



2016/2057(INI)

21.10.2016

AMENDMENTS

1 - 302

Draft report
Soledad Cabezón Ruiz
(PE587.690v01-00)

EU options for improving access to medicines
(2016/2057(INI))

Amendment 1

Karl-Heinz Florenz, Peter Liese, Andrey Kovatchev

Motion for a resolution

Citation 1 a (new)

Motion for a resolution

Amendment

- *having regard to Article 168 of the Treaty on the Functioning of the European Union, a high level of human health protection should be ensured in the definition and implementation of all Union policies and activities,*

Or. de

Amendment 2

Soledad Cabezón Ruiz

Motion for a resolution

Citation 1 a (new)

Motion for a resolution

Amendment

- *having regard to the Commission REFIT evaluation of the Council Regulation (EC) 953/2003 to avoid trade diversion into the European Union of certain key medicines (SWD(2016) 125 final)*

Or. en

Amendment 3

Nessa Childers

Motion for a resolution

Citation 1 a (new)

Motion for a resolution

Amendment

- ***having regard to article 81 of Directive 2001/83/EC on ensuring appropriate and continued supplies of medicinal products,***

Or. en

Amendment 4

Karl-Heinz Florenz, Peter Liese, Andrey Kovatchev

Motion for a resolution

Citation 1 b (new)

Motion for a resolution

Amendment

- ***having regard to the Commission's Inception Impact Assessment^{1a} on the strengthening of EU cooperation on Health Technology Assessment (HTA),***

^{1a} http://ec.europa.eu/smart-regulation/roadmaps/docs/2016_sante_14_4_health_technology_assessments_en.pdf

Or. de

Amendment 5

Karl-Heinz Florenz, Peter Liese, Andrey Kovatchev

Motion for a resolution

Citation 1 c (new)

Motion for a resolution

Amendment

- ***having regard to the HTA Network Strategy for EU Cooperation on Health Technology Assessment of 29 October 2014^{1b},***

^{1b}

Amendment 6
Soledad Cabezón Ruiz

Motion for a resolution
Citation 2 a (new)

Motion for a resolution

Amendment

- *having regard to the Communication from the Commission on inequalities in health published in 2013 in which it is recognised that health systems play an important role in reducing the risk of poverty or may help to reduce poverty,*

Amendment 7
Soledad Cabezón Ruiz

Motion for a resolution
Citation 2 b (new)

Motion for a resolution

Amendment

- *having regard to the conclusions of the Council on robust and sustainable health systems, reforms for sustainable health systems (efficiency, quality of innovation and prevention) of 2014,*

Amendment 8
Soledad Cabezón Ruiz

Motion for a resolution

Citation 3 a (new)

Motion for a resolution

Amendment

- *having regard to the Commission Communication on Secure, Innovative and accessible medicines: a renovated view for the pharmaceutical sector (COM(2008)666)*

Or. en

Amendment 9

José Inácio Faria, Jasenko Selimovic, Anneli Jäätteenmäki, Marian Harkin, Lieve Wierinck

Motion for a resolution

Citation 3 a (new)

Motion for a resolution

Amendment

- *having regard to the Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines*

Or. en

Amendment 10

Soledad Cabezón Ruiz

Motion for a resolution

Citation 3 b (new)

Motion for a resolution

Amendment

- *having regard the Council Conclusions of 1 December 2014 on Innovation for the benefit of patients*

Or. en

Amendment 11

José Inácio Faria, Jasenko Selimovic, Anneli Jäätteenmäki, Frédérique Ries, Lieve Wierinck

Motion for a resolution

Citation 4

Motion for a resolution

— having regard to *the antitrust procedure, Case AT.39612 – Perindopril (Servier), and to paragraphs 249 and 250 of the judgment of the Court of Justice of 14 February 1978 in Case 27/76 on excessive prices,*

Amendment

— having regard to paragraphs 249 and 250 of the judgment of the Court of Justice of 14 February 1978 in Case 27/76 on excessive prices;

Or. en

Amendment 12

Cristian-Silviu Buşoi

Motion for a resolution

Citation 4

Motion for a resolution

— *having regard to the antitrust procedure, Case AT.39612 – Perindopril (Servier), and to paragraphs 249 and 250 of the judgment of the Court of Justice of 14 February 1978 in Case 27/76 on excessive prices,*

Amendment

deleted

Or. en

Amendment 13

Nessa Childers

Motion for a resolution

Citation 5 a (new)

Motion for a resolution

Amendment

- *having regard to the importance of the recommendations of the report*

*prepared by the High-Level Panel on
Access to Health Technologies, convened
by the United Nations Secretary-General,
published in September 2016*

Or. en

Amendment 14
Francesc Gambús

Motion for a resolution
Citation 5 a (new)

Motion for a resolution

Amendment

- *having regard to Decision No
1082/2013/EU of the European
Parliament and of the Council of 22
October 2013 on serious cross-border
threats to health and repealing Decision
No 2119/98/EC,^{1 a}*

1 a

*[http://ec.europa.eu/health/preparedness_r
esponse/docs/decision_serious_crossborde
r_threats_22102013_es.pdf](http://ec.europa.eu/health/preparedness_response/docs/decision_serious_crossborder_threats_22102013_es.pdf)*

Or. es

Amendment 15
Margrete Auken

Motion for a resolution
Citation 5 a (new)

Motion for a resolution

Amendment

- *having regard to the Report of the
United Nations Secretary-General's High
Level Panel on access to medicines –
Promoting innovation and access to
health technologies – published in
September 2016;*

Or. en

Amendment 16
Lynn Boylan, Kateřina Konečná

Motion for a resolution
Citation 5 a (new)

Motion for a resolution

Amendment

- *having regard to the September 2016 United Nations Secretary-General's High-Level Panel on Access to Medicines Report on Promoting Innovation and Access to Health Technologies*

Or. en

Amendment 17
Karl-Heinz Florenz, Peter Liese, Andrey Kovatchev

Motion for a resolution
Citation 5 a (new)

Motion for a resolution

Amendment

- *having regard to the Council's conclusions on innovation for the benefit of patients of 1 December 2014^{1c},*

1c

http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/145978.pdf

Or. de

Amendment 18
Soledad Cabezón Ruiz

Motion for a resolution
Citation 5 a (new)

Motion for a resolution

Amendment

- ***having regard the Council Conclusions of European Health Minister of 16 April 2016***

Or. en

Amendment 19
Soledad Cabezón Ruiz

Motion for a resolution
Citation 5 b (new)

Motion for a resolution

Amendment

- ***having regard the Council Conclusions of 10 may 2006 on Common Values and Principles in EU Health Systems; the Council Conclusions of European Health Minister of 6 April 2011 and of 10 December 2013 on Health Systems Adequate and Sustainable***

Or. en

Amendment 20
Soledad Cabezón Ruiz

Motion for a resolution
Citation 5 c (new)

Motion for a resolution

Amendment

- ***having regard the Commission Communication on Effective, Available and Robust Health Systems of 4 April 2014 (COM(2014/215))***

Or. en

Amendment 21
Soledad Cabezón Ruiz

Motion for a resolution
Citation 5 d (new)

Motion for a resolution

Amendment

- *having regard to the Commission report on Towards Harmonised EU Assessment of Added therapeutic Value of Medicines*

Or. en

Amendment 22
Soledad Cabezón Ruiz

Motion for a resolution
Citation 5 e (new)

Motion for a resolution

Amendment

- *having regard to the Report of WHO Expert Committee "Selection of Essential Drugs" (Geneve 1977) and the review of Geneva of 7 December 2001 (EB109/8); and 2015; and the WHO report on Access to new medicines in Europe (March 2015); and the WHO Report on Priority Medicines for Europe and the world of 28 June 2013*

Or. en

Amendment 23
Soledad Cabezón Ruiz

Motion for a resolution
Citation 5 f (new)

Motion for a resolution

Amendment

- *having regard to the Regulation (EC 141/2000) on Orphan Medicinal*

Products

Or. en

Amendment 24
Soledad Cabezón Ruiz

Motion for a resolution
Citation 5 g (new)

Motion for a resolution

Amendment

- *having regard to Articles 168(1), (2), (4) and (7) TFEU on the EU's health competences,*

Or. en

Amendment 25
Soledad Cabezón Ruiz

Motion for a resolution
Citation 5 h (new)

Motion for a resolution

Amendment

- *having regard to the Article 35 of the Charter of Fundamental Rights in the EU and the article 6(1) TEU on right to health protection for European citizens,*

Or. en

Amendment 26
Soledad Cabezón Ruiz

Motion for a resolution
Citation 5 i (new)

Motion for a resolution

Amendment

- *having regard to Articles 101 and 102 TFEU laying down rules on*

competition,

Or. en

Amendment 27
Soledad Cabezón Ruiz

Motion for a resolution
Citation 5 j (new)

Motion for a resolution

Amendment

- *having regard the article 81 of
Directive 2001/83/EC on shortages
provisions*

Or. en

Amendment 28
Soledad Cabezón Ruiz

Motion for a resolution
Citation 5 k (new)

Motion for a resolution

Amendment

- *having regard to the Doha
Declaration on the TRIPS Agreement and
Public Health (WTO/MIN(01/DEC/2) and
Implementation of paragraph 6 of the
DOHA Declaration of 1 September 2003
(WTO/L/540)*

Or. en

Amendment 29
Soledad Cabezón Ruiz

Motion for a resolution
Citation 5 l (new)

Motion for a resolution

Amendment

- ***having regard to the Regulation (EC(816/2006) Compulsory Licensing of Patents Relating to the Manufacturer of Pharmaceutical for Export to Countries with Public Health Problems***

Or. en

Amendment 30
Francesc Gambús

Motion for a resolution
Citation 6 a (new)

Motion for a resolution

Amendment

- ***having regard to the joint procurement agreement approved by the Commission on 10 April 2014^{1a},***

1a

http://ec.europa.eu/health/preparedness_response/docs/jpa_agreement_medicalcountermeasures_en.pdf

Or. es

Amendment 31
Soledad Cabezón Ruiz

Motion for a resolution
Citation 6 a (new)

Motion for a resolution

Amendment

- ***having regard to the Nairobi Conference of 1985 on the rational use of drugs,***

Or. es

Amendment 32

Elisabetta Gardini, Cristian-Silviu Buşoi, Alojz Peterle, Giovanni La Via, Aldo Patriciello, Alessandra Mussolini

Motion for a resolution

Citation 7 a (new)

Motion for a resolution

Amendment

- *having regard to the report approved by the Committee on the Environment, Public Health and Food Safety and by the European Parliament on the amendment of the Regulation 726/2004;*

Or. en

Amendment 33

Cristian-Silviu Buşoi, Andrey Kovatchev

Motion for a resolution

Citation 7 a (new)

Motion for a resolution

Amendment

- *having regard to the obligations contained in Article 81 of European Directive 2001/83/EC, for the maintenance of an appropriate and continued supply of medicinal products;*

Or. en

Amendment 34

Eva Kaili

Motion for a resolution

Citation 7 a (new)

Motion for a resolution

Amendment

- *having regard to the report*

approved by the Committee on the Environment, Public Health and Food Safety and by the European Parliament on the amendment of the regulation 726/2004;

Or. en

Amendment 35
Peter Liese, Karl-Heinz Florenz

Motion for a resolution
Citation 7 a (new)

Motion for a resolution

Amendment

- *having regard to European Parliament resolution of 16 September 2015 on the Commission Work Programme 2016 (2015/2729(RSP))*

Or. de

Amendment 36
Daciana Octavia Sârbu

Motion for a resolution
Citation 7 a (new)

Motion for a resolution

Amendment

- *having regard to Directive 2001/83/EC and in particular Article 81 thereof;*

Or. en

Amendment 37
Peter Liese, Karl-Heinz Florenz

Motion for a resolution
Citation 7 b (new)

Motion for a resolution

Amendment

- ***having regard to European Parliament resolution of 11 September 2012 on voluntary and unpaid donation of tissues and cells (2011/2193(INI))***

Or. de

Amendment 38

Notis Marias

Motion for a resolution

Recital A

Motion for a resolution

A. whereas the Charter of Fundamental Rights of the European Union recognises the fundamental right of citizens to health and medical treatment²;

²The right to health care is the economic, social and cultural right to a universal minimum standard of health care to which all individuals are entitled.

Amendment

A. whereas the Charter of Fundamental Rights of the European Union recognises the fundamental right of citizens to health and medical treatment², ***which every EU Member State must protect***;

²The right to health care is the economic, social and cultural right to a universal minimum standard of health care to which all individuals are entitled.

Or. el

Amendment 39

Soledad Cabezón Ruiz

Motion for a resolution

Recital A a (new)

Motion for a resolution

Amendment

Aa. whereas the EU Charter of Fundamental Rights recognises the right to intellectual property, which seeks to guarantee investors and researchers a return on their investments, thus

safeguarding, promoting and stimulating innovation for the benefit of society;

Or. es

Amendment 40.
Piernicola Pedicini, Eleonora Evi, Marco Affronte

Motion for a resolution
Recital Aa (new)

Motion for a resolution

Amendment

Aa. whereas patients require and are entitled to maximum transparency when it comes to setting the price of medicines, the cost of investments in research and development, and the results of studies funded by public research or private research incentivised by public funds;

Or. it

Amendment 41
Mireille D'Ornano, Jean-François Jalkh, Sylvie Goddyn

Motion for a resolution
Recital A a (new)

Motion for a resolution

Amendment

Aa. whereas Article 168 of the Treaty on the Functioning of the European Union stipulates that decisions on their health systems fall within the competence of the Member States;

Or. fr

Amendment 42
Lynn Boylan

Motion for a resolution

Recital B

Motion for a resolution

B. whereas public health systems are crucial to guarantee universal access to health care;

Amendment

B. whereas public health systems are crucial to guarantee universal access to health care; ***believes this to be a fundamental right of European citizens; further believes this to be the only way to ensure equality in healthcare for citizens in all European Union Member States.***

Or. en

Amendment 43

Soledad Cabezón Ruiz

Motion for a resolution

Recital B a (new)

Motion for a resolution

Amendment

Ba. whereas the sustainability of health systems in the EU are faced with challenges such as population ageing, the chronification of illnesses, the development of new expensive technologies, and pharmaceutical expenses, the crisis has brought to light that developed countries also encounter problems with accessing drugs;

Or. es

Amendment 44.

