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REPORT

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

Committee on the Environment, Public Health and Food Safety

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CONTENTS

Page

MOTION FOR A EUROPEAN PARLIAMENT RESOLUTION

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

The European Parliament,

– having regard to its legislative resolution of 6 February 2013 on the proposal for a directive of the European Parliament and of the Council relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems[1],

– having regard to Article 168 of the Treaty on the Functioning of the European Union (TFEU), which lays down that a high level of human health protection should be ensured in the definition and implementation of all Union policies and activities,

– having regard to the Commission REFIT evaluation of Council Regulation (EC) No 953/2003 to avoid trade diversion into the European Union of certain key medicines (SWD(2016)0125),

– having regard to the obligations set out in Article 81 of Directive 2001/83/EC for the maintenance of an appropriate and continued supply of medicinal products,

– having regard to the Commission's Inception Impact Assessment[2] on the strengthening of EU cooperation on Health Technology Assessment (HTA),

– having regard to the HTA Network Strategy for EU Cooperation on Health Technology Assessment of 29 October 2014[3],

– having regard to the final report of the Commission's Pharmaceutical Sector Inquiry (SEC(2009)0952),

– having regard to the Commission's 2013 report entitled 'Health inequalities in the EU – Final report of a consortium. Consortium lead: Sir Michael Marmot'[4], in which it is recognised that health systems play an important role in reducing the risk of poverty or may help to reduce poverty,

– having regard to the Council's conclusions on innovation for the benefit of patients of 1 December 2014[5],

– having regard to the conclusions of the Employment, Social Policy, Health and Consumer Affairs Council's informal meeting on health of 18 April 2016,

– having regard to the Commission's 6th Report on the Monitoring of Patent Settlements

[1] OJ C 24, 22.1.2016, p. 119.
[2] http://ec.europa.eu/smart-regulation/roadmaps/docs/2016_sante_144_health_technology_assessments_en.pdf.
[3] http://ec.europa.eu/health/technology_assessment/docs/2014_strategy_eucooperation_hta_en.pdf.
[4] ec.europa.eu/health/social_determinants/docs/healthinequalitiesineu_2013_en.pdf.
[5] http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/145978.pdf.

in the pharmaceutical sector,

– having regard to the Commission's communication entitled 'Secure, Innovative and accessible medicines: a renovated view for the pharmaceutical sector' (COM(2008)0666),

– 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,

– having regard to the Council conclusions of 17 June 2016 on strengthening the balance in the pharmaceutical systems in the EU and its Member States,

– 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],

– 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,

– having regard to the Council conclusions of 10 May 2006 on common values and principles in EU health systems, and the conclusions of the Employment, Social Policy, Health and Consumer Affairs Council of 6 April 2011 and of 10 December 2013 on the reflection process on modern, responsive and sustainable health systems;

– having regard to the Commission's communication entitled 'Effective, Available and Robust Health Systems' (COM(2014)0215)),

– having regard to the Commission's report entitled 'Towards Harmonised EU Assessment of Added therapeutic Value of Medicines',

– having regard to the World Health Organisation report entitled 'WHO Expert Committee on the Selection of Essential Drugs, 17-21 October 1977 – WHO Technical Report Series, No. 615', the report by the WHO Secretariat of 7 December 2001 entitled 'WHO medicines strategy: Revised procedure for updating WHO's Model List of Essential Drugs' (EB109/8); the WHO report of March 2015 entitled 'Access to new medicines in Europe' and the WHO Report of 28 June 2013 entitled 'Priority Medicines for Europe and the World',

– having regard to Regulation (EC) 141/2000 on orphan medicinal products,

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

– having regard to Articles 101 and 102 TFEU laying down rules on competition,

– having regard to the Doha Declaration on the Agreement on Trade-Related Aspects of Intellectual Property Rights and Public Health (WTO/MIN(01/DEC/2) and to the implementation of Paragraph 6 of the Doha Declaration of 1 September 2003

[1] http://ec.europa.eu/health/preparedness_response/docs/decision_serious_crossborder_threats_22102013_es.pdf.

