

### EU HEALTH POLICY PLATFORM

### JOINT STATEMENT ON ANTIMICROBIAL RESISTANCE (AMR)

#### November 2017

This Joint Statement includes a two-page Executive Summary summarising the key points, presented as a **Call to Action** to European policymakers.

As civil society stakeholders, through the European Public Health Alliance (EPHA), we acknowledge the benefits of legitimate stakeholder partnerships to support delivery of the new Action Plan and extend our support to the European Commission on this most important issue.

#### INTRODUCTION

Led by EPHA, the undersigned organisations welcome the European Commission's new **EU One Health Action Plan against AMR**<sup>1</sup>, as proof of the need for joint efforts to combat the issue at European and global level. The Action Plan explicitly takes a multi-sectoral approach, and it embraces the needed global vision by linking EU efforts with those of international actors (incl. WHO, OECD, UN, G20, G7, TATFAR, OIE, FAO) and aiming to include AMR in trade agreements. It also mentions possibilities for funding Member States' actions against AMR and seeks to boost research and innovation in areas such as the development of new antimicrobials and alternative products, vaccines and diagnostic tests for treatment of infectious diseases in humans and animals.

The objective of this Joint Statement is to highlight areas where its signatories feel that more action is required than what is outlined in the Action Plan. In particular, we ask the European Commission and its Executive Agencies to provide extensive support, in terms of expertise and resources (including financial), to Member States and regions for the development and implementation of Action Plans given the persistent, significant differences in AMR prevalence and antimicrobial consumption in the European Union. We believe that extensive EU support will be indispensable to attain the objectives outlined in the three pillars of the Action Plan, including the ambition to act as a global best practice region, in the context of achieving the Sustainable Development Goals (SDGs).

Underlining that AMR is a complex and multi-faceted cross-border threat to health that cannot be tackled by individual countries alone, the signatories would like Europe to assume a strong role in the battle against AMR, which includes making full use of legislative and soft powers in a comprehensive and joined-up effort.

Further collaborative action needs to be taken now to implement strategic aims as set in the new Action Plan to enhance public health and animal health - in the name of individuals and patients, as well as for the benefit of European and national economies.

#### PRIORITY AREAS TO WORK ON

EPHA and the members of the Thematic Network on AMR welcome the publication of a revised action plan to combat the threat of AMR within Europe, which we fully support. However, a

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<sup>&</sup>lt;sup>1</sup>European Commission (2017), A European One Health Action Plan against Antimicrobial Resistance (AMR). https://ec.europa.eu/health/amr/sites/amr/files/amr\_action\_plan\_2017\_en.pdf

number of shortfalls have been identified that threaten its ambition. We therefore ask the European Commission to consider the following points as a matter of priority:

#### 1. Involve civil society in AMR-One Health policymaking.

Civil society stakeholders<sup>2</sup> are key to the successful adoption and implementation of the Action Plan; however, they are not currently included in the One Health Network or formally part of the Joint Action on AMR and healthcare associated infections.

The signatories of this Statement strongly feel that the successful and effective implementation of a One Health approach depends on transparency and on inputs from a diverse set of actors, including civil society organisations and NGOs, who are reliable partners in delivering the required set of measures and bringing about cultural change.

An appropriate and inclusive One Health civil society stakeholder group on AMR should be created and funded by the European Commission, which could potentially continue the work of the Thematic Network on AMR.

# 2. Support the development and implementation of National Action Plans and allocate adequate European funds to actions against AMR.

The annual data sets released by ECDC reveal enduring and significant differences in AMR prevalence and consumption of antimicrobials between countries in the European Union, and there are also large differences between regions within certain countries. AMR is often the most serious in countries where financial and human resources that can be mobilised to fight it are also the most limited. Measures against AMR require substantial and urgent investment in, *inter alia*, healthcare infrastructure (including technology), surveillance and monitoring systems, laboratory equipment, awareness-raising and professional training.

The UK Review on AMR has estimated the total cost of global action against AMR to 40 billion USD over 10 years and presents a compelling case to invest to reduce future human and financial loss in the future<sup>3</sup>.