Enrico Gasbarra

Motion for a resolution

Recital Ba (new)

Motion for a resolution

Amendment

Ba. whereas, also following the economic crisis and austerity policies, the

public coffers in Europe, and particularly in sectors that cover health spending, are under significant pressure due to sovereign debt and the need to limit spending;

Or. it

Amendment 45
Piernicola Pedicini, Eleonora Evi, Marco Affronte

Motion for a resolution
Recital B a (new)

Motion for a resolution

Amendment

Ba. whereas there are policy incoherencies between public health objectives, trade and intellectual property rules, and international human rights; whereas, nonetheless, State obligations include duties not only to respect, but to protect and fulfil the right to health;

Or. en

Amendment 46
Mireille D'Ornano, Jean-François Jalkh, Sylvie Goddyn

Motion for a resolution
Recital B a (new)

Motion for a resolution

Amendment

Ba. whereas, however, every Member State has its own national legislation and tax policy, including VAT rates and mechanisms to negotiate pharmaceutical product prices;

Or. fr

Amendment 47

José Inácio Faria, Jasenko Selimovic, Anneli Jäätteenmäki, Marian Harkin, Yana Toom

Motion for a resolution

Recital B a (new)

Motion for a resolution

Amendment

Ba. whereas the high prices of innovative medicines conflicts with the patients' and national health systems' ability to pay for pharmaceutical expenditure and hinders the fundamental right of citizens to health and medical treatment;

Or. en

Amendment 48

Sirpa Pietikäinen

Motion for a resolution

Recital B a (new)

Motion for a resolution

Amendment

Ba. whereas patients should have access to the healthcare and treatment options of their choice and preference, including to complementary and alternative therapies and medicines;

Or. en

Amendment 49

Alojz Peterle

Motion for a resolution

Recital B a (new)

Motion for a resolution

Amendment

Ba. whereas patients should have access to the healthcare and treatment options of their choice and preference,

*including to complementary and
alternative therapies and medicines;*

Or. en

Amendment 50
Margrete Auken

Motion for a resolution
Recital B a (new)

Motion for a resolution

Amendment

*Ba. whereas the third Sustainable
Development Goal of the United Nations
is to ensure healthy lives and promote
well-being for all at all ages;*

Or. en

Amendment 51
**Andrey Kovatchev, Cristian-Silviu Buşoi, Kateřina Konečná, Biljana Borzan, Karl-
Heinz Florenz, Karin Kadenbach**

Motion for a resolution
Recital B a (new)

Motion for a resolution

Amendment

*Ba. whereas pharmaceuticals are one
of the main pillars of healthcare rather
than mere objects of trade;*

Or. en

Amendment 52
Soledad Cabezón Ruiz

Motion for a resolution
Recital B a (new)

Motion for a resolution

Amendment

Ba. *whereas insufficient access to essential medicinal products poses a serious threat to the well-being*

Or. en

Amendment 53
Soledad Cabezón Ruiz

Motion for a resolution
Recital B b (new)

Motion for a resolution

Amendment

Bb. *whereas with a 20% return on investment, the pharmaceutical sector is one of the EU's most competitive, but it also creates 800 000 jobs and turns over EUR 200 billion per year; whereas the sector is facing up to important competitors such as the United States and the Asian market, and as a result strategies need to be put in place to enable it to become more competitive, for which quality of innovation may be key;*

Or. es

Amendment 54
Piernicola Pedicini, Eleonora Evi, Marco Affronte

Motion for a resolution
Recital B b (new)

Motion for a resolution

Amendment

Bb. *whereas access to innovative healthcare is to be conceived not only as access to new medicines containing an active substance or combination of active substances that has not been authorised before, but also as access to new tools,*

standards and approaches to therapies that bring a meaningful improvement over existing treatment with respect to outcomes that matter to patients;

Or. en

Amendment 55

Mireille D'Ornano, Jean-François Jalkh, Sylvie Goddyn

Motion for a resolution

Recital B b (new)

Motion for a resolution

Amendment

Bb. whereas Member States have sovereignty, in particular, over decisions on whether their national health systems should provide reimbursement for pharmaceutical products;

Or. fr

Amendment 56

Margrete Auken

Motion for a resolution

Recital B b (new)

Motion for a resolution

Amendment

Bb. whereas universal access to medicines depends on their timely availability and their affordability for everyone, without any geographical discrimination;

Or. en

Amendment 57

Soledad Cabezón Ruiz

Motion for a resolution
Recital B b (new)

Motion for a resolution

Amendment

Bb. whereas general concern exists in the society and authorities on access to medicines in Europe and on sustainability of health system

Or. en

Amendment 58
Margrete Auken

Motion for a resolution
Recital B c (new)

Motion for a resolution

Amendment

Bc. whereas trade and investment agreements regularly contain TRIPS-plus provisions that increase levels of intellectual property protection and enforcement that impede the ability of parties to use laws and policies promoting their human rights obligations to the fullest extent possible;

Or. en

Amendment 59
Soledad Cabezón Ruiz

Motion for a resolution
Recital B c (new)

Motion for a resolution

Amendment

Bc. having regard to the conclusions of the Council on robust and sustainable health systems, and reforms for sustainable health systems (efficiency, quality of innovation and prevention) of 2014,

Amendment 60
Soledad Cabezón Ruiz

Motion for a resolution
Recital B c (new)

Motion for a resolution

Amendment

Bc. whereas ensuring that patients have access to essential and affordable medicines is one of the core objectives of the EU and the WHO; and target of Millennium Development Goals

Or. en

Amendment 61
Soledad Cabezón Ruiz

Motion for a resolution
Recital B d (new)

Motion for a resolution

Amendment

Bd. whereas unequal access to medicines is not a new phenomenon, reported for the developing countries by WHO, but the recent economic crisis has only exacerbated the problem in developed countries also;

Or. en

Amendment 62
Cristian-Silviu Buşoi

Motion for a resolution
Recital C

Motion for a resolution

C. whereas *the prices of new medicines have increased during the past few decades to the point of being unaffordable for many European citizens;*

Amendment

C. whereas *pharmaceutical expenditure has remained constant, Member States are concerned with financing healthcare expenditures going forward given lower than expected economic growth, an ageing population and the high costs associated with treating patients with chronic diseases;*

Or. en

Amendment 63

Eva Kaili

Motion for a resolution

Recital C

Motion for a resolution

C. whereas the *prices of new medicines have increased during the past few decades to the point of being unaffordable for many European citizens;*

Amendment

C. whereas the *pharmaceutical expenditures make Member States highly concerned about their long-run financing capability given the anaemic economic growth and the demographic pressures;*

Or. en

Amendment 64

Margrete Auken

Motion for a resolution

Recital C

Motion for a resolution

C. whereas the prices of new medicines have increased during the past few decades to the point of being unaffordable for many European citizens;

Amendment

C. *whereas, following the expiry of the patents on blockbuster medicines, the pharmaceutical sector changed its business model towards acquisitions of niche market pharmaceutical assets;* whereas the prices of new medicines, *directly linked to the need for*

pharmaceutical companies to propose an attractive return on investments for their shareholders, have increased during the past few decades to the point of being unaffordable for many European *health care systems and* citizens;

Or. en

Amendment 65

Karl-Heinz Florenz, Peter Liese, Andrey Kovatchev, Ivo Belet

Motion for a resolution

Recital C

Motion for a resolution

C. whereas the prices of new medicines have increased during the past few decades to the point of *being unaffordable for many European citizens*;

Amendment

C. whereas, *in some cases*, the prices of new medicines have increased during the past few decades to the point of *threatening the sustainability of national healthcare systems*;

Or. de

Amendment 66

György Hölvényi, Alojz Peterle

Motion for a resolution

Recital C

Motion for a resolution

C. whereas the prices of new medicines have increased during the past few decades to the point of being unaffordable for many European citizens;

Amendment

C. whereas the prices of new medicines have increased during the past few decades to the point of being unaffordable for many European citizens *and seriously affecting the sustainability of the national health care systems*;

Or. en

Amendment 67
Monica Macovei

Motion for a resolution
Recital C

Motion for a resolution

C. whereas the prices of new medicines have increased during the past few decades to the point of being unaffordable for many European citizens;

Amendment

C. whereas the prices of new medicines have increased during the past few decades to the point of being unaffordable for many European citizens; ***whereas manufacturers limit the volumes by imposing supply quotas which create imbalances on the market***

Or. en

Amendment 68
Notis Marias

Motion for a resolution
Recital C

Motion for a resolution

C. whereas the prices of new medicines have increased during the past few decades to the point of being unaffordable for many European citizens;

Amendment

C. whereas the prices of new medicines have increased during the past few decades to the point of being unaffordable for many European citizens ***and particularly for citizens of the countries of southern Europe, such as Greece, Italy, Spain and Portugal;***

Or. el

Amendment 69
Soledad Cabezón Ruiz

Motion for a resolution
Recital C

Motion for a resolution

C. whereas the prices of new

Amendment

C. whereas the prices of new

medicines have increased during the past few decades to the point of being unaffordable for many European citizens;

medicines have increased during the past few decades to the point of being unaffordable for many European *health systems and* citizens;

Or. en

Amendment 70
Alojz Peterle

Motion for a resolution
Recital C a (new)

Motion for a resolution

Amendment

Ca. whereas the number of people diagnosed with cancer is rising every year and the combination of increased cancer incidence in the population and new technologically advanced cancer medicines results in a situation where the total cost of cancer is rising, which puts an unprecedented demand on healthcare budgets and makes treatment unaffordable for many cancer patients, thus leading to a risk that affordability or pricing of the medication will become a deciding factor in a patient's cancer treatment.

Or. en

Amendment 71
Soledad Cabezón Ruiz

Motion for a resolution
Recital C a (new)

Motion for a resolution

Amendment

Ca. whereas in 2014, outpatient pharmaceutical expenditure accounted for 17.1% of total health expenditure and for 1.41% of Gross Domestic Product (GDP) in the EU.

Amendment 72

Eva Kaili

Motion for a resolution

Recital D

Motion for a resolution

D. whereas *in addition to high prices, other barriers to access to medicines include shortages of essential medicines, the poor connection between clinical needs and research, unjustified administrative procedures, rigid patent rules and budget restrictions;*

Amendment

D. whereas *patient access to treatment is not only determined by the cost of medicines but by a variety of factors, including access to healthcare professionals and diagnostics, addressing healthcare system inefficiencies, clinical practice and the functioning of national pricing and reimbursement systems, measures aimed at improving patient access should address the determinants holistically;*

Amendment 73

Piernicola Pedicini, Eleonora Evi, Marco Affronte

Motion for a resolution

Recital D

Motion for a resolution

D. whereas in addition to high prices, other barriers to access to medicines include shortages of essential medicines, the poor connection between clinical needs and research, unjustified administrative procedures, rigid patent rules *and budget restrictions;*

Amendment

D. whereas in addition to high prices *and unaffordability*, other barriers to access to medicines include *austerity policies and linear cuts to healthcare spending*, shortages of essential medicines *and inappropriate use*, the poor connection between clinical needs and research, unjustified administrative procedures, rigid patent rules, *lack of sufficiently qualified and skilled healthcare workers;*

Amendment 74
Margrete Auken

Motion for a resolution
Recital D

Motion for a resolution

D. whereas in addition to high prices, other barriers to access to medicines include shortages of essential medicines, the poor connection between clinical needs and research, unjustified administrative procedures, *rigid patent rules* and budget restrictions;

Amendment

D. whereas in addition to high prices, other barriers to access to medicines include shortages of essential medicines, the poor connection between clinical needs and research, unjustified administrative procedures, *lack of competition, abusive strategies by manufacturers regarding the claim of patents in order to hinder the market entry of generic medicines* and budget restrictions;

Or. en

Amendment 75.
Damiano Zoffoli

Motion for a resolution
Recital D

Motion for a resolution

D. whereas in addition to high prices, other barriers to access to medicines include shortages of essential medicines, the poor connection between clinical needs and research, unjustified administrative procedures, rigid patent rules and budget restrictions;

Amendment

D. whereas in addition to high prices, other barriers to access to medicines include shortages of essential medicines, the poor connection between clinical needs and research, unjustified administrative procedures, rigid patent rules and budget restrictions *owing in particular to the economic crisis that has hit the European Union and austerity policies*;

Or. it

Amendment 76
Frédérique Ries, Françoise Grossetête

Motion for a resolution
Recital D

Motion for a resolution

D. whereas in addition to high prices, other barriers to access to medicines include shortages of essential medicines, ***the poor connection between clinical needs and research***, unjustified administrative procedures, rigid patent rules and budget ***restrictions***;

Amendment

D. whereas in addition to high prices, other barriers to access to medicines include shortages of essential medicines, ***the difficulty with always reconciling research and clinical needs***, unjustified administrative procedures ***and delays to marketing authorisation***, patent rules ***which are sometimes too*** rigid and budget ***choices with regard to reimbursement***;

Or. fr

Amendment 77
Notis Marias

Motion for a resolution
Recital D

Motion for a resolution

D. whereas in addition to high prices, other barriers to access to medicines include shortages of essential medicines, the poor connection between clinical needs and research, unjustified administrative procedures, rigid patent rules and budget restrictions;

Amendment

D. whereas in addition to high prices, other barriers to access to medicines include shortages of essential medicines, the poor connection between clinical needs and research, unjustified administrative procedures, rigid patent rules, ***inadequate funding by the EU for the health systems of its Member States*** and budget restrictions;

Or. el

Amendment 78
Carlos Zorrinho

Motion for a resolution
Recital D

Motion for a resolution

D. whereas in addition to high prices, other barriers to access to medicines include shortages of essential medicines, the poor connection between clinical needs and research, unjustified administrative procedures, rigid patent rules and budget restrictions;

Amendment

D. whereas in addition to high prices, other barriers to access to medicines include shortages of essential medicines, the poor connection between clinical needs and research, ***reimbursement systems, access to healthcare professionals and diagnostics***, unjustified administrative procedures, rigid patent rules and budget restrictions;

Or. en

Amendment 79
Sirpa Pietikäinen

Motion for a resolution
Recital D

Motion for a resolution

D. whereas in addition to high prices, other barriers to access to medicines include shortages of essential medicines, the poor connection between clinical needs and research, unjustified administrative procedures, rigid patent rules and budget restrictions;

Amendment

D. whereas in addition to high prices, other barriers to access to medicines include shortages of essential medicines, the poor connection between clinical needs and research, unjustified administrative procedures, ***unavailability of products***, rigid patent rules and budget restrictions;

Or. en

Amendment 80
Alojz Peterle

Motion for a resolution
Recital D

Motion for a resolution

D. whereas in addition to high prices, other barriers to access to medicines include shortages of essential medicines, the poor connection between clinical needs

Amendment

D. whereas in addition to high prices, other barriers to access to medicines include shortages of essential medicines, the poor connection between clinical needs

and research, unjustified administrative procedures, rigid patent rules and budget restrictions;

and research, unjustified administrative procedures, *unavailability of products*, rigid patent rules and budget restrictions;

Or. en

Amendment 81
Nessa Childers

Motion for a resolution
Recital D

Motion for a resolution

D. whereas in addition to high prices, other barriers to access to medicines include shortages of essential medicines, the poor connection between clinical needs and research, unjustified administrative procedures, rigid patent rules and budget restrictions;

Amendment

D. whereas in addition to high prices, other barriers to access to medicines include *widespread* shortages of essential *and other* medicines, the poor connection between clinical needs and research, unjustified administrative procedures, rigid patent rules and budget restrictions;

Or. en

Amendment 82.
Damiano Zoffoli

Motion for a resolution
Recital Da (new)

Motion for a resolution

Da. whereas the gradual ageing of the population will lead to an increase in healthcare costs and whereas the Member States will have to guarantee that a sufficient part of their budget is spent on the health and wellbeing of their citizens;

Or. it

Amendment 83
Cristian-Silviu Buşoi

Motion for a resolution
Recital D a (new)

Motion for a resolution

Amendment

Da. whereas a stable and predictable intellectual property and regulatory framework, as well as the proper and timely implementation thereof are essential to create an innovation-friendly environment, supporting patient access to innovative and effective treatments;

Or. en

Amendment 84
José Inácio Faria, Jasenko Selimovic, Marian Harkin, Yana Toom

Motion for a resolution
Recital D a (new)

Motion for a resolution

Amendment

Da. whereas the growing expenditure in the pharmaceutical sector prompts European cooperation and new policy measures at both EU and national level to enable selective investment in efficient and effective healthcare;

Or. en

Amendment 85
Françoise Grossetête, Frédérique Ries, Cristian-Silviu Buşoi

Motion for a resolution
Recital D a (new)

Motion for a resolution

Amendment

Da. whereas pricing and reimbursement decisions in Member States shall respect the safeguards put in place by EU law and avoid putting

patients at risk through off-label use for economic reasons or extrapolation;

Or. en

Amendment 86.

