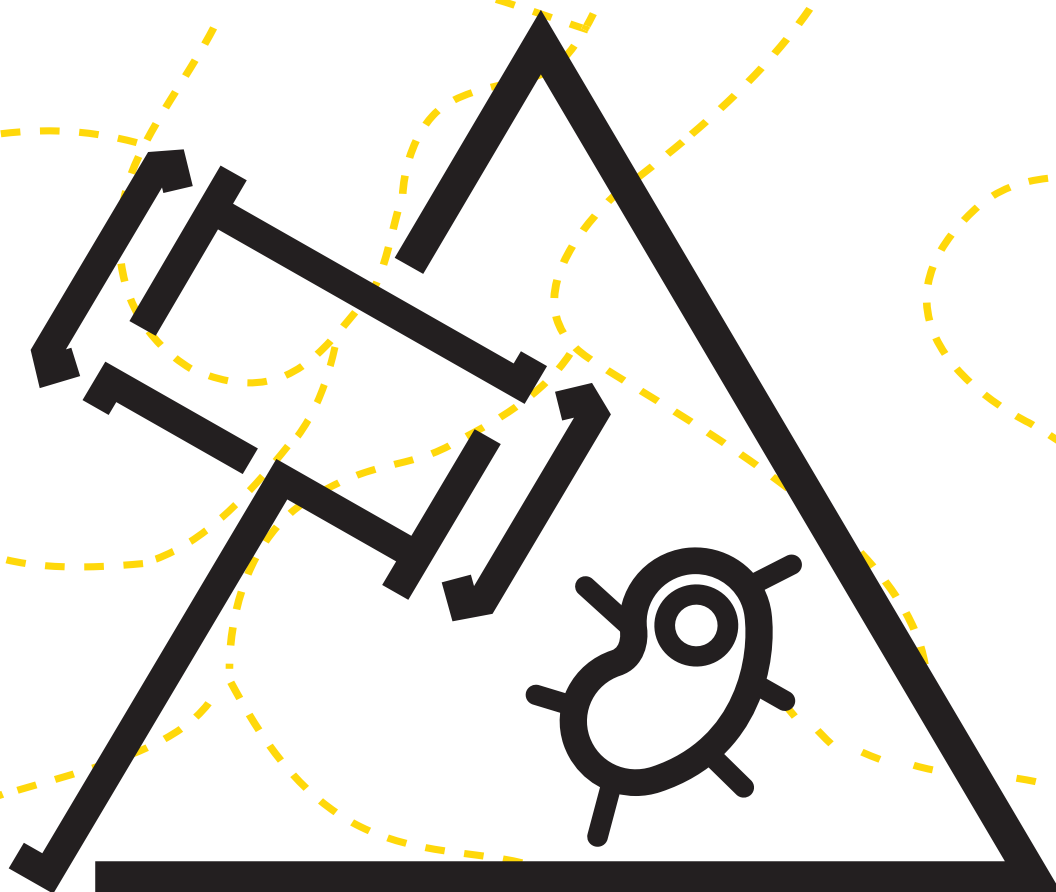




EUROPEAN  
HEALTH PARLIAMENT

# COMMITTEE ON ANTIMICROBIAL RESISTANCE

**Today's Actions  
for a Healthier Tomorrow**  
**2017-2018**



# COMMITTEE ON ANTIMICROBIAL RESISTANCE

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The views and opinion expressed in this article reflect the perspective of the European Health Parliament Committees collectively. It does not reflect the views of the individual EHP members, nor the views of their respective employers or partner organizations supporting the project.