The Action Plan requires investment and should therefore be accompanied by development and implementation funds for the Member States: a European AMR Fund should be created, which could be replenished in various ways (e.g. taxation, "pay or play" schemes as proposed by the UK Review on AMR<sup>4</sup>). The Fund should support national and regional health systems that lack the necessary operational infrastructure, technology, and skilled health workforce to adapt best practices to their circumstances. Surveillance systems should be enlarged to cover also results from easy applicable and rapid diagnostics for use in clinical practice.

Likewise, many countries are unaware of existing EU funds to combat AMR, spread across different programmes, which could be drawn upon for implementing national actions. Clear EU

 <sup>&</sup>lt;sup>2</sup> For the purpose of this statement, "civil society" is used as an umbrella term for a diverse set of contributors including healthcare and veterinary professionals, students, patients and consumers, members of the public health research community and many other stakeholders active at European, national and regional level.
 <sup>3</sup> O'Neill, J. (2016), *Tackling drug-resistant infections globally: final report and recommendations*

<sup>&</sup>lt;sup>4</sup> lbid., p.67

guidance and simplification is needed on how to access them. There should also be a robust assessment of their impact in relation to national targets.

#### 3. Address all aspects of the One Health approach.

The new Action Plan defines One Health as "a term used to describe a principle which recognises that human and animal health are interconnected, that diseases are transmitted from humans to animals and vice versa and must therefore be tackled in both. The One Health approach also encompasses the environment, another link between humans and animals and likewise a potential source of new resistant microorganisms"<sup>5</sup>. It thus recognises interfaces and transmission dynamics between humans, animals, plants and the environment as well as shared responsibilities with regard to AMR.

In comparison to human health, the Action Plan contains fewer initiatives in the area of animal health, agriculture and aquaculture. There is thus an opportunity for further action given the fact that, despite a decreasing trend, the 2017 Joint-Interagency (JIACRA) Report by EMA, ECDC and EFSA reveals that total consumption of antibiotics remains high in some countries in animals and/or in people<sup>6</sup>. Additionally, there is a risk of transmission of resistant bacteria between animals and people, e.g. via food products (especially meat and dairy), manure and faeces (leaving traces on fruit and vegetables), contamination of soil and rivers, and direct contact (farm animals and pets). It will be important to ensure the most effective implementation of the new EU Animal Health Law to improve husbandry practices, promote disease prevention through comprehensive animal health management including vaccination, hygiene and biosecurity measures, and reduce the need for antimicrobials in food-products and medicated feed offers an opportunity to effectively phase out the routine preventive use of antibiotics in livestock production. This would help ensure they remain effective where their use is vital, i.e. to treat sick animals.

Although the new Action Plan acknowledges the environment as a potential source of new resistant microorganisms, it calls for more research to better understand its contribution to the global spread of antimicrobial resistance in order to allow a risk-based approach. It also expresses the need for more evidence on the impact of industrial pollution by pharmaceutical companies without taking into account already existing evidence<sup>7</sup>, thereby postponing action. For example, the UK Review on AMR highlights growing evidence that the release of active pharmaceutical ingredients (APIs) into local waste waters acts as a driver for the development of drug resistance<sup>8</sup>, referring to a 2007 study by Swedish researchers<sup>9</sup>. This can quickly become a global problem, as resistant bacteria in the environment spread to people and animals and via international travel and trade worldwide.

To mitigate this situation, compliance with Good Manufacturing Practices (which include environmental criteria to be met by pharmaceutical manufacturers) should be encouraged, as

<sup>&</sup>lt;sup>5</sup> lbid., p.4

<sup>&</sup>lt;sup>6</sup> JIACRA Report, p.

 <sup>&</sup>lt;sup>7</sup> For example, a series of report released by Changing Markets Foundation and partners: <u>https://changingmarkets.org/portfolio/bad-medicine/</u>
 <sup>8</sup> O'Neill, J., op. cit., p.30

<sup>&</sup>lt;sup>9</sup> Larsson, DGI, Pollution from drug manufacturing: Review and perspectives. Philosophical Transactions of the Royal Society B, 2014, 369.

well as transparency in global supply chains and ethical procurement policies. Antibiotic residues in ground and surface water should be monitored to ensure compliance with the European Commission's forthcoming strategic approach to Pharmaceuticals in the Environment<sup>10</sup>. Thorough site inspections of pharmaceutical factories based outside of the European Union should be carried out by EU competent authorities with greater frequency to ensure that companies comply with GMP rules.