Piernicola Pedicini, Marco Affronte, Eleonora Evi

Motion for a resolution

Recital E

Motion for a resolution

E. whereas *the aim of* intellectual property *is to benefit society, guaranteeing investment returns to promote innovation, and whereas there is concern about the abuse/misuse thereof;*

Amendment

E. whereas *the system for protecting* intellectual property *is all too often used to generate economic benefits for pharmaceutical companies beyond lawful profit margins instead of according to the needs of patients, resulting in an irreconcilable conflict with the fundamental right to health;*

Or. it

Amendment 87

Frédérique Ries

Motion for a resolution

Recital E

Motion for a resolution

E. whereas the aim of intellectual property is to benefit society, guaranteeing investment returns to promote innovation, *and whereas* there is concern about *the abuse/misuse thereof;*

Amendment

E. whereas the aim of intellectual property is to benefit society, guaranteeing investment returns to promote innovation, *particularly considering that patent law contributes to the innovation cycle of medicines, even if* there is concern about *the granting of unoriginal or excessively broad patents;*

Or. fr

Amendment 88

Andrey Kovatchev, Cristian-Silviu Buşoi, Kateřina Konečná, Karl-Heinz Florenz, Karin Kadenbach

Motion for a resolution

Recital E

Motion for a resolution

E. whereas the aim of intellectual property is to benefit society, ***guaranteeing investment returns to*** promote innovation, and whereas there is concern about the abuse/misuse thereof;

Amendment

E. whereas the aim of intellectual property is to benefit society ***and*** promote innovation, and whereas there is concern about the abuse/misuse thereof; ***notes the Council Conclusions of 17 June 2016 inviting the Commission to conduct an evidence-based analysis on the overall impact of IP in promoting innovation;***

Or. en

Amendment 89

Margrete Auken

Motion for a resolution

Recital E

Motion for a resolution

E. whereas the aim of intellectual property is to benefit society, guaranteeing investment returns to promote innovation, and whereas ***there is concern*** about the abuse/misuse thereof;

Amendment

E. whereas the aim of intellectual property is to benefit society, guaranteeing investment returns to promote innovation ***and accessibility of the knowledge contained in patent applications, whereas the WTO Doha declaration on the TRIPS agreement and Public Health raised concerns about its effects on prices*** and whereas ***the Commission raised concerns in its sector inquiry*** about the abuse/misuse thereof;

Or. en

Amendment 90

Soledad Cabezón Ruiz

Motion for a resolution

Recital E

Motion for a resolution

E. whereas the aim of intellectual property is to benefit society, guaranteeing investment returns to promote innovation, and whereas there is concern about the abuse/misuse thereof;

Amendment

E. whereas the aim of intellectual property is to benefit society, guaranteeing investment returns to promote innovation, and whereas there is concern about the abuse/misuse thereof; ***whereas patent extensions or additional certificates may protect modifications without much added value, a better option than incentivising the pursuit of truly innovative new treatments and medicines;***

Or. es

Amendment 91

Lieve Wierinck, Gesine Meissner, Anneli Jäätteenmäki, Marian Harkin, Yana Toom, Jasenko Selimovic

Motion for a resolution

Recital E

Motion for a resolution

E. whereas the aim of intellectual property is to benefit society, guaranteeing investment returns to promote innovation, ***and whereas there is concern about the abuse/misuse thereof;***

Amendment

E. whereas the aim of intellectual property is to benefit society, guaranteeing investment returns to promote innovation ***and to diffuse knowledge;***

Or. en

Amendment 92

José Inácio Faria, Jasenko Selimovic, Marian Harkin, Yana Toom

Motion for a resolution

Recital E

Motion for a resolution

E. whereas the aim of intellectual property is to benefit society, ***guaranteeing***

Amendment

E. whereas the aim of intellectual property is to benefit society, ***incentivise***

investment returns to promote innovation, and whereas there is concern about the abuse/misuse thereof;

investments to promote innovation, and whereas there is concern about the abuse/misuse thereof;

Or. en

Amendment 93

Nikolay Barekov, Boleslaw G. Piecha

Motion for a resolution

Recital E

Motion for a resolution

E. whereas the aim of intellectual property is to *benefit society, guaranteeing* investment returns to promote innovation, and whereas there *is concern* about the abuse/misuse thereof;

Amendment

E. whereas the aim of intellectual property is to *guarantee* investment returns to promote innovation and whereas there *are concerns* about the abuse/misuse thereof;

Or. en

Amendment 94

Cristian-Silviu Buşoi, Andrey Kovatchev

Motion for a resolution

Recital E a (new)

Motion for a resolution

Amendment

Ea. whereas research on rare diseases is more challenging due to their complexity and difficulties in recruitment for clinical trials due to a limited number of patients, therefore requiring incentives for manufacturers to take the risk of investing in this area;

Or. en

Amendment 95

Peter Liese, Karl-Heinz Florenz

Motion for a resolution
Recital E a (new)

Motion for a resolution

Amendment

Ea. whereas significant progress has been made in recent decades as regards treating previously incurable diseases, meaning, for example, that no more patients die of HIV/AIDS in the EU today; however, there are still many diseases against which there is no optimal treatment (including cancer, which kills almost 1.3 million individuals in the EU every year);

Or. de

Amendment 96
Françoise Grossetête

Motion for a resolution
Recital E a (new)

Motion for a resolution

Amendment

Ea. whereas several years ago, a high-level European dialogue (the 'G10' between 2001 and 2002 then the Pharmaceutical Forum between 2005 and 2008) which brought together the key decision-makers and stakeholders in the health world decided to develop a shared strategic vision and to take specific steps to help with the competitiveness of the pharmaceutical sector;

Or. fr

Amendment 97
Margrete Auken

Motion for a resolution
Recital E a (new)

Motion for a resolution

Amendment

Ea. whereas the WTO TRIPS agreement provides since 1995 for patent flexibilities, such as compulsory licensing, i.e. when a government allows someone else than the patent owner to produce the patented product or process without the consent of the patent owner, for the domestic market only, and where the patent owner still has to be paid royalties;

Or. en

Amendment 98

György Hölvényi, Miroslav Mikolášik

Motion for a resolution

Recital E a (new)

Motion for a resolution

Amendment

Ea. whereas the pharmaceutical sector takes advantage of various innovation incentives such as supplementary protection certificate, data exclusivity or market exclusivity which aim at promoting valuable innovation fulfilling unmet medical needs, and whereas these incentives do not always prove to attain those objectives.

Or. en

Amendment 99

Jytte Guteland

Motion for a resolution

Recital E a (new)

Motion for a resolution

Amendment

Ea. whereas the increase of antimicrobial resistance in Europe is of

grave concern for citizens' health and the environment and requires prudent use of antibiotics as well as additional research and development of antibiotics with a novel mechanism of action.

Or. en

Amendment 100
Soledad Cabezón Ruiz

Motion for a resolution
Recital E a (new)

Motion for a resolution

Amendment

Ea. whereas only around 3% of health budgets goes towards measures to prevent and promote public health;

Or. es

Amendment 101
Margrete Auken

Motion for a resolution
Recital E b (new)

Motion for a resolution

Amendment

Eb. whereas the private sector currently holds a monopoly on the production facilities and whereas the EU has to face a widely recognised market failure leading to a lack of private investment in R&D in combating non-competitive segments for which the market does not provide sufficient financial return, such as antimicrobial resistance, rare diseases or poverty-related diseases;

Or. en

Amendment 102
Margrete Auken

Motion for a resolution
Recital E c (new)

Motion for a resolution

Amendment

Ec. whereas the number of new medicines put on the market has continuously been decreasing in last years and whereas among the new medicines, only 1% were seen as innovative or a real therapeutic advance by Prescrire, an independent critical drug information journal in France;

Or. en

Amendment 103
Margrete Auken

Motion for a resolution
Recital E d (new)

Motion for a resolution

Amendment

Ed. whereas the sector inquiry led by the Commission has shown that from 2000 – 2007 originator companies spent on average 17% of their turnover from prescription medicines on R&D worldwide (approximately 1.5% of turnover was spent on basic research to identify potential new medicines and 15.5% of turnover was spent on developing the identified potential medicines through trials into products sufficiently safe and efficacious to be marketed), while expenditure on marketing and promotional activities accounted for 23% of their turnover during the period;

Or. en

Amendment 104
Margrete Auken

Motion for a resolution
Recital E e (new)

Motion for a resolution

Amendment

Ee. whereas on 31st August 2016, on the basis of urgent public interest, the German Federal Patent Court issued a compulsory licence for an HIV drug as requested by the company Merck, after the patent holding company Shionogi had rejected Merck's offer for a voluntary worldwide license on the patent; whereas the NGO Médecins du Monde successfully filed a patent opposition to sofosbuvir, the active substance of a new drug against Hepatitis C owned by the company Gilead that was added to the WHO list of essential medicines in 2014, the EPO deciding on 5th October 2016 that Gilead's patent extended beyond the content of the patent application as filed;

Or. en

Amendment 105
Karl-Heinz Florenz, Peter Liese, Andrey Kovatchev

Motion for a resolution
Recital C

Motion for a resolution

Amendment

F. whereas the Commission has ***had to introduce*** incentives to promote research in areas such as rare diseases, ***and whereas 25 000 people die each year in the EU owing to lack of access to adequate antimicrobial drugs;***

F. whereas the Commission has ***introduced*** incentives to promote research in areas such as rare diseases;

Or. de

Amendment 106
Piernicola Pedicini, Eleonora Evi, Marco Affronte

Motion for a resolution
Recital F

Motion for a resolution

F. whereas the Commission has had to introduce incentives to promote research in areas such as rare diseases, **and** whereas **25 000 people die each year in the EU owing to lack of access to adequate antimicrobial drugs;**

Amendment

F. whereas the Commission has had to introduce incentives to promote research in areas such as rare diseases; whereas ***it is estimated that every year in the EU at least 25 000 people die of infections caused by resistant bacteria while only one novel class of antibiotics has been developed in the past 40 years;***

Or. en

Amendment 107
Lynn Boylan, Kateřina Konečná

Motion for a resolution
Recital F

Motion for a resolution

F. whereas the Commission has had to introduce incentives to promote research in areas such as rare diseases, and whereas 25 000 people die each year in the EU owing to lack of access to adequate antimicrobial drugs;

Amendment

F. whereas the Commission has had to introduce incentives to promote research in areas such as rare diseases, and whereas 25 000 people die each year in the EU owing to lack of access to adequate antimicrobial drugs; ***whereas drug-resistant diseases could cause 10 million deaths per annum worldwide by 2050***

Or. en

Amendment 108
Soledad Cabezón Ruiz

Motion for a resolution
Recital F

Motion for a resolution

F. whereas the **Commission** has had to introduce incentives to promote research in areas such as rare diseases, and whereas **25 000** people die each year in the EU owing to lack of access to adequate antimicrobial drugs;

Amendment

F. whereas the **EU legislature** has had to introduce incentives to promote research in areas such as rare diseases, and whereas **25 000** people die each year in the EU owing to lack of access to adequate antimicrobial drugs **with a cost is 1,5 billion euros year**;

Or. en

Amendment 109
Glenis Willmott

Motion for a resolution
Recital F

Motion for a resolution

F. whereas the Commission has had to introduce incentives to promote research in areas such as rare diseases, and whereas 25 000 people die each year in the EU owing to lack of access to adequate antimicrobial drugs;

Amendment

F. whereas the Commission has had to introduce incentives to promote research in areas such as rare diseases **and paediatric illnesses**, and whereas 25 000 people die each year in the EU owing to lack of access to adequate antimicrobial drugs;

Or. en

Amendment 110
Notis Marias

Motion for a resolution
Recital F

Motion for a resolution

F. whereas the Commission has had to introduce incentives to promote research in areas such as rare diseases, and **whereas** 25 000 people die each year in the EU owing to lack of access to adequate antimicrobial drugs;

Amendment

F. whereas the Commission has had to introduce incentives to promote research in areas such as rare diseases, and **deploring the fact that** 25 000 people die each year in the EU owing to lack of access to adequate antimicrobial drugs;

Amendment 111

Lieve Wierinck, Gesine Meissner, Frédérique Ries, Anneli Jäätteenmäki, Marian Harkin, Yana Toom, Jasenko Selimovic

Motion for a resolution

Recital F

Motion for a resolution

F. whereas the Commission has had to introduce incentives to promote research in areas such as rare diseases, and whereas 25 000 people die each year in the EU owing to lack of *access to* adequate antimicrobial drugs;

Amendment

F. whereas the Commission has had to introduce incentives to promote research in areas such as rare diseases, and whereas 25 000 people die each year in the EU owing to lack of adequate antimicrobial drugs;

Or. en

Amendment 112

Margrete Auken

Motion for a resolution

Recital F a (new)

Motion for a resolution

Amendment

F a. whereas there are currently no tools that prevent the public from paying medicines twice, via reimbursement guaranteed by the national public health systems and substantial contributions to financing R&D in the pharmaceutical sector through:

- public subsidies to research programmes such as Horizon 2020 and Innovative medicines initiatives (IMI) where attribution of funds is not yet subject to any condition regarding local employment and unpatentability of the results***
- tax credits***

Or. en

Amendment 113

Karl-Heinz Florenz, Peter Liese, Françoise Grossetête, Norbert Lins, Andrey Kovatchev

Motion for a resolution

Recital F a (new)

Motion for a resolution

Amendment

Fa. whereas the gap between the growing resistance to antimicrobial agents and the development of new antimicrobial agents is widening, and whereas 25 000 people die each year in the EU owing to lack of access to adequate antimicrobial agents;

Or. de

Amendment 114

Soledad Cabezón Ruiz

Motion for a resolution

Recital F a (new)

Motion for a resolution

Amendment

Fa. whereas the regulation on rare diseases has provided an important framework for promoting research on orphan drugs, considerably boosting the treatment of those diseases for which previously no alternative existed;

Or. es

Amendment 115

Elisabetta Gardini

Motion for a resolution

Recital F a (new)

Motion for a resolution

Amendment

F a. whereas the Advanced Therapy Medicinal Products (ATMPs) have the potential to reshape the treatment of a wide range of conditions, particularly in disease areas where conventional approaches are inadequate, and whereas only few ATMPs have been authorised so far;

Or. en

Amendment 116

Piernicola Pedicini, Eleonora Evi, Marco Affronte

Motion for a resolution

Recital F a (new)

Motion for a resolution

Amendment

Fa. whereas regulators are progressively lowering evidence requirements for approval of new medicines, by allowing smaller trials, surrogate endpoints and placebo comparisons;

Or. en

Amendment 117.