(WTO/L/540),

– having regard to Regulation (EC) No 816/2006 on compulsory licensing of patents relating to the manufacturer of pharmaceutical products for export to countries with public health problems,

– having regard to the joint procurement agreement approved by the Commission on 10 April 2014[1],

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

– 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 Regulation 726/2004,

– having regard to its resolution of 16 September 2015 on the Commission Work Programme 2016[2],

– having regard to its resolution of 11 September 2012 on voluntary and unpaid donation of tissues and cells[3],

– having regard to Rule 52 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinions of the Committee on Development, the Committee on Legal Affairs and the Committee on Petitions (A8-0040/2017),

A. whereas the Charter of Fundamental Rights of the European Union recognises the fundamental right of citizens to health and medical treatment[4];

B. whereas public health systems are crucial to guaranteeing universal access to health care, a fundamental right of European citizens; whereas health systems in the EU face challenges such as an ageing population, the increasing burden of chronic illnesses, the high cost of development of new technologies, high and rising pharmaceutical expenses, and the effects of the economic crisis on healthcare spending; whereas expenditure in the pharmaceutical sector in the EU accounted for 17.1 % of total health expenditure and 1.41 % of gross domestic product (GDP) in 2014; whereas these challenges prompt the need for European cooperation and new policy measures at both EU and national level;

C. whereas pharmaceuticals are one of the pillars of healthcare rather than a mere object of trade, and whereas insufficient access to essential medicinal products and high prices of innovative medicines pose a serious threat to the sustainability of national health care systems;

[1] http://ec.europa.eu/health/preparedness_response/docs/jpa_agreement_medicalcountermeasures_en.pdf
[2] Texts adopted, P8_TA(2015)0323.
[3] Texts adopted, P7_TA(2012)0320.
[4] The 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.

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

E. whereas ensuring patient access to essential medicines is one of the core objectives of the EU and the WHO, and of Sustainable Development Goal 3; whereas universal access to medicines depends on their timely availability and their affordability for everyone, without any geographical discrimination;

F. whereas competition is an important factor in the overall balance of the pharmaceutical market and can lower costs, reduce expenditure on medicines and improve timely access for patients to affordable medicines, with higher quality standards being observed in the research and development process;

G. whereas the entry of generics onto the market is an important mechanism for increasing competition, reducing prices and ensuring the sustainability of healthcare systems; whereas the market entry of generics should not be delayed and competition should not be distorted;

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

I. whereas, in many cases, the prices of new medicines have increased during the past few decades to the point of being unaffordable to many European citizens and of threatening the sustainability of national health care systems;

J. whereas in addition to high prices and unaffordability, other barriers to access to medicines include shortages of essential and other medicines, the poor connection between clinical needs and research, lack of access to healthcare and healthcare professionals, unjustified administrative procedures, delays between marketing authorisation and subsequent pricing and reimbursement decisions, unavailability of products, patent rules and budget restrictions;

K. whereas diseases such as hepatitis C can successfully be combated with early diagnosis, combined with new and old medicines, saving millions of people across the EU;

L. 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 has resulted 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, raising the risk that affordability or pricing of the medication will become a deciding factor in a patient's cancer treatment;

M. 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;

N. whereas the EU has had to introduce incentives to promote research in areas such as rare diseases and paediatric diseases; whereas the Orphan Medicinal Products Regulation has provided an important framework for promoting research on orphan

medicines, considerably improving the treatment of rare diseases for which no alternative existed previously, but whereas there are, however, concerns about its implementation;

O. whereas the gap between growing resistance to antimicrobial agents and the development of new antimicrobial agents is widening, and whereas drug-resistant diseases could cause 10 million deaths annually worldwide up to 2050; whereas it is estimated that every year in the EU, at least 25 000 people die of infections caused by resistant bacteria, to an annual cost of EUR 1.5 billion , while only one novel class of antibiotics has been developed in the past 40 years;