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## Karin Kadenbach

**Member of the European Parliament & Rapporteur for the ENVI Committee's Own Initiative Report on AMR**



*If the European Health Parliament did not exist, we would have to invent it. It is great to see young, talented professionals so engaged in shaping the future of healthcare policies in Europe. As a parliamentarian, I fully support initiatives such as the EHP which promote innovative thinking and contribute in a very concrete way to improve the work of policy-makers. I have enjoyed the collaboration with the Committee on Antimicrobial Resistance (AMR) and look forward to continuing our work together to tackle the global public health threat posed by resistant bacteria. The AMR Committee has produced some interesting ideas that will certainly inspire my day-to-day work at the European Parliament. For example, they underline the importance of involving stakeholders and establishing clear accountability when implementing policies at all levels; they call for the introduction of per-unit dispensing of antibiotics in pharmacies to facilitate appropriate use; they also emphasise the urgent need for new economic models to incentivise R&D in new antibiotics and vaccines to fight AMR. My sincere congratulations!*

## Robert Madelin

**Chairman, Fipra International**



*The huge strength of the EHP lies in the very broad range of expertise it contains. And in a field such as AMR, breadth is the key success factor: because the drivers of misuse of antibiotics are often rooted in social attitudes and deep-rooted practice and habit. The perspective offered here also accurately pinpoints the need for the AMR challenge to be met with a single and coherent network of actors, covering the animal health as well as human health communities. Global cooperation is certainly a necessary tool, and I welcome the link made to trade policy, where I personally prefer to see carrots rather than sticks deployed in the trade field. Overall, the AMR report makes yet again the case for health in the broad sense to be a European Union strategic priority, and not an object of sacrifice on the altar of localism.*

# Executive summary

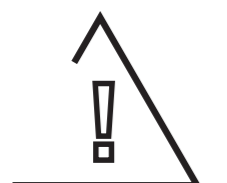
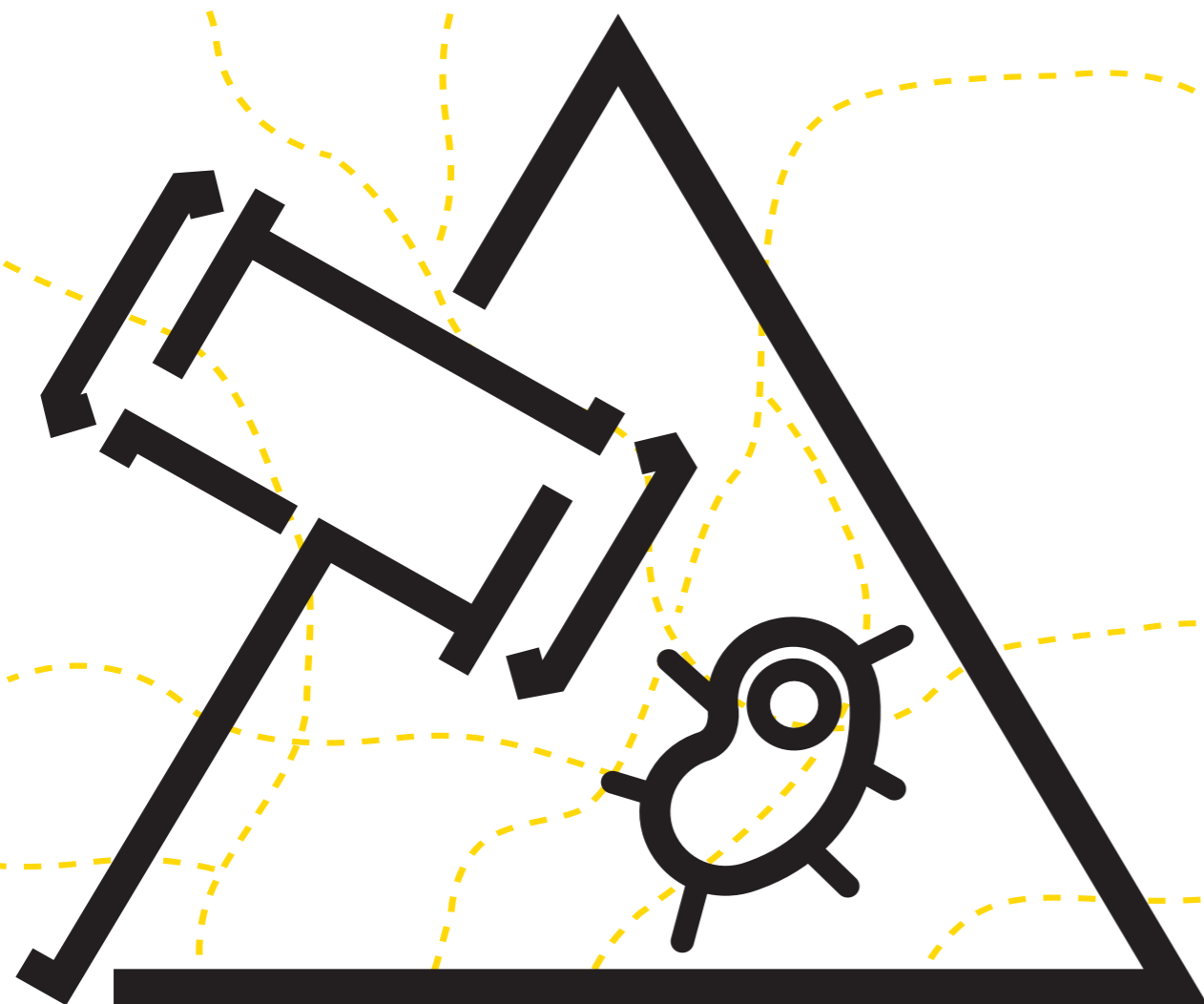
This report does not intend to merely echo the well identified priorities by the European Commission to tackle antimicrobial resistance (AMR), notably in the 2017 EU AMR Action Plan and the EU Prudent Use Guidelines.<sup>1</sup> We rather aim to present a non-exhaustive list of areas where closer cooperation can add value, and specific actions that, if properly implemented, can take us forward in the fight against AMR:

1. We suggest establishing an EU-level multi-stakeholder platform with **clear accountability mechanisms**, to support the work of the AMR One Health Network.
2. **Member States should consolidate their governance infrastructure** to implement AMR strategies, defining clear targets and responsibilities at appropriate levels.
3. **The scope of the work of the European Reference Networks should be expanded to cover emerging multi-drug resistant infections**, the improvement of patient treatment across the EU and the rapid exchange and analysis of data.
4. Given the key role **pharmacists** play in raising awareness about AMR, preventing infections and facilitating appropriate use of antibiotics, they **should be enabled to act as “public health ambassadors” and, for example, administer influenza vaccinations.**

5. **Per unit dispensing of antibiotics should be expanded across Member States** to increase appropriate use, adherence to treatment and reduce environmental impact.
6. We call for a **shift towards a prevention-based approach in animal health** to decrease the need for antibiotics. We also propose measures to increase transparency in the food chain to empower consumers to make informed choices.
7. We emphasise the importance of continuous **education of healthcare professionals on AMR**, and argue that prescription practices should be evidence-based.
8. EU Member States should **expand the use of green public procurement** of antibiotics to promote a “race to the top” in terms of sustainability.
9. New sustainable economic models should be implemented to **incentivise both early and late-stage R&D in new antibiotics and vaccines targeting areas of unmet need.**
10. The EU should aim to **export its best practices to third countries**, including by leveraging trade and development policy tools.