Piernicola Pedicini, Eleonora Evi, Marco Affronte

Motion for a resolution

Recital Fa (new)

Motion for a resolution

Amendment

Fa. whereas public investments in Research and Development play a key role in the development of innovative medicines;

Or. it

Amendment 118
Margrete Auken

Motion for a resolution
Recital G

Motion for a resolution

G. whereas the prices of medicines are usually negotiated by means of bilateral and confidential negotiations between the pharmaceutical industry and Member States;

Amendment

G. whereas the prices of medicines are usually negotiated by means of bilateral and confidential negotiations between the pharmaceutical industry and Member States ***and whereas strong asymmetry in negotiation powers is to deplore between globalised multinational pharmaceutical companies and individual Member States that are subject to fiscal and social competition among themselves and with third countries in an attempt to foster attractiveness of their labour market, fight against unemployment and resistance to offshoring blackmailing by the private sector;***

Or. en

Amendment 119
Cristian-Silviu Buşoi

Motion for a resolution
Recital G

Motion for a resolution

G. whereas the prices of medicines are ***usually negotiated by means of bilateral and confidential negotiations between the pharmaceutical industry and Member States;***

Amendment

G. whereas the prices of medicines are ***set in accordance with criteria laid out in national pricing and reimbursement regulations;***

Or. en

Amendment 120

Nikolay Barekov

Motion for a resolution

Recital G

Motion for a resolution

G. whereas the prices of medicines are usually negotiated by means of bilateral and confidential negotiations between the pharmaceutical industry and Member States;

Amendment

G. whereas the prices of medicines are usually negotiated by means of bilateral and confidential negotiations between the pharmaceutical industry and Member States; ***whereas the pharmaceutical industry is usually better informed about prices of medicines in different Member States than Member States themselves;***

Or. en

Amendment 121

Mireille D'Ornano, Jean-François Jalkh, Sylvie Goddyn

Motion for a resolution

Recital G

Motion for a resolution

G. whereas the prices of medicines are usually negotiated by means of bilateral and confidential negotiations between the pharmaceutical industry and Member States;

Amendment

G. whereas the prices of medicines are usually negotiated by means of bilateral and confidential negotiations between the pharmaceutical industry and Member States ***and whereas every Member State has their own price negotiation system;***

Or. fr

Amendment 122

Lieve Wierinck, Gesine Meissner, Frédérique Ries, Anneli Jäätteenmäki, Marian Harkin, Ulrike Müller, Jasenko Selimovic

Motion for a resolution

Recital G

Motion for a resolution

G. whereas the prices of medicines are usually negotiated by means of bilateral and confidential negotiations between the pharmaceutical industry and Member States;

Amendment

G. whereas the prices of medicines are usually negotiated by means of bilateral and confidential negotiations between the pharmaceutical industry and Member States, ***following rules set out in national reimbursement and pricing legislation;***

Or. en

Amendment 123

György Hölvényi, Alojz Peterle, Miroslav Mikolášik

Motion for a resolution

Recital G

Motion for a resolution

G. whereas the prices of medicines are usually negotiated by means of bilateral and confidential negotiations between the pharmaceutical industry and Member States;

Amendment

G. whereas, ***due to the current international reference pricing system,*** the prices of medicines are usually negotiated by means of bilateral and confidential negotiations between the pharmaceutical industry and Member States;

Or. en

Amendment 124

Marian Harkin

Motion for a resolution

Recital G a (new)

Motion for a resolution

Amendment

Ga. whereas the EU will need to oversee improvements in a range of fields that have an impact on how medicines are produced and distributed as well as ensuring the right of patients to all relevant information; particularly in the case of public health vaccination programmes;

Amendment 125
Francesc Gambús

Motion for a resolution
Recital G a (new)

Motion for a resolution

Amendment

Ga. whereas the Commission can use the joint procurement agreement on drugs, now signed by 20 Member States, to improve access to innovative medicines in more favourable conditions, and whereas that step will bring down the final cost for patients;

Or. es

Amendment 126
Mireille D'Ornano, Jean-François Jalkh, Sylvie Goddyn

Motion for a resolution
Recital H

Motion for a resolution

Amendment

H. whereas the majority of Member States have their own health care assessment agencies with their own standards; *deleted*

Or. fr

Amendment 127
Margrete Auken

Motion for a resolution
Recital H

Motion for a resolution

H. whereas the majority of Member States have their own health care assessment agencies with their own standards;

Amendment

H. whereas, ***in the absence of EU fiscal and social integrated policy***, the majority of Member States have their own health care assessment agencies with their own standards;

Or. en

Amendment 128
Soledad Cabezón Ruiz

Motion for a resolution
Recital H

Motion for a resolution

H. whereas the majority of Member States have their own health ***care*** assessment agencies with their own ***standards***;

Amendment

H. whereas the majority of Member States have their own health ***technology*** assessment agencies with their own ***criteria***;

Or. en

Amendment 129
Margrete Auken

Motion for a resolution
Recital I

Motion for a resolution

I. whereas the entry of generics onto the market is an important mechanism to reduce prices, and whereas ***there are*** clear concerns about the strategies to delay this entry;

Amendment

I. whereas the entry of generics onto the market is an important mechanism to reduce prices, ***remedy distorted competition, reduce expenditure on medicines and improve universal access to affordable medicines***, and whereas ***the Commission expressed*** clear concerns about the strategies to delay this entry;

Or. en

Amendment 130

Lieve Wierinck, Gesine Meissner, Frédérique Ries, José Inácio Faria, Anneli Jäätteenmäki, Marian Harkin, Yana Toom

Motion for a resolution

Recital I

Motion for a resolution

I. whereas the entry of generics onto the market is an important mechanism to reduce prices, ***and whereas there are clear concerns about the strategies to delay this entry;***

Amendment

I. whereas the entry of generics ***and biosimilars*** onto the market is an important mechanism to reduce prices ***and contributes to ensuring the sustainability of healthcare systems, and whereas market entry of generics and biosimilars should not be delayed;***

Or. en

Amendment 131

José Inácio Faria, Jasenko Selimovic

Motion for a resolution

Recital I

Motion for a resolution

I. whereas the entry of generics onto the market is an important mechanism to reduce prices, and whereas there are clear concerns about the strategies to delay this entry;

Amendment

I. whereas the entry of generics ***and biosimilars*** onto the market is an important mechanism to ***increase competition,*** reduce prices, and whereas there are clear concerns about the strategies to delay this entry;

Or. en

Amendment 132

Nessa Childers

Motion for a resolution

Recital I

Motion for a resolution

I. whereas the entry of generics onto the market is an important mechanism to reduce prices, and whereas there are clear concerns about the strategies to delay this entry;

Amendment

I. whereas the entry of generics ***and biosimilars*** onto the market is an important mechanism to reduce prices, and whereas there are clear concerns about the strategies to delay this entry;

Or. en

Amendment 133

György Hölvényi, Alojz Peterle, Miroslav Mikolášik

Motion for a resolution

Recital I

Motion for a resolution

I. whereas the entry of generics onto the market is an important mechanism to reduce prices, and whereas there are clear concerns about the strategies to delay this entry;

Amendment

I. whereas the entry of generics ***and biosimilars*** onto the market is an important mechanism to reduce prices, and whereas there are clear concerns about the strategies to delay this entry;

Or. en

Amendment 134

Soledad Cabezón Ruiz

Motion for a resolution

Recital I a (new)

Motion for a resolution

Ia. whereas while the organisation of health systems and of pharmaceutical provision, specifically pricing and reimbursement systems, is a national competence, the EU provides legislation on clinical trials, transparency in pricing, intellectual property, pharmacovigilance, authorisation competences and control of competence, and it is the biggest financial backer of public research;

Amendment

Amendment 135
Nikolay Barekov

Motion for a resolution
Recital I a (new)

Motion for a resolution

Amendment

I a. whereas the provision of therapeutic information is essential for medicinal products with self-medication purposes, and whereas existing EU rules lead to a lack of transparency for non-prescription homeopathic medicines;

Or. en

Amendment 136
Nessa Childers

Motion for a resolution
Recital I a (new)

Motion for a resolution

Amendment

Ia. whereas access to affordable and suitable diagnostic tests and vaccines is as critical as access to safe, effective and affordable medicines.

Or. en

Amendment 137
Mireille D'Ornano, Jean-François Jalkh, Sylvie Goddyn

Motion for a resolution
Recital I a (new)

Motion for a resolution

Amendment

Ia. stresses, however, that the generic

*medicines market share amounts to 48%
for the whole European Union;*

Or. fr

Amendment 138

Mireille D'Ornano, Jean-François Jalkh, Sylvie Goddyn

Motion for a resolution

Recital I b (new)

Motion for a resolution

Amendment

***Ib.** stresses that the generic medicines share should be even higher, but the production of new generic medicines is dependent on the formulation of innovative active ingredients;*

Or. fr

Amendment 139

Karl-Heinz Florenz, Peter Liese, Andrey Kovatchev

Motion for a resolution

Recital J

Motion for a resolution

Amendment

J. whereas under Article 168 of the Treaty on the Functioning of the European Union (TFEU), Parliament and the Council can, in order to meet common safety concerns, adopt measures setting high standards of quality and safety for medicinal products;

J. whereas under Article 168 of the Treaty on the Functioning of the European Union (TFEU), Parliament and the Council can, in order to meet common safety concerns, adopt measures setting high standards of quality and safety for medicinal products, *and whereas, in accordance with Article 114(3) of the TFEU, legislative proposals in the health sector shall take as a base a high level of protection;*

Or. de

Amendment 140

Mireille D'Ornano, Jean-François Jalkh, Sylvie Goddyn

Motion for a resolution

Recital J

Motion for a resolution

J. whereas under Article 168 of the Treaty on the Functioning of the European Union (TFEU), Parliament and the Council can, in order to meet common safety concerns, adopt measures setting high standards of quality and safety for medicinal products;

Amendment

J. whereas under Article 168 of the Treaty on the Functioning of the European Union (TFEU), Parliament and the Council can, in order to meet common safety concerns, adopt measures setting high standards of quality and safety for medicinal products, ***without forgetting that under the terms of the same article, the Member States' responsibilities include managing health and medical care services, and allocating resources to those services;***

Or. fr

Amendment 141

Nikolay Barekov

Motion for a resolution

Recital J a (new)

Motion for a resolution

Amendment

Ja. whereas it is necessary to use existing EU law to address the supply shortages of pharmaceuticals; whereas Article 81, Directive 2001/83/EU stipulates measures to prevent pharmaceutical shortages by the obligation upon manufacturers and distributors to safeguard the supplies at the national market, the so-called Public Service Obligation (PSO); whereas in many cases the PSO is not applied to manufacturers supplying the distributors, as indicated in a study commissioned by the European Commission^{1a};

Amendment 142.
Piernicola Pedicini, Eleonora Evi, Marco Affronte

Motion for a resolution
Recital Ja (new)

Motion for a resolution

Amendment

Ja. whereas diseases such as Hepatitis C can be successfully combated with early diagnosis combined with new and old medicines, saving millions of people across the EU; whereas patients with hepatic fibrosis diagnosed at stages F1, F2 and F3 in some Member States face huge problems in getting hold of Sofosbuvir, due to its extremely high price in the EU;

Or. it

Amendment 143
José Inácio Faria

Motion for a resolution
Recital J a (new)

Motion for a resolution

Amendment

Ja. whereas current EU legislation requires the demonstration of efficacy, safety and pharmaceutical quality before a new medicine can be authorized to enter the market; whereas despite this fact adverse drug reactions (ADR) are responsible for 3-10% of hospital admissions and the fifth most frequent cause of death;

Amendment 144
Herbert Dorfmann

Motion for a resolution
Recital J a (new)

Motion for a resolution

Amendment

Ja. whereas certain medicines are not available in some Member States, which can lead to problems with regard to patient care, particularly for patients living in a Member State other than their usual Member State of residence;

Or. de

Amendment 145
Peter Liese, Karl-Heinz Florenz

Motion for a resolution
Recital J a (new)

Motion for a resolution

Amendment

Ja. whereas the Regulation on advanced therapy medicinal products was introduced to promote EU-wide innovation in this area while ensuring safety, but only eight novel therapies have been approved to date;

Or. de

Amendment 146
Soledad Cabezón Ruiz

Motion for a resolution
Recital J a (new)

Motion for a resolution

Amendment

Ja. whereas a shortage of essential medicines is a common problem in the majority of Member States and particularly affects hospitals, along with antibiotics and cancer, emergency and cardiovascular treatments;

Or. es

Amendment 147

Lynn Boylan, Kateřina Konečná

Motion for a resolution

Recital J a (new)

Motion for a resolution

Amendment

Ja. whereas the European Medicines Agency launched a pilot project in 2014 known as 'adaptive pathways' which sought to provide access for patients to new medicines, by gathering evidence through real-life use to supplement clinical trials

Or. en

Amendment 148

György Hölvényi, Miroslav Mikolášik

Motion for a resolution

Recital J a (new)

Motion for a resolution

Amendment

Ja. whereas the European Medicines Agency led adaptive regulatory pathway process provoked intense debate on the risk/benefit relation of granting earlier market access to innovative medicines with less clinical data;

Amendment 149.
Enrico Gasbarra

Motion for a resolution
Recital Ja (new)

Motion for a resolution

Amendment

Ja. Whereas the European Parliament has shown its strong political commitment to this matter, above all by opening its current legislature to a more open policy for access to medicines;

Or. it

Amendment 150
Christel Schaldemose

Motion for a resolution
Recital J a (new)

Motion for a resolution

Amendment

Ja. whereas Regulation 141/2000/EC on orphan medicinal products provides extra incentives to develop medicine for medicine for patients with rare diseases;

Or. en

Amendment 151
Monica Macovei

Motion for a resolution
Recital J a (new)

Motion for a resolution

Amendment

Ja. whereas the composition of the medicinal products varies across

countries and this leads to a discrepancy among medicinal products in the Member States

Or. en

Amendment 152

Lynn Boylan, Kateřina Konečná

Motion for a resolution

Recital J b (new)

Motion for a resolution

Amendment

Jb. whereas people living with disabilities, as well as those with long term illnesses that are not life threatening but do hamper and hinder quality of life and make everyday living more difficult than for a person in full health, are the most vulnerable and need medicines the most;

Or. en

Amendment 153

Soledad Cabezón Ruiz

Motion for a resolution

Recital J b (new)

Motion for a resolution

Amendment

Jb. whereas while no definition has been adopted in the EU on access to drugs, the WHO provided a definition in 'Access to new medicines in Europe: technical review of policy initiatives and opportunities for collaboration and research' (Copenhagen, 2015)

Or. es

Amendment 154
György Hölvényi, Alojz Peterle

Motion for a resolution
Recital J b (new)

Motion for a resolution

Amendment

Jb. whereas parallel trade of medicinal products lead to excessive medicines outflow from member states where lower prices are applied.

