

Making progress to tackling antimicrobial resistance in Europe



A summary of European doctors'
actions on AMR in 2023



FOREWORD FROM THE PRESIDENT

Europe is facing a growing public health threat from AMR, and it is crucial for patients that we keep existing antibiotics working. Therefore, in 2023 our association accelerated our efforts to advocate for more European action on AMR. In April, we published our new policy, recalling that that prudent prescription of antibiotics is a responsibility of each practicing doctor in Europe and worldwide.

On 27 April 2023, we organised a fruitful high-level conference on AMR, which was warmly hosted by the Swedish Medical Association. Doctors, national policymakers, representatives of the European Commission and health stakeholders all contributed to an excellent discussion. The conference took place the day following the proposals for the [revision](#) of the EU's pharmaceutical legislation and [Council Recommendation](#) on AMR.

We need to act in collaboration with many partners and are committed to the One Health approach bringing together the human health, veterinary and environmental sectors. Therefore, we continue as committed partners with stakeholders across sectors to play our part in tackling AMR in Europe.

Dr Christiaan Keijzer
CPME President



New policy: Antimicrobial resistance crisis urgently needs greater European action

CPME has updated its policy on antimicrobial resistance (AMR), calling for greater EU action for a deepening crisis which is leaving doctors short of effective treatments for life-threatening infections.

AMR is one of the greatest global health threats, causing 1.2 million deaths each year, more than 35 thousand of which are in Europe.

Bacteria have evolved ways to resist antibiotics, accelerated by overuse or misuse of medicines, including in agriculture.

Whilst the effectiveness of current antibiotics is decreasing, no novel class of antibiotics has been brought to market since the 1980s. In addition, this winter medicine shortages in most European countries left doctors and patients without access to critical antibiotics.

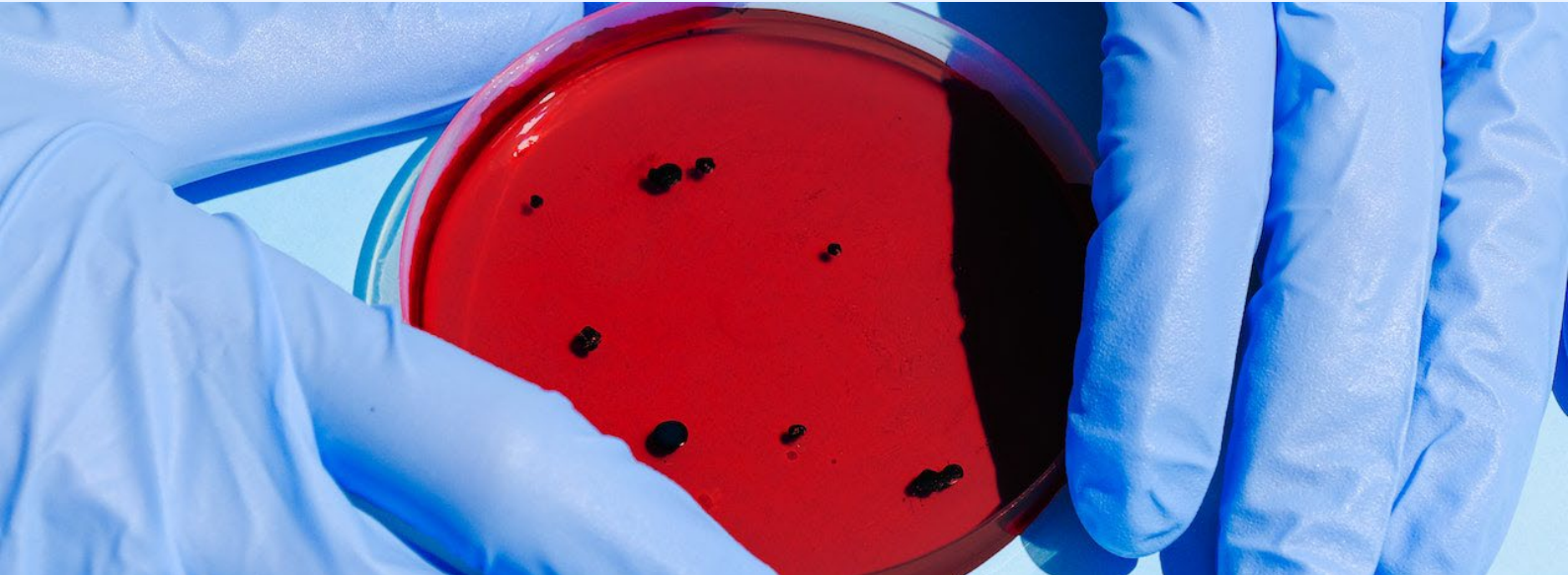
The policy makes recommendations on the One Health approach, prescribing of antibiotics, education and awareness raising, the use of digital technologies, access to established and novel antibiotics and on the environmental aspects of antimicrobial resistance.