## WALKING THE TALK ON ANTIMICROBIAL RESISTANCE

### Today's Actions for a Healthier Tomorrow



BUILDING  
AWARENESS



PREDICTING  
THREATS



EFFECTIVE  
DECISION-MAKING

## Introduction

*"The thoughtless person playing with penicillin treatment is morally responsible for the death of the man who succumbs to infection with the penicillin-resistant organism."*

Sir Alexander Fleming

Since the discovery of penicillin in 1943, antibiotics (and other antimicrobial treatments) have saved millions of lives and enabled unprecedented progress in modern medicine, ranging from complex surgical procedures to life-saving chemotherapy regimens. However, their inappropriate use has fostered the development of antimicrobial resistance (AMR) in bacterial organisms. In the EU alone, 25,000 deaths per year can be attributed to AMR, an economic loss of 1,5 billion EUR. **The cost of no action is simply too high:** if not tackled properly, by 2050 AMR could take 700 million lives per year globally with an impact of approximately 10 billion USD. AMR's disease burden would thus surpass that of cancer.<sup>2</sup>

As AMR continues to accelerate, an insufficient number of novel treatments are reaching the market due to both scientific and business challenges. The doomsday scenario of a 'post-antibiotic era' in which small injuries or infections could lead to death is on course to become reality within the coming century unless we take urgent and coordinated action. The increased awareness of the scale of the AMR threat has led to a proliferation of scientific research and policy initiatives in the past decade. AMR has risen to the top of the healthcare political agenda, with politicians recognising at the highest level the urgency of developing a "One Health" response, bringing together the human health, animal health and environmental dimensions of AMR. However, political attention is fruitless without accountability and concrete actions implemented and monitored at local, regional and national level. As final result of our work, we have identified a non-exhaustive list of actions that, if implemented properly, can reduce the gap between high-level political declarations and practical implementation of AMR strategies at European and Member State level.

# Recommendations

## RECOMMENDATION #1

### Establish an EU-level multi-stakeholder platform with clear accountability mechanisms

Translating political commitments into tangible results requires a concerted and innovative effort. **We recommend that the European Commission establish an EU-level multi-stakeholder platform involving patients, academia, industry, clinicians and policy-makers.** This shall not replicate the stakeholder platform of the EU Joint Action on AMR and Healthcare-Associated Infections (EU-JAMRAI), but rather complement the work of the “One Health Network” that currently only comprises Member States representatives. Clear accountability should be established, by setting specific targets and deliverables for each stakeholder, to be monitored and peer-reviewed twice a year.

## RECOMMENDATION #2

### Establish an adequate governance infrastructure to implement AMR strategies

In order to effectively implement AMR strategies, each Member State should establish an adequate governance infrastructure, reflecting the different ways national health systems across EU are managed. This infrastructure should include (some of) the following roles:

- **A local AMR coordinator** for each healthcare organisation (e.g. hospital, community health services unit), responsible to ensure AMR strategies are appropriately implemented at local level, by promoting

the adoption of hygiene and infection control guidelines; training and counselling healthcare professionals; collecting, monitoring and reporting infections, antibiotic use and resistance data.<sup>3,4</sup>

- **A regional AMR coordinator** for each territorial unit within a country (e.g. region, district), if applicable. He/she ensures compliance with national AMR strategies and epidemiological monitoring of antimicrobial-resistant infections, by coordinating strategies between healthcare organisations, local (e.g. schools) and national institutions (e.g. Ministry of health, national agencies). This would be particularly useful for countries where local and regional authorities have a major responsibility for organizing and delivering health services (e.g. decentralised or partially decentralised systems such as Italy, Spain or Austria).
- **A national AMR coordinator** to ensure implementation of WHO and EU-level strategies at country level, report and discuss AMR-related data, manage research funds and relevant findings, and share best practices.<sup>5</sup>

## RECOMMENDATION #3

### Expand European Reference Networks to emerging multi-resistant infectious diseases

Limited information is available on the treatment of emerging multi-resistant bacterial infections. The rapid spread and progression of these infections requires a prompt response that could be facilitated by stronger, structured European collaboration. **We recommend expanding the European Reference Networks (ERNs) to cover emerging multidrug-resistant infectious diseases.** We believe that the ERN

model can be used to facilitate rapid exchange of information on resistant pathogens and on potential effective treatments, allowing patient access to top-level European specialists. Setting up a ERN for multidrug-resistant infectious diseases can create opportunities for data sharing and, in the longer term, facilitate clinical trial recruitment and foster research. This network could also create a bridge between hospitals, clinical practice and laboratories via the spillover effect of creating an EU-wide alert mechanism on emerging resistant pathogens.