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

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

R. whereas 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;

S. whereas certain essential medicines are not available in many Member States, which can lead to problems with regard to patient care; whereas a number of medicine shortages can occur either because of illegitimate business strategies, such as "pay for delay" in the pharmaceutical sector, or political, manufacturing or distribution issues, or parallel trade; whereas Article 81 of Directive 2001/83/EU stipulates measures to prevent pharmaceutical shortages by means of a so-called public service obligation (PSO), which obligates manufacturers and distributors to safeguard supplies to national markets; whereas, in many cases, the PSO is not applied to manufacturers supplying the distributors, as indicated in a study commissioned by the Commission;

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

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

V. whereas since 1995 the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS agreement) provides for patent flexibilities, such as compulsory licensing;

W. whereas a European Medicines Agency (EMA) pilot project launched in 2014 known as 'adaptive pathways', which applies primarily to treatments in areas of high unmet medical need, has generated intense debate of the risk/benefit ratio of granting earlier market access to innovative medicines on the basis of less clinical data;

X. 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;

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

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

AA. whereas pricing and reimbursement of medicinal products are Member State competences and are regulated at national level; whereas the EU provides legislation on intellectual property, clinical trials, marketing authorisation, transparency in pricing, pharmacovigilance and competition; whereas the growing expenditure in the pharmaceutical sector, as well as the observed asymmetry in the negotiation capacities and information on pricing between pharmaceutical companies and Member States, prompts further European cooperation and new policy measures at both European and national level; whereas the prices of medicines are usually negotiated by means of bilateral and confidential negotiations between the pharmaceutical industry and Member States;

AB. whereas a majority of Member States have their own health technology assessment agencies, each with its own criteria;

AC. whereas under Article 168 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) TFEU, legislative proposals in the health sector shall take as a base a high level of protection;

Pharmaceutical market

1. Shares the concern expressed in the 2016 Council conclusions on strengthening the balance in the pharmaceutical systems in the EU;

2. Welcomes the Council conclusions of 17 June 2016 inviting the Commission to conduct an evidence-based analysis of the overall impact of intellectual property (IP) on innovation as well as on the availability – inter alia supply shortages and deferred or missed market launches – and accessibility of medicinal products;

3. Reiterates that the right to health is a human right recognised in both the Universal Declaration of Human Rights and the International Covenant on Economic, Social and Cultural Rights, and that this right concerns all Member States, given that they have ratified international human rights treaties that recognise the right to health; points out that for this right to be guaranteed, access to medicine, among other factors, must be ensured;

4. Recognises the value of citizens' initiatives such as the European Charter of Patients'

Rights, based on the Charter of Fundamental Rights of the European Union, and the European Patients' Rights Day celebrated each year on 18 April at local and national level in the Member States; invites the Commission to institutionalise the European Patients' Rights Day at EU level;

5. Points to the conclusions of the informal Council meeting of healthcare ministers held in Milan on 22 and 23 September 2014 during the Italian Council Presidency, at which occasion many Member States agreed on the need to make joint efforts to facilitate the sharing of best practices and enable swifter access for patients;

6. Stresses the need for consistency between all EU policies (global public health, development, research and trade) and underlines, therefore, that the issue of access to medicines in the developing world must be seen in a broader context;

7. Highlights the importance of both public and private R&D efforts in discovering new treatments; stresses that research priorities must address patients' health needs, while recognising the interest of pharmaceutical companies to generate financial returns on their investment; stresses that the regulatory framework must facilitate the best possible outcome for patients and public interest;

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

9. Encourages more transparency in the cost of R&D, including the proportion of publicly funded research and the marketing of medicines;

10. Underlines the role of European research projects and SMEs in improving access to medicines at the EU level; highlights the role of Horizon 2020 programme in this regard;

11. Recalls that the EU pharmaceutical industry is one of the most competitive industries in the Union; stresses that preserving a high level of quality of innovation is key to addressing patients' needs and to improving competitiveness; stresses that healthcare expenditure should be considered a public investment, and that quality medicines can improve public health and enable patients to live longer and healthier lives;

12. 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;

13. Believes that the opinions of European citizens voiced in petitions to the European Parliament are of fundamental importance and should be addressed by the European legislator as a matter of priority;