The policy highlights the doctors' role in tackling AMR and the importance of stewardship programmes along with infection prevention and control. The new policy calls for prevention of overuse of antibiotics in agriculture and of routine preventive use of antibiotics for healthy groups of animals. The policy also states that doctors should prioritise narrow-spectrum antibiotics while considering individual patient's needs.

Read our policy [here](#).

Event report: Addressing antimicrobial resistance in medical practice



Doctors, scientists, policy-makers and civil society gathered to discuss how to address antimicrobial resistance (AMR) in a joint event organised by CPME and the Swedish Medical Association (SMA) in Stockholm.

The panelists stressed four key messages:

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1. Urgent and comprehensive measures are needed

“If efforts to tackle AMR continue at the same pace, many more lives will be put in danger”.

Malin Grape (Swedish Ambassador on AMR) opened the conference by stressing the importance of sustainable access to antibiotics and the need for globally accessible innovation.

She said that urgent action, led by public health needs, is required to address AMR comprehensively including by prevention, prudent use of antimicrobials, surveillance, diagnostics, research and development, infection prevention and control, education and public awareness, and cross-sectoral European and international collaboration.



2. The role of doctors is crucial

Dr Diamantis Plachouras (ECDC) highlighted that the leadership and expertise of doctors is critical. They are essential in guiding prudent prescribing practices, implementing effective infection control measures, and educating patients and other healthcare professionals about responsible use of antimicrobials.

Prof. Bojana Beović (Slovenian Medical Chamber) focused on effective antimicrobial stewardship and highlighted that implementing evidence-based stewardship interventions leads to cost saving. She stressed a condition of adequate human resources needed.

Dr Thomas Tängdén (Strama) highlighted the promises of multi-disciplinary teams, provision of treatment guidelines, education of prescribers and individualised feedback.

3. Rapid diagnostics and prudent use play a pivotal role

Jaume Vidal (Health Action International) stressed that accurate and rapid diagnostics empower healthcare providers to identify the specific pathogens causing infections, determine their resistance profiles, and guide appropriate antibiotic use.

New funding approaches and strong political will is needed to ensure access to tested and effective novel diagnostics.

Aleksandra Opalska (European Commission) presented provisions supporting prudent use of antimicrobials included in the recently published proposal for the revision of the EU pharmaceutical legislation, such as an obligation to develop stewardship plans, packaging adjusted to treatment duration, awareness cards for patients.



4. A new approach to antibiotic R&D is urgently needed

Jean-Baptiste Perrin (HERA) presented a study assessing four kinds of pull incentive schemes. The study outcomes suggested focusing on revenue guarantee schemes.

He emphasised the need to agree on guiding principles to fairly share the burden at the EU and global level. HERA will continue exploring financial pull incentives complementary to the regulatory incentive proposed in the new EU pharmaceutical regulation.

Aleksandra Opalska (European Commission) shortly introduced the transferable exclusivity voucher (TEV) outlined in the proposal for the EU pharmaceutical legislation. She noted that the TEV would provide more certainty to small and medium-sized enterprises (SMEs), according to an EC consultation.

Helle Aagaard (ReAct Europe) highlighted the importance of SMEs in AMR R&D. React Europe sees the TEV as an overly expensive, untested incentive prioritising large pharmaceutical companies. Instead, she advocated for prioritising financial incentives under consideration by HERA, as well as focusing on the full implementation of a de-linked market model.

Looking at the other side of the market, where antibiotics are already developed, Jenny Hellman (Public Health Agency of Sweden) presented a Swedish pilot study of a new reimbursement model for new antibiotics.

The pharmaceutical companies were guaranteed a minimum revenue in return for providing the product on the market. A stock incentive portion was included, regardless of sales, to cover costs for maintaining availability. Preliminary results showed that this model helps to ensure faster and continuous access to antibiotics.

Magazine article: How do we pay for new antibiotics?



Marcin Rodzinka-Verhelle
EU Policy Adviser



Photo credit: Bin Kontan

Doctors are running out of antibiotics to treat patients.

Governments and institutions worldwide have invested billions of euros to push research and development to discover novel antibiotics. Yet, no new classes of antibiotics have been discovered since the 1980s.

The upcoming revision of the EU general pharmaceutical legislation is an opportunity for a new approach.

As antimicrobial resistance (AMR) increases, there is a consensus that both push and pull incentives are needed to stimulate antibiotic development.

