main objectives in this regard are (p. 5):
 - EU-wide action to combat AMR,
 - boosting research, development and innovation in the EU on combating AMR and
 - world-wide action to combat AMR.

► EU-wide action to combat AMR

Surveillance and the use of data to combat AMR

- The Commission wants to improve the surveillance of AMR among humans, animals and in the environment in order to recognise AMR at an early stage.
- For this it wants inter alia to
 - review existing EU legislation on monitoring AMR in the case of animals and food (p. 6),
 - develop new EU legislation for monitoring previously unknown AMR in bacteria that cause transmissible animal diseases, once resistance has been identified (p. 6),
 - make greater use of data from environmental monitoring – e.g. under the Water Framework Directive [2000/60/EC] – to combat AMR (p. 11) and
 - consider the development of EU measures to monitor AMR in the environment (p. 6).

- The Commission wants to improve the basis for political decisions on combating AMR by inter alia (p. 7)
 - providing data which shows the links between AMR and the use of antimicrobials,
 - defining outcome indicators to measure progress in combating AMR and
 - developing a model with the OECD to measure the cost-effectiveness of national measures.

The effectiveness of national measures and EU legislation to combat AMR

- The Commission wants to improve the coordination of national measures by inter alia (p. 8)
 - making regular information about the spread of AMR available at national and EU level via the AMR One Health network on combating AMR – that covers government experts and EU authorities in the human health, animal health, and environmental sectors – and
 - continuing to support the implementation of national One Health action plans against AMR.
- The Commission wants to improve the implementation of EU legislation for combating AMR by inter alia
 - continuing to monitor implementation by way of regular audits in the Member States (p. 8) and
 - developing training programmes on combating AMR for employees of supervisory authorities and for health professionals, which also inform them about current EU legislation (p. 8–9).

Reducing the use of antimicrobials

- The Commission wants to improve infection prevention and control, inter alia by supporting (p. 9)
 - good practices in hospitals for infection prevention and control,
 - vaccination in humans,
 - animal husbandry that reduces the risk of infection among animals.
- The Commission will ensure a more “prudent” use of antimicrobials inter alia by
 - raising awareness for and understanding of AMR, such as by supporting measures by the Member States to improve public awareness (p. 7),
 - developing EU guidelines for human medicine and supporting Member States in implementing existing guidelines for veterinary medicine (p. 10),
 - specifying EU legislation currently in legislative procedure relating to veterinary medicine, particularly regarding the question of which antimicrobials are reserved for human use (p. 10),
 - motivating “stakeholders” – such as in the areas of health, food and animal husbandry – to make more “responsible” use of antimicrobials (p. 11) and
 - creating incentives for “stakeholders” to use alternatives (p. 11).

Combating AMR in the environment

- The Commission wants to step up the fight against AMR in the environment – particularly in the case of water protection – inter alia by way of a proposal on reducing pharmaceuticals in the environment (p. 10, 11).

► **Boosting research, development and innovation on combating AMR**

Detection, surveillance and control of infectious diseases and AMR

- The Commission wants to support research inter alia in the following areas (p. 13):
 - the spread of AMR, particularly the pathways of transmission between animals and humans,
 - measures to prevent the development and spread of AMR particularly in hospitals, communities and animal husbandry,
 - early detection of AMR including by way of IT solutions and
 - electronic health (eHealth) solutions to improve the detection of disease outbreaks, such as to ensure more targeted prescription of antimicrobials.

Development of antimicrobials and alternatives, diagnostics and vaccinations

- The Commission wants – e.g. with its “Horizon 2020 Program” for Research and Innovation – inter alia to support:
 - the development of new antimicrobials and alternative treatments (p. 13),
 - the development of new diagnostic tools – i.e. products to diagnose infections or AMR such as on-site tests for doctors – particularly in the form of IT solutions (p. 14),
 - the development of vaccines for humans and animals (p. 14),
 - the improved use of available antimicrobials (p. 13),
 - an EU-wide clinical research network, which will inter alia speed up clinical studies on antimicrobial products and lower their costs (p. 13).
 - the development of [undefined] “economic models”, which give companies greater incentive to develop vaccines, diagnostics and alternative treatments (p. 15) and
 - the development of new or improved “Health Technology Assessment” (HTA) approaches – i.e. methods to assess the efficiency of new technologies – (p. 15).