From a One Health perspective, there are major data gaps regarding European surveillance and monitoring in all dimensions of AMR: human medicine, agriculture and the environment.

Furthermore, it is necessary to frame AMR more forcefully as a serious and urgent public health problem with serious and life-threatening consequences for humans and animals. It is therefore extremely important to promote prudent use of antibiotics, especially last-line antibiotics, in hospitals and other healthcare settings, as well as at home and in all other relevant environments (e.g. long-term care).

In addition, AMR is a development issue since lack of access to effective antibiotics and shortages remains a serious problem in many countries, including in Europe, and a rise in AMR would amplify existing health inequalities as vulnerable groups will suffer first when fewer antibiotics are available<sup>11</sup>. Moreover, availability and access to effective antimicrobial medicines is a prerequisite for attaining most of the 17 SDGs<sup>12</sup>.

International trade and increased mobility of people and animals in our globalised world are further factors that require consideration, e.g. through imports of meat and other food products from countries that do not necessarily follow the same high standards as the EU, as drug-resistant bacteria can easily cross continents.

Europe must thus take a broad view and achieve policy coherence defining clear ambitions to achieve between different areas (healthcare, agriculture, food safety, environment, consumer policies, trade, technology, innovation, development, etc.) to take global leadership.

#### 4. Improve and regularly update the data on AMR burden in Europe.

Knowing the real extent of the problem is a prerequisite for allocating appropriate resources and tackling AMR effectively. The signatories support the collection of improved and timely data on the AMR burden. Their use should drive actions that improve the risks from AMR and reassure Europeans that funds allocated to this purpose are used appropriately.

An outdated figure from 2007 - 25,000 deaths caused annually by AMR in the EU, Iceland and Norway - is still quoted in the Action Plan although it refers to only five antibiotic-resistant bacteria.<sup>13</sup> The signatories are pleased that ECDC will be releasing updated figures that will

<sup>&</sup>lt;sup>10</sup> A Roadmap is available at <u>https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-2210630\_en</u>

<sup>&</sup>lt;sup>1</sup>Jasovský, Dušan et al., (2016), Antimicrobial Resistance—a Threat to the World's Sustainable Development. *Uppsala Journal of Medical Sciences* 1213 (2016): 159–164. *PMC*. Web. 17 Oct. 2017.

<sup>&</sup>lt;sup>2</sup> Final note prepared by OECD, WHO, FAO and OIE, 29 June 2017, *Tackling Antimicrobial Resistance, Ensuring Sustainable R&D*.

https://www.google.be/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0ahUKEwjuwo7S1YvXAh VCWBoKHeD5D0EQFggrMAA&url=http%3A%2F%2Fwww.oecd.org%2Fg20%2Fsummits%2Fhamburg%2FTackling-Antimicrobial-Resistance-Sustainable-RD.pdf&usg=A0vVaw2v9q63GDBsjHiCfA21u887

<sup>&</sup>lt;sup>18</sup> ECDC/EMEA Joint Technical Report: The bacterial challenge: time to react. 2009, EMEA/576176/2009.

cover more types of antibiotic-resistant bacteria so that AMR actions can be improved, commensurate with the current status quo.

In addition, it will be necessary to develop a system that contains updated statistics on a regular basis. In the veterinary sector, the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC<sup>14</sup>) is collecting sales/use data of antibiotics in animals, and the European Food Safety Agency (EFSA) is collecting resistance data in animals and animal products. It is important to continue this monitoring and work in a holistic and coordinated approach under the scope of One Health. The JIACRA reports provide a good example of collecting and analysing aggregated sales data of antimicrobials for humans and animals, and this effort should be continued.

Data collection does not only need to be intensified, but also improved. The size of samples has a big impact on the reliability of the data resulting in a potentially limited response to a pressing issue. This was already highlighted by the WHO in its "AMR Global Report on Surveillance"<sup>5</sup> and remains valid. Furthermore, the way in which the data are quantified can be improved in certain countries, including most of the Member States the ECDC reports on.<sup>6</sup> It is important for Member States to collaborate in the area of research and increase funding by enhancing their coordination and collaborations, research activities, and pooling resources.<sup>77</sup>

