Basic information

2017/2254(INI) INI - Own-initiative procedure	Procedure completed
European One Health action plan against antimicrobial resistance (AMR) **Subject** 3.10.08 Animal health requirements, veterinary legislation and pharmacy 4.20.01 Medicine, diseases 4.20.02 Medical research 4.20.05 Health legislation and policy	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	KADENBACH Karin (S&D)	01/09/2017
	Shadow rapporteur SOMMER Renate (PPE) PIECHA Bolesław G. (ECR) FEDERLEY Fredrick (ALDE) BOYLAN Lynn (GUE/NGL) PEDICINI Piernicola (EFDD) MÉLIN Joëlle (ENF)	

Committee for opinion	Rapporteur for opinion	Appointed
ITRE Industry, Research and Energy	WIERINCK Lieve (ALDE)	26/10/2017
AGRI Agriculture and Rural Development	CARTHY Matt (GUE/NGL)	16/11/2017

European Commission

Commission DG	Commissioner
Health and Food Safety	ANDRIUKAITIS Vytenis Povilas

Key events

Date	Event	Reference	Summary
		COM(2017)0339	Summary

29/06/2017	Non-legislative basic document published		
14/12/2017	Committee referral announced in Parliament		
20/06/2018	Vote in committee		
12/07/2018	Committee report tabled for plenary	A8-0257/2018	Summary
12/09/2018	Debate in Parliament		
13/09/2018	Decision by Parliament	T8-0354/2018	Summary
13/09/2018	Results of vote in Parliament		
13/09/2018	End of procedure in Parliament		

Technical information

Procedure reference	2017/2254(INI)
Procedure type	INI - Own-initiative procedure
Procedure subtype	Initiative
Legal basis	Rules of Procedure EP 55
Other legal basis	Rules of Procedure EP 165
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/8/11029

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE613.613	31/01/2018	
Committee opinion	ITRE	PE613.604	22/02/2018	
Amendments tabled in committee		PE619.155	07/03/2018	
Amendments tabled in committee		PE619.156	07/03/2018	
Committee opinion	AGRI	PE615.417	26/04/2018	
Committee report tabled for plenary, single reading		A8-0257/2018	12/07/2018	Summary
Text adopted by Parliament, single reading		T8-0354/2018	13/09/2018	Summary

European Commission

Document type	Reference	Date	Summary
Commission document (COM)	COM(2017)0339	29/06/2017	Summary
Commission response to text adopted in plenary	SP(2018)829	11/03/2019	

National parliaments

Document type	Parliament /Chamber	Reference	Date	Summary
Contribution	CZ_SENATE	COM(2017)0339	14/12/2017	

European One Health action plan against antimicrobial resistance (AMR)

2017/2254(INI) - 12/07/2018 - Committee report tabled for plenary, single reading

The Committee on the Environment, Public Health and Food Safety adopted an own-initiative report by Karin KADENBACH (S&D, AT) on a European One Health Action Plan against Antimicrobial Resistance (AMR).

Members noted that the excessive and incorrect use of antibiotics and poor infection control practices in both human and veterinary medicine have progressively rendered antimicrobial resistance (AMR) a massive threat to human and animal health. The misuse of antibiotics is eroding their efficacy. In terms of human health, 50 % of antibiotic prescriptions written for humans are ineffective.

Stressing that the correct and prudent use of antimicrobials is essential to limiting the emergence of AMR, the committee made the following key observations and recommendations:

The EU as a best-practice region: Members stressed that the One Health principle must play a central role in tackling AMR, reflecting the fact that the health of people and animals and the environment are interconnected. They called for **measurable and binding AMR objectives with ambitious targets**, both in the European One Health Action Plan and in national action plans, to enable benchmarking. They also called on the Commission to publish a **mid-term evaluation** and **ex-post evaluation** of the One Health Action Plan.

Some of the many antimicrobials used in both humans and animals are critical for preventing or treating life-threatening infections in humans, and Members considered that **the use of these antimicrobials on animals should tbe banned**. These antimicrobials should be **reserved for the treatment of humans alone** in order to preserve their efficacy. The Commission should specify which antibiotics are to be reserved for the treatment of certain infections in humans. In addition, Members called for the promotion of public health messages regarding the responsible use of antibiotics, particularly prophylactic use.

In terms of **animal health**, the report noted that high-density farming may involve antibiotics being improperly fed to livestock on farms to promote faster growth, and that they are also widely used for prophylactic purposes. It called for the **phasing out of the routine prophylactic and metaphylactic use** (i.e. treating a group of animals when only one shows signs of infection) of antimicrobials in groups of farm animals and called for **the use of last-resort antibiotics to be banned altogether in food-producing animals**. Instead, Members stressed the importance of good animal husbandry, hygiene practices, farm management and investments in these areas The Commission was urged to present a **new EU strategy on animal welfare.**

With regard to **prophylactic use in humans**, the committee called on Member States to review all existing protocols, especially for prophylactic use during surgery. It cited the examples of good practice, such as the PIRASOA programme, and encouraged the development of mechanisms through which to share best practices and protocols.

