European Parliament
2014-2019

Committee on Legal Affairs

2016/2057(INI)

4.10.2016

AMENDMENTS
1 - 93

Draft opinion
Pascal Durand
(PE589.174v01-00)

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

AM_Com_NonLegOpinion

Amendment 1
Daniel Buda

Draft opinion
Recital A

Draft opinion	*Amendment*
A. whereas protection of health is a fundamental right enshrined in the European Convention on Human Rights;	A. whereas protection of health is a fundamental right ***recognised in Article 35 of the Charter of Fundamental Rights of the European Union and Article 168 of the Treaty on the Functioning of the European Union, and*** enshrined in the European Convention on Human Rights;

Or. ro

Amendment 2
Enrico Gasbarra

Draft opinion
Recital A

Draft opinion	*Amendment*
A. whereas protection of health is a fundamental right enshrined in the European Convention on Human Rights;	A. whereas protection of health is a fundamental right enshrined in the European Convention on Human Rights; ***whereas also the promotion of health is referred to in Articles 6 and 168 of the Treaty on the Functioning of the European Union;***

Or. it

Amendment 3
Notis Marias

Draft opinion
Recital A

Draft opinion	*Amendment*
A. whereas protection of health is a fundamental right enshrined in the European Convention on Human Rights;	A. whereas protection of health is a fundamental right ***of all citizens*** enshrined in the European Convention on Human Rights;

Or. el

Amendment 4
Marie-Christine Boutonnet, Joëlle Mélin

Draft opinion
Recital A

Draft opinion	*Amendment*
A. whereas protection of health is a fundamental right ***enshrined in*** the ***European Convention on Human Rights***;	A. whereas protection of health is a fundamental right ***guaranteed by*** the ***Member States***;

Or. fr

Amendment 5
Daniel Buda

Draft opinion
Recital A a (new)

Draft opinion	*Amendment*
	Aa. whereas, in accordance with Article 168 of the Treaty on the Functioning of the European Union concerning the protection of public health, a high level of human health protection should be guaranteed in the definition and implementation of all EU policies and activities; whereas, in this respect, the Union and Member States should foster cooperation with third countries and the competent international organisations in the sphere of public health;

Or. ro

Amendment 6
Daniel Buda

Draft opinion
Recital A b (new)

Draft opinion	*Amendment*
	Ab. whereas, under Article 35 of the Charter of Fundamental Rights of the European Union everyone is guaranteed the right to access[1a] preventive and curative healthcare and to benefit from medical treatment under the conditions established by national laws and practices;
	[1a] access must correlate to the patient's financial means, since otherwise the product may be available on the market, but its price will render it inaccessible.

Or. ro

Amendment 7
Daniel Buda

Draft opinion
Recital A c (new)

Draft opinion	*Amendment*
	Ac. whereas patients who are EU citizens should have access to innovative medicines that are safe in quality terms and sold on the market at an accessible price;

Or. ro

Amendment 8
Daniel Buda

Draft opinion
Recital A d (new)

Draft opinion	*Amendment*
	Ad. whereas there is a need for voluntary cooperation between Member States with a view to increasing the financial accessibility of medicinal products and ensuring EU citizens have suitable access to them;

Or. ro

Amendment 9
Enrico Gasbarra

Draft opinion
Recital B

Draft opinion	*Amendment*
B. whereas ***EU*** public budgets, ***including those*** covering health expenditure, are under significant ***constraints***;	B. whereas***, also as a result of the economic crisis and austerity policies, European*** public budgets, ***in particular for the sectors*** covering health expenditure, are under significant ***pressure because of sovereign debts and the requirements to contain spending***;

Or. it

Amendment 10
Cecilia Wikström

Draft opinion
Recital B

Draft opinion	*Amendment*
B. whereas ***EU*** public budgets, including those covering health	B. whereas ***many of the EU Member States'*** public budgets, including those

expenditure, are under significant constraints;

covering health expenditure, are under significant constraints; ***whereas Member States have exclusive competence to fix the prices of medicinal products;***

Or. en

Amendment 11
Daniel Buda

Draft opinion
Recital B

Draft opinion	*Amendment*
B. whereas EU public budgets, including those covering health expenditure, are under significant constraints;	B. whereas EU public budgets, including those covering health expenditure ***at national EU Member State level***, are under significant constraints;

Or. ro

Amendment 12
Notis Marias

Draft opinion
Recital B

Draft opinion	*Amendment*
B. whereas ***EU*** public budgets, including those covering health expenditure, are under significant constraints;	B. whereas ***the*** public budgets ***of EU Member States such as Greece***, including those covering health expenditure, are under significant constraints;

Or. el

Amendment 13
Marie-Christine Boutonnet, Joëlle Mélin

Draft opinion
Recital B

Draft opinion	*Amendment*
B. whereas ***EU*** public budgets, including those covering health expenditure, are under significant constraints;	B. whereas ***Member States'*** public budgets, including those covering health expenditure, are under significant constraints;

Or. fr

Amendment 14
Angel Dzhambazki, Kosma Złotowski

Draft opinion
Recital C

Draft opinion	*Amendment*
C. whereas the WTO Doha Declaration on the TRIPS Agreement and Public Health acknowledges the role of intellectual property protection in the development of new medicines, while expressing concerns about its effects on prices;	C. whereas the WTO Doha Declaration on the TRIPS Agreement and Public Health acknowledges the role of intellectual property protection in the development of new medicines, while expressing concerns about its effects on prices***, while especially keeping in mind drug development cycles***;