#### 5. Analyse and benchmark collected data.

The EU scientific agencies (ECDC, EFSA, EMA) have delivered on the Action Plan's commitment to developing a set of key outcome indicators to assess progress on reduction of AMR and antimicrobial consumption<sup>18</sup>. This provides an opportunity towards targets and goals supporting a reduction in AMR. The signatories feel that establishing optimal targets at country level is crucial, and that there is European added value in helping to define and attain them, as well as to ensure that they are SMART. Ambitious, time-bound quantitative and relative reduction targets are a core element of successful AMR strategies in several European countries, where they have not only been achieved but even surpassed<sup>19, 20,21</sup>. Moreover, all European countries should provide comparable monitoring data to ensure that national contributions follow a holistic One Health approach. The One Health-AMR Network should be required to motivate, assist and monitor Member States to meet the commitments proposed in each national Action Plan and check that actions are sufficient and effective.

The existing data on antibiotic sales/use, germ resistance levels, the number of healthcare associated infections or communicable diseases and the AMR burden should serve through the new Action Plan as a benchmark for national reduction targets. Making use of such benchmarking systems would make it easier and more transparent to compare European countries' efforts in implementing actions to tackle AMR, including commitments for overall reduction of AMR prevalence, overall reduction in HCAI, reduction of excessive consumption

<sup>&</sup>lt;sup>14</sup><u>http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document\_listing/document\_listing\_000302.jsp</u> <sup>15</sup> WHO (2014). Antimicrobial Resistance: Global Report on Surveillance. Available at:

http://www.who.int/drugresistance/documents/surveillancereport/en/

<sup>&</sup>lt;sup>16</sup> <u>http://www.sciencedirect.com/science/article/pii/S2052297515000293</u>
<sup>17</sup> http://www.sciencedirect.com/science/article/pii/S1473309915003503

 <sup>&</sup>lt;sup>18</sup> ECDC, EFSA and EMA Joint Scientific Opinion on a list of outcome indicators as regards surveillance of antimicrobial resistance and antimicrobial consumption in humans and food-producing animals

<sup>&</sup>lt;sup>19</sup> Letter to Dutch Parliament about the approach to AMR (see p. 7)

<sup>&</sup>lt;sup>20</sup> National Strategy against Antibiotic Resistance 2015–2020

<sup>&</sup>lt;sup>21</sup> Ecoantibio: action and experience of containment of AMR in veterinary sector (see slide 14)

and reduction in antimicrobial prescriptions in humans and animals. Exchange of experience through the One Health Network should be encouraged and promoted.

In the veterinary field, a well-established system of surveillance and monitoring of sales of antibiotics in food producing animals has been implemented (ESVAC). Nevertheless, this should be further improved, e.g. by collecting mandatory information on antibiotic consumption by animal species, age categories and type of farming system, etc. to allow for benchmarking and better analysis of the collected information.

#### 6. Make full use of EU legislative powers in AMR relevant sectors.

The lack of a legislative component on the human health side to combat AMR in the Action Plan is likely to increase the current gaps between Member States. In contrast, the new draft veterinary medicines and medicated feed proposals and the recently adopted "Animal Health Law" give the EU a strong legislative basis for tackling AMR in animal health. The updated EU veterinary medicines law which is currently under discussion puts in the centre the fight against antimicrobial resistance and places emphasis on responsible use of antibiotics in animals. The European Parliament, when it voted last year<sup>22</sup>, supported prohibiting the routine preventive use of antibiotics, and restricting the veterinary use of antibiotics that are critically important (CIA) for human medicine, such as fluoroquinolones and cephalosporins (3<sup>rd</sup> and 4<sup>th</sup> generation). We now call on Member States to back these measures as swiftly as possible.

In line with the application of a One Health approach - it is important that EU legislation supports AMR action in other areas, *inter alia* in food safety, consumer protection, agriculture and environmental protection<sup>23</sup>. In healthcare policy, where EU competencies are limited, the gravity of AMR as a cross-border phenomenon requires increased inter-sectoral efforts. In particular, efforts on infection prevention practices, biosecurity and hygiene measures, prescription guidelines, rapid patient screening as well as monitoring and surveillance on a comparable basis should be facilitated.

Existing legislation on illegal practices related to non-pharmacy availability of antibiotics should be enforced at Member State level. An effective system of antibiotic labelling and packaging should be proposed to manufacturers to provide better information for consumers on appropriate use, disposal, and risks associated with misuse.