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

15. Notes that it is in the interests of patients, in cases of unmet medical needs, to obtain

fast access to new innovative medicines; stresses, however, that the fast-tracking of marketing authorisations should not become the rule, but should only be used in cases of high unmet medical need and must not be motivated by commercial considerations; recalls that robust clinical trials and thorough pharmacovigilance monitoring are necessary to assess the quality, efficacy and safety of new medicines;

16. Notes with concern that 5 % of all hospital admissions in the EU are due to adverse drug reactions (ADRs) and that ADRs are the fifth leading cause of hospital death;

17. Draws attention to the Declaration on the TRIPS Agreement and Public Health, adopted in Doha on 14 November 2001, which states that the TRIPS agreement should be implemented and interpreted in a way that is good for public health – encouraging both access to existing medicines and the development of new ones; takes note, in this regard, of the decision of 6 November 2015 of the WTO TRIPS Council to extend the drug patent exemption for the least developed countries (LDCs) until January 2033;

18. Highlights the critical need to develop local capacities in developing countries, in terms of pharmaceutical research, in order to bridge the persisting gap in research and medicines production through product-development public-private partnerships and the creation of open centres of research and production;

Competition

19. Deplores the litigation cases aiming to delay generic entry; notes that, according to the final report of the Commission's Pharmaceutical Sector Inquiry, the number of litigation cases quadrupled between 2000 and 2007, that almost 60 % of the cases concerned second generation patents and that they took, on average, two years to be resolved;

20. 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;

21. Points out that biosimilar medicines enable increased competition, reduced prices and savings for healthcare systems, thus helping to improve access to medicines for patients; stresses that the added value and economic impact of biosimilar medicines on the sustainability of healthcare systems should be analysed, their market entry should not be delayed, and, where necessary, measures to support their introduction to the market should be examined;

22. Highlights that value-based pricing of medicines can be misused as a profit-maximisation economic strategy, leading to the setting of prices that are disproportionate to the cost structure, running counter to an optimal distribution of social welfare;

23. Recognises that off-label use of medicines can bring benefits to patients when approved alternatives are absent; notes with concern that patients are subjected to growing risks owing to the lack of a solid evidence base proving the safety and efficacy of off-label use, to the lack of informed consent and to increased difficulty in monitoring adverse

effects; underlines that certain population sub-groups, such as children and the elderly, are particularly exposed to this practice;

Pricing and transparency

24. Points out that patients are the weakest link in access to medicines, and that difficulties with accessing medicines should not have negative repercussions for them;

25. Notes that most national and regional health technology assessment agencies are already using various clinical, economic and social benefit criteria to evaluate new medicines in order to support their decisions on pricing and reimbursement;

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

27. 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;

28. Stresses that health technology assessments (HTA) must be an important and effective instrument for improving access to medicines, contributing to the sustainability of national healthcare systems, allowing for the creation of incentives for innovation, and delivering high therapeutic added value to patients; notes, in addition, that the introduction of joint HTAs at EU level would avoid the fragmentation of assessment systems, the duplication of efforts and the misallocation of resources within the EU;

29. Points out that, with a view to developing safe and effective patient-oriented health policies and to making health technology as effective as possible, evaluating that technology should be a multidisciplinary process that summarises the medical, social, economic and ethical information on the use of the technology by employing high standards, and by doing so in a systematic, independent, objective, reproducible and transparent manner;

30. Considers that the price of a medicine should cover the cost of the development and production of that medicine, and should be adequate for the specific economic situation of the country in which it is marketed, as well as being in line with the therapeutic added value it brings to patients, while ensuring patient access, sustainable healthcare and reward for innovation;

31. Points out that even when a new medicine is of high added value, the price should not be so high as to prevent sustainable access to it in the EU;

32. Believes that the real therapeutic added value of a medicine, the social impact, the cost benefit, the budget impact, and the efficiency for the public health system, all need to be taken into account when determining the pricing and reimbursement procedures for medicines;

33. Notes with concern that, owing to the lower negotiating power of small and lower income countries, medicines are comparatively less affordable in such Member States, especially in the field of oncology; 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 this brings to negotiations between industry and national health systems;

34. Points out that Directive 89/105/EEC has not been revised in 20 years and that, in the meantime, important changes have taken place in the medicine system in the EU;

