



2017/2254(INI)

18.1.2018

AMENDMENTS

1 - 96

Draft opinion

Lieve Wierinck

A European One Health Action Plan against Antimicrobial Resistance (AMR)
(2017/2254(INI))

Amendment 1
Michèle Rivasi
on behalf of the Verts/ALE Group

Draft opinion
Recital –A (new)

Draft opinion

Amendment

-A. whereas the main cause of AMR is the excessive use of antibiotics and up to half of antibiotics used in humans are unnecessary and inappropriate, changing the way antibiotics are used is the single most important action needed to slow down the development of AMR;

Or. en

Amendment 2
Michèle Rivasi
on behalf of the Verts/ALE Group

Draft opinion
Recital –A a (new)

Draft opinion

Amendment

-Aa. whereas the consumption of antibiotics decreases as knowledge on the correct use of antibiotics increases;

Or. en

Amendment 3
Michèle Rivasi
on behalf of the Verts/ALE Group

Draft opinion
Recital –A b (new)

Draft opinion

Amendment

-Ab. whereas the spread of antimicrobials has contributed to the declining effectiveness of existing antimicrobials and more research is needed to develop alternative treatments;

Or. en

Amendment 4
Michèle Rivasi
on behalf of the Verts/ALE Group

Draft opinion
Recital –A c (new)

Draft opinion

Amendment

-Ac. whereas development and spread of antimicrobials in the environment is also a growing concern, requiring further research;

Or. en

Amendment 5
Michèle Rivasi
on behalf of the Verts/ALE Group

Draft opinion
Recital A

Draft opinion

Amendment

A. whereas antimicrobial resistance (AMR)-related challenges will increase in the years ahead and effective action is reliant on continued, **cross-sectoral** investments in research & innovation (R&I), so that better **tools**, products and approaches can be developed following a One Health approach;

A. whereas antimicrobial resistance (AMR)-related challenges will **tremendously** increase in the years ahead and **inaction is projected to cause yearly millions of deaths globally**, effective action is **primarily** reliant **on better knowledge, prevention and reduced usage of antimicrobials, as well as** on continued, **cross-sectoral** investments in research & innovation (R&I), so that better **and alternative treatments**, products and

approaches can be developed following a One Health approach;

Or. en

Amendment 6
Neoklis Sylikiotis, Xabier Benito Ziluaga

Draft opinion
Recital A

Draft opinion

A. whereas antimicrobial resistance (AMR)-related challenges will increase in the years ahead and effective action is reliant on continued, cross-sectoral investments in research & innovation (R&I), so that better tools, products and approaches can be developed following a One Health approach;

Amendment

A. whereas antimicrobial resistance (AMR)-related challenges will increase in the years ahead and effective action is reliant on ***two equally important strategies: on the one hand***, continued, cross-sectoral investments in research & innovation (R&I) ***and, on the other hand, comprehensive strategies for timely tackling the excessive and inappropriate use of antimicrobials both in humans and animals***, so that better tools, products and approaches can be developed following a One Health approach;

Or. en

Amendment 7
Bendt Bendtsen

Draft opinion
Recital A

Draft opinion

A. whereas antimicrobial resistance (AMR)-related challenges will increase in the years ahead and effective action is reliant on continued, cross-sectoral investments in research & innovation (R&I), so that better tools, products and approaches can be developed following a

Amendment

A. whereas antimicrobial resistance (AMR)-related challenges will increase in the years ahead and effective action is reliant on continued, cross-sectoral investments in research & innovation (R&I), ***including investments in both the public and the private sector***, so that

One Health approach;

better tools, products and approaches can be developed following a One Health approach;

Or. en

Amendment 8
Soledad Cabezón Ruiz

Draft opinion
Recital A

Draft opinion

A. whereas antimicrobial resistance (AMR)-related challenges will increase in the years ahead and effective action is reliant on continued, cross-sectoral investments in research & innovation (R&I), so that better tools, products and approaches can be developed following a One Health approach;

Amendment

A. whereas antimicrobial resistance (AMR)-related challenges will increase in the years ahead and effective action is reliant on continued, cross-sectoral investments in research & innovation (R&I), so that **new antibiotics**, better tools, products, **devices** and approaches can be developed following a One Health approach;

Or. en

Amendment 9
Cristian-Silviu Buşoi, Anna Záborská

Draft opinion
Recital A

Draft opinion

A. whereas antimicrobial resistance (AMR)-related challenges will increase in the years ahead and effective action is reliant on continued, cross-sectoral investments in research & innovation (R&I), so that better tools, products and approaches can be developed following a One Health approach;

Amendment

A. whereas antimicrobial resistance (AMR)-related challenges will increase in the years ahead and effective action is reliant on continued, cross-sectoral investments in research & innovation (R&I), so that better tools, products and approaches, **also on long term**, can be developed following a One Health approach;

Amendment 10
Soledad Cabezón Ruiz

Draft opinion
Recital A a (new)

Draft opinion

Amendment

Aa. whereas the “Council conclusions on the next steps under a One Health approach to combat antimicrobial resistance”^{1a} ask the Commission and the Member States to align strategic research agendas of existing EU R&D initiatives on new antibiotics, alternatives and diagnostics within a One Health Network on AMR;

1a

<http://www.consilium.europa.eu/en/press/press-releases/2016/06/17/epsco-conclusions-antimicrobial-resistance/>

Or. en

Amendment 11
Anna Záborská, Cristian-Silviu Buşoi

Draft opinion
Recital A a (new)

Draft opinion

Amendment

Aa. whereas the political declaration endorsed by Heads of State at the United Nations General Assembly in New York in September 2016 signalled the world’s commitment to taking abroad, coordinated approach to address the root causes of antimicrobial resistance across multiple sectors;

Amendment 12
Michèle Rivasi
on behalf of the Verts/ALE Group

Draft opinion
Recital A a (new)