Boosting research: Members felt that, in order to encourage research into new antimicrobials, **incentives are needed**, including longer periods of protection for technical documentation on new medicines, commercial protection of innovative active substances, and protection for significant investments in data generated to improve an existing antimicrobial product or to keep it on the market. They called on the Commission to analyse **current R&D incentive models,** including the 'transferable market exclusivity' model, with a view to designing new ones and defining the regulatory pathway. Members also called for:

- the launch a public platform for publicly funded R&D projects in AMR and for the coordination of all R&D actions;
- a fast-track procedure whereby the use antimicrobials approved for industrial or agricultural purposes but suspected of having a severe negative impact on AMR may be temporarily prohibited until further studies have been carried out;
- the development of non-antibiotic alternatives for animal health, including growth promoters, and in the development of new molecules for the development of new antibiotics.

Shaping the global agenda: the committee asked for a clear commitment on the part of the EU and the Member States to launching a crosscutting global strategy to combat AMR, covering policy areas such as international trade, development and agriculture. It noted that the use of antibiotics as growth promoters in food-producing animals has been banned in the EU since 2006, but that in countries outside the EU antibiotics can still be used in animal feed as growth promoters. It called on the Commission to include a **clause in all free trade agreements** stipulating that food imported from third countries must not have been produced using antibiotics as growth promoters, with a view to ensuring a level playing field for EU livestock farming and aquaculture and in order to mitigate AMR.

Lastly, the report called on the Commission to implement collaborative research programmes with third countries to reduce the overuse of antibiotics.

European One Health action plan against antimicrobial resistance (AMR)

2017/2254(INI) - 13/09/2018 - Text adopted by Parliament, single reading

The European Parliament adopted by 589 votes to 12 with 36 abstentions, a resolution on a European One Health Action Plan against Antimicrobial Resistance (AMR).

Members noted that the excessive and incorrect use of antibiotics and poor infection control practices in both human and veterinary medicine have progressively rendered antimicrobial resistance (AMR) a massive threat to human and animal health. The misuse of antibiotics is eroding their efficacy. In terms of human health, 50 % of antibiotic prescriptions written for humans are ineffective.

Stressing that the **correct and prudent use of antimicrobials** is essential to limiting the emergence of AMR, Parliament made the following key observations and recommendations:

The EU as a best-practice region: Members stressed that the One Health principle must play a central role in tackling AMR, reflecting the fact that the health of people and animals and the environment are interconnected. They called for **measurable and binding AMR objectives with ambitious targets**, both in the European One Health Action Plan and in national action plans, to enable benchmarking.

Parliament asked the Commission and Member States to **restrict the sale of antibiotics** by the human and animal health professionals who prescribe them and to remove any incentives – financial or otherwise – for the prescription of antibiotics, while continuing to ensure sufficiently rapid access to emergency veterinary medicine.

Some of the many antimicrobials used in both humans and animals are critical for preventing or treating life-threatening infections in humans. Members considered that **the use of these antimicrobials on animals should be banned**. These antimicrobials should be **reserved for the treatment of humans alone** in order to preserve their efficacy.

The Commission should specify which antibiotics are to be reserved for the treatment of certain infections in humans. In addition, Members called for: (i) firm action against the **illegal sale of antimicrobial products** or their sale without a doctor's or veterinarian's prescription in the EU; (ii) the promotion of **public health messages** regarding the responsible use of antibiotics, particularly prophylactic use.

With regard to **animal health**, Parliament called for the phasing out of the routine prophylactic and metaphylactic use of antimicrobials in groups of farm animals and called for the use of last-resort antibiotics to be banned altogether in food-producing animals.

With regard to **prophylactic use in humans**, Parliament called on Member States to review all existing protocols, especially for prophylactic use during surgery. It cited the examples of good practice, such as the PIRASOA programme, and encouraged the development of mechanisms through which to share best practices and protocols.

Members believed that requirements to ensure that **labelling** makes reference to antibiotic use would improve consumer knowledge and enable consumers to make a more informed choice. They called on the Commission to create a harmonised system for labelling based on animal welfare standards and good animal husbandry practices.

Boosting research: Members felt that, in order to encourage research into new antimicrobials, **incentives are needed**. They called on the Commission to establish an **EU priority pathogen list** (PPL), taking into account the WHO's global PPL, for both humans and animals, thereby clearly establishing future research and development priorities.

The resolution also called for:

- the launch a **public platform** for publicly funded R&D projects in AMR and for the coordination of all R&D actions;
- a **fast-track procedure** whereby the use antimicrobials approved for industrial or agricultural purposes but suspected of having a severe negative impact on AMR may be temporarily prohibited until further studies have been carried out;
- the development of **non-antibiotic alternatives** for animal health, including growth promoters, and in the development of new molecules for the development of new antibiotics.

