

Tuesday 23 October 2001

7. Use of antimicrobial agents in human medicine (procedure without debate)

A5-0318/2001

European Parliament resolution on the proposal for a Council recommendation on the prudent use of antimicrobial agents in human medicine (COM(2001) 333 – C5-0411/2001 – 2001/2164(COS))

The European Parliament,

- having regard to the proposal for a Council recommendation (COM(2001) 333 – C5-0411/2001),
 - having regard to Rule 152(4) of the EC Treaty,
 - having regard to Rule 47(1) of its Rules of Procedure,
 - having regard to the report of the Committee on the Environment, Public Health and Consumer Policy (A5-0318/2001),
1. Calls on the Commission and the Council to take account of the following modifications:
 2. Instructs its President to forward this resolution to the Council and Commission.

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MODIFICATIONS
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Modification 1

Recital 1

(1) The use of antimicrobial agents has greatly contributed to improvements in health. Such 'antimicrobial agents' have been introduced for decades to treat communicable diseases and prevent infections. For the purposes of this Recommendation, antimicrobial agent means substance produced either synthetically or naturally by bacteria, fungus or plants, used to kill or inhibit the growth of micro-organisms including bacteria, viruses and fungus, and of parasites, in particular protozoa, exhibiting the phenomenon of resistance. However, their use has also resulted in certain selected microbes previously sensitive to these agents developing resistance, so-called 'antimicrobial resistance'. This leads to increased danger, to prolonged suffering of the individual, and to enhanced costs for health care and society. Therefore concerted action is necessary at Community level to contain this problem by encouraging the prudent use of antimicrobial agents in human medicine and better hygiene and infection control;

(1) The use of antimicrobial agents has greatly contributed to improvements in health. Such 'antimicrobial agents' have been introduced for decades to treat communicable diseases and prevent infections. For the purposes of this Recommendation, antimicrobial agent means substance produced either synthetically or naturally by bacteria, fungus or plants, used to kill or inhibit the growth of micro-organisms including bacteria, viruses and fungus, and of parasites, in particular protozoa, exhibiting the phenomenon of resistance. However, their use has also resulted in certain selected microbes previously sensitive to these agents developing resistance, so-called 'antimicrobial resistance'. This leads to increased danger, to prolonged suffering of the individual, and to enhanced costs for health care and society. Therefore concerted action is necessary at Community level to contain this problem by encouraging the prudent use of antimicrobial agents in human medicine and better hygiene and infection control. **Such action cannot be taken in isolation from measures to combat resistance to antibiotics in veterinary medicine, animal feedingstuffs and crop growing (including GM crops).**

Modification 2

Recital 2

(2) The Council of the European Union on 8 June 1999 adopted a Resolution on antibiotic resistance 'A strategy against the microbial threat'. The Resolution highlights that antimicro-

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bial resistance increases morbidity and mortality due to communicable diseases leading not only to a diminution of quality of life but also to additional health and medical care costs, and that *actions need* to be taken at Community level;

antimicrobial resistance increases morbidity and mortality due to communicable diseases leading not only to a diminution of quality of life but also to additional health and medical care costs, and that *action needs* to be taken at Community level **to reduce the use of antimicrobial agents in veterinary as well as human medicine, and to ban any use of antimicrobial agents for non-therapeutic purposes, and the use of antibiotic resistance genes in GMOs, which may be disseminated in the environment;**

Modification 3

Recital 6

(6) Surveillance *on* prescription and consumption of antimicrobial agents should form an essential component for an overall surveillance strategy to address the problem of antimicrobial resistance;

(6) Surveillance *of the* prescription and consumption of antimicrobial agents **in all fields** should form an essential component for an overall surveillance strategy to address the problem of antimicrobial resistance;

Modification 4

Recital 7

(7) An important step to avoid or even reverse further increases in resistant micro-organisms would be to reduce unnecessary and inappropriate use of antimicrobial agents. General principles and methods for the prudent use of these agents in humans must be identified, and defined and implemented;

(7) An important step to avoid or even reverse further increases in resistant micro-organisms would be to reduce unnecessary and inappropriate use of antimicrobial agents. General principles and methods for the prudent use of these agents in humans, **animals and plants** must be identified, and defined and implemented;

Modification 5

Recital 11

(11) There is also a relationship between the occurrence of antimicrobial resistant pathogens in humans and their occurrence in animals and the environment. This Recommendation **does not preclude** further initiatives in other areas;

(11) There is also a relationship between the occurrence of antimicrobial resistant pathogens in humans and their occurrence in animals and the environment. This Recommendation **requires** further initiatives in other areas, **in particular to combat antimicrobial resistance in veterinary medicine, animal feedingstuffs and crop growing (including GMOs);**