Or. en

Amendment 155
Christel Schaldemose

Motion for a resolution
Recital J b (new)

Motion for a resolution

Amendment

Jb. whereas an healthy and competitive market for medicinal products benefits from vigilant competition law scrutiny;

Or. en

Amendment 156.
Piernicola Pedicini, Eleonora Evi, Marco Affronte

Motion for a resolution
Recital Jb (new)

Motion for a resolution

Amendment

Jb. Whereas to date the EU has not had a strategic plan for combating HCV;

Or. it

Amendment 157
Damiano Zoffoli, Soledad Cabezón Ruiz

Motion for a resolution
Paragraph 1

Motion for a resolution

1. Recalls that the EU pharmaceutical industry is one of the most competitive industries in Europe *and that* quality innovation is key to *improving its* competitiveness;

Amendment

1. Recalls that the EU pharmaceutical industry is one of the most competitive industries in Europe; *stresses that preserving a high quality of* innovation is key to *continue addressing patients' needs and to improve the* competitiveness *of the pharmaceutical industry*;

Or. en

Amendment 158
Margrete Auken

Motion for a resolution
Paragraph 1

Motion for a resolution

1. Recalls that the EU pharmaceutical industry is one of the most competitive industries in Europe and that quality innovation *is* key to improving its competitiveness;

Amendment

1. Recalls that the EU pharmaceutical industry is one of the most competitive industries in Europe and that quality, *safety and efficacy of* innovation *are* key to improving its competitiveness;

Or. en

Amendment 159
Lieve Wierinck, Gesine Meissner, Frédérique Ries, José Inácio Faria, Marian Harkin, Yana Toom, Jasenko Selimovic

Motion for a resolution
Paragraph 1

Motion for a resolution

1. Recalls that the EU pharmaceutical industry is one of the most competitive

Amendment

1. Recalls that the EU pharmaceutical industry is one of the most competitive *and*

industries in Europe and that quality innovation is key to improving its competitiveness;

strategic industries in Europe and that quality innovation is key to improving its competitiveness;

Or. en

Amendment 160
José Inácio Faria

Motion for a resolution
Paragraph 1 a (new)

Motion for a resolution

Amendment

1a. Shares the concern expressed in the 2016 Council Conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States, acknowledging an imbalance in the national pharmaceutical systems in the EU due to complex interactions between measures to promote innovation and the assessment of medicinal products, and pricing and reimbursement decisions at national level leading to suboptimal outcomes for patients and society;

Or. en

Amendment 161
Soledad Cabezón Ruiz

Motion for a resolution
Paragraph 1 a (new)

Motion for a resolution

Amendment

1a. Recalls that under Article 168 of the Treaty on the Functioning of the European Union, a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities

Amendment 162
Cristian-Silviu Buşoi, Andrey Kovatchev

Motion for a resolution
Paragraph 1 a (new)

Motion for a resolution

Amendment

1a. Stresses the importance of medicines in improving public health enabling patients to live longer and better lives, thereby supporting the productivity of our societies and economic growth.

Or. en

Amendment 163
Frédérique Ries, Françoise Grossetête

Motion for a resolution
Paragraph 1 a (new)

Motion for a resolution

Amendment

1a. Stresses that in a European Union which is suffering deindustrialisation, the pharmaceutical sector remains an important industrial pillar and a driving force for job creation;

Or. fr

Amendment 164
Mireille D'Ornano, Jean-François Jalkh, Sylvie Goddyn

Motion for a resolution
Paragraph 1 a (new)

Motion for a resolution

Amendment

1a. Stresses that the pharmaceutical

industry creates some 800 000 jobs in the European Union;

Or. fr

Amendment 165

Mireille D'Ornano, Jean-François Jalkh, Sylvie Goddyn

Motion for a resolution

Paragraph 1 b (new)

Motion for a resolution

Amendment

Ib. Stresses, however, that almost 80% of the European pharmaceutical industry's ingredients for new active substances are imported, above all, from India and China, and that its dependence on imports threatens the self-sufficiency of the European Union and its Member States and, in the long term, European consumers' health;

Or. fr

Amendment 166

Christofer Fjellner

Motion for a resolution

Paragraph 2

Motion for a resolution

Amendment

2. Regrets that the research priorities of the pharmaceutical industry are profit-oriented rather than patient-oriented; *deleted*

Or. en

Amendment 167

Lieve Wierinck, Gesine Meissner, Frédérique Ries, José Inácio Faria, Ulrike Müller, Jasenko Selimovic

Motion for a resolution
Paragraph 2

Motion for a resolution

Amendment

2. *Regrets that the research priorities of the pharmaceutical industry are profit-oriented rather than patient-oriented;*

deleted

Or. en

Amendment 168
Karl-Heinz Florenz, Peter Liese, Andrey Kovatchev

Motion for a resolution
Paragraph 2

Motion for a resolution

Amendment

2. *Regrets that the research priorities of the pharmaceutical industry are profit-oriented rather than patient-oriented;*

2. *Notes that the employees of pharmaceutical companies are primarily interested in medical progress and the well-being of patients, but that pharmaceutical companies ultimately want to make a profit, which means that the political framework has to create the best possible outcome for patients and the general public;*

Or. de

Amendment 169
Nikolay Barekov, Bolesław G. Piecha

Motion for a resolution
Paragraph 2

Motion for a resolution

Amendment

2. Regrets that the research priorities of the pharmaceutical industry are profit-oriented *rather than patient-oriented;*

2. Regrets that the research priorities of the pharmaceutical industry are *often only* profit-oriented *and do not always take into account the real needs of patients; highlights that although making profit is a fully comprehensible incentive*

to operate on any market, the pharmaceutical products market is specific as it benefits from its customer vulnerability, lack of experience and high volumes of public spending;

Or. en

Amendment 170.
Enrico Gasbarra

Motion for a resolution
Paragraph 2

Motion for a resolution

2. *Regrets* that the research priorities of the pharmaceutical industry *are profit-oriented rather than patient-oriented;*

Amendment

2. *Requests* that the research priorities of the pharmaceutical industry *be consistently oriented towards making European production competitive as well as sustainable and affordable for the patient;*

Or. it

Amendment 171
Notis Marias

Motion for a resolution
Paragraph 2

Motion for a resolution

2. Regrets that the research priorities of the pharmaceutical industry are profit-oriented rather than patient-oriented;

Amendment

2. Regrets that the research priorities of the pharmaceutical industry are profit-oriented rather than patient-oriented *and condemns the EU's position in having turned medicine from a public good into a commodity;*

Or. el

Amendment 172
Margrete Auken

Motion for a resolution
Paragraph 2

Motion for a resolution

2. Regrets that the research priorities of the pharmaceutical industry are profit-oriented rather than patient-oriented;

Amendment

2. Regrets that *as long as medicines are considered to be regular consumer goods, unresolved policy incoherencies between trade and intellectual property rules, public health objectives and international human rights lead to a situation where* the research priorities of the pharmaceutical industry are profit-oriented rather than patient-oriented;

Or. en

Amendment 173
Mireille D'Ornano, Jean-François Jalkh, Sylvie Goddyn

Motion for a resolution
Paragraph 2

Motion for a resolution

2. Regrets that the research priorities of the pharmaceutical industry are profit-oriented rather than patient-oriented;

Amendment

2. Regrets that the research priorities of the pharmaceutical industry are profit-oriented rather than patient-oriented; *points out that public health as a domain can sometimes be irrational; some general and expensive screenings are passing fads, rather than proper, effective screenings, and screenings targeted according to risk and followed up with more comprehensive examinations would be more appropriate;*

Or. fr

Amendment 174
Cristian-Silviu Buşoi

Motion for a resolution
Paragraph 2

Motion for a resolution

2. ***Regrets*** that the research priorities of the pharmaceutical industry ***are profit-oriented rather than patient-oriented***;

Amendment

2. ***Notes*** that the research priorities of the pharmaceutical industry ***reflect a balance between patient medical needs and the likelihood of generating the return on investment necessary to continue investing in future innovation***;

Or. en

Amendment 175

Françoise Grossetête, Frédérique Ries, Elisabetta Gardini, Cristian-Silviu Buşoi

Motion for a resolution
Paragraph 2

Motion for a resolution

2. ***Regrets*** that the research priorities of the pharmaceutical industry ***are profit-oriented rather than patient-oriented***;

Amendment

2. ***Notes*** that the research priorities of the pharmaceutical industry ***encompass ensuring better treatment for patients and generating financial returns***;

Or. en

Amendment 176

Nicola Caputo, Marc Tarabella

Motion for a resolution
Paragraph 2 a (new)

Motion for a resolution

Amendment

2a. Notes with concern an increasing number of examples of market failure in a number of Member States, where patients access to effective and affordable essential medicines is endangered by very high and unsustainable price levels, market withdrawal of products that are out-of-patent or when new products are not

introduced to national markets for business economic strategies, and that individual governments have sometimes limited influence in such circumstances;

Or. en

Amendment 177

José Inácio Faria, Jasenko Selimovic, Marian Harkin, Yana Toom

Motion for a resolution

Paragraph 2 a (new)

Motion for a resolution

Amendment

2a. Notes that over 7000 innovative medicines are in the development pipeline with much expected therapeutic benefit for patients; considers that some current pricing strategies for innovative medicines and their combined budgetary impact pose a threat to the sustainability of health care systems and therefore might not be accessible for those who need it;

Or. en

Amendment 178

Lynn Boylan, Kateřina Konečná

Motion for a resolution

Paragraph 2 a (new)

Motion for a resolution

Amendment

2a. Deplores the fact that there are 18 million people across the EU without access to health care; also finds it alarming that in a period of relative prosperity with many advances in healthcare, medicines and technology, there appears to be very little advancement in creating sustainable solutions for those without healthcare or medicines;

Amendment 179
Françoise Grossetête, Angélique Delahaye

Motion for a resolution
Paragraph 2 a (new)

Motion for a resolution

Amendment

2a. Criticises the fact that health expenses continue to be seen only as a cost and not as an investment, and that medicine is always the first variable in economic measures in our healthcare systems;

Or. fr

Amendment 180
Eva Kaili

Motion for a resolution
Paragraph 2 a (new)

Motion for a resolution

Amendment

2a. Stresses that patients' organizations should be better involved in the definition of private and public clinical trials research strategies, to ensure that they meet the true unmet needs of the European patients;

Or. en

Amendment 181
Mireille D'Ornano, Jean-François Jalkh, Sylvie Goddyn

Motion for a resolution
Paragraph 2 a (new)

Motion for a resolution

Amendment

2a. *Points out that the costs of research and development activities are difficult to assess because of the experimental nature inherent in scientific research;*

Or. fr

Amendment 182
Soledad Cabezón Ruiz

Motion for a resolution
Paragraph 2 a (new)

Motion for a resolution

Amendment

2a. *whereas spending on R&D and private research efforts is important to discovering new treatments and the economic growth of the EU;*

Or. es

Amendment 183
Soledad Cabezón Ruiz

Motion for a resolution
Paragraph 2 a (new)

Motion for a resolution

Amendment

2a. *Notes that the research priorities of pharmaceutical industry have to address health patient needs.*

Or. en

Amendment 184
Lynn Boylan

Motion for a resolution
Paragraph 2 b (new)

Motion for a resolution

Amendment

2b. *Points out that although pharmaceutical companies often argue that their R+D costs are prohibitively expensive, data shows that these companies' spend on marketing actually far outstrips R+D costs*

Or. en

Amendment 185

José Inácio Faria, Jasenko Selimovic, Marian Harkin, Yana Toom

Motion for a resolution
Paragraph 2 b (new)

Motion for a resolution

Amendment

2b. *Notes with concern the recent scientific trends that lead to investments being steered to low volume, high priced medicines, leaving other important areas neglected;*

Or. en

Amendment 186

José Inácio Faria, Marian Harkin, Yana Toom

Motion for a resolution
Paragraph 2 c (new)

Motion for a resolution

Amendment

2c. *Notes that in a context of highly priced medicines in the innovative pharmaceutical sector, market research data show that R&D investment is often substantially lower than sales and marketing expenditure; Highlights the fact that this puts at risk the sustainability*

of European healthcare systems and indicates the persistence of inappropriate market rewards which should be corrected;

Or. en

Amendment 187

José Inácio Faria, Jasenko Selimovic, Marian Harkin, Yana Toom

Motion for a resolution

Paragraph 2 d (new)

Motion for a resolution

Amendment

2d. Calls on Member States to build on the example of existing initiatives in Europe to place negative incentives on the marketing expenditure by the pharmaceutical industry such as a contribution system towards an innovation fund aimed at promoting independent research in areas of interest for the National Health Services that are insufficiently addressed by commercial research, (e. g. antimicrobial resistance), and for patient populations normally excluded by clinical studies such as children, pregnant women and the elderly;

Or. en

Amendment 188

Lieve Wierinck, Gesine Meissner, Marian Harkin, Ulrike Müller, Yana Toom, Jasenko Selimovic

Motion for a resolution

Paragraph 3

Motion for a resolution

Amendment

3. Stresses that transparency *of the* cost of *development and clinical trials is crucial in order to set a fair price;*

3. Stresses that *more* transparency *in the proportion of publicly funded research is needed, and that when assessing the*

total cost of a drug, it is necessary to take into account the costs for research and development, including research failures and clinical trials, and the whole pharmaceutical value chain;

Or. en

Amendment 189
Cristian-Silviu Buşoi

Motion for a resolution
Paragraph 3

Motion for a resolution

Amendment

3. *Stresses that transparency of the cost of development and clinical trials is crucial in order to set a fair price;*

deleted

Or. en

Amendment 190
Mireille D'Ornano, Jean-François Jalkh, Sylvie Goddyn

Motion for a resolution
Paragraph 3

Motion for a resolution

Amendment

3. Stresses that transparency of the cost of development and clinical trials is crucial in order to set a fair price;

3. Stresses that transparency of the cost of development and clinical trials is crucial in order to set a fair price; *points out, in this regard, the importance of clinical trials when it comes to avoiding scandals such as the Avastin scandal (bevacizumab antibody);*

Or. fr

Amendment 191.
Enrico Gasbarra

Motion for a resolution
Paragraph 3

Motion for a resolution

3. Stresses that transparency of the cost of development and clinical trials is crucial in order to set a fair price;

Amendment

3. Stresses that transparency of the cost of development and clinical trials is crucial in order to set a fair price, *as indicated in Directive 89/105*;

Or. it

Amendment 192
Annie Schreijer-Pierik

Motion for a resolution
Paragraph 3

Motion for a resolution

3. Stresses that transparency of the cost of development and clinical trials is crucial in order to set a fair price;

Amendment

3. Stresses that transparency of the cost of development and clinical trials, *whether ex ante or ex post*, is crucial in order to set a fair price;

Or. nl

Amendment 193
Daciana Octavia Sârbu

Motion for a resolution
Paragraph 3

Motion for a resolution

3. Stresses that transparency of the cost of development *and* clinical trials is crucial in order to set a fair price;

Amendment

3. Stresses that *full* transparency of the cost of *research and* development, *including* clinical trials is crucial in order to set a fair price;

Or. en

Amendment 194
Soledad Cabezón Ruiz

Motion for a resolution
Paragraph 3

Motion for a resolution

3. Stresses that transparency of the cost of development and clinical trials is crucial in order to set a fair price;

Amendment

3. Stresses that transparency of the cost of development *of medicines* and clinical trials is crucial in order to set a fair price;

Or. en

Amendment 195
Nessa Childers

Motion for a resolution
Paragraph 3

Motion for a resolution

3. Stresses that transparency of the cost of *development* and clinical trials is crucial in order to set a fair price;

Amendment

3. Stresses that *full* transparency of the cost of *R&D* and clinical trials is crucial in order to set a fair price;

Or. en

Amendment 196
Elisabetta Gardini, Cristian-Silviu Buşoi, Alojz Peterle, Françoise Grossetête, Giovanni La Via, Aldo Patriciello, Alessandra Mussolini

Motion for a resolution
Paragraph 3 a (new)

Motion for a resolution

Amendment

3 a. Stresses that patients' organisations should be better involved in the definition of private and public clinical trials research strategies, to ensure that they meet the true unmet needs of European patients;

Amendment 197
György Hölvényi

Motion for a resolution
Paragraph 3 a (new)

Motion for a resolution

Amendment

3a. Stresses that marketing cost contribute to the price of medicines to a much higher extent than R&D costs.

