



EUROPEAN PARLIAMENT

2009 - 2014

Committee on the Environment, Public Health and Food Safety

PE472.302v01-00

26.9.2011

AMENDMENTS

1 - 51

Draft motion for a resolution

Françoise Grossetête

on behalf of the PPE Group

Linda McAvan

on behalf of the S&D Group

Theodoros Skylakakis

on behalf of the ALDE Group

Miroslav Ouzký

on behalf of the ECR Group

Bart Staes

on behalf of the Verts/ALE Group

Kartika Tamara Liotard

on behalf of the GUE/NGL Group

Oreste Rossi

on behalf of the EFD Group

(PE472.229v01-00)

The public health threat of antimicrobial resistance

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PE472.302v03-00

EN

United in diversity

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Amendment 1
Mairead McGuinness

Draft motion for a resolution
Citation 1 a (new)

Draft motion for a resolution

Amendment

- having regard to the European Food Safety Authority (EFSA) Scientific Opinion "on the public health risks of bacterial strains producing extended-spectrum β -lactamases and/or AmpC β -lactamases in food and food-producing animals" of August 2011;

Or. en

Amendment 2
Françoise Grossetête

Draft motion for a resolution
Recital D

Draft motion for a resolution

Amendment

D. whereas the launch of every new antibiotic has been and will be followed by resistance in the targeted bacteria; whereas ***a constant*** development of new antimicrobial agents ***can not keep pace with the development of resistances and*** thus points to the priority of ensuring that the use of antibiotics is effectively controlled and limited to necessary treatment only,

D. whereas the launch of every new antibiotic has been and will be followed by resistance in the targeted bacteria; whereas ***the maintenance of an effective capacity to combat infectious disease requires both the*** development of new antimicrobial agents ***and improved conservation of existing antibiotic resources;*** thus points to the priority of ensuring that the use of antibiotics is effectively controlled and limited to necessary treatment only,

Or. en

Amendment 3
Kartika Tamara Liotard
on behalf of the GUE/NGL Group

Draft motion for a resolution
Recital F a (new)

Draft motion for a resolution

Amendment

Fa. whereas a high percentage of hospital-acquired infections are caused by highly resistant bacteria such as methicillin-resistant Staphylococcus aureus (MRSA),

Or. en

Amendment 4
Bill Newton Dunn

Draft motion for a resolution
Recital F a (new)

Draft motion for a resolution

Amendment

Fa. whereas resistant strains of bacteria constitute a serious risk to patient safety in terms of Healthcare Associated Infection, such as C. difficile and MRSA.

Or. en

Amendment 5
Horst Schnellhardt
Christa Klaß

Draft motion for a resolution
Recital H

Draft motion for a resolution

Amendment

H. whereas ***there are clear links between the use of antibiotics for veterinary purposes and the development of resistance in humans; whereas despite the ban of the use of antibiotics as growth promoters, there seems to be no significant decrease in the consumption of antibiotics in the veterinary sector, which***

H. whereas ***the role of animals, of food of animal origin, and of resistant bacteria occurring in animal husbandry in the transfer of AMR to humans and the potential dangers resulting thereof may not be sufficiently clear; whereas the use of antibiotics in sub-therapeutic levels in animal husbandry is prohibited in the EU,***

continue to be used systematically for "prophylactic" purposes due to unsustainable agricultural practices,

Or. en

Amendment 6
Esther Herranz García

Draft motion for a resolution
Recital H

Draft motion for a resolution

H. *whereas there are clear links between the use of antibiotics for veterinary purposes and the development of resistance in humans*; whereas despite the ban of the use of antibiotics as growth promoters, *there seems to be no significant* decrease in the consumption of antibiotics in the veterinary sector, *which continue to be used systematically for "prophylactic" purposes due to unsustainable* agricultural practices,

Amendment

H. whereas despite the ban of the use of antibiotics as growth promoters *and the* decrease in the consumption of antibiotics in the veterinary sector, *additional efforts are required to avoid inappropriate* "prophylactic" purposes *by improving* agricultural practices, *contributing to minimizing the potential risk associated to the use of antibiotics for veterinary purposes and the development of resistance in humans,*