Draft opinion

Amendment

Aa. whereas phagetherapy is considered an effective complementary treatment to antibiotics that is showing positive results, is gaining growing scientific interest including by the pharmaceutical companies, but is however lacking sufficient research support at EU level;

Or. en

Amendment 13
Cristian-Silviu Buşoi, Françoise Grossetête, Anna Záborská

Draft opinion
Recital A a (new)

Draft opinion

Amendment

Aa. whereas in the past 40 years only one novel class of antibiotics has been developed, despite the spreading and progress of new resistant bacteria, moreover there is clear evidence of resistance to new agents within existing classes of antibiotics;

Or. en

Amendment 14
Neoklis Sylikiotis, Xabier Benito Ziluaga

Draft opinion
Recital A a (new)

Draft opinion

Amendment

Aa. whereas excessive and inappropriate use of antibiotics both in humans and animals is turning AMR into a massive threat for the future of humankind;

Or. en

Amendment 15
Anna Záborská, Cristian-Silviu Buşoi

Draft opinion
Recital A b (new)

Draft opinion

Amendment

Ab. whereas more than 100 companies have signed Davos declaration in January 2016, which calls for collective action to create a sustainable and predictable market for antibiotics, vaccines and diagnostics, that enhances conservation for new and existing treatments. It also calls for coordinated action to improve prevention of infections, hygiene, stewardship and conservation measures;

Or. en

Amendment 16
Cristian-Silviu Buşoi, Anna Záborská

Draft opinion
Recital A b (new)

Draft opinion

Amendment

Ab. whereas awareness of prevention and of the misuse of antimicrobials is still low across Member States; and whereas

vaccination is an effective way of preventing infections that would need treatment with antibacterials and thereby reducing development of resistance;

Or. en

Amendment 17
Anna Záborská, Cristian-Silviu Buşoi

Draft opinion
Recital A c (new)

Draft opinion

Amendment

Ac. whereas nosocomial infections represents major threat in preserving and guarantee basic health care all over the world;

Or. en

Amendment 18
Soledad Cabezón Ruiz

Draft opinion
Recital B a (new)

Draft opinion

Amendment

Ba. whereas the Joint Programming Initiative on AMR has committed 52.95 million euro so far and further 14.4 million euro in its current call this year; whereas the IMI has seven projects on AMR, under the umbrella of the ND4BB programme, with a total budget of more than 600 million euro among European Commission funding contribution and pharma companies in kind contribution;

Or. en

Amendment 19
Anna Záborská, Cristian-Silviu Buşoi

Draft opinion
Recital B a (new)

Draft opinion

Amendment

Ba. whereas antimicrobial resistance can only be effectively addressed on global level and with engagement of private sector;

Or. en

Amendment 20
Anna Záborská, Cristian-Silviu Buşoi

Draft opinion
Recital B b (new)

Draft opinion

Amendment

Bb. whereas science and research play a crucial role in the development of standards in the fight against AMR;

Or. en

Amendment 21
Soledad Cabezón Ruiz

Draft opinion
Recital C

Draft opinion

Amendment

C. whereas different funding instruments under H2020 ***will deliver*** research results on AMR, in particular: the Innovative Medicines Initiative (IMI), with a focus on all aspects of antibiotic development including research into AMR mechanisms, drug discovery, drug development, and economics and

C. whereas ***the*** different funding instruments under H2020 ***need to continue delivering*** research results on AMR, in particular: the Innovative Medicines Initiative (IMI), with a focus on all aspects of antibiotic development including research into AMR mechanisms, drug discovery, drug development, and

stewardship; the European and Developing Countries Clinical Trials Partnership (EDCTP), with a focus on the development of new and improved drugs, vaccines, microbicides and diagnostics against HIV/AIDS, tuberculosis and malaria; the Joint Programming Initiative on AMR (JPIAMR), with a focus on consolidation of otherwise fragmented national research activities; the European Research Council (ERC), with its ‘investigator-driven’ or ‘bottom-up’ research projects; the InnovFin Infectious Diseases Financial Facility (IDFF), for close-to-market projects; and the SME Instrument and Fast Track to Innovation (FTI) which support SMEs in developing novel solutions and tools to prevent, diagnose and treat infectious diseases and improve infection control;

economics and stewardship; the European and Developing Countries Clinical Trials Partnership (EDCTP), with a focus on the development of new and improved drugs, vaccines, microbicides and diagnostics against HIV/AIDS, tuberculosis and malaria; the Joint Programming Initiative on AMR (JPIAMR), with a focus on consolidation of otherwise fragmented national research activities; the European Research Council (ERC), with its ‘investigator-driven’ or ‘bottom-up’ research projects; the InnovFin Infectious Diseases Financial Facility (IDFF), for close-to-market projects; and the SME Instrument and Fast Track to Innovation (FTI) which support SMEs in developing novel solutions and tools to prevent, diagnose and treat infectious diseases and improve infection control;

Or. en

Amendment 22

Michèle Rivasi

on behalf of the Verts/ALE Group

Draft opinion

Recital C

Draft opinion

C. whereas different funding instruments under H2020 *will* deliver research results on AMR, in particular: the Innovative Medicines Initiative (IMI), with a focus on all aspects of antibiotic development including research into AMR mechanisms, drug discovery, drug development, and economics and stewardship; the European and Developing Countries Clinical Trials Partnership (EDCTP), with a focus on the development of new and improved drugs, vaccines, microbicides and diagnostics against HIV/AIDS, tuberculosis and malaria; the

Amendment

C. whereas different funding instruments under H2020 *might* deliver research results on AMR, in particular: the Innovative Medicines Initiative (IMI), with a focus on all aspects of antibiotic development including research into AMR mechanisms, drug discovery, drug development, and economics and stewardship; the European and Developing Countries Clinical Trials Partnership (EDCTP), with a focus on the development of new and improved drugs, vaccines, microbicides and diagnostics against HIV/AIDS, tuberculosis and malaria; the