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

36. Notes that the EURIPID project needs more transparency from Members States to include the real prices paid by them;

37. Believes that a strategic breakthrough is needed in the area of disease prevention, as it can be considered a key factor in reducing the use of medicines and in guaranteeing, at the same time, a high level of human health protection; calls on the EU and the Member States to reinforce legislation aimed at supporting sustainable food production, and to take all necessary initiatives to promote healthy and safe habits such as healthy nutrition;

EU competences and cooperation

38. Recalls that under Article 168 TFEU, a high level of human health protection is to be ensured in the definition and implementation of all Union policies and activities;

39. Stresses the importance of enhancing transparency and of increasing voluntary collaboration among Member States in the field of pricing and reimbursement of medicinal products, in order to ensure the sustainability of healthcare systems and preserve the rights of European citizens to access quality healthcare;

40. Recalls that transparency in all EU and national institutions and agencies is crucial to the well functioning of democracy, and that experts involved in the authorisation process should have no conflicts of interest;

41. Welcomes initiatives such as the Innovative Medicines Initiative (IMI), which bring together the private and public sectors in order to stimulate research and accelerate patients' access to innovative therapies addressing unmet medical needs; regrets, however, the low level of public return on public investment in the absence of access conditionalities to EU public funding; further notes that IMI 2, the second and current phase of IMI, is largely financed by EU taxpayers, highlighting the necessity of enhanced EU leadership in prioritising public health needs for IMI 2 research and in the inclusion of broad data sharing, shared health IP management policies, transparency and a fair public return on investment;

42. Highlights the EU procedure for joint procurement of medicines used for the acquisition of vaccines in accordance with Decision No 1082/2013/EU; encourages Members States to make full use of this tool, for example in case of shortages of infant vaccines;

43. Notes with concern that the EU lags behind the USA as regards a standardised and transparent reporting mechanism on the causes of medicines shortages; invites the

Commission and the Member States to propose, and to put in place, such an instrument for evidence-based policy-making;

44. Recalls the importance of the digital health agenda and the need to prioritise the development and the implementation of eHealth- and mHealth-related solutions to ensure safe, reliable, accessible, modern and sustainable new health care models to patients, caregivers, healthcare professionals and payers;

45. Recalls that LDCs are the most affected by poverty-related diseases, especially HIV/AIDS, malaria, tuberculosis, diseases of the reproductive organs, and infectious and skin diseases;

46. Highlights the fact that, in developing countries, women and children have less access to medicines than adult men owing to the lack of availability, accessibility, affordability and acceptability of treatment as a result of discrimination based on cultural, religious or social factors and of poor-quality health facilities;

47. Considering that tuberculosis has become the world's leading infectious killer and that the most dangerous form of the disease is the multi-drug resistant one; underlines the importance of tackling the emerging antimicrobial resistance (AMR) crisis, including through the funding of research and development for new tools for vaccines, diagnostics and treatment for tuberculosis, while ensuring sustainable and affordable access for those new tools, to make sure that no one is left behind;

Recommendations

48. Calls for national and EU-wide measures to guarantee the right of patients to universal, affordable, effective, safe and timely access to essential and innovative therapies, to guarantee the sustainability of EU public healthcare systems, and to ensure future investment in pharmaceutical innovation; stresses that patient access to medicines is a shared responsibility of all actors of the healthcare system;

49. Calls on the Council and the Commission to reinforce the negotiation capacities of Member States in order to ensure affordable access to medicines across the EU;

50. Welcomes the report of the United Nations Secretary-General's High-Level Panel on Access to Medicines, and calls on the Commission and on Member States to take steps to implement the recommendations made therein;

51. Notes that the repurposing of existing drugs for new indications can be accompanied by a price increase; asks the Commission to collect and analyse data on price increases in cases of drug repurposing and to report back to Parliament and to the Council on the balance and proportionality of the incentives that encourage industry to invest in drug repurposing;

52. Calls on the Member States to develop closer collaboration in order to fight such market fragmentation, in particular by developing shared HTA processes and results, and to work on shared criteria to instruct price and reimbursement decisions at national level;