Combating AMR in the environment

- The Commission wants inter alia to support (p. 16):
 - research into the release and spread of antimicrobials and resistant pathogens into the environment and
 - the development of risk assessment and monitoring methodologies for AMR in the environment as well as technologies enabling the degradation of antimicrobials in the environment.

► World-wide action to combat AMR

- The Commission will continue to contribute to international organisations – such as the World Health Organisation (WHO) – (p. 17) on inter alia
 - the development of international frameworks, standards and guidelines to combat AMR,
 - the development of a global AMR monitoring system under the WHO Global Action Plan to combat AMR.
- The Commission wants to support worldwide harmonisation of the registration of pharmaceuticals (p. 17).
- The Commission wants to strengthen collaboration with third countries in combating AMR by
 - trying to incorporate EU measures for combating AMR into trade agreements (p.18),
 - exchanging ideas with the European Parliament, Member States and stakeholders on how to avoid competitive disadvantages for EU producers as a result of measures to combat AMR (p. 18) and
 - supporting existing EU candidate and potential candidate countries as well as other third countries covered by the European Neighbourhood Policy, to align their regulations with EU legislation (p. 18).
- The Commission wants to support developing countries to combat AMR, inter alia by way of (p. 19):
 - regional AMR training workshops in the areas of food and animal health and
 - programmes to combat infectious diseases – such as the “Global Alliance for Vaccines and Immunisations (GAVI)” – in the “least developed countries”.
- The Commission wants to promote a more globally oriented and coordinated research, such as between international research initiatives (p. 19).

Policy Context

In 2001, the Commission published its “Community Strategy against Antimicrobial Resistance” [COM(2001) 333]. This was followed, in 2011, by the “Action Plan against the Rising Threats from Antimicrobial Resistance” [COM(2011) 748], which already incorporated the concept of “One Health” (p. 3). Nevertheless, the AMR problem continued to increase. In June 2016, the Council published a Conclusion calling for a comprehensive new action plan (p. 4). In addition, a review of the 2011 Action Plan [SWD(2016) 347] was carried out and, in the spring of 2017, in the run-up to the new Action Plan, a public consultation took place (p. 4).

Options for Influencing the Political Process

Directorates General:	DG Health and Food Safety (leading)
Committees of the European Parliament:	Environment, Public Health and Food Safety (leading), Agriculture and Rural Development
Federal Ministries:	Health (leading)
Committees of the German Bundestag:	Health Committee (leading)

ASSESSMENT

Economic Impact Assessment

Ordoliberal Assessment

EU-wide efforts to combat AMR that include all Member States equally **are appropriate because resistant pathogens spread** – for example due to the movement of people or the food trade – **across borders**. Thus, national efforts by individual Member States to combat AMR may easily be impaired by insufficient measures taken by other Member States. Even EU measures alone do not provide a truly effective means of combating AMR. Dangerous, multi-resistant pathogens also come to the EU from third countries. Amid globalisation, the problem of the cross-border spread of AMR has been exacerbated by increased movement of people and trade in goods. **The EU’s efforts**, spearheaded by the Commission, **for worldwide action to combat AMR** through contribution to international organisations and collaboration with third countries, particularly developing countries, **are therefore also essential for successfully combating AMR in the EU**.

Impact on efficiency and individual freedom of choice

Only effective monitoring and use of data can facilitate a more science-based approach in combating AMR. Defining evidence-based outcome indicators for measuring progress in combating AMR can support effective action because measuring the success of measures taken is the only way to judge whether they are effective or need to be extended or modified. Likewise, a model for measuring the cost-effectiveness of national measures enables the Member States to assess their own measures more effectively and to adapt them appropriately on the basis of these findings.