Joint Programming Initiative on AMR (JPIAMR), with a focus on consolidation of otherwise fragmented national research activities; the European Research Council (ERC), with its ‘investigator-driven’ or ‘bottom-up’ research projects; the InnovFin Infectious Diseases Financial Facility (IDFF), for close-to-market projects; and the SME Instrument and Fast Track to Innovation (FTI) which support SMEs in developing novel solutions and tools to prevent, diagnose and treat infectious diseases and improve infection control;

Joint Programming Initiative on AMR (JPIAMR), with a focus on consolidation of otherwise fragmented national research activities; the European Research Council (ERC), with its ‘investigator-driven’ or ‘bottom-up’ research projects; the InnovFin Infectious Diseases Financial Facility (IDFF), for close-to-market projects; and the SME Instrument and Fast Track to Innovation (FTI) which support SMEs in developing novel solutions and tools to prevent, diagnose and treat infectious diseases and improve infection control;

Or. en

Amendment 23
Soledad Cabezón Ruiz

Draft opinion
Recital C a (new)

Draft opinion

Amendment

Ca. whereas the 50% of antibiotics prescriptions in humans are inadequate and the 25% of consumption in humans are not well administrated; whereas the 30% of hospitalised people use antibiotics and the most critical group of multidrug resistant bacteria poses a particular threat in hospitals, nursing homes and among patients whose care requires devices such as ventilators and blood catheters;

Or. en

Amendment 24
Anna Záborská, Cristian-Silviu Buşoi

Draft opinion
Recital C a (new)

Draft opinion

Amendment

Ca. whereas effective fight against AMR must be part of the broader international initiative with engaging as many international institutions, agencies and experts as possible;

Or. en

Amendment 25

Lieve Wierinck, Fredrick Federley, Dominique Riquet

Draft opinion

Recital C a (new)

Draft opinion

Amendment

Ca. whereas the Commission has committed to invest more than EUR 200 million in AMR for the last 3 years of Horizon 2020;

Or. en

Amendment 26

Soledad Cabezón Ruiz

Draft opinion

Recital C b (new)

Draft opinion

Amendment

Cb. whereas bacteria are constantly evolving, the R&D and regulatory environments are complex, targeted infections are sometimes rare and the expected returns remain limited;

Or. en

Amendment 27

Michèle Rivasi
on behalf of the Verts/ALE Group

Draft opinion
Paragraph –1 (new)

Draft opinion

Amendment

-1. Emphasises the need to decrease the usage of antibiotics in order to slowdown the further development of AMR;

Or. en

Amendment 28
Soledad Cabezón Ruiz

Draft opinion
Paragraph 1

Draft opinion

Amendment

1. Emphasises the need to increase funding for R&I in epidemiology and immunology for AMR pathogens and healthcare-associated infections (HAI);

1. Emphasises the need to increase funding for R&I in epidemiology and immunology for AMR pathogens and healthcare-associated infections (HAI), **in new antimicrobial drug resistance mechanisms, in developing new therapeutics diagnostics and preventing measures, including vaccines, and in drug delivery technologies and approaches, such as exploiting host immunity to kill resistant microbes; points out that the study of mechanisms of antibiotic resistance and the development of medical devices for the etiology of diseases are key areas for adequate use, and appropriate prescribing of antibiotic; calls therefore not only on new drugs but on new medical devices as well;**

Or. en

Amendment 29

Michèle Rivasi

on behalf of the Verts/ALE Group

Draft opinion

Paragraph 1

Draft opinion

1. Emphasises the need to increase funding for R&I in epidemiology and immunology for AMR pathogens and healthcare-associated infections (HAI);

Amendment

1. Emphasises the need to increase funding for R&I in epidemiology and immunology for AMR pathogens and healthcare-associated infections (HAI) **as well as to increase the funding of alternative treatments for humans and animals;**

Or. en

Amendment 30

Rolandas Paksas

Draft opinion

Paragraph 1

Draft opinion

1. Emphasises the need to increase funding for R&I in epidemiology and immunology for AMR pathogens and healthcare-associated infections (HAI);

Amendment

1. Emphasises the need to **encourage the use of metagenomics methods and to** increase funding for R&I in epidemiology and immunology for AMR pathogens and healthcare-associated infections (HAI);

Or. It

Amendment 31

Lieve Wierinck, Fredrick Federley

Draft opinion

Paragraph 1

Draft opinion

1. Emphasises the need to increase funding for R&I in epidemiology and

Amendment

1. Emphasises the need to increase funding for R&I in epidemiology and

immunology for AMR pathogens and healthcare-associated infections (HAI);

different treatments in immunology for AMR pathogens and healthcare-associated infections (HAI);

Or. en

Amendment 32
Soledad Cabezón Ruiz

Draft opinion
Paragraph 1 a (new)

Draft opinion

Amendment

1a. *Emphasises that AMR has become one of the most important public health problems; nevertheless, insists that, although new antibiotics are needed, the origin of the problem lies above all in the their wrong usage, making it a priority to work in this area.*

Or. es

Amendment 33
Soledad Cabezón Ruiz

Draft opinion
Paragraph 1 a (new)

Draft opinion

Amendment

1a. *Underlines the need of efficiency and coordination of research actions; welcomes therefore initiatives as the ERA-NET for establishing synergies between the Joint Programming Initiative on Antimicrobial Resistance Research and Horizon 2020;*

Or. en

Amendment 34
Rolandas Paksas

Draft opinion
Paragraph 1 a (new)

Draft opinion

Amendment

1a. Stresses the need to provide investment and market incentives to promote research and development, to deliver new antimicrobials, vaccines, rapid diagnostics and alternative antimicrobial therapies;

Or. en

Amendment 35
Michèle Rivasi
on behalf of the Verts/ALE Group

Draft opinion
Paragraph 1 a (new)