53. 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 the 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;

54. Calls on the Commission to propose a new directive on transparency of price-setting procedures and reimbursement systems, taking into account the challenges of the market;

55. Calls for a new Transparency Directive to replace Directive 89/105/EEC with the aim of ensuring effective controls and full transparency on the procedures used to determine the prices and the reimbursement of medicinal products in the Member States;

56. Calls on the Member States to implement Directive 2011/24/EU on the application of patients' rights in cross-border healthcare in a fair way, avoiding limitations to the application of the rules on reimbursement of cross-border healthcare, including the reimbursement of medicines, that could constitute a means of arbitrary discrimination or an unjustified obstacle to free movement;

57. Calls on the Commission to monitor and assess in an effective way the implementation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare in the Member States, and to plan and carry out a formal evaluation of this directive that includes complaints, infringements and all transposition measures;

58. Calls on the Commission and the Member States to foster R&D driven by patients' unmet needs, such as by researching new antimicrobials, coordinating public resources for healthcare research in an effective and efficient manner, and promoting the social responsibility of the pharmaceutical sector;

59. Calls on the Member States to build on the example of existing initiatives in the EU to place negative incentives for marketing expenditures by the pharmaceutical industry, such as a contribution system towards an innovation fund aimed at promoting independent research in areas of interest to national health services that are insufficiently addressed by commercial research (e.g. AMR) and to patient populations normally excluded by clinical studies, such as children, pregnant women and the elderly;

60. Highlights the threat of growing antimicrobial resistance and the urgency of the threats of AMR recently recognised by the UN; calls on the Commission to increase its actions to combat AMR, to promote R&D in this area, and to present a new and comprehensive EU Action Plan based on the 'One Health' approach;

61. Acknowledges that the incentives put forward by the Paediatric Medicines Regulation have not proved effective in driving innovation in medicines for children, namely in the fields of oncology and neonatology; calls on the Commission to examine existing obstacles and to propose measures to promote advancement in this area;

62. Calls on the Commission to promote initiatives for guiding public and private-sector

research towards bringing out innovative medicines for curing childhood illnesses;

63. Calls on the Commission to begin immediate work on the report required under Article 50 of the Paediatric Medicines Regulation, and to amend the legislation to address the lack of innovation in paediatric oncology treatments, by revising the criteria for allowing a Paediatric Investigation Plan (PIP) waiver and by ensuring that PIPs are implemented early in a drug's development, so that children are not waiting longer than necessary for access to innovative new treatments;

64. Calls on the Commission to promote public and private-sector research into medicines for female patients, to remedy gender inequality in research and development and to allow all citizens to benefit from fairer access to medicines;

65. Urges the Commission and the Member States to adopt strategic plans to ensure access to life-saving medicines; calls, in this regard, for the coordination of a plan to eradicate hepatitis C in the EU using tools such as European joint procurement;

66. Calls for the framework conditions in the areas of research and medicine policy to be established in a way that promotes innovation, particularly against diseases, such as cancer, that cannot yet be treated to a satisfactory degree;

67. Calls on the Commission to take further action to foster the development of, and patient access to, ATMPs;

68. Calls on the Commission to analyse the overall impact of IP on innovation on, and on patient access to, medicines, by means of a thorough and objective study, as requested by the Council in conclusions of 17 June 2016, and, in particular, to analyse in this study the impact of supplementary protection certificates (SPCs), data exclusivity and market exclusivity on the quality of innovation and competition;

69. Calls on the Commission to evaluate the implementation of the regulatory framework for orphan medicines (especially as regards the concept of unmet medical need, how this concept is interpreted and what criteria need to be fulfilled in order to identify unmet medical need), to provide guidance on priority unmet medical need, to evaluate existing incentive schemes to facilitate the development of effective, safe and affordable medicines for rare diseases compared to the best available alternative, to promote the European register of rare diseases and reference centres, and to ensure the legislation is correctly implemented;

70. Welcomes the pharmacovigilance legislation of 2010 and 2012; calls on the Commission, the EMA and the Member States to continue the monitoring and public reporting of the implementation of the pharmacovigilance legislation, and to guarantee post-authorisation assessments of the effectiveness and adverse effects of medicines;