Or. en

Amendment 15
Cecilia Wikström

Draft opinion
Recital C

Draft opinion	*Amendment*
C. whereas the WTO Doha Declaration on the TRIPS Agreement and Public Health ***acknowledges*** the role of intellectual property protection in the development of new medicines***, while expressing concerns about its effects on prices***;	C. whereas the WTO Doha Declaration on the TRIPS Agreement and Public Health ***underlines*** the role of intellectual property protection in the development of new medicines;

Or. en

Amendment 16
Rosa Estaràs Ferragut, Emil Radev, Tadeusz Zwiefka

Draft opinion
Recital C

Draft opinion	*Amendment*
C. whereas the WTO Doha Declaration on the TRIPS Agreement and Public Health ***acknowledges the role of*** intellectual property protection ***in*** the development of new medicines**,** while ***expressing*** concerns about its effects on prices;	C. whereas the WTO Doha Declaration on the TRIPS Agreement and Public Health ***recognises that*** intellectual property protection ***is important for*** the development of new medicines while ***recognising*** concerns about its effects on prices;

Or. en

Amendment 17
Daniel Buda

Draft opinion
Recital D

Draft opinion	*Amendment*
D. whereas competition can lower costs, reduce expenditure on medicines and improve access to affordable medicines;	D. whereas competition can lower costs, reduce expenditure on medicines and improve access to affordable medicines**,** ***with higher quality standards being observed in the research and development process***;

Or. ro

Amendment 18
Angel Dzhambazki, Kosma Złotowski

Draft opinion
Recital D

Draft opinion	*Amendment*
D. whereas competition ***can lower costs, reduce expenditure on medicines and improve*** access to affordable medicines;	D. whereas competition ***is an important factor in the overall balance of the pharmaceutical market and may positively affect an improved*** access to affordable medicines ***and foster more research and innovation***;

Or. en

Amendment 19
Marie-Christine Boutonnet, Joëlle Mélin

Draft opinion
Recital D

Draft opinion	*Amendment*
D. whereas competition can lower costs, reduce expenditure on medicines and improve access to affordable medicines;	D. whereas competition ***based on smart protectionism*** can lower costs, reduce expenditure on medicines and improve access to affordable medicines;

Or. fr

Amendment 20
Cecilia Wikström

Draft opinion
Recital D

Draft opinion	*Amendment*
D. whereas ***competition can lower costs, reduce expenditure on medicines and*** improve access to ***affordable*** medicines;	D. whereas ***the legal protection of inventions contribute to the progress of science and technology and therefore*** improve access to medicines;

Or. en

Amendment 21
Notis Marias

Draft opinion
Recital D

Draft opinion	*Amendment*
D. whereas ***competition can lower costs, reduce expenditure on medicines and improve access to affordable medicines***;	D. whereas ***economic freedom in the pharmaceuticals sector is undermining the fundamental right to health of all citizens;***

Or. el

Amendment 22
Marie-Christine Boutonnet, Joëlle Mélin

Draft opinion
Recital D a (new)

Draft opinion	*Amendment*
	Da. whereas the EU will need to oversee improvements in a range of fields that have an impact on how medicines are produced and distributed;

Or. fr

Amendment 23
Daniel Buda

Draft opinion
Recital D b (new)

Draft opinion	*Amendment*
	Db. whereas special consideration should be awarded to access to medicines for patients, particularly in the less developed Member States;

Or. ro

Amendment 24
Daniel Buda

Draft opinion
Recital D c (new)

Draft opinion	*Amendment*
	Dc. whereas it is important for medicines to be made available in a timely manner with a view to facilitating patients' access to treatment and increasing the efficiency of national health systems;

Or. ro

Amendment 25
Rosa Estaràs Ferragut, Emil Radev, Tadeusz Zwiefka

Draft opinion
Recital E

Draft opinion	*Amendment*
E. whereas the rationale ***for*** patent rights is to make investment in innovation attractive and to ensure that the knowledge contained in patent applications is accessible;	E. whereas the rationale ***of*** patent rights is to make investment in innovation ***possible and*** attractive and to ensure that the knowledge contained in patent applications is accessible;

Or. en

Amendment 26
Daniel Buda

Draft opinion
Recital E a (new)

Draft opinion	*Amendment*
	Ea. whereas there is a need to devise a system of high-quality patents, granted

through accessible and efficient procedures, which afford all stakeholders the requisite level of legal certainty;

Or. ro

Amendment 27
Enrico Gasbarra

Draft opinion
Recital E b (new)

Draft opinion	*Amendment*
	Eb. having regard to the strong political commitment of the European Parliament, especially since the beginning of the current parliamentary term, in favour of a more open policy on access to medicines;

Or. it

Amendment 28
Luke Ming Flanagan

Draft opinion
Recital E c (new)

Draft opinion	*Amendment*
	Ec. whereas cannabis-based medicines are proven safe and effective in the treatment of many serious illnesses, and are legal in many countries (including within the EU);

Or. en

Amendment 29
Daniel Buda

Draft opinion
Recital E d (new)