Draft opinion

Amendment

1a. Calls to invest the EU funds in the context of Horizon 2020 and the next EU Framework Programme into research and development of alternative, albeit complementary, treatments such as phagotherapy;

Or. en

Amendment 36
Lieve Wierinck, Fredrick Federley, Dominique Riquet

Draft opinion
Paragraph 1 a (new)

Draft opinion

Amendment

1a. Urges the need to enable antimicrobial stewardship in order to

improve evidence-based prescribing;

Or. en

Amendment 37
Neoklis Sylikiotis, Xabier Benito Ziluaga

Draft opinion
Paragraph 1 a (new)

Draft opinion

Amendment

1a. Emphasises the need to increase funding for R&I regarding the rare diseases (orphan drugs);

Or. en

Amendment 38
Soledad Cabezón Ruiz

Draft opinion
Paragraph 1 b (new)

Draft opinion

Amendment

1b. Highlights the fact that AMR rates vary widely among the Member States, for which reason it is crucial to coordinate national plans with specific targets and it is in this area of coordination and monitoring of national strategies that the Commission plays a key role;

Or. es

Amendment 39
Neoklis Sylikiotis, Xabier Benito Ziluaga

Draft opinion
Paragraph 1 b (new)

Draft opinion

Amendment

1b. Emphasises the need to increase the funding for different instruments under H2020 so as to boost the research for improving our knowledge on detection, emergence and spread of AMR, prevention measures and effective infection control;

Or. en

Amendment 40

Michèle Rivasi

on behalf of the Verts/ALE Group

Draft opinion

Paragraph 1 b (new)

Draft opinion

Amendment

1b. Stresses the urgent need for in-depth research on the impact of presence antimicrobial substances on food crops and animal feed on the development of AMR, and on microbial community in soil;

Or. en

Amendment 41

Lieve Wierinck

Draft opinion

Paragraph 1 b (new)

Draft opinion

Amendment

1b. Inquires further cautious exploration of the possibilities of the use of off-label medicines as an alternative and as an additional treatment in AMR;

Or. en

Amendment 42
Neoklis Sylikiotis, Xabier Benito Ziluaga

Draft opinion
Paragraph 1 c (new)

Draft opinion

Amendment

1c. Recalls that the most rapid and cost-effective strategy for addressing AMR is to ensure the adequate and rational use of the existing antimicrobials; highlights that all actors involved in the antimicrobials life-cycle chain shall take responsibility and cooperate towards this goal, including in particular the pharmaceutical, health and livestock industries; calls on the Commission to update and strengthen its guidelines and requirements for a prudent and rational use of antimicrobials in humans and animals;

Or. en

Amendment 43
Soledad Cabezón Ruiz

Draft opinion
Paragraph 1 c (new)

Draft opinion

Amendment

1c. Recalls that health is a factor which affects productivity and competitiveness, as well as being one of the assets which is most valued by the public; stresses, therefore, that the establishment of national and European objectives to combat AMR should form part of the political and economic agenda of the EU.

Or. es

Amendment 44
Lieve Wierinck, Fredrick Federley, Dominique Riquet

Draft opinion
Paragraph 1 c (new)

Draft opinion

Amendment

1c. Underlines the need to invest in research and innovation dedicated to improvement of vaccination in order to support prevention;

Or. en

Amendment 45
Soledad Cabezón Ruiz

Draft opinion
Paragraph 1 d (new)

Draft opinion

Amendment

1d. Recalls that it is estimated that AMR could result in up to 10 million deaths per year by 2050 unless there is a change of course; highlights that more than 9 million of the estimated deaths would occur outside the EU, in developing countries, notably in Asia and Africa, and that AMR infections and resistance are contagious and do not respect borders; owing to the cross-border nature of this threat, stresses, therefore, the urgent need for global action rather than action limited to the EU; for this reason, calls on a clear commitment by the EU and the Member States to launch a global, worldwide strategy to combat AMR to guarantee its success, a strategy which should be cross-sectoral covering areas such as, inter alia, trade and international trade agreements, development policy, including considerations to improve

health conditions in developing countries, agricultural policy, banning the use of antibiotics in healthy animals to fatten them up.

Or. es

Amendment 46
Soledad Cabezón Ruiz

Draft opinion
Paragraph 1 e (new)

Draft opinion

Amendment

1e. Stresses that a third of prescriptions are issued in primary care, for which reason the prescription guidelines ought primarily to take account of this sector.

Or. es

Amendment 47
Bendt Bendtsen

Draft opinion
Paragraph 2

Draft opinion

Amendment

2. Calls for the development of various push and pull incentives to create new medicines and medical devices; believes that incentives are meaningful when they are sustainable over the long term, stimulate investment across the entire product development and life cycle, target key public health priorities, and support appropriate medicinal use;

2. Calls for ***incentivisation of the industry, such as*** the development of various push and pull incentives, to create new medicines and medical devices; believes that incentives are meaningful when they are sustainable over the long term, stimulate investment across the entire product development and life cycle, target key public health priorities, and support appropriate medicinal use;

Or. en

Amendment 48

Michèle Rivasi

on behalf of the Verts/ALE Group

Draft opinion

Paragraph 2

Draft opinion

2. Calls for the development of various push and pull incentives to ***create new medicines and medical devices***; believes that incentives are meaningful when they are sustainable over the long term, stimulate investment across the entire product development and life cycle, target key public health priorities, and support appropriate medicinal use;

Amendment

2. Calls for the development of various push and pull incentives to ***find and implement new treatments***; believes that incentives are meaningful when they are sustainable over the long term, stimulate investment across the entire product development and life cycle, target key public health priorities, and support appropriate medicinal use;

Or. en

Amendment 49

Lieve Wierinck, Dominique Riquet

Draft opinion

Paragraph 2 – subparagraph 1 (new)

Draft opinion

Amendment

Considers that the pull models can exist of, but are not limited to the following models:

- ***Transferable Market Exclusivities (TME):TMEs are a type of pull mechanisms that grants the new antibiotic market additional months of additional market exclusivity that can be transferred to another compound with a better commercial opportunity. This model could only work under the following conditions: defined length of the extension of exclusivity; distribute exclusivity amongst diverse compounds and each compound can only benefit from a TME once;***

sufficient notice: public disclosure of target compound for TME utilisation;

- *Lump sum Market Entry Reward (MER): increasing the revenue of new antimicrobials by directly through a cash payment upon market entry. These lump sum payment model could only work if the following conditions are met: scientifically sound criteria for entitlement to a reward, basing eligibility criteria on lists issued by the WHO or other relevant bodies; a pre-defined maximum number of rewards for priority pathogen and/or target product profile, defined by relevant organisations based on current and future medical need;*
- *National or personal insurance model: as part of national or personal health insurance, citizens can ensure the access and development of new antimicrobials;*

Or. en

Amendment 50
Miapetra Kumpula-Natri

Draft opinion
Paragraph 2 a (new)

Draft opinion

Amendment

2a. Recognises the differences between Member States in the practices and levels of use of antimicrobial medicines; calls for enhanced cooperation and sharing of best practices between Member States to develop evidence-based guidance to the use of antimicrobial medicines, to combat over usage of antimicrobial medicines and to foster research into AMR;

Or. en

Amendment 51

Cristian-Silviu Buşoi, Françoise Grossetête, Anna Záborská

Draft opinion

Paragraph 2 a (new)

Draft opinion

Amendment

2a. *Calls for the use of transferable market exclusivities as an option of meaningful incentives, which would allow the licensee of a new antimicrobial compound to extend to exclusivity of another compound, provided that they are applied with due consideration to the sustainability of healthcare systems;*

Or. en

Amendment 52

Neoklis Sylikiotis, Xabier Benito Ziluaga

Draft opinion

Paragraph 2 a (new)

Draft opinion

Amendment

2a. *Calls on the Commission to ensure that substantial R&D efforts are made for increasing knowledge and properly assessing the role of the human, animal and manufacturing waste streams play in the development and spread of AMR, as foreseen in the One-Health action plan;*

Or. en

Amendment 53

Lieve Wierinck, Fredrick Federley, Dominique Riquet

Draft opinion

Paragraph 2 a (new)

Draft opinion

Amendment

2a. *Underlines the importance of identifying and addressing specific access, market sustainability and supply bottlenecks for existing antibiotics, diagnostics and vaccines, and the development of innovative financing and procurement mechanisms to resolve them;*

Or. en

Amendment 54
Soledad Cabezón Ruiz

Draft opinion
Paragraph 2 a (new)

Draft opinion

Amendment

2a. *Highlights the fact that more than 20 new classes of antibiotics were developed until the 1960s and that only a few new types of antibiotics have reached the market since then;*

Or. en

Amendment 55
Soledad Cabezón Ruiz

Draft opinion
Paragraph 2 b (new)

Draft opinion

Amendment

2b. *Points out that this little interest from pharmaceutical companies in developing new antibiotics is caused by the short returns on investments; remembers that the antibiotics are medicines with which the patient is cured and their use is always temporary, what means that the development of new*

antibiotics cannot be linked to the usual economic model industry is used to, as for example chronic diseases in which the patient has to use the drug continuously and there is no cure, being then benefits higher than in the case of antibiotics;

Or. en

Amendment 56
Soledad Cabezón Ruiz

Draft opinion
Paragraph 2 c (new)

Draft opinion

Amendment

2c. Remembers that both institutions, the European Parliament and the Council have asked to review current incentives (i.e. orphan medicines regulation), due to the misused of them and the high final price; calls therefore on the Commission to analyse current R&D incentives models in order to design specific new ones for both, orphan medicines and antibiotics;

Or. en

Amendment 57
Soledad Cabezón Ruiz

Draft opinion
Paragraph 2 d (new)

Draft opinion

Amendment

2d. Recalls on the need of transparency of real costs when there are public funds and on the delinkage of R&D costs from products prices and sales volumes; in this regard, highlights that guaranteeing affordability and access to quality antibiotics must be the final aim of

Amendment 58
Soledad Cabezón Ruiz

Draft opinion
Paragraph 2 e (new)

Draft opinion

Amendment

2e. Underlines the importance of working on a definition of R&D costs, where disbursements disconnected from the production chain and direct and indirect subsidies are subtracted;

Amendment 59
Soledad Cabezón Ruiz

Draft opinion
Paragraph 3

Draft opinion

Amendment

3. Expresses the urgent need to foster partnerships throughout the EU in order to enhance the exchange of best practices and improve knowledge on AMR;

3. Expresses the urgent need to foster partnerships throughout the EU in order to enhance the exchange of best practices and improve knowledge on AMR; *believes in the need of different models of collaboration through the impulse from the public sector and the involvement of industry; recognises that the capacities of industry play a key role in R&D of AMR; notwithstanding the above, stresses that further public prioritisation and coordination are required for R&D in this urgent topic; therefore calls on the Commission to launch a Public Network for the coordination of all public funded R&D projects in AMR, similar to the*

Amendment 60

Cristian-Silviu Buşoi, Françoise Grossetête, Anna Záborská

Draft opinion

Paragraph 3

Draft opinion

3. Expresses the urgent need to foster partnerships throughout the EU in order to enhance the exchange of best practices and improve knowledge on AMR;

Amendment

3. Expresses the urgent need to foster partnerships throughout the EU in order to enhance the exchange of best practices and improve knowledge on AMR; ***encourages further pursuing private-public collaborations, such as the Innovative Medicine Initiative (IMI) programmes "New Drugs for Bad Bugs", COMBACTE, TRANSLOCATION, Drive AB or ENABLE, to harness the power of collaboration; furthermore encourages public-private partnerships aiming to foster innovation in the field;***