## RECOMMENDATION #4

### Maximise the role of pharmacists in infection prevention and the fight against AMR

Pharmacists are key stakeholders in the fight against AMR, due to their role on the front-line of the healthcare system. They can provide advice on the effective and rational use of medicines, and, in some countries, they offer services such as vaccinations. We recommend maximising pharmacists’ potential to act in the fight against AMR:

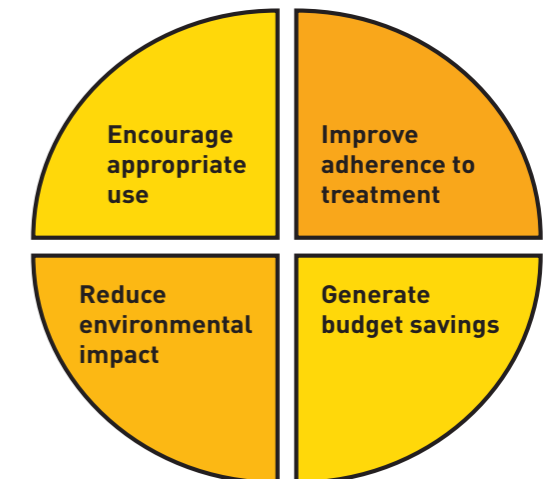
- All EU Member States should allow pharmacists to vaccinate against influenza, drawing on the models of those countries where this is already best practice. Increasing vaccination against influenza can reduce secondary bacterial infections and viral infections for which antibiotics are incorrectly prescribed.<sup>6</sup>
- Given appropriate clinical evidence, we encourage the administration of simple diagnostic tests by trained pharmacists, with the aim of reducing antibiotic misuse.
- Pharmacists should be encouraged to instruct patients on the proper use of antibiotics and raise their awareness of AMR. Particular emphasis could be placed on the importance of completing a course of antibiotics, appropriate disposal of leftover medicines and the use of alternatives such as over-the-counter (OTC) treatments for viral infections.

## RECOMMENDATION #5

### Packaging of antibiotics should be adapted to allow per unit dispensing of antibiotics

Considering the EU’s objective to become a “best-practice region” on AMR, **we recommend that EU Member States allow per unit dispensing of antibiotics.** Allowing per unit dispensing of antibiotics would address imbalances between prescriptions and packaging, facilitate adherence to treatment and decrease misuse of antibiotics.<sup>7</sup> This could generate health expenditure savings for national healthcare systems that reimburse prescription medicines. To support this process, **the European Commission should gather data on the benefits of per unit dispensing,** including the impact on adherence to treatment, economic benefits and positive environmental effects.

### Potential benefits of per unit dispensing of antibiotics



## RECOMMENDATION #6

### Shift to infection prevention in animal health as part of the “One Health” approach

We should reduce the need for antibiotics in animals and encourage a shift towards a more prevention-based approach:

- We recommend increasing research into veterinary vaccines and providing incentives to vaccinate animals. The example of Norway, where vaccinating salmon helped reduce antibiotic use in aquaculture to virtually zero, should be followed.<sup>8</sup>
- We also encourage the development and uptake of affordable rapid diagnostic tests for veterinary professionals and livestock owners, with the aim of switching to a prevention and diagnostic-led approach to animal health.

In order to enable consumers to make informed choices, we recommend that meat products that respect antibiotic stewardship requirements be labelled as such. An existing example is Italy, where the retailer Coop uses the label “bred without the use of antibiotics”.<sup>9</sup> We also call on all stakeholders in the food chain to collect and publish data on antibiotic use. An EU-wide requirement in this sense should be explored to increase transparency and consumer awareness in the Single Market.