Draft opinion	*Amendment*
	Ed. whereas intellectual property protection is essential in the field of access to medicines and whereas there is a need to identify mechanisms that can help combat the phenomenon of counterfeit medicines;

Or. ro

Amendment 30
Enrico Gasbarra

Draft opinion
Paragraph 1

Draft opinion	*Amendment*
1. Highlights the fact that the WTO TRIPS Agreement provides flexibilities to patent rights, such as compulsory licensing, which have proved to be a major tool in bringing prices to reasonable levels;	1. Highlights the fact that the WTO TRIPS Agreement provides flexibilities to patent rights, such as compulsory licensing, which have proved to be a major tool in bringing prices to reasonable levels; ***hopes that the mechanism for granting and issuing compulsory licences is freed from discretionary judgement and bureaucratic constraints in order to encourage those less developed countries which possess suitable capacities to start production of medicines locally, thereby helping to avoid difficulties in accessing medicines to treat the most vulnerable sectors of the population;***

Or. it

Amendment 31
Cecilia Wikström

Draft opinion
Paragraph 1

Draft opinion	*Amendment*
1. ***Highlights the fact*** that the WTO TRIPS Agreement provides flexibilities to patent rights, such as compulsory licensing, which have ***proved to be a major tool in bringing prices to reasonable levels***;	1. ***Notes*** that the WTO TRIPS Agreement provides flexibilities to patent rights, such as compulsory licensing, which have ***brought prices down; However, underlines that the exclusivity periods granted through patent law and other mechanisms provide incentives to originator companies to continue innovating***;

Or. en

Amendment 32
Rosa Estaràs Ferragut, Emil Radev, Tadeusz Zwiefka

Draft opinion
Paragraph 1

Draft opinion	*Amendment*
1. Highlights ***the fact*** that the WTO TRIPS Agreement provides flexibilities to patent rights, such as compulsory licensing, which ***have proved to be a major*** tool in ***bringing prices to reasonable levels***;	1. Highlights that the WTO TRIPS Agreement provides flexibilities to patent rights, such as compulsory licensing, which ***can be used as an effective*** tool in ***exceptional circumstances established by the law of each WTO member to address public health problems***;

Or. en

Amendment 33
Stefano Maullu

Draft opinion
Paragraph 1

Draft opinion	*Amendment*
1. Highlights the fact that the WTO TRIPS Agreement provides flexibilities to patent rights, such as compulsory licensing, which ***have proved to be a major tool in***	1. Highlights the fact that the WTO TRIPS Agreement provides flexibilities to patent rights, such as compulsory licensing, which ***should be used only in exceptional***

bringing prices to reasonable levels;	***circumstances , when all other alternatives have been exhausted***;

Or. en

Amendment 34
Notis Marias

Draft opinion
Paragraph 1

Draft opinion	*Amendment*
1. Highlights the fact that the WTO TRIPS Agreement provides flexibilities to patent rights, such as compulsory licensing, which have proved to be a major tool in bringing prices to reasonable levels;	1. *(Does not apply to English version)*

Or. el

Amendment 35
Marie-Christine Boutonnet, Joëlle Mélin

Draft opinion
Paragraph 1 a (new)

Draft opinion	*Amendment*
	1a. Stresses the importance of observing the principle of subsidiarity, as each Member State must address any shortcomings on the basis of its own particular requirements;

Or. fr

Amendment 36
Marie-Christine Boutonnet, Joëlle Mélin

Draft opinion
Paragraph 1 b (new)

Draft opinion	*Amendment*
	1b. Calls for support for the progress achieved by the pharmaceutical industry, hitherto driven by European SMEs, which have transformed the standard of healthcare in Europe and helped to prolong life expectancy;

Or. fr

Amendment 37
Marie-Christine Boutonnet, Joëlle Mélin

Draft opinion
Paragraph 2

Draft opinion	*Amendment*
2. Considers that exclusive protection periods granted to pharmaceuticals through patents or other mechanisms hinder competition, lead to high prices and negatively impact access to needed medicines;	***deleted***

Or. fr

Amendment 38
Angel Dzhambazki

Draft opinion
Paragraph 2

Draft opinion	*Amendment*
2. Considers that exclusive protection periods granted to pharmaceuticals through patents or other mechanisms hinder competition, lead to high prices and negatively impact access to needed medicines;	***deleted***

Or. en

Amendment 39
Jiří Maštálka

Draft opinion
Paragraph 2

Draft opinion	*Amendment*
2. Considers that exclusive protection periods granted to pharmaceuticals through patents or other mechanisms hinder competition, lead to high prices and negatively impact access to needed medicines;	2. Considers that exclusive protection periods granted to pharmaceuticals through patents or other mechanisms hinder competition, lead to high prices and negatively impact access to needed medicines; ***observes that the EU´s current biomedical R&D system based on IP monopolies has proved a failure to deliver accessible and affordable lifesaving medicines, and that the EU has not received sufficient return on its public investment in biomedical R&D with regards to the property on the outcome of research;***

Or. en

Amendment 40
Daniel Buda

Draft opinion
Paragraph 2

Draft opinion	*Amendment*
2. Considers that exclusive protection periods granted to pharmaceuticals through patents or other mechanisms ***hinder competition***, lead to ***high prices and negatively*** impact access to needed medicines;	2. Considers that exclusive protection periods granted to pharmaceuticals through patents or other mechanisms ***may help sustain research and development departments***, ***but*** lead to ***a decrease in competition during those periods, with the higher price for medicines, established on the basis of research costs, potentially having an adverse*** impact ***on their purchase by consumers, and even acting to limit*** access to needed medicines;