Amendment 61

Neoklis Sylikiotis, Xabier Benito Ziluaga

Draft opinion

Paragraph 3

Draft opinion

3. Expresses the urgent need to foster partnerships throughout the EU in order to enhance the exchange of best practices and improve knowledge on AMR;

Amendment

3. ***Emphasises that the EU should be at the forefront of the fight to address AMR, providing practical guidance to ensure sustainable effective action, in line with the Global Action Plan agreed by the World Health Assembly in 2015;***

expresses the urgent need to foster partnerships throughout the EU in order to enhance the exchange of best practices and improve knowledge on AMR;

Or. en

Amendment 62
Rolandas Paksas

Draft opinion
Paragraph 3

Draft opinion

3. Expresses the urgent need to foster partnerships throughout the EU in order to enhance the exchange of best practices and improve knowledge on AMR;

Amendment

3. Expresses the urgent need ***to build a more holistic system for monitoring AMR issues, linking data on resistance, consumption and sales of antimicrobials to prescribing trends and other factors and*** to foster partnerships throughout the EU in order to enhance the exchange of best practices and improve knowledge on AMR;

Or. en

Amendment 63
Rolandas Paksas

Draft opinion
Paragraph 3

Draft opinion

3. Expresses the urgent need to foster partnerships throughout the EU in order to enhance the exchange of best practices and improve knowledge on AMR;

Amendment

3. Expresses the urgent need to foster partnerships throughout the EU in order to enhance the exchange of best practices and improve knowledge on AMR; ***points out that particular attention must be paid to strengthening cooperation with the biotechnology research and industry sectors;***

Amendment 64

Michèle Rivasi

on behalf of the Verts/ALE Group

Draft opinion

Paragraph 3

Draft opinion

3. Expresses the urgent need to foster partnerships throughout the EU in order to enhance the exchange of best practices and improve knowledge on AMR;

Amendment

3. Expresses the urgent need to foster partnerships throughout the EU in order to enhance the exchange of best practices ***in reducing the use of antibiotics*** and improve knowledge on AMR;

Or. en

Amendment 65

Anna Záborská, Cristian-Silviu Buşoi

Draft opinion

Paragraph 3

Draft opinion

3. Expresses the urgent need to foster partnerships ***throughout*** the EU in order to enhance the exchange of best practices and improve knowledge on AMR;

Amendment

3. Expresses the urgent need to foster partnerships ***within*** the EU ***and beyond*** in order to enhance the exchange of best practices and improve knowledge on AMR;

Or. en

Amendment 66

Soledad Cabezón Ruiz

Draft opinion

Paragraph 3 a (new)

Draft opinion

Amendment

3a. Welcomes, regarding alternatives business models to promote R&D, initiatives as the Global Antibiotic Research and Development Partnership - GARDP initiative-, that explores alternative business models since the market has failed to sufficiently support the development of new antibiotics; remembers that the new business models need to be sustainable, needs-driven, evidence-based and guided by principles of affordability, effectiveness, efficiency and equity, in the benefit of patients;

Or. en

Amendment 67
Lieve Wierinck, Fredrick Federley, Dominique Riquet

Draft opinion
Paragraph 3 a (new)

Draft opinion

Amendment

3a. Underlines the importance of improvement and dedication of Public Private Partnerships and collaborations between industry, SMEs and public researchers to overcome the scientific challenges of creating new antibiotics, vaccines and diagnostics;

Or. en

Amendment 68
Neoklis Sylikiotis, Xabier Benito Ziluaga

Draft opinion
Paragraph 3 a (new)

Draft opinion

Amendment

3a. Underlines that the EU should co-fund the Member States so as to help

them establish and implement their national One-Health action plans against AMR;

Or. en

Amendment 69
Soledad Cabezón Ruiz

Draft opinion
Paragraph 3 b (new)

Draft opinion

Amendment

3b. Welcomes the conclusions of the “WHO, WIPO, WTO Joint Technical Symposium on Antimicrobial Resistance: how to foster innovation, access and appropriate use of antibiotics”^{4a} where new R&D models were discussed to incentivize R&D while delinking the profitability of an antibiotic from volumes sold to correct the antibiotics market;

^{4a}

<http://www.wipo.int/publications/en/details.jsp?id=4197>.

Or. en

Amendment 70
Lieve Wierinck, Fredrick Federley, Dominique Riquet

Draft opinion
Paragraph 3 b (new)

Draft opinion

Amendment

3b. Urges the Commission to develop a mission on AMR in the future FP9 with a cross-sectorial and interdisciplinary approach;

Amendment 71
Rolandas Paksas

Draft opinion
Paragraph 4

Draft opinion

4. Stresses the need to improve data collection on a systemic level throughout the EU, and to monitor and act rapidly on AMR-related trends and developments; points out the added value of eHealth and digitalisation, which offer the opportunity to pool and cumulate data on AMR;

Amendment

4. ***Calls for strengthening global surveillance of AMR and antimicrobial usage in humans, animals and the environment to better understand the problem and inform actions***; stresses the need to improve data collection on a systemic level throughout the EU, and to monitor and act rapidly on AMR-related trends and developments; points out the added value of eHealth and digitalisation, which offer the opportunity to pool and cumulate data on AMR;

Amendment 72
Cristian-Silviu Buşoi, Anna Záborská

Draft opinion
Paragraph 4

Draft opinion

4. Stresses the need to improve data collection on a systemic ***level*** throughout the EU, and to monitor and act rapidly on AMR-related trends and developments; points out the added value of eHealth and digitalisation, which offer the opportunity to pool and cumulate data on AMR;

Amendment

4. Stresses the need to improve data collection on ***prevalence, patterns and us/misuse on a systemic manner*** throughout the EU, and to monitor and act rapidly on AMR-related trends and developments; points out the added value of eHealth and digitalisation, which offer the opportunity to pool and cumulate data on AMR;