Or. en

Amendment 7
Britta Reimers

Draft motion for a resolution
Recital H

Draft motion for a resolution

H. *whereas there are clear links between the use of antibiotics for veterinary purposes and the development of resistance in humans*; whereas despite the ban of the use of antibiotics as growth promoters, there seems to be no significant decrease in the consumption of antibiotics

Amendment

H. *whereas a considerable part of antimicrobial resistance is prescribed for use in animals and AMR affects both humans and animals and can also pass from both humans to animals and animals to humans, this is a truly cross-cutting matter which calls for a*

in the veterinary sector, which continue to be used systematically for "prophylactic" purposes due to unsustainable agricultural practices,

coordinated approach at community level, whereas despite the ban of the use of antibiotics as growth promoters, there seems to be no significant decrease in the consumption of antibiotics in the veterinary ***and human*** sector, which continue to be used systematically for "prophylactic" purposes due to unsustainable agricultural practices,

Or. en

Amendment 8
Mairead McGuinness

Draft motion for a resolution
Recital H a (new)

Draft motion for a resolution

Amendment

Ha. whereas good husbandry minimises the need for antibiotics,

Or. en

Amendment 9
Horst Schnellhardt
Christa Klaß

Draft motion for a resolution
Recital H a (new)

Draft motion for a resolution

Amendment

Ha. whereas antimicrobial resistance in humans is often caused by inadequate doses of antibiotic medicines, by incorrect treatments and through the constant exposure of pathogens to antimicrobial agents in hospitals,

Or. en

Amendment 10
Horst Schnellhardt
Christa Klaß

Draft motion for a resolution
Recital I

Draft motion for a resolution

I. whereas action ***against resistance to antimicrobial agents*** in human medicines ***can therefore not to be taken in isolation from measures to combat resistance to antimicrobial agents*** in veterinary medicines, animal feeding stuffs and crop growing,

Amendment

I. whereas action ***to ensure the efficacy of antibiotic treatments needs to be mindful of use*** in human medicines, veterinary medicines, animal feeding stuffs and crop growing,

Or. en

Amendment 11
Mairead McGuinness

Draft motion for a resolution
Recital I a (new)

Draft motion for a resolution

Ia. whereas EPRUMA is an existing European multi-stakeholder initiative promoting the responsible use of veterinary medicines; notes that the One-Health concept covers both human and veterinary medicines and that EPRUMA recognises antimicrobials as a One Health issue,

Amendment

Or. en

Amendment 12
Theodoros Skylakakis

Draft motion for a resolution
Recital J

Draft motion for a resolution

J. whereas antimicrobial resistance is a phenomenon which clearly has cross-border implications and the occurrence of an outlier effect which would most probably not be manageable with the current resources and knowledge, cannot be excluded,

Amendment

J. whereas antimicrobial resistance is a phenomenon which clearly has cross-border implications and the occurrence of an outlier effect which would most probably not be manageable with the current resources and knowledge, cannot be excluded ***and can have unpredictable medical, social and economic setbacks,***

Or. en

Amendment 13
Theodoros Skylakakis

Draft motion for a resolution
Recital J a (new)

Draft motion for a resolution

Amendment

Ja. whereas antimicrobial resistance is a phenomenon that involves non-renewable global resources, is caused by human activity and it is linked to our behaviour,

Or. en

Amendment 14
Kartika Tamara Liotard
on behalf of the GUE/NGL Group

Draft motion for a resolution
Recital J a (new)

Draft motion for a resolution

Amendment

Ja. whereas inappropriate and irrational use of antimicrobial medicines provides favourable conditions for resistant microorganisms to emerge, spread and persist,

Amendment 15
Mairead McGuinness

Draft motion for a resolution
Paragraph 1 a (new)

Draft motion for a resolution

Amendment

1a. Calls on the Commission to address the lack of information on EU-wide antibiotic use in veterinary medicines by gathering high quality, comparable, species-specific data for each member state;

Or. en

Amendment 16
Philippe Juvin

Draft motion for a resolution
Paragraph 2 - third indent

Draft motion for a resolution

Amendment

- the need for the development of new antimicrobial agents and alternatives,

- the need for ***the research and*** the development of new antimicrobial agents and alternatives,