Or. en

Amendment 198
José Inácio Faria, Jasenko Selimovic, Anneli Jäätteenmäki, Marian Harkin, Yana Toom

Motion for a resolution
Paragraph 3 a (new)

Motion for a resolution

Amendment

3a. Recalls that robust clinical trials are necessary to assess the efficacy and safety of medicines;

Or. en

Amendment 199
Christofer Fjellner

Motion for a resolution
Paragraph 4

Motion for a resolution

Amendment

4. Stresses that the interests of the pharmaceutical industry favour short trials and fast access to the market;

deleted

Or. en

Amendment 200
Cristian-Silviu Buşoi

Motion for a resolution
Paragraph 4

Motion for a resolution

4. Stresses that the interests of *the pharmaceutical industry* favour *short trials* and fast access to *the market*;

Amendment

4. Stresses that the interests of *patients* favour *more efficient trials* and fast access to *safe and effective medicines*;

Or. en

Amendment 201.
Piernicola Pedicini, Eleonora Evi, Marco Affronte

Motion for a resolution
Paragraph 4

Motion for a resolution

4. Stresses that *the interests of the pharmaceutical industry* favour *short trials and* fast access to the market;

Amendment

4. Stresses that the *short trials that allow the pharmaceutical industry* fast access to the market *must always be the exception and not the rule for authorising new medicines, must not be motivated by commercial considerations, and must never sacrifice the rights guaranteed to the participants of clinical trials*;

Or. it

Amendment 202
Margrete Auken

Motion for a resolution
Paragraph 4

Motion for a resolution

4. Stresses that *the interests of the pharmaceutical industry* favour short trials

Amendment

4. Stresses that, *as trade and intellectual property rules were not*

and fast access to the market;

developed with the goal of protecting the right to health, the interests of private patent holders favour short trials and fast access to the market;

Or. en

Amendment 203

Andrey Kovatchev, Cristian-Silviu Buşoi, Kateřina Konečná

Motion for a resolution

Paragraph 4

Motion for a resolution

4. Stresses that *the interests of the pharmaceutical industry* favour *short trials* and fast access to *the market*;

Amendment

4. Stresses that, *especially in case of unmet needs, the interests of patients* favour *more efficient* trials and fast access to *safe and effective medicines*;

Or. en

Amendment 204

Lieve Wierinck, Gesine Meissner, Marian Harkin, Ulrike Müller, Yana Toom, Jasenko Selimovic

Motion for a resolution

Paragraph 4

Motion for a resolution

4. Stresses that the interests of the pharmaceutical industry *favour short trials and* fast access to the market;

Amendment

4. Stresses that *it is in* the interests of the pharmaceutical industry *and patients to ensure* fast access to the market *for innovative medicines both in-patent and off-patent*;

Or. en

Amendment 205

Damiano Zoffoli, Soledad Cabezón Ruiz

Motion for a resolution
Paragraph 4

Motion for a resolution

4. **Stresses** that the interests of the pharmaceutical industry favour short trials and fast access to the market;

Amendment

4. **Notes** that the interests of the pharmaceutical industry favour short trials and fast access to the market; **stress however the importance to prefer robust clinical trials in order to better assess the efficacy and safety of medicines;**

Or. en

Amendment 206

Françoise Grossetête, Frédérique Ries, Elisabetta Gardini, Cristian-Silviu Buşoi

Motion for a resolution
Paragraph 4

Motion for a resolution

4. Stresses that the interests of the pharmaceutical industry **favour** short trials and fast access to the market;

Amendment

4. Stresses that, **in case of unmet medical needs**, the interests of the **patients and the** pharmaceutical industry **may require** short trials and fast access to the market;

Or. en

Amendment 207

Christel Schaldemose

Motion for a resolution
Paragraph 4

Motion for a resolution

4. Stresses that the interests of the pharmaceutical industry favour short trials and fast access to the market;

Amendment

4. Stresses that the interests of the pharmaceutical industry favour short trials and fast access to the market; **but recalls that clinical trials are necessary to assess the efficacy and safety of medicines;**

Or. en

Amendment 208
Soledad Cabezón Ruiz

Motion for a resolution
Paragraph 4

Motion for a resolution

4. Stresses that the interests of the pharmaceutical industry favour short trials and fast access to the market;

Amendment

4. Stresses that the interests of the pharmaceutical industry favour short trials and fast access to the market, *for example, adaptive licensing*;

Or. es

Amendment 209
Annie Schreijer-Pierik

Motion for a resolution
Paragraph 4

Motion for a resolution

4. Stresses that the interests of the pharmaceutical industry favour short trials and fast access to the market;

Amendment

4. Stresses that the interests of the pharmaceutical industry *in the Union* favour short trials and fast access to the market;

Or. nl

Amendment 210
José Inácio Faria, Jasenko Selimovic, Frédérique Ries, Lieve Wierinck, Yana Toom

Motion for a resolution
Paragraph 4 a (new)

Motion for a resolution

Amendment

4a. Notes the fragmentation of the pharmaceutical market in the EU and acknowledges the increased administrative burdens and the higher costs that it implies for industry; Highlights that this is an obstacle to the sector's competitiveness and to the

expansion of spin-off and young companies seeking to enter the market, pulling away from Europe investment in this innovative sector; Stresses that such barriers bring important delays to patients' access to new medicines;

Or. en

Amendment 211

Lynn Boylan

Motion for a resolution

Paragraph 4 a (new)

Motion for a resolution

Amendment

4a. Stresses that the fast-tracking of medicines and the circumvention of the standard risk assessment for licensing a medicine should not become the norm and must be restricted to only a very select number of medicines, for which an objective need must be clearly met. Calls therefore on the European Commission and the European Medicines Agency to precisely define unclear terms upon which the adaptive pathways mechanism is based such as 'unmet medical need'

Or. en

Amendment 212

Lieve Wierinck, Gesine Meissner, Frédérique Ries, Marian Harkin

Motion for a resolution

Paragraph 4 a (new)

Motion for a resolution

Amendment

4a. Welcomes the adaptive pathways pilot project and the PRIME scheme by the European Medicines Agency as a way to ensure timely access to medicines for patients with unmet medical needs,

without compromising on patient safety;

Or. en

Amendment 213
Krzysztof Hetman

Motion for a resolution
Paragraph 4 a (new)

Motion for a resolution

Amendment

4a. Underlines the role of European research projects and SMEs in improving the access to medicines at the European level, highlights the role of Horizon 2020 programme in this respect.

Or. en

Amendment 214
Christel Schaldemose

Motion for a resolution
Paragraph 4 a (new)

Motion for a resolution

Amendment

4a. Note with concerns that industry 'interactions with health-sector stakeholders are poorly regulated, which may lead to conflict of interest and biased decisions;

Or. en

Amendment 215
José Inácio Faria, Jasenko Selimovic, Frédérique Ries, Marian Harkin, Lieve Wierinck, Yana Toom

Motion for a resolution
Paragraph 4 b (new)

Motion for a resolution

Amendment

4b. *Calls on Member States to develop closer collaboration to fight such market fragmentation, namely to develop shared Health Technology Assessment processes and results, and to work on shared criteria to instruct price and reimbursement decisions at national level;*

Or. en

Amendment 216

Lynn Boylan, Kateřina Konečná

**Motion for a resolution
Paragraph 4 b (new)**

Motion for a resolution

Amendment

4b. *Notes with concern that 5% of all hospital admissions in the EU are due to an adverse drug reaction (ADR) and ADRs are the 5th leading cause of hospital death*

Or. en

Amendment 217

Lynn Boylan

**Motion for a resolution
Paragraph 4 c (new)**

Motion for a resolution

Amendment

4c. *Highlights the concern expressed by healthcare professionals, civil society organisations and regulators that adaptive pathways which rely on limited preliminary clinical data, surrogate outcomes and observational studies risk incorrect conclusions on the benefit-harm of new drugs; regrets the approach of the*

Amendment 218

Lynn Boylan

Motion for a resolution

Paragraph 4 d (new)

Motion for a resolution

Amendment

4d. Notes with concern that a central element of the adaptive pathways mechanism is reliance upon 'real world data' i.e. observational data instead of data gathered during clinical trials

Amendment 219

Soledad Cabezón Ruiz

Motion for a resolution

Subheading 2 a (new)

Motion for a resolution

Amendment

Points out that innovation should help to improve people's quality of life by solving their health problems, along with other challenges such as the sustainability of the health systems, and that, in any case, it should not be a factor of inequality in health;

Amendment 220

Soledad Cabezón Ruiz

Motion for a resolution

Subheading 2 a (new)

Motion for a resolution

Amendment

Emphasises that research and innovation is crucial for Europe's growth and development; on health must be focused on safe, qualitative sustainable and affordable medicines.

Or. en

Amendment 221

José Inácio Faria, Jasenko Selimovic, Anneli Jäätteenmäki, Frédérique Ries, Marian Harkin, Lieve Wierinck, Yana Toom

**Motion for a resolution
Paragraph 4 c (new)**

Motion for a resolution

Amendment

4c. Considers innovation in the pharmaceutical sector to be crucial in order to address unmet medical needs;

Or. en

Amendment 222

Soledad Cabezón Ruiz

**Motion for a resolution
Subheading 2 b (new)**

Motion for a resolution

Amendment

Recalls intellectual property grants companies the right to a legal monopoly that need to be regulated to avoid the conflict with the right to health protection and that can be compatible with the quality of innovation, competitiveness or public interest

Or. en

Amendment 223
Christofer Fjellner

Motion for a resolution
Paragraph 5

Motion for a resolution

5. Recalls that IP rights ***allow a legal monopoly***, which needs to be carefully regulated ***to avoid conflict with the right to health protection and*** to promote quality of innovation and competitiveness;

Amendment

5. Recalls that IP rights ***allows a limited period of exclusivity***, which needs to be carefully regulated to promote quality of innovation and competitiveness;

Or. en

Amendment 224
Françoise Grossetête, Karl-Heinz Florenz, Frédérique Ries, Elisabetta Gardini,
Cristian-Silviu Buşoi

Motion for a resolution
Paragraph 5

Motion for a resolution

5. Recalls that IP rights ***allow a legal monopoly, which needs to be*** carefully regulated to avoid conflict with the right to health protection and to promote quality of innovation and competitiveness;

Amendment

5. Recalls that IP rights ***provide a limited period of exclusivity, which is*** carefully regulated ***and monitored by the authorities*** to avoid conflict with the right to health protection and to promote quality of innovation and competitiveness;

Or. en

Amendment 225
Lieve Wierinck, Gesine Meissner, Marian Harkin, Yana Toom

Motion for a resolution
Paragraph 5

Motion for a resolution

5. Recalls that IP rights allow ***a legal monopoly***, which needs to be carefully ***regulated to avoid conflict*** with the right to

Amendment

5. Recalls that IP rights allow ***for a clearly defined period of exclusivity***, which needs to be carefully ***balanced*** with

health protection and *to* promote quality of innovation and competitiveness;

the right to health protection and *should* promote quality of innovation and competitiveness;

Or. en

Amendment 226.

Piernicola Pedicini, Eleonora Evi, Marco Affronte

Motion for a resolution

Paragraph 5

Motion for a resolution

5. Recalls that IP rights allow a legal monopoly, which needs to be carefully regulated to avoid conflict with the right to health protection *and to promote quality of innovation and competitiveness*;

Amendment

5. Recalls that IP rights allow a legal monopoly, which needs to be carefully regulated to avoid conflict with the right to health protection; *calls on the competent authorities to carefully apply the principle of the originality of patents, and to therefore avoid pandering to the market strategy (by always giving patents the green light) of pharmaceutical companies to keep a patent for a medicine for as long as possible by making non-essential changes, for example by adding bulking agents, to be able to continue holding the monopoly over that medicine*;

Or. it

Amendment 227

Margrete Auken

Motion for a resolution

1414

Motion for a resolution

5. Recalls that IP rights allow a legal monopoly, which needs to be carefully regulated to avoid conflict with the right to health protection and to promote quality of innovation and competitiveness;

Amendment

5. Recalls that IP rights allow a legal monopoly, which needs to be carefully regulated *and effectively implemented* to avoid conflict with the right to health protection and to promote quality of innovation and competitiveness;

Amendment 228.

Enrico Gasbarra

Motion for a resolution

Paragraph 5

Motion for a resolution

5. Recalls that IP rights allow a legal monopoly, which needs to be carefully regulated to avoid conflict with the right to health protection and to promote quality of innovation and competitiveness;

Amendment

5. Recalls that IP rights allow a legal monopoly, which needs to be carefully regulated to avoid conflict with the right to health protection and to promote quality of innovation and competitiveness;

therefore calls on the Commission to introduce good practices aimed at encouraging positive conditionality with the aim of promoting forms of sharing and the increased movement of patents;

Or. it

Amendment 229.

Enrico Gasbarra

Motion for a resolution

Paragraph 5a (new)

Motion for a resolution

5a. To this effect, asks the Commission to commit itself to carrying out an analysis of the patent system for medicines, in particular to check whether patents for medicines obstruct innovation and the movement of products in delicate and non-competitive sectors, such as the treatment of rare diseases;

Or. it

Amendment 230

Lieve Wierinck, Gesine Meissner, Frédérique Ries, José Inácio Faria, Marian Harkin, Ulrike Müller, Yana Toom, Jasenko Selimovic

Motion for a resolution

Paragraph 5 a (new)

Motion for a resolution

Amendment

5a. Recognises that a balanced and strong, functioning and effective intellectual property environment, that is line with international commitments of the European Union, is important for supporting and promoting access to innovative, safe, effective and quality medicinal products in the European Union;

Or. en

Amendment 231

Cristian-Silviu Buşoi

Motion for a resolution

Paragraph 5 a (new)

Motion for a resolution

Amendment

5a. Stresses that research and development is essential to address unmet medical needs, and should be thus incentivized accordingly, to ensure best treatments for patients, and to enhance socio-economic value through job creation and knowledge clusters.