Reducing the use of antimicrobials is essential for combating AMR because excessive use is one of the main causes of AMR.

Improving the prevention and control of infection plays an important role in this since it helps to ensure that diseases do not arise in the first place and thus antimicrobials do not need to be used so frequently. Vaccinations, for example, prevent the incidence and spread of bacterial infections not only directly but also by warding off secondary bacterial infections which can often occur when viral infections – such as influenza – weaken the immune system. Moreover, the development of modern diagnostic techniques is necessary to enable doctors themselves to tell the difference between bacterial and viral infections and to determine resistance on-site. In many cases, this can prevent the unnecessary or inappropriate use of antibiotics. Existing diagnostics are frequently impracticable because results often come too late, e.g. only after several days.

Limiting the use of antimicrobials admittedly amounts to market intervention, i.e. the rationing of demand, but **can be justified by the fact that the individual user** of an antimicrobial promotes the development of AMR in relation to the particular product thus reducing the benefit of the product for subsequent users whilst not taking account of the corresponding social costs when making the decision to use them. The consequence is that the individual user **tends to use more antimicrobials** and more frequently **than is socially justifiable**. This is true for the use of antimicrobials in hospitals and in prescriptions from doctors as well as in animal husbandry.

Raising awareness for and understanding of AMR can also prevent users from using antimicrobials inappropriately or in situations where they do not work. Many users, for example, fail to take antibiotics for the entire prescribed period of use and therefore do not fully eliminate the pathogens or they wrongly use antibiotics against viral infections. This sort of use favours AMR, wastes resources and may even cause harm to users.

EU aid for the development of new antimicrobials – particularly antibiotics – **will help to cover future needs** for new drugs. It is also **unproblematic in ordopolitical terms insofar as it is restricted to pre-competitive basic research** for the discovery of new effective approaches – like that conducted in universities for example – because this does not put individual companies at an advantage and does not have the effect of distorting competition.

Impact on Growth and Employment

Negligible.

Impact on Europe as a business location

Negligible.

Legal Assessment

Legislative Competency

The EU can adopt measures to supplement the health protection policies of Member States (Art. 168 (1), sub-para. 2, sentence 1 TFEU). This includes, in particular, measures for monitoring, early warning of and combating serious cross-border threats to health (Art. 168 (1) sub-para. 2, sentence 2, and (5) TFEU) and therefore also antimicrobial resistance. However, the EU is only permitted to support the Member States and encourage cooperation between individual Member States (Art. 168 (2), sub-para. 1 TFEU), but not to adopt any measures which have the effect of harmonising the law of the Member States (Art. 2 (5) in conjunction with Art. 6 (a) TFEU). This does not apply to measures in the veterinary field which have as their direct objective the protection of public health (Art. 168 (4) (b) TFEU) nor to measures setting high standards of quality and safety for drugs and medicinal products (Art. 168 (4) (c) TFEU). In such cases, EU measures prevail (Art. 2 (2) TFEU).

The envisaged measures will mainly – insofar as this is currently conceivable – serve to encourage and support health protection measures in the Member States. Areas of harmonisation binding on the Member States are only envisaged in the veterinary field and serve the direct protection of public health – by preventing resistance in the case of animal diseases which can be passed to humans.

Subsidiarity

Subject to the wording of their content, the envisaged measures will probably comply with the principle of subsidiarity because antimicrobial resistance is a cross-border risk and combating it at a global and EU level is more effective than at national level.

Proportionality with Respect to Member States

Dependent on the actual wording of the measure.

Conclusion

Efforts to combat AMR are advisable both EU wide and globally because resistant pathogens spread across borders. Reducing the use of antimicrobials is essential for combating AMR. Limiting the use can be justified by the fact that the individual user tends to use more antimicrobials than is socially justifiable. EU aid for the development of new antimicrobials will help to cover future needs. It is unproblematic in ordopolitical terms insofar as it is restricted to basic research.