Or. ro

Amendment 41
Rosa Estaràs Ferragut, Emil Radev, Tadeusz Zwiefka

Draft opinion
Paragraph 2

Draft opinion	*Amendment*
2. Considers that exclusive protection periods granted to pharmaceuticals through patents or other mechanisms ***hinder*** competition***, lead to high prices and negatively impact*** access to needed medicines;	2. Considers that exclusive protection periods granted to pharmaceuticals through patents or other mechanisms ***are an important tool to encourage R&D and provide incentives to innovation; acknowledges, at the same time, the importance of promoting*** competition ***and preventing cases of market abuse, as well as the need of ensuring*** access to needed medicines ***at affordable prices and guaranteeing the sustainability of national healthcare systems***;

Or. en

Amendment 42
Victor Negrescu

Draft opinion
Paragraph 2

Draft opinion	*Amendment*
2. Considers ***that*** exclusive protection periods ***granted*** to pharmaceuticals through patents or other mechanisms hinder competition, lead to high prices and negatively impact access to needed medicines;	2. Considers ***there to be a need to rethink the mechanism for granting*** exclusive protection periods to pharmaceuticals through patents or other mechanisms ***since these currently*** hinder competition, lead to high prices and negatively impact access to needed medicines;

Or. ro

Amendment 43
Notis Marias

Draft opinion
Paragraph 2

Draft opinion	*Amendment*
2. ***Considers*** that exclusive protection periods granted to pharmaceuticals through patents or other mechanisms hinder competition, lead to high prices and negatively impact access to needed medicines;	2. ***Stresses*** that exclusive protection periods granted to pharmaceuticals through patents or other mechanisms hinder competition, lead to high prices and negatively impact access to needed medicines;

Or. el

Amendment 44
Stefano Maullu

Draft opinion
Paragraph 2

Draft opinion	*Amendment*
2. ***Considers that exclusive protection periods granted to pharmaceuticals through patents or other mechanisms hinder competition, lead to high prices and negatively impact access to needed medicines***;	2. ***Recognises the key contribution of IP-intensive industries such as the pharmaceutical sector in enhancing the competitiveness of European economy and delivering growth and high-quality jobs in the EU***;

Or. en

Amendment 45
Cecilia Wikström

Draft opinion
Paragraph 2

Draft opinion	*Amendment*
2. Considers that exclusive protection periods granted to pharmaceuticals through patents or other mechanisms ***hinder***	2. Considers that exclusive protection periods granted to pharmaceuticals through patents or other mechanisms ***is essential to***

competition, lead to high prices and negatively impact access to needed medicines;	***promote innovation and the development of new*** medicines;

Or. en

Amendment 46
Marie-Christine Boutonnet, Joëlle Mélin

Draft opinion
Paragraph 2 a (new)

Draft opinion	*Amendment*
	2a. Reiterates that part of the reason why businesses are becoming less competitive and why welfare spending is so high is that EU rules – including rules on drug pricing – are too burdensome;

Or. fr

Amendment 47
Angel Dzhambazki, Kosma Złotowski

Draft opinion
Paragraph 2 b (new)

Draft opinion	*Amendment*
	2b. Considers that for a certain time period exclusive protection periods may be necessary in order to not disrupt the drug trial periods and thereby end the drug development cycle;

Or. en

Amendment 48
Angel Dzhambazki, Kosma Złotowski

Draft opinion
Paragraph 2 c (new)

Draft opinion	*Amendment*
	2c. Notes, that awareness and monitoring is an important aspect of the competent authorities and believes, that improved awareness campaigns are a tool to improve a better understanding of the complex drug development processes for both business and consumers;

Or. en

Amendment 49
Marie-Christine Boutonnet, Joëlle Mélin

Draft opinion
Paragraph 3

Draft opinion	*Amendment*
3. Recalls that the Pharmaceutical Sector Inquiry Report adopted by the Commission in 2009 showed that manufacturers of medicines have developed abusive strategies in connection with patent claims in order to hinder market entry of generic medicines, which should be avoided;	***deleted***

Or. fr

Amendment 50
Enrico Gasbarra

Draft opinion
Paragraph 3

Draft opinion	*Amendment*
3. Recalls that the Pharmaceutical Sector Inquiry Report adopted by the Commission in 2009 showed that manufacturers of medicines have developed abusive strategies in connection	3. Recalls that the Pharmaceutical Sector Inquiry Report adopted by the Commission in 2009 showed that manufacturers of medicines have developed abusive strategies in connection

with patent claims in order to hinder market entry of generic medicines, which should be avoided;	with patent claims in order to hinder market entry of generic medicines, which should be avoided; ***Asks the Commission to act responsibility and in particular to introduce tougher checks on possible cases of infringements of internal market and competition rules;***