Modification 6

Recital 11a (new)

(11a) The strategy against microbial resistance needs to be a global one and should cover not only human medicine but also veterinary medicine, animal production and plant protection;

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Modification 7

Chapter I, paragraph 1, subparagraph 1

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| <p>(1) gather reliable, comparable data by means of a laboratory based system of the susceptibility of pathogens to antimicrobial agents. The data should be amenable to time trend analysis and early warnings and to <i>monitor</i> spread of resistance at national, regional and community level;</p> | <p>(1) gather reliable data, comparable at Community level, by means of a laboratory based system <i>on</i> the susceptibility in vitro of pathogens to antimicrobial agents and their clinical implications. The data should be amenable to time trend analysis and early warnings and to <i>monitoring the</i> spread of resistance at national, regional and community level;</p> |
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Modification 8

Chapter I, paragraph 1, subparagraph 2

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| <p>(2) collect data on prescription and consumption of antimicrobial agents on national, regional, hospital and community level, involving prescribers, pharmacists and other parties collecting such data, in order to be able to potentially link prescription and consumption of antimicrobial agents to the development of pathogens resistant to those agents.</p> | <p>(2) collect data on prescription and consumption of antimicrobial agents in all their forms and in all fields at national, regional, hospital and community level, involving prescribers, pharmacists and other parties collecting such data, in order to be able to potentially link prescription and consumption of antimicrobial agents to the development of pathogens resistant to those agents.</p> |
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Modification 9

Chapter I, paragraph 2, subparagraph 1, indent 2

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| <p>— Setting rules for the use of other antimicrobial agents that are not subject to requirements for prescription-only use and an assessment of the need for changes;</p> | <p>— Setting rules for the use of other antimicrobial agents, including those for local use, that are not subject to requirements for prescription-only use and an assessment of the need for changes;</p> |
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Modification 10

Chapter I, paragraph 2, subparagraph 1, indent 3

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| <p>— Establishment of clinical and microbiological criteria for rapid on-the-spot diagnosis of infections, and</p> | <p>— Establishment of clinical and microbiological criteria and the evaluation of tests for rapid on-the-spot diagnosis of bacterial or viral infections, and of tests for sensitivity to antimicrobial agents, and</p> |
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Modification 11

Chapter I, paragraph 2, subparagraph 1, indent 4

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| <p>— Optimising choice of drug, dosage and duration for the treatment and prevention of infections.</p> | <p>— Optimising <i>the</i> choice of drug, dosage and duration for the treatment and prevention of infections, on the basis of microbiological and clinical criteria and the patient's personal data and medical history (individualised treatment).</p> |
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Modification 12

Chapter I, paragraph 2, subparagraph 1, indent 4a (new)

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| <p>— Comparative and critical assessment of the effectiveness of antimicrobial agents used for preventive purposes;</p> | |
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Modification 13

Chapter I, paragraph 2, subparagraph 3

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| <p>(3) Encouraging national immunisation programmes to progressively eliminate vaccine preventable diseases,</p> | <p>(3) Encouraging national immunisation programmes to progressively eliminate vaccine preventable diseases, after a continuous assessment of the vaccines concerned and the immunisation programmes under consideration,</p> |
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Modification 14

Chapter I, paragraph 3, subparagraph 1

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| <p>(1) teaching principles and guidelines on the appropriate use of antimicrobial agents by incorporation into undergraduate and postgraduate training and in regular continuous training for physicians, dentists, pharmacists and nurses and others in the medical profession, using effective good practice methods with continuous feedback;</p> | <p>(1) teaching principles and guidelines on the appropriate use of antimicrobial agents by incorporation into undergraduate and postgraduate training and in regular continuous training, independent of the drugs industry, for physicians, dentists, pharmacists and nurses and others in the medical profession, using effective good practice methods with continuous feedback;</p> |
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Modification 15

Chapter I, paragraph 3, subparagraph 3

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| <p>(3) training on immunisation programmes and their role in preventing infections, thereby reducing outbreaks of diseases and thus the demand for antimicrobial agents.</p> | <p>(3) in-service and updated training on immunisation programmes, their role, their effectiveness and their relevance in preventing infections, thereby reducing outbreaks of diseases and thus the demand for antimicrobial agents.</p> |
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Modification 16

Chapter I, paragraph 3, subparagraph 3a (new)

- (3a) **monitoring the information, promotions and advertising channelled to the medical profession by the drugs industry and ensuring observance of good prescribing practice;**

Modification 17

Chapter I, paragraph 4, subparagraph 3a (new)

- (3a) **prohibiting any advertising addressed to the general public promoting antibiotics;**