Or. en

Amendment 17
Horst Schnellhardt
Christa Klaß

Draft motion for a resolution
Paragraph 3

Draft motion for a resolution

3. Calls on the Commission to propose without delay a legislative framework for action against antimicrobial resistance,

Amendment

3. Calls on the Commission to propose without delay a legislative framework for action against antimicrobial resistance, ***by promoting "responsible use"-initiatives and supporting dissemination of and information about those,***

Or. en

Amendment 18
Mairead McGuinness

Draft motion for a resolution
Paragraph 3

Draft motion for a resolution

3 Calls on the Commission to propose without delay a legislative framework for action against antimicrobial resistance,

Amendment

3. Calls on the Commission to propose without delay a legislative framework for action against antimicrobial resistance ***through promotion of and support for responsible use initiatives;***

Or. en

Amendment 19
Marit Paulsen

Draft motion for a resolution
Paragraph 4 a (new)

Draft motion for a resolution

4a. Emphasises that the ultimate objective is to maintain antimicrobials as an effective tool to combat disease, both in animals and in humans, while keeping the use of antimicrobials to the strict necessary,

Or. en

Amendment 20
Theodoros Skylakakis

Draft motion for a resolution
Paragraph 6 a (new)

Draft motion for a resolution

Amendment

6a. notes that in this phenomenon, we are as weak as the weakest link, therefore particular attention should be paid in countries with high levels of antimicrobial resistance,

Or. en

Amendment 21
Christofer Fjellner

Draft motion for a resolution
Paragraph 8 a (new)

Draft motion for a resolution

Amendment

8a. Recognises that patients' lack of adherence and compliance with prescriptions, such as ignoring to complete the course of treatment or not following the dosage recommendations, contributes heavily to antimicrobial resistance,

Or. en

Amendment 22
Theodoros Skylakakis

Draft motion for a resolution
Paragraph 9 a (new)

Draft motion for a resolution

Amendment

9a. Emphasises the fact that in the framework of the prudent use of antimicrobial agents, attention needs to be paid by the relevant actors on the better use of antibiotics currently available, through examining closely at the dosage, the treatment duration and the drug combination,

Or. en

Amendment 23

Françoise Grossetête

Draft motion for a resolution

Paragraph 10

Draft motion for a resolution

Amendment

10. Welcomes therefore the annual European Antibiotic Awareness Day on 18 November, to raise awareness of the public health threat of antimicrobial resistance and to call for a more responsible use of antibiotics,

10. Welcomes therefore the annual European Antibiotic Awareness Day on 18 November, to raise awareness of the public health threat of antimicrobial resistance and to call for a more responsible use of antibiotics, **by multiple actions in Member States,**

Or. en

Amendment 24

Peter Liese

Françoise Grossetête

Mairead McGuinness

Draft motion for a resolution

Paragraph 12

Draft motion for a resolution

Amendment

12. Welcomes therefore the European Antimicrobial Resistance Surveillance System (**EARSS**), while recognising that several difficulties continue to exist with

12. Welcomes therefore **the work begun by** the European Antimicrobial Resistance Surveillance System **and now continued by ECDC on the gathering of high**

respect to data access and quality of data in some of the countries,

quality, comparable, EU-wide data on antimicrobial resistance, while recognising that several difficulties continue to exist with respect to data access and quality of data in some of the countries. ***Welcomes also the work begun by the European Surveillance of Antimicrobial Consumption project and now continued by ECDC on gathering high quality, comparable EU-wide data on antimicrobial consumption,***

Or. en

Amendment 25
Christofer Fjellner

Draft motion for a resolution
Paragraph 12

Draft motion for a resolution

12. Welcomes therefore the European Antimicrobial Resistance Surveillance System (EARSS), while recognising that several difficulties continue to exist with respect to data access and quality of data in some of the countries,

Amendment

12. Welcomes therefore the ***work begun by the*** European Antimicrobial Resistance Surveillance System (EARSS) ***and now continued by the ECDC on the gathering of EU-wide data on antimicrobial resistance***, while recognising that several difficulties continue to exist with respect to data access and quality of data in some of the countries,