Or. it

Amendment 51
Daniel Buda

Draft opinion
Paragraph 3

Draft opinion	*Amendment*
3. Recalls that the Pharmaceutical Sector Inquiry Report adopted by the Commission in 2009 showed that manufacturers of medicines have developed abusive strategies in connection with patent claims in order to hinder market entry of generic medicines, which should be avoided;	3. Recalls that the Pharmaceutical Sector Inquiry Report adopted by the Commission in 2009 showed that manufacturers of medicines have developed abusive strategies in connection with patent claims in order to hinder market entry of generic medicines, which should be avoided***, while observing that generic medicines respect the requisite quality standards set to ensure effective treatment***;

Or. ro

Amendment 52
Rosa Estaràs Ferragut, Emil Radev, Tadeusz Zwiefka

Draft opinion
Paragraph 3

Draft opinion	*Amendment*
3. Recalls that the Pharmaceutical Sector Inquiry Report ***adopted*** by the Commission in 2009 ***showed that manufacturers of medicines have developed abusive strategies in connection***	3. Recalls that the Pharmaceutical Sector Inquiry Report ***led*** by the Commission in 2009 ***indicated a number of problems in companies' practices that, among other factors such as shortcomings***

with patent claims in order to hinder market entry of generic medicines***, which should be avoided***;	***in the regulatory framework, potentially contribute to delays to the*** market entry of generic medicines ***and emphasised the importance of stronger competition law enforcement***;

Or. en

Amendment 53
Notis Marias

Draft opinion
Paragraph 3

Draft opinion	*Amendment*
3. Recalls that the Pharmaceutical Sector Inquiry Report adopted by the Commission in 2009 showed that manufacturers of medicines have developed abusive strategies in connection with patent claims ***in order to hinder market entry of generic medicines, which should be avoided***;	3. Recalls that the Pharmaceutical Sector Inquiry Report adopted by the Commission in 2009 showed that manufacturers of medicines have developed abusive strategies in connection with patent claims;

Or. el

Amendment 54
Cecilia Wikström

Draft opinion
Paragraph 3

Draft opinion	*Amendment*
3. Recalls that the Pharmaceutical Sector Inquiry Report adopted by the Commission in 2009 showed that manufacturers of medicines have developed ***abusive*** strategies in connection with patent claims in order to hinder market entry of generic medicines, which should be avoided;	3. Recalls that the Pharmaceutical Sector Inquiry Report adopted by the Commission in 2009 showed that ***some*** manufacturers of medicines have developed ***aggressive*** strategies in connection with patent claims in order to hinder market entry of generic medicines, which should be avoided;

Or. en

Amendment 55
Angel Dzhambazki

Draft opinion
Paragraph 3

Draft opinion	*Amendment*
3. Recalls that the Pharmaceutical Sector Inquiry Report adopted by the Commission in 2009 showed that manufacturers of medicines have developed abusive strategies in connection with patent claims in order to hinder market entry of generic medicines, which should be avoided;	3. Recalls that the Pharmaceutical Sector Inquiry Report adopted by the Commission in 2009 showed that ***some*** manufacturers of medicines have developed abusive strategies in connection with patent claims in order to hinder market entry of generic medicines, which should be avoided;

Or. en

Amendment 56
Stefano Maullu

Draft opinion
Paragraph 3

Draft opinion	*Amendment*
3. Recalls that the Pharmaceutical Sector Inquiry Report adopted by the Commission in 2009 ***showed that manufacturers of medicines have developed abusive strategies in connection with patent claims in order to hinder market entry of generic medicines, which should be avoided***;	3. Recalls that the Pharmaceutical Sector Inquiry Report adopted by the Commission in 2009 ***identified the numerous regulatory obstacles that need to be addressed to achieve more efficient innovative and off-patent pharmaceutical markets***;

Or. en

Amendment 57
Angel Dzhambazki, Kosma Złotowski

Draft opinion
Paragraph 3 a (new)

Draft opinion	*Amendment*
	3a. Notes that certain markets may benefit from more efficient monitoring and training for competent authorities as well as better inter-governmental cooperation in terms of exchange of best-practises;

Or. en

Amendment 58
Marie-Christine Boutonnet, Joëlle Mélin

Draft opinion
Paragraph 4

Draft opinion	*Amendment*
4. Calls on the Commission to undertake a critical review of the impact of intellectual-property-related incentives on biomedical innovation, to explore alternatives to monopolies for the financing of medical R&D and to evaluate the functioning of the applicable limitations to patent allocations;	***deleted***

Or. fr

Amendment 59
Jiří Maštálka

Draft opinion
Paragraph 4

Draft opinion	*Amendment*
4. Calls on the Commission to undertake a critical review of the impact of intellectual-property-related incentives on biomedical innovation, to explore alternatives to monopolies for the financing of medical R&D and to evaluate the	4. Calls on the Commission to undertake a critical review of the impact of intellectual-property-related incentives on biomedical innovation, to explore alternatives to monopolies for the financing of medical R&D and to evaluate the

functioning of the applicable limitations to patent allocations***;***	functioning of the applicable limitations to patent allocations ***and to safeguard the right of countries to regulate and preserve policy space in order to guarantee universal access to medicines;***

Or. en

Amendment 60
Cecilia Wikström

Draft opinion
Paragraph 4

Draft opinion	*Amendment*
4. Calls on the Commission to ***undertake a critical review of*** the impact of intellectual-property-related incentives on biomedical innovation***,*** to explore alternatives ***to monopolies*** for the financing of medical R&D ***and to evaluate the functioning of the applicable limitations to patent allocations***;	4. Calls on the Commission to ***assess*** the impact of intellectual-property-related incentives on biomedical innovation ***and*** to explore alternatives for the financing of medical R&D;