Or. en

Amendment 232

Christofer Fjellner

Motion for a resolution

Paragraph 6

Motion for a resolution

Amendment

6. *Emphasises that most medicines are not examples of genuine innovation, but often ‘me-too’ or ‘evergreening’ products, which are permitted notably by complementary patent extensions;* ***deleted***

Or. en

Amendment 233

Frédérique Ries, Gesine Meissner, Lieve Wierinck

Motion for a resolution

Paragraph 6

Motion for a resolution

Amendment

6. *Emphasises that most medicines are not examples of genuine innovation, but often ‘me-too’ or ‘evergreening’ products, which are permitted notably by complementary patent extensions;* ***deleted***

Or. en

Amendment 234

José Inácio Faria, Jasenko Selimovic, Marian Harkin, Yana Toom

Motion for a resolution

Paragraph 6

Motion for a resolution

Amendment

6. *Emphasises that most medicines are not examples of genuine innovation, but often ‘me-too’ or ‘evergreening’ products, which are permitted notably by complementary patent extensions;*

6. *Recalls that incremental innovation for patented molecules such as repurposing, reformulation and the development of new medicines for the same indication (“me-too” substances) may offer incremental value to patients, to patients sub-groups and to health care systems; believes that the added value of such medicines should be carefully assessed and measurable benefits should*

be demonstrated prior to price and reimbursement decisions; warns against the potential misuse of IP protection rules allowing for the "evergreening" of patent rights;

Or. en

Amendment 235

Eva Kaili

Motion for a resolution

Paragraph 6

Motion for a resolution

6. Emphasises that *most* medicines *are not examples of genuine innovation, but often 'me-too' or 'evergreening' products, which are permitted notably by complementary patent extensions;*

Amendment

6. Emphasises that *new* medicines *bringing insufficient added clinical value do not provide genuine innovation;*

Or. en

Amendment 236

Elisabetta Gardini, Cristian-Silviu Buşoi, Alojz Peterle, Giovanni La Via, Aldo Patriciello, Alessandra Mussolini

Motion for a resolution

Paragraph 6

Motion for a resolution

6. Emphasises that *most* medicines *are not examples of genuine innovation, but often 'me-too' or 'evergreening' products, which are permitted notably by complementary patent extensions;*

Amendment

6. Emphasises that *new* medicines *bringing insufficient added clinical value do not provide genuine innovation;*

Or. en

Amendment 237

Françoise Grossetête

Motion for a resolution
Paragraph 6

Motion for a resolution

6. Emphasises that **most medicines are not examples of genuine innovation, but often** ‘me-too’ or ‘evergreening’ products, which are permitted notably by complementary patent extensions;

Amendment

6. Emphasises that **some medicines are examples of breakthroughs in innovation, despite the existence of** ‘me-too’ or ‘evergreening’ products, which are permitted notably by complementary patent extensions;

Or. fr

Amendment 238.
Enrico Gasbarra

Motion for a resolution
Paragraph 6

Motion for a resolution

6. Emphasises that most medicines are not examples of genuine innovation, but often ‘me-too’ or ‘evergreening’ products, which are permitted notably by complementary patent extensions;

Amendment

6. Emphasises that most medicines are not examples of genuine innovation, but often ‘me-too’ or ‘evergreening’ products, which are permitted notably by complementary patent extensions; ***calls on the Commission to propose measures for limiting this phenomenon to the Member States;***

Or. it

Amendment 239
Soledad Cabezón Ruiz

Motion for a resolution
Paragraph 6

Motion for a resolution

6. Emphasises that **most** medicines are not examples of genuine innovation, but often ‘me-too’ or ‘evergreening’ products,

Amendment

6. Emphasises that **many** medicines are not examples of genuine innovation, but often ‘me-too’ or ‘evergreening’

which are permitted notably by
complementary patent extensions;

products, which are permitted notably by
complementary patent extensions;

Or. en

Amendment 240

**Lieve Wierinck, Gesine Meissner, Frédérique Ries, José Inácio Faria, Marian Harkin,
Yana Toom, Jasenko Selimovic**

Motion for a resolution Paragraph 6 a (new)

Motion for a resolution

Amendment

6a. Recognises that medical innovation is also coming from known off-patent molecules through finding new indications, drug reformulations or new innovative combinations and stresses the importance to deliver to patients more customized treatments delivering better efficacy, less side effects, better adherence and better quality of life, to avoid disease exacerbations and costly therapeutic escalations;

Or. en

Amendment 241

Nessa Childers

Motion for a resolution Paragraph 6 a (new)

Motion for a resolution

Amendment

6a. Contests the adequacy of secondary patenting where marginal or insignificant changes in therapeutic effect are observed;

Or. en

Amendment 242
Christofer Fjellner

Motion for a resolution
Paragraph 7

Motion for a resolution

Amendment

7. *Stresses that the high level of public funds used for R&D is not reflected in the pricing;* *deleted*

Or. en

Amendment 243
Lieve Wierinck, Gesine Meissner, Frédérique Ries, Jasenko Selimovic

Motion for a resolution
Paragraph 7

Motion for a resolution

Amendment

7. *Stresses that the high level of public funds used for R&D is not reflected in the pricing;* *deleted*

Or. en

Amendment 244
Nessa Childers

Motion for a resolution
Paragraph 7

Motion for a resolution

Amendment

7. Stresses that the high level of public funds used for R&D is not reflected in the pricing;

7. Stresses that the high level of public funds used for R&D is not reflected in the pricing; ***underlines the need to require full transparency and public disclosure of research and development costs when EU funds are invested in the development of new medicines***

Or. en

Amendment 245
Cristian-Silviu Buşoi

Motion for a resolution
Paragraph 7

Motion for a resolution

Amendment

7. ***Stresses that the high level of public funds used for R&D is not reflected in the pricing;***

deleted

Or. en

Amendment 246
Margrete Auken

Motion for a resolution
Paragraph 7

Motion for a resolution

Amendment

7. Stresses that the high level of public funds used for R&D is not reflected in the pricing;

7. Stresses that the high level of public funds used for R&D is not reflected in the pricing ***due to the lack of traceability of the public funds in the patenting and licensing conditions, impeding a fair public return on public investment;***

Or. en

Amendment 247
Mireille D'Ornano, Jean-François Jalkh, Sylvie Goddyn

Motion for a resolution
Paragraph 7

Motion for a resolution

Amendment

7. Stresses that the high level of public funds used for R&D is not reflected in the ***pricing;***

7. Stresses that the high level of public funds used for R&D is not ***always*** reflected in the ***final price of medicines;***

Amendment 248

Notis Marias

Motion for a resolution

Paragraph 7

Motion for a resolution

7. Stresses that the **high** level of public funds used for R&D is not reflected in the pricing;

Amendment

7. Stresses that the level of public funds used for R&D is not reflected in the pricing;

Or. el

Amendment 249

Francesc Gambús

Motion for a resolution

Paragraph 7 a (new)

Motion for a resolution

7a. Calls on the Commission to set out a clear definition on added value drugs, as taking that step could result in an increase in R&D investment in Europe;

Amendment

Or. es

Amendment 250

Jytte Guteland

Motion for a resolution

Paragraph 7 a (new)

Motion for a resolution

7a. Recalls that inequalities between women and men persist in national health systems; stresses the important role of the pharmaceutical industry and national

Amendment

health authorities in ensuring that medicinal research and development does not discriminate diseases where a majority of patients are women.

Or. en

Amendment 251
Christel Schaldemose

Motion for a resolution
Paragraph 7 a (new)

Motion for a resolution

Amendment

7a. Stresses that the provisions in 141/2000/EC should only be applicable for rare diseases, when a substantial development has taken place and other best alternatives are not already available; the legislation should not be misused for driving up prices;

Or. en

Amendment 252
Soledad Cabezón Ruiz

Motion for a resolution
Paragraph 7 a (new)

Motion for a resolution

Amendment

7a. Notes the concern surrounding the correct application of the medical necessity criterion not covered by the regulation on rare diseases and its possible effect on the growing number of orphan drug authorisations;

Or. es

Amendment 253.
Piernicola Pedicini, Eleonora Evi, Marco Affronte

Motion for a resolution
Paragraph 7a (new)

Motion for a resolution

Amendment

7a. Highlights the need for greater transparency in communicating research and development costs to the public, above all when public funds, whether these are from the EU or elsewhere, are invested in the development of new medicines.

Or. it

Amendment 254
Margrete Auken

Motion for a resolution
Paragraph 7 a (new)

Motion for a resolution

Amendment

7a. Recalls that the WTO TRIPS Agreement provides for flexibilities to patent rights, such as compulsory licensing, which have proven to be a major tool to introduce competition and bring prices to reasonable levels;

Or. en

Amendment 255
Margrete Auken

Motion for a resolution
Paragraph 7 b (new)

Motion for a resolution

Amendment

7b. Calls on the Commission to set up an EU easily searchable and regularly updated database on the flexibilities to patent rights requested/used in Member States and on filed patent oppositions and

the outcome thereof;

Or. en

Amendment 256
Francesc Gambús

Motion for a resolution
Paragraph 7 b (new)

Motion for a resolution

Amendment

7b. *Emphasises that medicinal product innovation, in both molecules and simplification to improve adherence, may boost the public finances of European public health systems;*

Or. es

Amendment 257
Frédérique Ries, Françoise Grossetête

Motion for a resolution
Paragraph 8

Motion for a resolution

Amendment

8. *Deplores the large number of litigation cases aiming to delay generic entry;*

8. *Stresses the importance of having generic medicines and biosimilar medicines in good time in order to help patients to access pharmaceutical therapies,*

Or. fr

Amendment 258
Soledad Cabezón Ruiz

Motion for a resolution
Paragraph 8

Motion for a resolution

8. Deplores the large number of litigation cases *aiming to* delay generic entry;

Amendment

8. Deplores the large number of litigation cases *that* delay generic entry; *according to the Commission's report on the pharmaceutical sector published in 2008, the number of litigation cases quadrupled between 2000 and 2007, almost 60% of the cases concerned second generation patents and on average they took two years to be resolved;*

Or. es

Amendment 259
Christofer Fjellner

Motion for a resolution
Paragraph 8

Motion for a resolution

8. *Deplores* the large number of litigation cases *aiming to delay generic entry;*

Amendment

8. *Notes* the large number of litigation cases *on generics;*

Or. en

Amendment 260
Notis Marias

Motion for a resolution
Paragraph 8

Motion for a resolution

8. *Deplores* the large number of litigation cases aiming to delay generic entry;

Amendment

8. *Condemns* the large number of litigation cases aiming to delay generic entry;

Or. el

Amendment 261
Karl-Heinz Florenz, Peter Liese, Andrey Kovatchev

Motion for a resolution
Paragraph 8

Motion for a resolution

8. Deplores the **large number of** litigation cases aiming to delay generic entry;

Amendment

8. Deplores the litigation cases aiming to delay generic entry;

Or. de

Amendment 262
Nikolay Barekov, Bolesław G. Piecha

Motion for a resolution
Paragraph 8 a (new)

Motion for a resolution

8a. Stresses that the development of generic and biosimilar medicines is often the only way to allow poorer parts of the population access pharmaceutical products;

Or. en

Amendment 263
José Inácio Faria, Jasenko Selimovic, Marian Harkin, Yana Toom

Motion for a resolution
Paragraph 9

Motion for a resolution

9. Stresses that better regulation will promote competitiveness; also recognises the importance and effectiveness of antitrust tools against anti-competitive behaviours such as the abuse or misuse of patent systems and of the system for authorisation of medicines, in violation of Articles 101 and/or 102 of the TFEU;

Amendment

9. Stresses that better regulation will promote competitiveness; also recognises the importance and effectiveness of antitrust tools against anti-competitive behaviours such as the abuse or misuse of patent systems and of the system for authorisation of medicines, in violation of Articles 101 and/or 102 of the TFEU; **calls on the Commission to carry out an in-**

depth analysis of the existing Intellectual Property legislation in the pharmaceutical sector with a focus on divergent interpretation and litigation cases and, where necessary, to bring forward a legislative review to ascertain legal clarity and the correct implementation and use of legal provisions in order to safeguard legitimate intellectual property and patent rights, as well as public interest;

Or. en

Amendment 264

José Inácio Faria, Jasenko Selimovic, Anneli Jäätteenmäki, Marian Harkin, Yana Toom

Motion for a resolution

Paragraph 9 a (new)

Motion for a resolution

Amendment

9a. Calls on the Commission to revise the Transparency Directive with a focus on guaranteeing timely entry into the market for generic and biosimilar medicines, ending patent linkage according to Commission's guidelines, accelerating pricing and reimbursement decisions for generics and precluding the multiple reassessment of the elements supporting marketing authorisation; Believes that this will maximise savings for national health budgets, improve affordability, accelerate patient access and prevent administrative burdens for generic and biosimilar companies;

Or. en

Amendment 265

Soledad Cabezón Ruiz

Motion for a resolution

Paragraph 9 a (new)

Motion for a resolution

Amendment

9a. *Points out that biosimilar medicines may provide savings for health systems and help to improve access to medicines for patients, for which their added value and efficiency in the system should be taken into account, their potential impact should be analysed and, where appropriate, measures to support their introduction into the market should be studied;*

Or. es

Amendment 266

Mireille D'Ornano, Jean-François Jalkh, Sylvie Goddyn

Motion for a resolution

Paragraph 9 a (new)

Motion for a resolution

Amendment

9a. *Stresses, nevertheless, that with regard to the free movement of goods and, in the case in point, of pharmaceutical products, among the Member States, pharmaceutical products imported from another Member State now represent some 30% of sales of pharmaceutical products in the European Union;*

Or. fr

Amendment 267

Christel Schaldemose

Motion for a resolution

Paragraph 9 a (new)

Motion for a resolution

Amendment

9a. *Deplores that a number of drugs shortages occur because of unfair*

business economic strategies such as "pay for delay" in the pharmaceutical sector;

Or. en

Amendment 268

Mireille D'Ornano, Jean-François Jalkh, Sylvie Goddyn

Motion for a resolution

Paragraph 9 b (new)

Motion for a resolution

Amendment

9b. Stresses that this significant share of pharmaceutical products moved between Member States on the European pharmaceutical product markets (hereafter 'parallel trade') does not lower or level the costs of pharmaceutical products in the European Union and that, on the other hand, the consequence of this parallel trade has been a rise in the number of counterfeit pharmaceutical products recorded in the European Union, and it therefore poses a significant health risk to consumers;

Or. fr

Amendment 269

José Inácio Faria, Jasenko Selimovic, Marian Harkin, Yana Toom

Motion for a resolution

Paragraph 9 b (new)

Motion for a resolution

Amendment

9b. Calls on the Commission to monitor regularly patent settlement agreements that may restrict generic market entry into the market in exchange for benefits transferred from the originator to the generic company;

Or. en

Amendment 270

José Inácio Faria, Jasenko Selimovic, Frédérique Ries, Marian Harkin, Lieve Wierinck

Motion for a resolution

Paragraph 9 c (new)