Or. en

Amendment 26
Horst Schnellhardt
Christa Klaß

Draft motion for a resolution
Paragraph 12

Draft motion for a resolution

12. Welcomes therefore the European Antimicrobial Resistance Surveillance System (EARSS), while recognising that several difficulties continue to exist with respect to data access and quality of data in some of the countries,

Amendment

12. Welcomes therefore the European Antimicrobial Resistance Surveillance System (EARSS) **and European Surveillance of Veterinary Antimicrobial Consumption (ESVAC)**, while recognising that several difficulties continue to exist with respect to data access and quality of data in some of the countries,

Or. en

Amendment 27
Linda McAvan

Draft motion for a resolution
Paragraph 12

Draft motion for a resolution

12. Welcomes therefore the European Antimicrobial Resistance Surveillance System (EARSS), while recognising that several difficulties continue to exist with respect to data access and quality of data in some of the countries,

Amendment

12. Welcomes therefore the European Antimicrobial Resistance Surveillance System (EARSS), **and the European Surveillance of Veterinary Antimicrobial Consumption project (ESVAC)** while recognising that several difficulties continue to exist with respect to data access and quality of data in some of the countries,

Or. en

Amendment 28
Christofer Fjellner

Draft motion for a resolution
Paragraph 12 a (new)

Draft motion for a resolution

12a. Welcomes the work begun by the European Surveillance of Antimicrobial Consumption project, now continued by the ECDC, on the gathering of EU-wide

Amendment

data on antimicrobial resistance,

Or. en

Amendment 29
Theodoros Skylakakis

Draft motion for a resolution
Paragraph 12 a (new)

Draft motion for a resolution

Amendment

12a. Emphasises the importance of diagnostics in the fight against antimicrobial resistance and calls for more investment on this field as well as for a more efficient and better use of the current diagnostic tools,

Or. en

Amendment 30
Peter Liese
Françoise Grossetête
Mairead McGuinness

Draft motion for a resolution
Paragraph 13

Draft motion for a resolution

Amendment

13. Calls on the Commission *to propose* without delay a harmonised *Antimicrobial Resistance Surveillance System*,

13. Calls on the Commission , *ECDC and other relevant EU agencies to work together* without delay to develop *a harmonised and integrated monitoring systems for antimicrobial resistance and antimicrobial use in Europe, including early warning response for new resistance mechanisms and strain,*

Or. en

Amendment 31
Christofer Fjellner

Draft motion for a resolution
Paragraph 13

Draft motion for a resolution

13. Calls on the Commission to propose without delay a harmonised Antimicrobial Resistance Surveillance System,

Amendment

13. Calls on the Commission to propose without delay a harmonised **and integrated** Antimicrobial Resistance Surveillance System, **including early warning and response for new resistance mechanisms and strains,**

Or. en

Amendment 32
Philippe Juvin

Draft motion for a resolution
Subtitle

Draft motion for a resolution

The need for the development of new antimicrobial agents and alternatives

Amendment

The need for **the research** and the development of new antimicrobial agents and alternatives

Or. en

Amendment 33
Françoise Grossetête

Draft motion for a resolution
Paragraph 15

Draft motion for a resolution

15. Considers the decline in research and development to be the result of a market failure and calls upon the Commission to make proposals to create or improve incentives for the pharmaceutical industry to intensify investments in research and development of new antimicrobial agents

Amendment

15. Considers the decline in research and development to be the result of a market failure and calls upon the Commission to make proposals, **via regulatory pathways and other types of measures,** to create or improve incentives for the pharmaceutical industry to intensify investments in

and in possible alternatives, *whilst recognising that medicine will not be able to keep pace with the development of resistance caused by inappropriate use of antibiotics,*

research and development of new antimicrobial agents and in possible alternatives,

Or. en

Amendment 34
Christofer Fjellner

Draft motion for a resolution
Paragraph 15

Draft motion for a resolution

15. Considers the decline in research and development to be the result of a market failure and calls upon the Commission to make proposals to create or improve incentives for the pharmaceutical industry to intensify investments in research and development of new antimicrobial agents and in possible alternatives, *whilst recognising that medicine will not be able to keep up with the development of resistance caused by inappropriate use of antibiotics,*