Shaping the global agenda: Parliament asked for a clear commitment on the part of the EU and the Member States to launching a crosscutting global strategy to combat AMR, covering policy areas such as international trade, development and agriculture. It noted that the use of antibiotics as growth promoters in food-producing animals has been banned in the EU since 2006, but that in countries outside the EU antibiotics can still be used in animal feed as growth promoters. It called on the Commission to include a **clause in all free trade agreements** stipulating that food imported from third countries must not have been produced using antibiotics as growth promoters.

Lastly, Members called on the Commission to implement collaborative research programmes with third countries to reduce the overuse of antibiotics.

European One Health action plan against antimicrobial resistance (AMR)

2017/2254(INI) - 29/06/2017 - Non-legislative basic document

PURPOSE: to present a new European action plan to strengthen the fight against antimicrobial resistance (AMR).

BACKGROUND: according to the World Health Organization (WHO), AMR already presents a serious social and economic burden. It is estimated to be responsible for **25,000 deaths per year in the EU alone and 700,000 deaths per year globally**, and might cause more deaths than cancer by 2050. In the EU alone it is estimated that AMR costs **EUR 1.5 billion annually** in healthcare costs and productivity losses

The EU was quick to recognise the importance of tackling AMR. The 2001 Community strategy against AMR was reinforced by the 2011 Commission action plan, notable for its **One Health** approach, addressing AMR in both humans and animals.

In view of the challenges of antimicrobial resistance at regional and global levels, **the Union is at the forefront of combating this phenomenon.** Since 1999, the Commission has invested more than EUR 1.3 billion in antimicrobial resistance research.

Responding to the request of the Member States set out in the Council conclusions of 17 June 2016, the new plan proposed by the Commission is based on the first action plan, implemented from 2011 to 2016. It is based on the recommendations of an independent external evaluation, as well as the views expressed by stakeholders in an open public consultation.

Based on the "One health" approach, the plan is motivated by the need for the Union to play a leading role in the fight against the phenomenon of antimicrobial resistance and to add value to the actions Member States.

Its overarching goal is to preserve the possibility of effective treatment of infections in humans and animals. It provides a **framework for continued action** to reduce the emergence and spread of AMR and to increase the development and availability of new effective antimicrobials inside and outside the EU.

CONTENT: the main objectives of this new plan revolve around the following three major pillars:

Pillar 1: making the EU a best practice region: as the evaluation of the 2011 action plan highlighted, this will require **better evidence**, better coordination and surveillance, and better control measures. EU action will help Member States in establishing, implementing and monitoring their own **national One Health action plans** on AMR, which they agreed to develop at the 2015 World Health Assembly.

The Commission's support will include:

- providing evidence-based data, with the support of the Union agencies, on possible links between the consumption of antimicrobial agents and the occurrence of antimicrobial resistance in humans and food-producing animals;
- reviewing EU implementing legislation on monitoring AMR in zoonotic and commensal bacteria in farm animals and food;
- supporting Member States in raising awareness at national level through specific communication tools;
- co-funding projects and collaborate with WHO to assist EU Member States in the development and implementation of national action plans to combat antimicrobial resistance;
- developing training programmes for the competent authorities of Member States and health professionals;
- contributing to improving patient safety in hospitals by supporting good practices in infection prevention and control;
- developing EU guidelines for the prudent use of antimicrobials in human medicine;
- adopting a Union policy on pharmaceuticals in the environment.

Pillar 2: boosting research, development and innovation: the aims are to: (i) close current knowledge gaps, (ii) provide novel solutions and tools to prevent and treat infectious diseases, and (iii) improve diagnosis in order to control the spread of AMR. The Commission will work in partnership with Member States and industry, including small and medium-sized enterprises (SMEs), to tackle AMR in **bacteria, viruses, fungi and parasites**. Special attention will be given to the WHO priority list of pathogens as well as to tuberculosis, HIV/AIDS, malaria and neglected infectious diseases.

In particular, the Commission intends to support research with a view to:

- improving **early detection** and better understanding the problems of antimicrobial resistance in the European health care, livestock and food production sectors;
- developing **new drugs and treatments**, including alternatives, as well as innovative anti-infective approaches and products for both humans and animals;
- developing new and **effective preventive vaccines** and new diagnostic tools in particular on-site tests in humans and animals;
- filling gaps in knowledge about the release of resistant microorganisms and antimicrobials into the environment.

Pillar 3: intensifying EU efforts worldwide to shape the global agenda: in an increasingly interconnected world, the Commission will:

- strengthen the global presence of the Union by contributing to the normative work of multilateral organizations such as WHO, the World Animal Health Organisation (OIE), the Food and Agriculture Organisation (FAO) and international fora;
- promote **standards** and measures taken by the Union to combat antimicrobial resistance in the context of trade agreements;
- contribute to the reduction of antimicrobial resistance in **least developed countries** through programs to control infectious diseases.

Progress will be reviewed at regular intervals as part of the One Health network on antimicrobial resistance, to guide individual Member States in their actions and to decide on the appropriateness of further action at Union level.