Or. en

Amendment 61
Stefano Maullu

Draft opinion
Paragraph 4

Draft opinion	*Amendment*
4. Calls on the Commission to undertake a critical review of the impact of intellectual-property-related incentives on biomedical innovation, to explore alternatives to ***monopolies*** for the financing of medical R&D ***and to evaluate the functioning of the applicable limitations to patent allocations***;	4. Calls on the Commission to undertake a critical review of the impact of intellectual-property-related incentives on biomedical innovation, to explore ***credible and efficient*** alternatives to ***patents*** for the financing of medical R&D;

Or. en

Amendment 62
Angel Dzhambazki, Kosma Złotowski

Draft opinion
Paragraph 4

Draft opinion	*Amendment*
4. Calls on the Commission to undertake a critical review of the impact of intellectual-property-related incentives on biomedical innovation, to explore alternatives to monopolies for the financing of medical R&D and to ***evaluate the functioning of the applicable limitations to patent allocations***;	4. Calls on the Commission to undertake a critical review of the impact of intellectual-property-related incentives on biomedical innovation, to explore alternatives to monopolies for the financing of medical R&D and to ***assess areas where existing legislation may benefit from a modernisation or streamlining approach***;

Or. en

Amendment 63
Rosa Estaràs Ferragut, Emil Radev, Tadeusz Zwiefka

Draft opinion
Paragraph 4

Draft opinion	*Amendment*
4. Calls on the Commission to undertake a critical review of the impact of intellectual-property-related incentives on biomedical innovation, to explore alternatives to ***monopolies*** for the financing of medical R&D and to evaluate the functioning of the applicable limitations to patent ***allocations***;	4. Calls on the Commission to undertake a critical review of the impact of intellectual-property-related incentives on biomedical innovation, to explore ***effective*** alternatives to ***patents*** for the financing of medical R&D and to evaluate the functioning of the applicable limitations to patent ***rights***;

Or. en

Amendment 64
Pascal Durand, Enrico Gasbarra

Draft opinion
Paragraph 4 a (new)

Draft opinion	*Amendment*
	4a. Calls on the Commission to explore the implementation of delinkage mechanisms, characterized by the uncoupling of R&D costs and the end prices of health products, to finance research and development as mentioned in the report of the United Nations Secretary General's high level Panel on access to medicines - Promoting innovation and access to health technologies; [1a]
	1a https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf

Or. en

Amendment 65
Enrico Gasbarra

Draft opinion
Paragraph 4 b (new)

Draft opinion	*Amendment*
	4b. Calls on the Commission to implement a coherent policy at EU level that favours the principle of access to medicines in all the various aspects of EU legislation, starting with international trade and a revision of the laws on patents and infringements of copyright;

Or. it

Amendment 66
Daniel Buda

Draft opinion
Paragraph 4 c (new)

Draft opinion	*Amendment*
	4c. Calls on the Commission to identify the most effective mechanisms to help combat the phenomenon of counterfeit medicines, in order to ensure intellectual property protection and guarantee a high level of health protection;

Or. ro

Amendment 67
Emil Radev

Draft opinion
Paragraph 4 d (new)

Draft opinion	*Amendment*
	4d. Calls on the European Commission and Member States to strike a balance between stimulating innovation, protecting innovators and ensuring that innovations are of maximum benefit to society;

Or. bg

Amendment 68
Angel Dzhambazki

Draft opinion
Paragraph 5

Draft opinion	*Amendment*
5. Calls on the European Patent Office (EPO) and the Member States to grant patents on health products that strictly fulfil the patentability requirements of novelty, inventive step	***deleted***

and industrial applicability as enshrined in the European Patent Convention;

Or. en

Amendment 69
Marie-Christine Boutonnet, Joëlle Mélin

Draft opinion
Paragraph 5

Draft opinion	*Amendment*
5. Calls on the European Patent Office (EPO) and the Member States to grant patents on health products that strictly fulfil the patentability requirements of novelty, inventive step and industrial applicability ***as enshrined in the European Patent Convention***;	5. Calls on the European Patent Office (EPO) and the Member States to grant patents on health products that strictly fulfil the patentability requirements of novelty, inventive step and industrial applicability;

Or. fr

Amendment 70
Stefano Maullu

Draft opinion
Paragraph 5

Draft opinion	*Amendment*
5. Calls on the European Patent Office (EPO) and the Member States to grant patents on health products that strictly fulfil the patentability requirements of novelty, inventive step and industrial applicability as enshrined in the European Patent Convention;	5. Calls on the European Patent Office (EPO) and the Member States to ***continue to*** grant patents on health products that strictly fulfil the patentability requirements of novelty, inventive step and industrial applicability as enshrined in the European Patent Convention;

Or. en

Amendment 71
Rosa Estaràs Ferragut, Emil Radev, Tadeusz Zwiefka

Draft opinion
Paragraph 5

Draft opinion	*Amendment*
5. Calls on the European Patent Office (EPO) and the Member States to grant patents on health products that strictly fulfil the patentability requirements of novelty, inventive step and industrial applicability as enshrined in the European Patent Convention;	5. Calls on the European Patent Office (EPO) and the Member States to ***continue to*** grant patents on health products that strictly fulfil the patentability requirements of novelty, inventive step and industrial applicability as enshrined in the European Patent Convention;