Amendment

15. Considers the decline in research and development to be the result of a market failure and calls upon the Commission to make proposals to create or improve incentives for the pharmaceutical industry to intensify investments in research and development of new antimicrobial agents and in possible alternatives,

Or. en

Amendment 35
Theodoros Skylakakis

Draft motion for a resolution
Paragraph 16

Draft motion for a resolution

16. Recalls the need for more research on new antimicrobials as well as on possible alternatives within the EU's Research Framework Programmes,

Amendment

16. Recalls the need for more research on new antimicrobials as well as on possible alternatives within the EU's Research Framework Programmes *and encourages*

*collaborative research on EU level which
can have efficiency -gaining
opportunities,*

Or. en

Amendment 36
Christofer Fjellner

Draft motion for a resolution
Paragraph 16 a (new)

Draft motion for a resolution

Amendment

*16a. Notes that the lack of rapid
diagnostics has contributed to both
antibiotic overuse and rising costs of
development,*

Or. en

Amendment 37
Françoise Grossetête

Draft motion for a resolution
Paragraph 16 a (new)

Draft motion for a resolution

Amendment

*16a. Recognises the need to promote
complementary measures such as the use
of effective vaccines to prevent infections
as included in the Council Conclusions
on innovative incentives for effective
antibiotics of 1 December 2009,*

Or. en

Amendment 38
Françoise Grossetête

Draft motion for a resolution

Paragraph 17

Draft motion for a resolution

17. Calls on the Commission to ensure that measures on antimicrobial resistance and public health are part of a holistic approach on antimicrobial resistance, recognising the links with measures to combat resistance to antimicrobial agents in veterinary medicines, animal feeding stuffs and crop growing,

Amendment

17. Calls on the Commission to ensure that measures on antimicrobial resistance and public health are part of a holistic approach on antimicrobial resistance, recognising the links with measures to combat resistance to antimicrobial agents in veterinary medicines, animal feeding stuffs and crop growing, ***specifically with regards to the risk of cross-transmission,***

Or. en

Amendment 39 Christofer Fjellner

Draft motion for a resolution Paragraph 17 a (new)

Draft motion for a resolution

Amendment

17a. Welcomes efforts to align and improve the regulatory assessment of the new antibiotics,

Or. en

Amendment 40 Horst Schnellhardt Christa Klaß

Draft motion for a resolution Paragraph 18

Draft motion for a resolution

18. Calls on the Commission to ***tackle the problem of the large-scale use of antibiotics in livestock farming in the field of veterinary medicine.***

Amendment

18. Calls on the Commission to ***continue to support EARRS and ESVAC in gathering data on the use of antibiotics as a base for future measures to ensure responsible use.***

Or. en

Amendment 41
Françoise Grossetête

Draft motion for a resolution
Paragraph 18

Draft motion for a resolution

18. Calls on the Commission to tackle the problem of the large-scale use of antibiotics in livestock farming in the field of veterinary medicine.

Amendment

18. Calls on the Commission to tackle the problem of the large-scale use of antibiotics in livestock farming in the field of veterinary medicine, ***in particular through a better analysis and comparison of existing data and a better collection of new data on human and animal health,***

Or. en

Amendment 42
Marit Paulsen

Draft motion for a resolution
Paragraph 18 a (new)

Draft motion for a resolution

18a. Calls, in particular, for the establishment of good practices for animal husbandry, which minimise the risk for antimicrobial resistance; emphasizes that these practices should in particular apply to young animals which are brought together from different breeders and thus increase the risk of communicable diseases,

Or. en

Amendment 43
Horst Schnellhardt
Christa Klaß

Draft motion for a resolution
Paragraph 19

Draft motion for a resolution

19. Calls on the Commission to make legislative proposals to phase out the prophylactic use of antibiotics in livestock farming,

Amendment

19. Calls on the Commission to make legislative proposals to phase out the prophylactic use of antibiotics in livestock farming, ***by taking into consideration scientifically-based, clearly defined criteria for the need to prophylactically use antibiotics, which shall be drawn up by the European Medicines Agency.***

Or. en

Amendment 44
Linda McAvan
Kriton Arsenis

Draft motion for a resolution
Paragraph 19 a (new)

Draft motion for a resolution

Amendment

19a. Stresses that the livestock and intensive fish farming sectors should focus on preventing disease through good hygiene, housing and animal husbandry, as well as strict biosecurity measures, rather than by the prophylactic use of antibiotics.