Motion for a resolution

Amendment

9c. Calls on the Commission to introduce a Supplementary Protection Certificate (SPC) manufacturing waiver to Regulation 469/2009 allowing the production of generic and biosimilar medicines in Europe, with the purpose of exporting them to countries without SPCs or where these have expired earlier, without undermining the exclusivity granted under the SPC regime in protected markets; believes that such provisions could have a positive impact on access to high quality medicines in developing and least developed countries and on increasing manufacturing and R&D in Europe, creating new jobs and stimulating economic growth;

Or. en

Amendment 271

Mireille D'Ornano, Jean-François Jalkh, Sylvie Goddyn

Motion for a resolution

Paragraph 9 c (new)

Motion for a resolution

Amendment

9c. Stresses that for the reasons outlined in paragraphs 9a and 9b of this text, it is important to regulate the parallel trade of pharmaceutical products;

Or. fr

Amendment 272

José Inácio Faria, Anneli Jäätteenmäki, Marian Harkin, Yana Toom

Motion for a resolution

Paragraph 9 d (new)

Motion for a resolution

Amendment

9d. *Highlights that some Member States have achieved particularly low prices by the use of large-scale tendering in generic medicines; Notes with concern that excessive focus on short-term cost-savings may lead to medium- and long-term unintended consequences such as market concentration in the generic industry, and increased risk of shortages due to lack of redundancy in the system and lack of financial motivation to produce low-profit margin medicines, as well as low-volume drugs;*

Or. en

Amendment 273

José Inácio Faria, Jasenko Selimovic, Yana Toom

Motion for a resolution

Paragraph 9 e (new)

Motion for a resolution

Amendment

9e. *Highlights that value-based pricing of medicines can be misused as a profit-maximization economic strategy, which in that case leads to the setting of prices that are disproportionate to its cost structure, regardless of an optimal distribution of social welfare*

Or. en

Amendment 274

José Inácio Faria, Marian Harkin, Yana Toom

Motion for a resolution
Paragraph 9 f (new)

Motion for a resolution

Amendment

9f. *Considers that pricing and reimbursement decisions need to consider the added value of innovative medicines while avoiding unilateral appropriation of such value; stresses that new and fairer pricing models should aim at shared and balanced stakeholder benefit, by ensuring payers' sustainability, patients' health gains and proportionate industry profits;*

Or. en

Amendment 275
Eva Kaili

Motion for a resolution
Paragraph 10

Motion for a resolution

Amendment

10. Stresses that most national assessment agencies are already using clinical, economic and social benefit criteria to assess new drugs in terms of pricing and reimbursement;

10. Stresses that most national assessment agencies are already using clinical, economic and social benefit criteria to assess new drugs in terms of pricing and reimbursement ***and stresses the importance of increasing collaboration among Member States in the field of pricing and reimbursement of medicinal products to ensure sustainability of the healthcare systems and preserve the rights of the European citizens to access quality healthcare;***

Or. en

Amendment 276
Elisabetta Gardini, Cristian-Silviu Buşoi, Alojz Peterle, Giovanni La Via, Aldo Patriciello, Alessandra Mussolini

Motion for a resolution
Paragraph 10

Motion for a resolution

10. Stresses that most national assessment agencies are already using clinical, economic and social benefit criteria to assess new drugs in terms of pricing and reimbursement;

Amendment

10. Stresses that most national assessment agencies are already using clinical, economic and social benefit criteria to assess new drugs in terms of pricing and reimbursement ***and stresses the importance of increasing collaboration among Member States in the field of pricing and reimbursement of medicinal products to ensure sustainability of healthcare systems and preserve the rights of European citizens to access quality healthcare;***

Or. en

Amendment 277
Soledad Cabezón Ruiz

Motion for a resolution
Paragraph 10

Motion for a resolution

10. Stresses that most national assessment agencies are already using clinical, economic and social benefit criteria to assess new drugs in terms of pricing and reimbursement;

Amendment

10. Stresses that most national assessment agencies are already using ***a large and varied*** clinical, economic and social benefit criteria to assess new drugs in terms of pricing and reimbursement; ***to assess the added value of medicines to improve access to medicines and to preserve health systems sustainability.***

Or. en

Amendment 278
Karl-Heinz Florenz, Peter Liese, Andrey Kovatchev

Motion for a resolution
Paragraph 10

Motion for a resolution

10. Stresses that most national assessment agencies are already using clinical, economic and social benefit criteria to *assess new drugs in terms of* pricing and reimbursement;

Amendment

10. Stresses that most national assessment agencies are already using clinical, economic and social benefit criteria to *evaluate new drugs in order to support their decisions on* pricing and reimbursement;

Or. de

Amendment 279

Mireille D'Ornano, Jean-François Jalkh, Sylvie Goddyn

Motion for a resolution

Paragraph 10 a (new)

Motion for a resolution

Amendment

10a. Stresses, however, that every Member State has its own evaluation criteria and methods for negotiating tariffs with the pharmaceutical industry, and that the pharmaceutical product tariff differentials between Member State amount to around 25%, and sometimes range from 1 to 16 for generic medicines;

Or. fr

Amendment 280

José Inácio Faria, Anneli Jäätteenmäki, Marian Harkin, Yana Toom

Motion for a resolution

Paragraph 10 a (new)

Motion for a resolution

Amendment

10a. Notes with concern that data supporting the assessment of the added value of innovative medicines is often scarce and not sufficiently convincing to support solid decision making on pricing;

Or. en

Amendment 281
Françoise Grossetête, Angélique Delahaye

Motion for a resolution
Paragraph 10 a (new)

Motion for a resolution

Amendment

10a. *points out that competence for pricing and reimbursement decisions falls exclusively to Member States;*

Or. fr

Amendment 282
Elisabetta Gardini, Cristian-Silviu Buşoi, Alojz Peterle, Giovanni La Via, Alberto Cirio, Aldo Patriciello, Alessandra Mussolini

Motion for a resolution
Paragraph 10 a (new)

Motion for a resolution

Amendment

10a. *Recognises that pricing and reimbursement of medicinal products are competences of Member States;*

Or. en

Amendment 283
José Inácio Faria, Jasenko Selimovic, Anneli Jäätteenmäki, Marian Harkin, Yana Toom

Motion for a resolution
Paragraph 10 b (new)

Motion for a resolution

Amendment

10b. *Considers that independent and good quality evidence is crucial to determine the cost-effectiveness of new medicines;*

Or. en

Amendment 284
José Inácio Faria

Motion for a resolution
Paragraph 10 c (new)

Motion for a resolution

Amendment

10c. Notes that more dynamic pricing models such as outcomes-based pricing or managed entry agreements for innovative medicines, that imply conditional reimbursement and flexible pricing, require a solid evidence basis; highlights the difficulty of collecting both patient-relevant data and healthcare resource utilization data in real healthcare settings; stresses the need for stakeholder involvement and collaborative efforts between Member States and the Commission to step up advancement in the infrastructure necessary to capture outcomes data, through registries and interoperable electronic patient records, e-health and big data analysis, in respect of data privacy;

Or. en

Amendment 285
José Inácio Faria

Motion for a resolution
Paragraph 10 d (new)

Motion for a resolution

Amendment

10d. Underlines in this context, the need for independent processes of data collection and analysis and for transparency;

Or. en

Amendment 286
José Inácio Faria

Motion for a resolution
Paragraph 10 e (new)

Motion for a resolution

Amendment

10e. Acknowledges the advantages of using adaptive licensing of new medicines to lower development costs and promote faster patient access; Underlines that a higher degree of uncertainty regarding the safety and effectiveness of a new medicine at the point of entry into the market is inherent to adaptive licensing in comparison with traditional licensing; Recognises the persistence of deficiencies in the current implementation of post-marketing surveillance system; Believes that adaptive licensing should be restricted to specific cases of high unmet medical need and calls the European Commission and the European Medicines Agency to put in place guidelines in order to ensure patient safety; Acknowledges the potential of adaptive pathways for adaptive pricing decision of new medicines, once patient safety is adequately ensured;

Or. en

Amendment 287
Margrete Auken

Motion for a resolution
Paragraph 11

Motion for a resolution

Amendment

11. Stresses the importance of assessing the real therapeutic evidence-based added value of new medicines compared to the best available alternative;

11. Stresses the importance of assessing the real therapeutic evidence-based added value of new medicines compared to the best available alternative; ***therefore calls on the Commission to extend the definition of added therapeutic***

value used for paediatric medicines to all medicines, as follows:

"Added therapeutic value could be based on one or more of the following:

- reasonable expectation of safety and efficacy for an authorised or new medicinal product to treat a condition, where no authorised medicinal product is on the market;*
- expected improvement in efficacy, as compared with the current standard of care for the treatment, diagnosis or prevention of the condition concerned;*
- expected improvement in safety, as regards adverse reactions or potential medication errors as compared with the current standard of care;*
- improved dosing scheme or method of administration (e.g. number of doses per day, oral compared with intravenous administration, reduced treatment duration) leading to improved safety, efficacy or compliance;*
- availability of a new clinically relevant formulation or pharmaceutical form;*
- different mechanism of action, with a scientific explanation of the potential advantage in terms of improved efficacy or safety;*
- unsatisfactory nature of existing treatments and need for alternative methods expected to involve an - improved benefit-risk balance; and*
- expected improvement in the quality of life;"*

Or. en

Amendment 288

José Inácio Faria, Jasenko Selimovic, Frédérique Ries, Marian Harkin, Lieve Wierinck, Yana Toom

Motion for a resolution
Paragraph 11 a (new)

Motion for a resolution

Amendment

11a. *Highlights the technical nature of Relative Efficacy and Effectiveness Assessment (REA) and of Therapeutic Added Value (ATV) procedures; Notes that differences in methodological approaches and quality of evidence required at Member State level contribute to unnecessary fragmentation and increased burden for industry;*

Or. en

Amendment 289
Soledad Cabezón Ruiz

Motion for a resolution
Paragraph 11 a (new)

Motion for a resolution

Amendment

11a. *Calls on the Commission to clarify the patent period, specially its expiration to analyse the impact of supplementary extensions, data exclusivity or market exclusivity on competitiveness and quality of innovation*

Or. en

Amendment 290
Sirpa Pietikäinen

Motion for a resolution
Paragraph 11 a (new)

Motion for a resolution

Amendment

11a. *Calls for the Commission and the Member States to agree on a common definition for added therapeutic value of*

*medicines and aim at harmonised
practices in its assessment;*

Or. en

Amendment 291

José Inácio Faria, Jasenko Selimovic, Frédérique Ries, Marian Harkin, Lieve Wierinck

Motion for a resolution

Paragraph 11 b (new)

Motion for a resolution

Amendment

11b. Calls on Member States and the Commission to pursue efforts to develop shared capacities, data and methodologies; Calls on the Commission to put forward a proposal for a common framework for REA and ATV to be carried out at European level, with the participation of expert representatives from Member States; Believes this should be done within the existing institutional context and in respect of national competences concerning social and economic considerations within pricing and reimbursement decisions;

Or. en

Amendment 292

Soledad Cabezón Ruiz

Motion for a resolution

Paragraph 11 b (new)

Motion for a resolution

Amendment

11b. Calls the Commission to promote pharmaceutical and ethical behaviour transparency on the clinical trials and on the real cost of R&D in face to the authorisation and assessment innovation

Or. en

Amendment 293
Soledad Cabezón Ruiz

Motion for a resolution
Paragraph 11 c (new)

Motion for a resolution

Amendment

11c. Call on the Council to push a rational use of medicines in all Europe, to involve professional in prescribing by active principles and promoting the generic medicines administration

Or. en

Amendment 294
Soledad Cabezón Ruiz

Motion for a resolution
Paragraph 11 d (new)

Motion for a resolution

Amendment

11d. Call on the Commission to continue monitoring the internal competition in accordance to articles 101 and 102 TFEU and to present a biannual report

Or. en

Amendment 295
Soledad Cabezón Ruiz

Motion for a resolution
Paragraph 11 e (new)

Motion for a resolution

Amendment

11e. Notes that some countries classify the drugs based on the different levels of innovation in the process of their HTA

and are reimbursing in base of that level

Or. en

Amendment 296

José Inácio Faria

Motion for a resolution

Paragraph 12 a (new)

Motion for a resolution

Amendment

12a. Highlights that current pricing systems such as international reference pricing limits access to innovative medicines in EU countries with comparatively lower GDP per capita; notes with concern that due to the lower negotiating power of small and lower income countries, medicines are comparatively less affordable in such Member States, namely in the oncology area; Regrets, in the context of international reference pricing, the lack of transparency in list prices of medicines as compared to actual prices and the information asymmetry that it brings to negotiations between industry and national health systems;

Or. en

Amendment 297

Soledad Cabezón Ruiz

Motion for a resolution

Paragraph 12 a (new)

Motion for a resolution

Amendment

12a. Points out that, with a view to developing safe and effective patient-oriented health policies and making health technology as effective as possible, evaluating that technology should be a

multidisciplinary process which summarises the medical, social, economic and ethical information on the use of the technology by employing high standards and in a systematic, independent, objective, reproducible and transparent manner.

Or. es

Amendment 298
Sirpa Pietikäinen

Motion for a resolution
Paragraph 12 a (new)

Motion for a resolution

Amendment

12a. Welcomes the Commission's work on creating more indicators to measure the outcomes of health care operations; Calls for the inclusion of added therapeutic value of a drug as an indicator when deciding on the reimbursement of medicines, as it happens that often drugs and personalised medicines with a higher price tag bring savings for the health care system in the longer term due to their more rapid efficacy;

Or. en

Amendment 299
Nicola Caputo, Marc Tarabella

Motion for a resolution
Paragraph 12 a (new)

Motion for a resolution

Amendment

12a. Recognises that innovative pricing solutions which align payment to outcomes and which are flexible enough to account for patients' and public payers' purchasing power, burden of illness and/or preferences, can contribute to the

sustainability of healthcare systems and should be more widely used to enhance patients access to innovative medicines while addressing affordability constraints;

Or. en

Amendment 300

Françoise Grossetête, Frédérique Ries, Elisabetta Gardini, Cristian-Silviu Buşoi

Motion for a resolution

Paragraph 12 a (new)

Motion for a resolution

Amendment

12a. Stresses that in the framework of pricing and reimbursement decisions, Member States should not re-assess the elements on which the European marketing authorisation is based, including the quality, safety, efficacy or bioequivalence of the medicinal product leading to delayed access for patients;

Or. en

Amendment 301

Cristian-Silviu Buşoi

Motion for a resolution

Paragraph 12 a (new)

Motion for a resolution

Amendment

12a. Draws attention to the fact that several obstacles still exist to capture the full potential of incremental innovation notably related to known non-patented molecules, due to the lack of pricing and market access pathways to enable the recognition of the benefits of these medicines;

Or. en

Amendment 302
José Inácio Faria

Motion for a resolution
Paragraph 12 b (new)

Motion for a resolution

Amendment

12b. Highlights that international reference pricing is a driver of delayed market entry for innovative medicines in lower income Member States and of medicines shortages through parallel trade; Invites Member States and the Commission to promote closer cooperation towards a voluntary agreement on a differential pricing system that should reflect factors such as differences in income per capita, and which could enhance overall welfare;

Or. en