## RECOMMENDATION #7

### Encourage responsible and evidence-based prescription behaviour

It is crucial that healthcare professionals remain updated in infection prevention and on current AMR guidelines and best practices. We recommend that all Member States introduce compulsory training on prevention and control strategies for AMR within continuous education programmes. Similarly, studies have shown that feedback mechanisms may reduce prescriptions and encourage the appropriate use of antibiotics.<sup>10</sup> We recommend that Member States move to integrate prescription feedback mechanisms in antibiotic stewardship programmes. Individual healthcare providers would receive feedback from national health systems concerning their use of antibiotics relative to

other prescribers in the region. This would target the misuse of antibiotics notably in the primary care setting. In addition, this measure could reduce variations in medical practice and increase compliance with national evidence-based guidelines.

## RECOMMENDATION #8

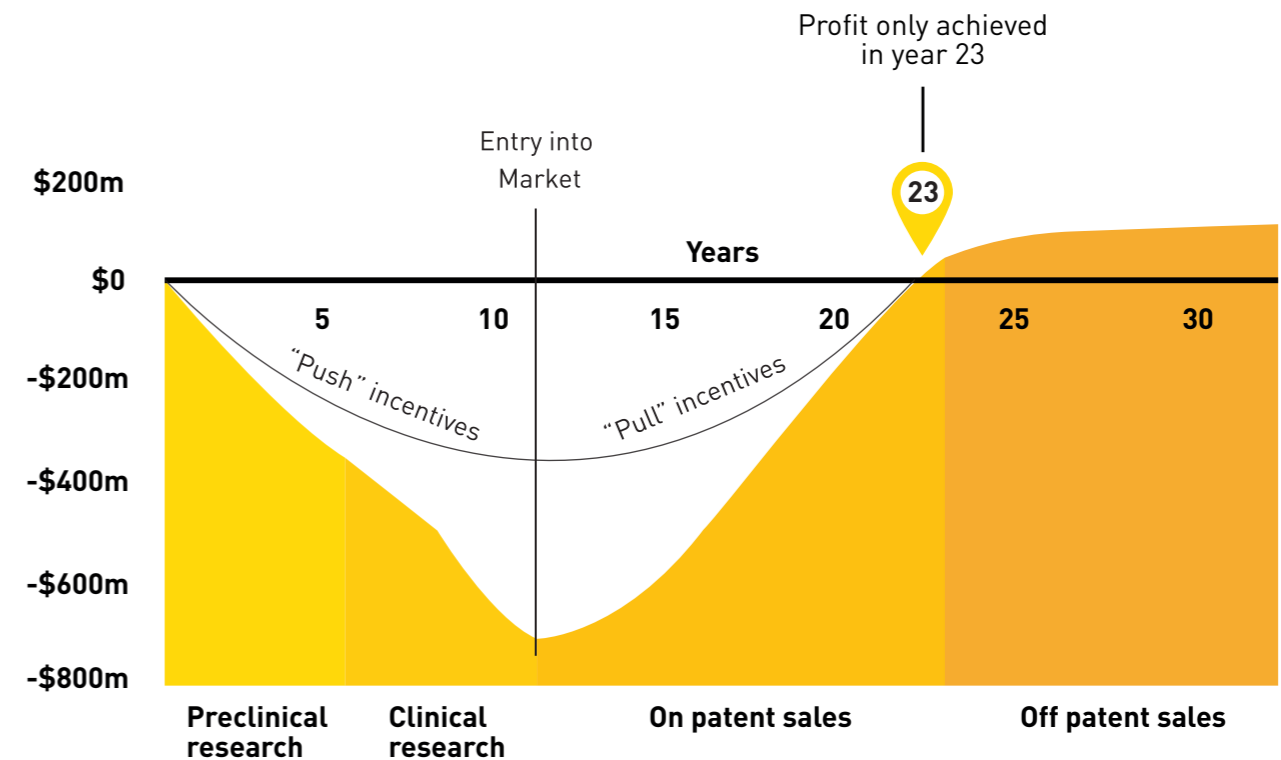
### Expand the use of green public procurement of antibiotics