Modification 18

Chapter I, paragraph 4, subparagraph 3b (new)

- (3b) **encouraging home treatment wherever feasible;**

Modification 19

Chapter I, paragraph 4, subparagraph 3c (new)

- (3c) **encouraging clinical and laboratory practice and methods to reduce the duration of hospital care without jeopardising the outcome of the treatment;**

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Modification 20

Chapter II

II. cooperate with the Commission in the development of indicators for monitoring prescribing practices of antimicrobial agents on the basis of the evidence-based principles and guidelines on good practice for the management of communicable diseases within two years of the adoption of this Recommendation, and evaluate these indicators once developed with regard to potential improvements of prescribing practices and feedback to prescribers;

II. cooperate with the Commission in the development of indicators for monitoring prescribing practices of antimicrobial agents on the basis of the ***in vitro and clinical*** evidence-based principles and guidelines on good practice for the management of communicable diseases within two years of the adoption of this Recommendation, and evaluate these indicators once developed with regard to potential improvements of prescribing practices and feedback to prescribers;

Modification 21

Chapter III

III. establish and implement control systems on good practice of marketing of antimicrobial agents to ensure compliance with the evidence-based principles and guidelines on good practice for the management of communicable diseases within two years of the adoption of this Recommendation;

III. establish and implement control systems on good practice for marketing antimicrobial agents to ensure compliance with the ***in vitro and clinical*** evidence-based principles and guidelines on good practice for the management of communicable diseases within two years of the adoption of this Recommendation;

Modification 22

Chapter IV

IV. initiate with other Member States and the Commission activities aimed at harmonising and updating the product information (SPC) for antibacterial medicinal products ***particularly related*** to indications, dose and dose regimen ***and prevalence of acquired resistance***;

IV. initiate with other Member States and the Commission activities aimed at harmonising and updating the product information (SPC) for antibacterial medicinal products ***which have been subject to clinical and epidemiological studies and studies based solely on in vitro microbiological arguments, with particular reference*** to indications, dose and dose regimen;

Modification 23

Chapter Va (new)

Va. adopt, in the Council, framework legislation to confine the use of antimicrobial agents to therapeutic purposes alone, in all fields, and to prohibit the use of antibiotic resistance genes in GMOs which may be disseminated in the environment;

Modification 24

Paragraph 5

5. to keep matters covered by this Recommendation ***under review***, with a view to its revision and updating, and submit an annual report to the Council on the basis of Member States' annual reports;

5. to keep ***under review and coordinate*** matters covered by this Recommendation, with a view to its revision and updating, and submit an annual report to the Council on the basis of Member States' annual reports;

Modification 25

Paragraph 6a (new)

6a. to propose without delay a global Community legislative framework for action against antimicrobial resistance, seeking to confine the use of antimicrobial agents to thera-

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peutic purposes alone, in all fields, and to prohibit the use of antibiotic resistance genes in GMOs, which may be disseminated in the environment;

Modification 26

Paragraph 6b (new)

6b. to strengthen the close cooperation between the Member States, the applicant countries and other parties concerned at international level in order to deal more effectively at international and intercontinental level with the spread of disease and antimicrobial resistance arising from the increase in international trade and travel;

Modification 27

Paragraph 6c (new)

6c. to promote a global strategy in all the relevant sectors: public health, veterinary medicine and plant health.

8. Undertakings for collective investment in transferable securities (UCITS) ***II

A5-0324/2001

1.

European Parliament legislative resolution on the Council common position for adopting a European Parliament and Council directive amending Council Directive 85/611/EEC on the coordination of laws, regulations and administrative provisions relating to undertakings for collective investment in transferable securities (UCITS), with regard to investments of UCITS (7551/1/2001 – C5-0296/2001 – 1998/0243(COD))

(Codecision procedure: second reading)

The European Parliament,

- having regard to the Council common position (7551/1/2001 – C5-0296/2001),
- having regard to its position at first reading⁽¹⁾ on the Commission proposal to Parliament and the Council (COM(1998) 449)⁽²⁾,
- having regard to the amended Commission proposal (COM(2000) 329)⁽³⁾,
- having regard to Article 251(2) of the EC Treaty,
- having regard to Rule 80 of its Rules of Procedure,
- having regard to the recommendation for second reading of the Committee on Economic and Monetary Affairs (A5-0324/2001),

1. Amends the common position as follows;
2. Instructs its President to forward its position to the Council and Commission.

⁽¹⁾ OJ C 339, 29.11.2000, p. 220.

⁽²⁾ OJ C 280, 9.9.1998, p. 6.

⁽³⁾ OJ C 311 E, 31.10.2000, p. 302.