The use of antibiotics as growth promoters in animals has been banned since 2006. However, on a global level this is not yet the case, including in the United States. It is thus important that EU standards are adopted in other parts of the world and even more crucial that international trade agreements (e.g. TTIP) do not dismantle the progress made in Europe.

There is also a need for mandatory data collection at national level. As mentioned above, in the veterinary sector ESVAC has collected information on sales of antimicrobial medicines in food-producing animals across the EU since 2005. The report is presented annually and currently contains data from all EU Member States, Iceland, Norway and Switzerland. Although collection of data has been voluntary so far, it is expected to become mandatory once the new regulation on veterinary medicinal products is adopted and comes to force. Additionally, moving from

<sup>&</sup>lt;sup>22</sup> European Parliament press release (10 March 2016).

<sup>&</sup>lt;sup>23</sup> A. Garde / EPHA (2017). EU law and competence to tackle antimicrobial resistance.

sales data to collecting use data, as foreseen in the ESVAC vision and strategy 2016-2020<sup>24</sup>, will allow for a more thorough analysis of needs and impacts.

#### 7. Nurture and actively involve healthcare professionals, including students.

Doctors, pharmacists, nurses, veterinarians, dentists, other professions and students play a key role in averting the AMR health crisis. Hence, they must benefit from educational curricula and life-long learning through properly funded continuous professional training that allows them to act as antimicrobial stewards, champions, counsellors and good practice implementers. In addition, patients should have access to evidence-based, health literacy friendly information in order to make informed decisions about their care and treatment, in partnership with their health professionals.<sup>25</sup>

EU-wide curricula for health professionals and students should highlight the risks of AMR related to inappropriate prescribing, dosage, use, and disposal. The education and training of healthcare professionals is essential given that they play an important role in shaping patients' attitudes towards antimicrobials. A "One Health culture" should thus be integrated into educational curricula, and inter-sectorial collaboration should be strongly encouraged. Multidisciplinary common antimicrobial stewardship programmes should be established and facilitated by the EU throughout Europe, both on- and offline, to encourage collaborative responses to the problem.

All prescribers should be encouraged to become advocates of responsible use and practise the "as little as possible, as much as necessary" axiom. More national initiatives and responsible use guidelines<sup>26</sup>, linked to corrective action mechanisms, are needed, and the EU should promote and disseminate these via the One Health Network.

Best practices and actions demonstrating health professionals' many initiatives, e.g. to promote prudent use of antibiotics and antibiotic stewardship, raise awareness of AMR, and improve vaccination coverage<sup>27,28,29,30</sup> should be disseminated and encouraged across Europe. Already existing initiatives at European level (e.g., dissemination of the European Antibiotic Awareness Day communication toolkit for professionals in hospitals and other healthcare settings) shall be supported with sufficient funding and resources.

The EU Action Plan also does not address the chronic lack of specialised medical staff in some Member States, which is severely affecting the fight against AMR. The ECDC states that one of the measures to prevent the spread of highly resistant bacteria is ensuring that hospitals have an adequate ratio of appropriately trained infection control practitioners (ICP) to beds. A ratio of

<sup>&</sup>lt;sup>24</sup>http://www.ema.europa.eu/docs/en\_GB/document\_library/Regulatory\_and\_procedural\_guideline/2017/02/WC500 221116.pdf

<sup>&</sup>lt;sup>25</sup> The NICE guidelines produced in the UK in 2015 can provide a good example of what such a partnership should look like: <u>http://www.nice.org.uk/guidance/ng15</u>

<sup>&</sup>lt;sup>26</sup> For example, existing EU Guidelines for the prudent use of antimicrobials in human health and in veterinary medicine

<sup>&</sup>lt;sup>27</sup> PGEU (2017), *The Community Pharmacy Contribution to Tackling AMR*. <u>http://www.pgeu.eu/en/press/242:pr-pgeu-releases-best-practice-paper-on-amr.html</u>

<sup>28</sup> http://www.eahp.eu/practice-and-policy/antimicrobial-resistance

<sup>&</sup>lt;sup>29</sup> www.epruma.org

<sup>&</sup>lt;sup>30</sup> https://www.esicm.org/ictv-antimicrobial-resistance-call-for-action/

1 ICP per 250 beds has been the standard; newer evidence may support a ratio of 1 ICP per 100 beds. There is a wide variation of the ratio of ICPs to beds in hospitals across Europe<sup>31</sup>.