The pharmaceutical industry argues for greater alignment of funding and pull incentive schemes to deal with the threat.

The challenge with the antimicrobials market is that they are unable to generate unit sale-based revenues large enough to sustain investments, while it is in the interest of everyone to administer as little as possible.

A new approach is needed.

A new comprehensive alternative market model is needed to ensure sustainable and equitable access to antibiotics. While push incentives have been widely considered and implemented, the pull side is still very much under debate.



Photo credit: Ligoroko

The cost of the proposed transferable exclusivity voucher, from both a social and health perspective, may be too high.

One of the proposed pull incentives is a transferable exclusivity voucher.

This voucher would allow the developer of a novel antibiotic product to benefit from an additional period of market protection on another product in its portfolio. The voucher could also be traded to another company.

This incentive is based on a broader framework for regulating the pharmaceutical market and the protection awarded to registered and marketed medicines existing in the European Union.

The vouchers do not require direct funding from national governments and often are pictured as effective and sufficient tool.

However, indirect costs for health systems and ethical considerations seem to outweigh its potential benefits.

Firstly, the funding of this incentive is based on a significant extension of the protection period for other medicines. This may mean a disproportionate level of subsidising one area of healthcare at the expense of another. This would also have the effect of delaying generic market entry, which undermines competition and takes away market predictability. The total cost of this incentive, from both a social and health perspective, may be too high.

Secondly, vouchers do not contribute to the rational consumption of antibiotics, because they still make additional profit conditional on the quantity of the product sold.

To help fighting AMR, the vouchers would have to apply only to antibiotics that meet public health needs, and that the public health value is demonstrated through showing benefit in clinical situations against multi-drug resistant infections.



Photo credit: Vitalii Petrushenko

Due to the nature of the use of antibiotics (the less the better), the current market model is not appropriate and is not in line with public health objectives.

A new incentive is needed to decouple the revenue from the new antibiotic from the quantity sold (delinkage).

Examples of such incentives are market entry rewards, guarantees for minimum turnover and milestone payments. These direct payments are paid to developers for bringing a product to the market or contributing to a certain stage of R&D, without linking it to the sale volume.

In the past, the European Commission awarded the Horizon prize for better use of antibiotics. The added value of the prize system is, unlike patents and monopolies, rewarding innovation that brings social value and addresses unmet medical need.

In the fully delinked model, the payments are the main revenue for the antibiotic while units are sold at a contractually agreed price.

Market entry rewards, if implemented correctly, promote stewardship and access.

Importantly, the prize system requires significant upfront public investments. However, through reallocation of resources that are already dedicated to encouraging innovation through the intellectual property rights system, this would not generate additional public spending.

A number of initiatives have demonstrated the value and potential of such models e.g., DNDi and GARDP.

The European Union should build on these examples and implement them broadly, also as non-legislative measures, including in the European Health Emergency Preparedness and Response Authority (HERA).

One health: strengthening collaboration on AMR with stakeholders across sectors



The fight against antimicrobial resistance is a joint responsibility.

Doctors, veterinarians, patients, and farmers, alongside European and national authorities, and society as a whole, strive to join forces for the common good.

European doctors remain committed partners to work together to implement the One Health approach in Europe.

To this end we participate in the EU's AMR One Health Network, and we presented at the latest meeting on 21 September 2023.

To enhance further cooperation on the One Health approach in Europe, CPME and the Federation of Veterinarians of Europe (FVE) [renewed](#) our Memorandum of Understanding in 2022.

The signed memorandum emphasises that European doctors and veterinarians strive to continue to lead the way in preventing zoonoses, containing antimicrobial resistance and providing healthcare for humans and animals by recognising the interdependence of the two sectors and the implementation of science-based approaches.

FVE contributed a guest article to our winter 2023 [magazine](#) exploring how doctors and veterinarians are strengthening collaboration, particularly in applying the One Health approach.

Statement: urging immediate action on medicine shortages for autumn and winter



Last winter, almost all EU countries reported shortages of commonly used medicines, including antibiotics.

Our statement urges the European Union to take immediate action to avoid a repeat of last winter, when the shortages put patients at risk and the compromised the work of healthcare professionals.

Read our statement [here](#).

Doctors also share concerns over a possible negative impact of a shortage of narrow spectrum antibiotics on the spread of AMR.

The statement makes six clear recommendations to the European Commission and the Member States:

- Forecast medicine demand and plan production
- Communicate with healthcare professionals as early as possible
- Involve clinicians and patients in the development of the EU list of critical medicines
- Set up a voluntary sharing mechanism for Member States to exchange medicines in shortage
- Revise procurement policies
- Become more independent in production of essential medicines