Or. en

Amendment 45
Kriton Arsenis

Draft motion for a resolution
Paragraph 19 b (new)

Draft motion for a resolution

Amendment

19b. New Notes that pharmaceutical residues that have been disposed improperly end up in our waterways thus increasing unintentional exposure to a variety of substances linked to antibiotic resistance. Calls on the Commission to promote further research on the impact of long term exposure to pharmaceutical residues through water and soil,

Or. en

Amendment 46
Horst Schnellhardt
Christa Klaß

Draft motion for a resolution
Paragraph 20

Draft motion for a resolution

Amendment

20. Calls for a separation between the active ingredients and effect mechanisms used in human medicine and veterinary medicine to the extent possible to reduce the risk of resistance against antibiotics being transferred from livestock to humans,

20. Calls for a separation between the active ingredients and effect mechanisms used in human medicine and veterinary medicine to the extent possible to reduce the risk of resistance against antibiotics being transferred from livestock to humans, ***which must, however, not impose restrictions on effective treatment options,***

Or. en

Amendment 47
Horst Schnellhardt
Christa Klaß

Draft motion for a resolution
Paragraph 21

Draft motion for a resolution

21. Considers that the use of so called "last resort" antibiotics targeting problematic human pathogens should be prohibited for agricultural use,

Amendment

21. Considers that the use of so called "last resort" antibiotics targeting problematic human pathogens should be ***allowed in agricultural use only under clearly defined circumstances***,

Or. en

Amendment 48
Kriton Arsenis

Draft motion for a resolution
Paragraph 21 a (new)

Draft motion for a resolution

Amendment

21a. Notes that the recently approved GM starch potato Amflora contains an antibiotic resistance marker gene, the use of which risks reducing the efficacy of widely used antibiotics. Calls on the Commission, under the precautionary principle, to ban GMOs which contain genes expressing resistance to antibiotics in use for medical or veterinary treatment,

Or. en

Amendment 49
Horst Schnellhardt
Christa Kläß

Draft motion for a resolution
Paragraph 22

Draft motion for a resolution

Amendment

22. Calls on the Commission to strengthen the close operation with the World Health Organisation (WHO) and other relevant parties and organisations at international level in order to deal more effectively at a

22. Calls on the Commission to strengthen the close operation with the World Health Organisation (WHO), ***the World Organisation for Animal Health (OIE)*** and other relevant parties and organisations

global level with antimicrobial resistance, and welcomes in this context the establishment of the EU-US Transatlantic task force on urgent antimicrobial resistance (TATFAR),

at international level in order to deal more effectively at a global level with antimicrobial resistance, and welcomes in this context the establishment of the EU-US Transatlantic task force on urgent antimicrobial resistance (TATFAR),

Or. en

Amendment 50
Mairead McGuinness

Draft motion for a resolution
Paragraph 22

Draft motion for a resolution

22. Calls on the Commission to strengthen the close operation with the World Health Organisation (WHO) and other relevant parties and organisations at international level in order to deal more effectively at a global level with antimicrobial resistance, and welcomes in this context the establishment of the EU-US Transatlantic task force on urgent antimicrobial resistance (TATFAR),

Amendment

22. Calls on the Commission to strengthen the close *co-operation* with the World Health Organisation (WHO), *the World Organisation for Animal Health (OIE)* and other relevant parties and organisations at international level in order to deal more effectively at a global level with antimicrobial resistance, and welcomes in this context the establishment of the EU-US Transatlantic task force on urgent antimicrobial resistance (TATFAR),

Or. en

Amendment 51
Theodoros Skylakakis

Draft motion for a resolution
Paragraph 22 a (new)

Draft motion for a resolution

22a. Calls on the Commission to ensure that sufficient financial and human resources are available to implement the relevant strategies,

Amendment