Amendment 73
Soledad Cabezón Ruiz

Draft opinion
Paragraph 4 a (new)

Draft opinion

Amendment

4a. Highlights the need of an EU data collection system on the right use of all antibiotics. asks, therefore, for the development of protocols for prescription and use of antibiotics at a EU level recognising the responsibility of veterinarians and primary care doctors among others; asks also for the compulsory collection, at a national level, of all prescriptions of antibiotics, and its registration in a database of the using and prescription of antibiotics controlled and coordinated by experts in infections to spread the knowledge on the best use of them;

Or. en

Amendment 74
Neoklis Sylikiotis, Xabier Benito Ziluaga

Draft opinion
Paragraph 4 a (new)

Draft opinion

Amendment

4a. Stresses the importance to improve awareness and understanding of AMR through effective sanitation, prevention measures, education and training, including EU public awareness campaigns and targeted training for health professionals, pharmacists, veterinarians and livestock breeders;

Or. en

Amendment 75

Lieve Wierinck, Fredrick Federley, Dominique Riquet

Draft opinion

Paragraph 4 a (new)

Draft opinion

Amendment

4a. Emphasises the need to analyse big data coming from different industry sectors;

Or. en

Amendment 76

Soledad Cabezón Ruiz

Draft opinion

Paragraph 4 b (new)

Draft opinion

Amendment

4b. Underlines, regarding patients and healthcare systems, the different measures comprised in the EDCD report “Last-line antibiotics are failing: options to address this urgent threat to patients and healthcare systems”^{7a}, especially measures to avoid the spread of highly resistant bacteria in hospitals such as: mandatory reporting of all patients who were carriers of highly resistant bacteria to public health authorities; mandatory isolation of hospitalised carriers and creation of a multidisciplinary professional taskforce reporting directly to the Ministry of Health; Asks for the inclusion of this measures in the European Semester;

^{7a}

<https://ecdc.europa.eu/sites/portal/files/media/en/publications/Publications/antibioti>

Amendment 77

Lieve Wierinck, Fredrick Federley, Dominique Riquet

Draft opinion

Paragraph 4 b (new)

Draft opinion

Amendment

4b. Highlights the importance of environmental data in order to have an overview of all aspects affecting AMR;

Or. en

Amendment 78

Lieve Wierinck, Fredrick Federley, Dominique Riquet

Draft opinion

Paragraph 4 c (new)

Draft opinion

Amendment

4c. Underlines the lack of collection of data on the impact on health and socioeconomic burden of AMR on an EU-level and global scale;

Or. en

Amendment 79

Lieve Wierinck, Fredrick Federley, Dominique Riquet

Draft opinion

Paragraph 4 d (new)

Draft opinion

Amendment

4d. Asks the Member States to improve

and enable the access to personalized care of patients;

Or. en

Amendment 80
Soledad Cabezón Ruiz

Draft opinion
Paragraph 5

Draft opinion

5. Underlines the systemic nature of AMR; supports the Commission's renewed commitment to promoting EU actions and leadership in fighting AMR, including internationally; highlights the need for enhanced collaboration, including in R&I, and the role of science diplomacy, in fostering synergies and optimising resource allocation.

Amendment

5. Underlines the systemic nature of AMR; supports the Commission's renewed commitment to promoting EU actions and leadership in fighting AMR, including internationally; highlights the need for enhanced collaboration, including in R&I, and the role of science diplomacy, in fostering synergies and optimising resource allocation; ***calls on the Commission to create partnerships as PRIMA or EDCTP for international R&D projects on Health, comprising different geographical regions and the most sensible health topics as AMR, vaccines, cancer or access to medicines;***

Or. en

Amendment 81
Soledad Cabezón Ruiz

Draft opinion
Paragraph 5 a (new)

Draft opinion

Amendment

5a. Welcomes the WHO ranking list of 20 Worst Antibiotic-Resistant Pathogens^{2a}; calls on urgent R&D projects on this priority list of antibiotic-resistant bacteria in order to create drugs

to fight them; highlights however that research on new drugs is not the only action needed and that misused and over-use must be tackled in both humans and animals as this is contributing to the rising threat of antibiotic resistance;

2a

<http://www.who.int/mediacentre/news/releases/2017/bacteria-antibiotics-needed/en/>.

Or. en

Amendment 82
Neoklis Sylikiotis, Xabier Benito Ziluaga

Draft opinion
Paragraph 5 a (new)

Draft opinion

Amendment

5a. Underlines the significant part that the pharmaceutical industry shall play in this long-term effort on Combating AMR. Calls on the Commission to further explore the requirements of this contribution by the pharmaceutical industry, namely, inter alia, by asking for AMR information in the labelling of antimicrobial products and involving the industry in the monitoring and evaluation of the average use of each commercialized product;

Or. en

Amendment 83
Anna Záborská, Cristian-Silviu Buşoi

Draft opinion
Paragraph 5 a (new)

Draft opinion

Amendment

5a. *Calls for the strengthening AMR surveillance national systems in developing countries in order to achieve the standardization of results;*

Or. en

Amendment 84
Rupert Matthews

Draft opinion
Paragraph 5 a (new)

Draft opinion

Amendment

5a. *Notes the positive externalities/spillover effects of new antimicrobials on public health and science;*

Or. en

Amendment 85
Lieve Wierinck, Dominique Riquet, Fredrick Federley

Draft opinion
Paragraph 5 a (new)

Draft opinion

Amendment

5a. *Calls upon the G7, G20 and BRICS to act and work in close collaboration;*

Or. en

Amendment 86
Lieve Wierinck, Fredrick Federley, Dominique Riquet

Draft opinion

Paragraph 5 b (new)