The 2017 EU Action Plan emphasises the need to address the environmental dimension of AMR. We call on the EU to lead a “race to the top” in terms of sustainability. Positive competition among manufacturers aiming to reach European markets could be promoted by making broader use of green public procurement (GPP).<sup>11</sup> Building on best practices in Member States such as Sweden, public procurers at national, regional and local level (e.g. hospitals) should value the environmental quality of antibiotics. In cases where the active pharmaceutical ingredient (API) is the same, and the therapeutic effect is proven to be equivalent, the more sustainable, environmentally-friendly antibiotics should be preferred.<sup>12</sup> We recommend that the EU-JAMRAI develops a common set of guidelines on green procurement, to be adopted by all Member States.<sup>13</sup>

## RECOMMENDATION #9

### Develop new, sustainable economic models to incentivise R&D

New antibiotics and vaccines to prevent infections are a life insurance for future generations. However, alongside the intrinsic scientific and regulatory challenges in this area, the current volume-based business model is unable to attract private investment due to the need for prudent use of antibiotics. So far, the EU has provided funding mainly to de-risk early-stage research (“push incentives”), e.g. through the New Drugs for Bad Bugs (ND4BB) programme within IMI. However, robust “pull” incentive mechanisms are also needed to bring novel antibiotics to patients. To incentivise both early and late-stage R&D, while encouraging appropriate use, we urgently need new economic models in which the return on investment is at least partially de-linked from the volume sold.



REVIEW ON ANTIMICROBIAL RESISTANCE (ADAPTED)<sup>14</sup>

By 2020 the European Commission, in collaboration with the EU-JAMRAI, should:

- Define and regularly update an EU list of priority pathogens to direct antibiotics and vaccines R&D towards major areas of unmet need, building upon the WHO’s list.
- Perform a comparative analysis of “pull” incentive options at EU level,<sup>15</sup> sustainable over the long-term and with a clearly identified funding source.
- Define clear “public health safeguards” attached to the incentives: these could include industry commitments on access, availability, appropriate use, promotional activities and sustainable manufacturing of new antibiotics.

## RECOMMENDATION #10

### Promote EU AMR best practices in third countries

We support the European Commission’s objective to shape the global AMR agenda, both via global fora (WHO, OIE, UN) and with key partners (e.g. the US, through the TATFAR).<sup>16</sup> While in the long term coordinated global action remains the most desirable option, the urgency of the AMR threat requires concrete short-term measures. We recommend that the EU leverages the attractiveness of its Single Market and trade policy tools, notably to enforce the ban on the use of antibiotics in animals as growth promoters in third countries. The EU should also provide technical and financial assistance to developing countries, for example to improve antibiotic stewardship and surveillance programmes.

# Conclusions

## OUR MESSAGE TO EUROPEAN POLITICAL LEADERS

Research and innovation in the field of antimicrobials have brought undisputable benefits to society. However, their inappropriate use has accelerated the pace of AMR, fundamentally threatening the achievements of modern medicine. Although AMR has become a top political priority in Europe and globally, there is still a gap between high-level statements and concrete actions that needs to be addressed.

Our work does not stop here. The European Health Parliament's AMR Committee, building on the recommendations included in this report, will continue to proactively engage with EU policy-makers and key stakeholders in the run-up to the 2019 European elections, with the aim of building strategic partnerships to ensure AMR is high on the political agenda of the next European Commission. We will advocate for national and European political groups to include options to tackle AMR in their manifestos. We will also call for tangible and ambitious commitments on AMR and in healthcare more broadly in the ongoing negotiations for the next Multiannual Financial Framework (2021-2027).

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