For example, in the 10 years since EU accession, more than 43,000 healthcare workers have asked Romanian authorities for the certificate of conformity needed to work in other Member States<sup>32</sup>, leaving the national doctors-to-patient ratio well below the European average. More specifically, a 2015 Ministry of Health report on the surveillance, prevention and control activities for healthcare associated infections in 11 healthcare facilities in Bucharest found that "the specialised staff needed for the control and prevention of nosocomial infections (microbiologist, epidemiologist, infectious diseases specialist) is lacking or insufficient".<sup>33</sup> Staff shortages in human healthcare systems and in the veterinary sector, as well as lack of other health system resources contribute to escalating AMR related problems both at national level and in a cross-border context.<sup>34</sup>

## 8. Put into practice existing evidence and continue scientific research to get a better understanding.

Existing knowledge has already helped some EU Member States to become best practice examples in addressing AMR and their measures should be quickly taken over and adapted by countries lagging behind.

Last year, EFSA and EMA have jointly reviewed measures taken in the EU to reduce the need for and use of antimicrobials in food-producing animals, and the resultant impacts on antimicrobial resistance (RONAFA Opinion)<sup>35</sup>. Reduction strategies have been implemented successfully in some Member States. For example, The Netherlands has phased out routine preventative use of antibiotics in animals, has achieved large reductions in farm antibiotics use and cut farm use of critically important antibiotics in main food-animal species by over 90% in three years, contributing to a fall of livestock-associated MRSA in people<sup>36</sup>. Sweden has achieved an over 40% decrease of antibiotics prescription since mid-1990s in healthcare, while in animal health, it has achieved the lowest use of antibiotics in the EU, with a 60% decrease since the mid-1980s, and has banned the routine use of antibiotics since 1980s<sup>37</sup>. Also in the field of animal health, Denmark achieved a large reduction of farm antibiotic use, while targeted initiatives (e.g., "yellow card") have resulted in 22% reduction of antibiotics use in pigs, five years before the target year<sup>38</sup>. Germany succeeded in reducing the use of antibiotics by 57% since 201<sup>p9</sup>, and recent figures published by ESVAC also show significant reductions.<sup>40</sup> A total of 30 European countries submitted data on sales or prescriptions to ESVAC in 2015; for the 25 countries reporting sales data for 2011-2015, an overall decline of 13.4% in sales of CIAs was

<sup>33</sup> http://www.comunicatemedicale.ro/boli-infectioase/3859-rezultate-evaluare-prezenta-infec-tii-nosocomiale-in-

<sup>&</sup>lt;sup>31</sup> https://ecdc.europa.eu/sites/portal/files/media/en/publications/Publications/antibiotic-resistance-policy-briefing.pdf <sup>32</sup> http://www.ms.ro/wp-content/uploads/2016/10/3.Notă-fundamentare.pdf

spitale-si-planul-de-masuri-ce-va-fi-elaborat-de-ministerul-sanatatii/

<sup>&</sup>lt;sup>34</sup> EPHA (2017), In the Red Zone. Antimicrobial Resistance – Lessons from Romania. Available at <u>https://epha.org/in-the-red-zone/</u>

<sup>35</sup> See: https://www.efsa.europa.eu/en/efsajournal/pub/4666

<sup>&</sup>lt;sup>36</sup> http://www.saveourantibiotics.org/the-issue/learning-from-others/

<sup>&</sup>lt;sup>37</sup> Ministry of Health and Social Affairs, Swedish strategy to combat antibiotic resistance (2016)

<sup>&</sup>lt;sup>38</sup> <u>https://www.foedevarestyrelsen.dk/english/Animal/MRSA/Pages/Low\_use\_of\_antibiotic\_in\_Denmark.aspx</u> <sup>39</sup> <u>https://www.bvl.bund.de/DE/08\_Presseinfothek/01\_Fuerjournalisten/01\_Presse\_und\_Hintergrundinformationen/05\_T</u>

ierarzneimittel/2017/\_09\_11\_pi\_Antibiotikaabgabemenge2016.html

<sup>&</sup>lt;sup>40</sup> http://www.ema.europa.eu/docs/en\_GB/document\_library/Report/2017/10/WC500236750.pdf

observed, and a noticeable decrease in sales was also identified for some of the most-selling countries over the same period.