Draft opinion

Amendment

5b. Urges to scale up and combine the numerous international programmes on EU and international level in order to facilitate and support the programmes of European Antimicrobial Resistance Network (EARS-Net), European Surveillance of Antimicrobial Consumption Network (ESAC-Net), Central Asian and Eastern European Surveillance of Antimicrobial Resistance (CAESAR), Joint Interagency Antimicrobial Consumption and Resistance Analysis (JIACRA), , Institutional Programme for the Prevention and Control of Healthcare Associated Infections and Appropriate Use of Antimicrobials (PIRASAO), WHO Antimicrobial Medicines Consumption Network (AMC), European & Developing Countries Clinical Trials Partnership(EDCTP) and Poverty Related and Neglected Diseases (PRND)^{1a};

^{1a} Damage done by Poverty Related and Neglected Diseases within the EU in the year 2015: almost 10.000 Deaths in the EU, 30.000 new HIV infections, mosquito transmitting dengue and chikungunya reported in many parts of Europe. Cf. Global Burden of Disease Results Tool, WHO and European Centre for Disease Prevention and Control.

Or. en

Amendment 87
Soledad Cabezón Ruiz

Draft opinion
Paragraph 5 b (new)

5b. Welcomes the new WHO recommendations aim to help preserving the effectiveness of antibiotics that are important for human medicine by reducing their unnecessary use in animals^{3a}; highlights that in some countries, approximately 50-70% of total consumption of medically important antibiotics is in the animal sector, largely for growth promotion in healthy animals; asks, in the framework of the One Health approach, to include this topic in the Trade Policy of the EU and in negotiations with international organisations as WTO and associated or third countries, shaping a global policy in order to ban the use of antibiotics for fattening healthy animals;

^{3a}

http://www.who.int/foodsafety/areas_work/antimicrobial-resistance/cia_guidelines/en/.

Or. en

Amendment 88
Neoklis Sylikiotis, Xabier Benito Ziluaga

Draft opinion
Paragraph 5 b (new)

5b. Recalls, as stated in the Commission Guidelines for the prudent use of antimicrobials in veterinary medicine, that the untargeted use of antimicrobials, its use in sub-therapeutic doses and its use for inappropriate periods of time severely increases the risk of development of AMR; stresses that the EU livestock industry must remain a global

leader in phasing out the misuse of antimicrobials as a matter of routine, specially through feed and drinking water, and calls on the Commission for further strengthening the requirements for the use of antimicrobials in the livestock industry;

Or. en

Amendment 89
Anna Záborská, Cristian-Silviu Buşoi

Draft opinion
Paragraph 5 b (new)

Draft opinion

Amendment

5b. Stresses the importance of closer cooperation between industry and the university and scientific establishment, so as to facilitate the creation of dedicated structures within universities and scientific centres for the purpose of fighting against AMR;

Or. en

Amendment 90
Rupert Matthews

Draft opinion
Paragraph 5 b (new)

Draft opinion

Amendment

5b. Emphasises that, to be effective, incentives must meet or exceed the costs of developing new drugs over their life-cycle;

Or. en

Amendment 91
Soledad Cabezón Ruiz

Draft opinion
Paragraph 5 c (new)

Draft opinion

Amendment

5c. Remembers that classic generation of antibiotics, based on a series of antibiotic modification techniques obtained from nature, is exhausted and that R&D investments to create a new generation should break the classical antibiotic paradigm; welcomes new techniques that have already being developed as for example, monoclonal antibodies that reduce the virulence of the bacteria, not killing it, but rendering it useless;

Or. en

Amendment 92
Rupert Matthews

Draft opinion
Paragraph 5 c (new)

Draft opinion

Amendment

5c. Emphasises the potential role for European research bodies to take global leadership roles, for example in G7 and G20 fora;

Or. en

Amendment 93
Soledad Cabezón Ruiz

Draft opinion
Paragraph 5 d (new)

5d. Underlines the importance of European initiatives as the ECDC programmes for infectious diseases as AIDS, TB or Malaria, Points out that these initiatives are examples of good practices of the responsiveness and good functioning of the EU in view of the need for new antibiotics, and that the ECDC should have a key role in the prioritisation of R&D needs, in the coordination of actions and involvement of all actors, in enhancing cross-sectorial work and in capacity building through R&D networks;

Or. en

Amendment 94
Soledad Cabezón Ruiz

Draft opinion
Paragraph 5 e (new)

5e. Brings up the report “Tackling drug-resistant infections globally: final report and recommendations”^{5a} that estimates the cost of taking global action on AMR is up to 40 billion USD over a 10-year period what means what is tiny in comparison to the cost of inaction and it is also a very small fraction of what the G20 countries spend on healthcare today: about 0.05 percent; calls on the Commission to analyse these figures and the possibility to impose a tax on the industry for public health in the framework of its social responsibility;

^{5a} https://amr-review.org/sites/default/files/160518_Final%20paper_with%20cover.pdf.

Amendment 95
Soledad Cabezón Ruiz

Draft opinion
Paragraph 5 f (new)

Draft opinion

Amendment

5f. Welcomes the Davos Declaration on Combating Antimicrobial Resistance launched at the World Economic Forum in Davos on January 2016, where pharmaceutical, biotechnology and diagnostics industries “recognise the success of programmes to improve global access to drugs in HIV, TB, and malaria and call for a similar collaborative effort to address issues of access to antibiotics”^{6a};

^{6a} https://amr-review.org/sites/default/files/Industry_Declaration_on_Combating_Antimicrobial_Resistance_UPDATED%20SIGNATORIES_MAY_2016.pdf.

Or. en

Amendment 96
Soledad Cabezón Ruiz

Draft opinion
Paragraph 5 g (new)

Draft opinion

Amendment

5g. Alerts that the FAO estimates that the use of antibiotics and pesticides in agriculture will dramatically increase; calls on the Commission and member States to study new methods to eliminate the residues of pesticides and antibiotics

*on food; asks, as well, for the ban of the
use of last-line antibiotics in the
veterinary field;*

Or. en