Or. en

Amendment 72
Notis Marias

Draft opinion
Paragraph 5

Draft opinion	*Amendment*
5. Calls on the European Patent Office (EPO) and the Member States to grant patents on health products that strictly fulfil the patentability requirements of novelty, inventive step and industrial applicability as enshrined in the European Patent Convention;	5. Calls on the European Patent Office (EPO) and the Member States to grant patents ***only*** on health products that strictly fulfil the patentability requirements of novelty, inventive step and industrial applicability as enshrined in the European Patent Convention;

Or. el

Amendment 73
Cecilia Wikström

Draft opinion
Paragraph 5

Draft opinion	*Amendment*
5. ***Calls on*** the European Patent Office (EPO) and the Member States ***to*** grant patents on health products that strictly fulfil the patentability requirements	5. ***Notes that*** the European Patent Office (EPO) and the Member States grant patents on health products that strictly fulfil the patentability requirements of

of novelty, inventive step and industrial applicability as enshrined in the European Patent Convention;	novelty, inventive step and industrial applicability as enshrined in the European Patent Convention;

Or. en

Amendment 74
Marie-Christine Boutonnet, Joëlle Mélin

Draft opinion
Paragraph 6

Draft opinion	*Amendment*
6. Calls on the Commission to encourage Member States to fully implement existing patent limitations and flexibilities when confronted with excessive pricing or abuse of monopoly rights;	***deleted***

Or. fr

Amendment 75
Jiří Maštálka

Draft opinion
Paragraph 6

Draft opinion	*Amendment*
6. Calls on the Commission to encourage Member States to fully implement existing patent limitations and flexibilities when confronted with excessive pricing or abuse of monopoly rights;	6. Calls on the Commission to encourage Member States to fully implement existing patent limitations and flexibilities when confronted with excessive pricing or abuse of monopoly rights; ***underlines the key role played by public investments in R&D and highlight the importance of implementing measures to ensure a public health return on investments when EU funds are financing medical R&D, including the provision of conditions attached to public R&D funding that ensure biomedical research results in suitable and affordable medicine;***

Or. en

Amendment 76
Enrico Gasbarra

Draft opinion
Paragraph 6

Draft opinion	*Amendment*
6. Calls on the Commission to encourage Member States to fully implement existing patent limitations and flexibilities when confronted with excessive pricing or abuse of monopoly rights;	6. Calls on the Commission to encourage Member States to fully implement existing patent limitations and flexibilities when confronted with excessive pricing or abuse of monopoly rights; ***calls in this respect on the Commission to undertake to carry out an analysis of the patent system for medicinal products within the internal market, in particular to check whether patents for drugs facilitate the movement of products in fragile, non-competitive sectors, such as the treatment of rare diseases;***

Or. it

Amendment 77
Rosa Estaràs Ferragut, Emil Radev, Tadeusz Zwiefka

Draft opinion
Paragraph 6

Draft opinion	*Amendment*
6. Calls on the Commission to encourage Member States to fully implement existing patent limitations and flexibilities ***when confronted with excessive pricing or abuse of monopoly rights***;	6. Calls on the Commission to encourage Member States to fully implement existing patent limitations and flexibilities ***in duly justified cases, such as cases of national emergencies, other circumstances of extreme urgency or anti-competitive practices***;

Or. en

Amendment 78
Emil Radev

Draft opinion
Paragraph 6

Draft opinion	*Amendment*
6. Calls on the Commission to encourage Member States to fully implement existing patent limitations and flexibilities when confronted with excessive pricing or abuse of monopoly rights;	6. Calls on the Commission to encourage Member States to fully implement existing patent limitations and flexibilities when confronted with excessive pricing or abuse of monopoly rights***, especially as regards medicines for rare diseases***;

Or. bg

Amendment 79
Cecilia Wikström

Draft opinion
Paragraph 6

Draft opinion	*Amendment*
6. Calls on the ***Commission to encourage*** Member States to fully ***implement existing patent limitations and flexibilities when confronted with*** excessive pricing ***or abuse of monopoly rights***;	6. Calls on the Member States to fully ***cooperate and exchange information and expertise among each other in order to prevent*** excessive pricing ***of medicines and to ensure market access of generic products***;

Or. en

Amendment 80
Angel Dzhambazki, Kosma Złotowski

Draft opinion
Paragraph 7

Draft opinion	*Amendment*
7. Calls on the Commission to establish full transparency on the results of publicly financed R&D so that patenting and licensing conditions guarantee a public health return on public investments and reflect the structure of R&D funding.	***deleted***

Or. en

Amendment 81
Enrico Gasbarra

Draft opinion
Paragraph 7

Draft opinion	*Amendment*
7. Calls on the Commission to establish full transparency on the results of publicly financed R&D so that patenting and licensing conditions guarantee a public health return on public investments and reflect the structure of R&D funding.	7. Calls on the Commission to establish full transparency on the results of publicly financed R&D so that patenting and licensing conditions guarantee a public health return on public investments and reflect the structure of R&D funding***; Calls on the Commission to introduce best practices so as to encourage a positive conditionality with the aim of promoting forms of sharing and a greater circulation of patents.***

Or. it

Amendment 82
Rosa Estaràs Ferragut, Emil Radev, Tadeusz Zwiefka

Draft opinion
Paragraph 7

Draft opinion	*Amendment*
7. Calls on the Commission to establish full transparency on the results of	7. Calls on the Commission ***and the Member States*** to establish full

publicly financed R&D so that patenting and licensing conditions guarantee a public health return on public investments and reflect the structure of R&D funding.	transparency on the results of publicly financed R&D so that patenting and licensing conditions guarantee a public health return on public investments and reflect the structure of R&D funding.