In recent years, G7 countries have also been sharing their best practice examples in different AMR action areas, such as: strengthening the One Health approach, where they emphasize the need for "building a bridge between public health, health care, animal health and the agricultural sector is essential and has to be improved in all fields (politics, economics, and research) and on all levels (international, national, and local)"; Combating and preventing infections through a range of interventions like hand hygiene, the use of quality indicators to assess performance in hospitals, development of guidelines and training for healthcare professionals and establishing "networks including hospitals, ambulatory care, nursing homes, laboratories and public health institutions (which) contribute to the implementation of interventions across all health sectors"; promoting the responsible use of antibiotics through antibiotic stewardship programmes built on evidence-based recommendations and guidelines. awareness- and knowledge-raising among healthcare professionals and the general public as well as improving animal health in order to reduce antibiotic treatment in food production; strengthening the surveillance systems that monitor AMR and antibiotic use, HAI, and animal health, which allow early detection of resistance and effective interventions; and supporting research and development "by increasing basic research, epidemiological research as well as the development of and access to new antimicrobials, treatment alternatives and rapid diagnostic tools for use in both people and animals.41"

Although the new Action Plan includes research directions that are key to responding effectively to the AMR crisis in the future, it does not mention the need for more social science and behavioural psychology research that would support wider implementation of interventions that are already yielding results in some European countries. Such research would be particularly useful to understand the various reasons for irrational and unnecessary consumption and prescribing, which are often culturally, socially and economically determined. The EU should enable research into assessing and comparing behavioural change interventions for antimicrobial prescribing that take into account cultural differences, as well as translational research into how antimicrobials are being used.

9. Adopt a "prevention is better than cure" approach.

Preventing infection within and outside of health and care settings is vital to reduce the demand for antibiotics.

The Action Plan points out the important role of preventing infection, hygiene measures and other practices, which reduce the need for antimicrobials and consequently the opportunities for infectious microorganisms to develop and spread resistance. In spite of this, the Action Plan does not encourage actions to reduce healthcare associated infections (HAIs), such as the adoption of clear guidelines on active surveillance systems for key resistant bacteria to screen high risk patients or the use of innovative technologies to reduce infection spread and contamination of the environment.

<sup>&</sup>lt;sup>41</sup><u>https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3\_Downloads/G/G7/Best-Practices-Broschuere\_G7.pdf</u>

HAIs account for twice the burden of 31 infectious diseases<sup>42</sup>. C.difficile infections alone – the 8th most frequently detected microorganism among HAIs - are responsible for over 120,000 cases in acute care hospitals in the EU/EEA each year.<sup>43</sup> A concrete action plan should be developed to ensure follow-up and implementation of the relevant parts of the 2009 Council recommendation on patient safety including the prevention and control of healthcare associated infections<sup>44</sup>, subsequent reports by the European Parliament<sup>45</sup>, and the 2014 Council conclusions on Patient Safety and Quality of Care.<sup>46</sup>

Moreover - to scale up prevention and ensure a full range of options - the potential contribution of alternative practices that can help maintain health and diminish the reliance on antimicrobials should be further explored.

There is a great need to increase investment in public health measures for preventing noncommunicable diseases (NCDs), including dental caries. For example, in the UK tooth decay is the most common reason for children aged between five and nine to require hospital and antibiotic treatment.<sup>47</sup> Increased investment in time, resources, public health prevention measures and messages are essential.

In addition, multi-stakeholder platforms and cross-sectorial alliances to fight AMR should be encouraged to engage different interests in a common goal.48,49

#### 10. Support and promote the use of rapid diagnostic tests (RDTs).

RDTs are necessary tools, in both medical and veterinary practice, to assist with the identification of the causing factor of a disease and with the selection of the right antimicrobial. Under the Joint Programming Initiative on AMR<sup>50</sup>, a one-year working group is set up to identify barriers for the development, implementation and use of rapid diagnostic tests (RTDs), and to develop a roadmap for future solutions to tackle AMR. Unfortunately, the new Action Plan does not sufficiently address the issues of uptake and access to RDTs in the human and veterinary sectors. Among others, there is a need for a European monitoring programme, a boost for the development of clinical evidence, new financial/reimbursement models at country level that cover RDTs, and the establishment of a rapid diagnostic market stimulus in Europe.