Or. en

Amendment 83
Jiří Maštálka

Draft opinion
Paragraph 7

Draft opinion	*Amendment*
7. Calls on the Commission to establish full transparency on the results of publicly financed R&D so that patenting and licensing conditions guarantee a public health return on public investments and reflect the structure of R&D funding.	7. Calls on the Commission to establish full transparency ***and public disclosure*** on the results of publicly financed R&D so that patenting and licensing conditions guarantee a public health return on public investments and reflect the structure of R&D funding.

Or. en

Amendment 84
Cecilia Wikström

Draft opinion
Paragraph 7

Draft opinion	*Amendment*
7. Calls on the Commission to ***establish full transparency on the results of publicly financed R&D so that patenting and licensing conditions guarantee a public health return on public investments and reflect the structure of R&D funding***.	7. Calls on the Commission to ***study the different factors which cause excessive prices, such as national regulatory and economic approaches, and to assess how those issues could be tackled at European level***.

Or. en

Amendment 85
Jiří Maštálka

Draft opinion
Paragraph 7 a (new)

Draft opinion	*Amendment*
	7a. Stress the importance of developing a comprehensive access to medicines policy that ensures that all EU policies (global public health, development, research and trade) are consistent with, and beneficial for, access to affordable medicines for citizens in the EU and low-and middle-income countries alike, calls on the Commission to further explore the numerous tools providing new incentives for health technology innovation, such as mechanisms delinking the costs of research and development from the end product, as outlined by the World Health Organisation Global Strategy Plan of action (2008) and in the recent United Nations Secretary General's high level Panel on access to medicines - Promoting innovation and access to health technologies

Or. en

Amendment 86
Luke Ming Flanagan

Draft opinion
Paragraph 7 b (new)

Draft opinion	*Amendment*
	7b. Calls on the Commission to establish a comprehensive transnational patent drugs price comparison website, so that citizens in individual Member States can see at a glance how and where they are being overcharged for their prescriptions, and to expose all instances

of overcharging.

Or. en

Amendment 87
Daniel Buda

Draft opinion
Paragraph 7 c (new)

Draft opinion	*Amendment*
	7c. The following are prerequisites when it comes to establishing instruments that can lead to transparent assessment of the level of access to medicines:
	(a) analysis of the relationship between the benefits deriving from the original medicinal products with an impact on European health systems, with reference to the distribution point, and the price, which must be applied on the basis of the research and innovation costs;
	(b) analysis of whether patients' access to generic medicines really is of a significantly higher level than for the original products, with a view to ensuring health protection and enhancing consumers' quality of life;
	(c) analysis of the risk-benefit ratio for access to generic medicines;
	(d) assessment of the information communicated both to consumers and to healthcare professionals, and of the provisions attached to the generic medicines process versus that for original products.

Or. ro

Amendment 88
Enrico Gasbarra

Draft opinion
Paragraph 7 d (new)

Draft opinion	*Amendment*
	7d. Calls again on the Commission to give political impetus to the proposal to amend Directive 89/105 in order to obtain more transparent and thus more reasonable prices; asks the Commission to step up efforts, as provided by the law in force, to ensure public access to appropriate information on the safety and effectiveness of medicines;

Or. it

Amendment 89
Victor Negrescu

Draft opinion
Paragraph 7 e (new)

Draft opinion	*Amendment*
	7e. Calls on the Commission to request the Member States to define public policies and produce statistical evidence on the number of chronically ill persons, broken down by illness, and the forecast for the coming 5 to 10 years;

Or. ro

Amendment 90
Emil Radev

Draft opinion
Paragraph 7 f (new)

Draft opinion	*Amendment*
	7f. Stresses the need to establish robust health systems, based on new pricing models.

Or. bg

Amendment 91
Victor Negrescu

Draft opinion
Paragraph 7 g (new)

Draft opinion	*Amendment*
	7g. Calls on the Commission to launch discussions on devising a procedure for establishing (on the basis of age, type of chronic illness, income, etc.) the socially-disadvantaged categories to which innovative medicines could be made available, on an exceptional basis, before the patent expires;

Or. ro

Amendment 92
Enrico Gasbarra

Draft opinion
Paragraph 7 h (new)

Draft opinion	*Amendment*
	7h. Asks the Commission to pay particular attention to 'evergreening', i.e. the practice whereby slight modifications of existing products are patented as new inventions in order to perpetuate the patent and the privileges arising therefrom;

Or. it

Amendment 93
Victor Negrescu

Draft opinion
Paragraph 7 i (new)

Draft opinion	*Amendment*
	7i. Calls on the Commission to introduce transparent mechanisms for correctly setting the price of medicines available on the market.

Or. ro