Funding should be provided for, and companies should be encouraged to invest in, diagnostic tools, including rapid diagnostic tests for use in humans and animals. The UK Review on AMR has noted that, due to reliance on empirical diagnosis, viral infections are often misdiagnosed as bacterial infections and vice versa. More refined tests will enable more precise prescribing,

<sup>&</sup>lt;sup>42</sup> Cassini, A. & Plachouras, D. Burden of healthcare associated infections in Europe. Presentation at Second Global Ministerial Summit on Patient Safety, Bonn, 29-30 March 2017

<sup>43</sup> ECDC website, https://ecdc.europa.eu/en/clostridium-difficile-infections/facts

<sup>&</sup>lt;sup>44</sup> Council Recommendation of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections (2009/C 151/01)

<sup>&</sup>lt;sup>45</sup> European Parliament Report 2013/2022(INI); European Parliament report 2014/2207(INI)

<sup>&</sup>lt;sup>46</sup> Council conclusions on patient safety and quality of care, including the prevention and control of healthcareassociated infections and antimicrobial resistance (15441/14)

<sup>&</sup>lt;sup>47</sup> https://www.rcseng.ac.uk/library-and-publications/college-publications/docs/report-childrens-oral-health/ 48 For example, the FVE-CPME-CED Memorandum of Understanding (2015)

http://doc.cpme.eu:591/adopted/2015/CPME\_AD\_Board\_23052015\_016\_FINAL\_EN\_FVE\_CPME\_MoU\_One\_Health. pdf <sup>49</sup> CPME-CED-FVE joint guidelines to the public and to health professionals,

http://fve.org/veterinary/medicines.php#ONEHEALTH http://fve.org/veterinary/medicines.php#ONEHEALTH\_HP 50 http://www.jpiamr.eu/

thereby reducing unnecessary use of antibiotics. Remuneration and reimbursement schemes should facilitate the use of appropriate diagnosis tests before any antibiotic prescription in human and animal health.

#### 11. Empower patients and raise public awareness.

According to the European Commission's Eurobarometer Survey on antibiotic consumption, large numbers of Europeans are unaware that antibiotics are ineffective against viruses (57%) and against colds and influenza (44%). The differences between countries and within social groups are quite large. The use of antibiotics is higher among those with lower levels of education (39%) and in worse economic circumstances (44%). It has been shown that consumption decreases as knowledge increases, as well as that knowledge increases among people who have received information on antibiotics. Health literacy<sup>51</sup> and awareness-raising thus have a great role to play in this respect.

Relevant policies preventing illegal sale of pharmaceuticals, the common EU logo initiative<sup>52</sup>, but also health literacy policies and antibiotics awareness campaigns help improve people's (including animal keepers') knowledge and encourage prudent use behaviours.

<sup>&</sup>lt;sup>51</sup>See for example WHO (2013), *Health Literacy - The Solid Facts*. Available at www.euro.who.int/\_\_data/assets/pdf\_file/0008/190655/e96854.pdf <sup>52</sup>https://ec.europa.eu/health/human-use/eu-logo\_en

#### **Signing Organisations**

Association for Natural Medicine in Europe BEUC : The European Consumer Organisation **Biomérieux** Center for Clinical Epidemiology and Outcomes Research (CLEO) **Changing Markets Foundation** Clinica Occulista, Policlinico San Martino CNRS **Council of European Dentists** Department of Public Health, University of Medicine, Tirana Albania EU Eye European Academy of Paediatrics European Community of Consumer Cooperatives European Federation for Complementary and Alternative Medicine **European Patients Forum** European Pharmaceutical Students Association European Public Health Alliance **European Respiratory Society** European Society of Intensive Care Medicine ESICM **European Specialist Nurses Organisation** Federation of Veterinarians of Europe Fundoción para la Formación e Investigación de los Profesionales de la Salud de Extremadura, Junta de Extremedura Health Action International Health First Europe IDIVAL – Biomedical Research Institute, Spain International Federation of Medical Students' Associations Malta Health Network Medtech Europe Pharmaceutical Group of the European Union Romanian Health Observatory Royal College of Nursing **Royal College of Physicians** Vienna Vaccine Safety Initiative World Federation of Public Health Associations