71. Calls on the Commission to collaborate with the EMA, and with stakeholders, with a view to introducing a Code of Practice for mandatory reporting of adverse events and of outcomes for off-label use of medicines, and to ensuring patients' registries in order to strengthen the evidence base and mitigate risks for patients;

72. Calls on the Commission to promote open data in research on medicines where public

funding is involved, and to encourage conditions such as affordable pricing and non-exclusivity, or co-ownership of IP for projects funded by EU public grants such as Horizon 2020 and IMI;

73. Calls on the Commission to promote ethical behaviour and transparency in the pharmaceutical sector, especially regarding clinical trials and the real cost of R&D, in the authorisation and assessment of innovation procedure;

74. Notes the use of adaptive pathways to promote faster access to medicines for patients; underlines the higher degree of uncertainty regarding the safety and effectiveness of a new medicine when it enters the market; highlights the concern expressed by healthcare professionals, civil society organisations and regulators regarding adaptive pathways; stresses the crucial importance of the proper implementation of the post-marketing surveillance system; considers that adaptive pathways should be restricted to specific cases of high unmet medical need, and calls on the Commission and the EMA to put in place guidelines to ensure patient safety;

75. Calls on the Commission to guarantee a thorough assessment of quality, safety and efficacy in any fast-track approval process, and to ensure that such approvals are made possible by means of conditional authorisation, and only in exceptional circumstances where a clear unmet medical need has been identified, and to ensure that a transparent and accountable post-authorisation process to monitor safety, quality and efficacy is in place, as well as sanctions for non-compliance;

76. Calls on the Commission and the Member States to set up a framework to promote, guarantee and reinforce the competitiveness and use of generic and biosimilar medicines, guaranteeing their faster entry onto the market and monitoring unfair practices in accordance with Articles 101 and 102 TFEU, and to present a biannual report in this regard; calls as well on the Commission to monitor patent settlement agreements between originator and generic industry that may be misused to restrict the market entry of generics;

77. Calls on the Commission to continue and, where possible, to intensify the monitoring and investigation of potential cases of market abuse, including so-called ‘pay for delay’, excessive pricing and other forms of market restriction specifically relevant to the pharmaceutical companies operating within the EU, in accordance with Articles 101 and 102 TFEU;

78. Calls on the Commission to introduce an 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 countries and LDCs, and on increasing manufacturing and R&D in the EU, creating new jobs and stimulating economic growth;

79. Calls on the Commission to observe and reinforce the EU competition legislation and its competencies on the pharmaceutical market in order to counter abuse and promote fair prices for patients;

80. Calls on the Commission to enhance dialogue on unmet medical needs between all relevant stakeholders, patients, healthcare professionals, regulators, HTA bodies, payers and developers throughout the life spans of medicines;

81. Calls on the Commission to propose legislation on a European system for health technology assessment as soon as possible, to harmonise transparent HTA criteria in order to assess the added therapeutic value of medicines compared with the best available alternative taking into account the level of innovation and value for the patients among others, to introduce compulsory relative effectiveness assessments at EU level as a first step for new medicines, and to put in place a European classification system to chart their therapeutic added value level, using an independent and transparent procedure that avoids conflicts of interests;

82. Calls on the Council to increase cooperation between the Member States as regards price-setting procedures, in order that they may share information about, in particular, negotiation agreements and good practices, and avoid unnecessary administrative requirements and delays; calls on the Commission and the Council to analyse the clinical, economic and social criteria that some national HTA agencies already apply, while respecting the competences of the Member States;

83. Calls on the Commission and the Members States to agree on a common definition of ‘added therapeutic value of medicines’, with the participation of expert representatives from the Member States; notes in this regard the definition of ‘added therapeutic value’ used for paediatric medicines;

84. Calls on the Commission and the Member States to identify and/or develop frameworks, structures and methodologies to meaningfully incorporate patient evidence at all stages of the medicines R&D cycle, from early dialogue to regulatory approval, HTA, relative effectiveness assessments, and pricing and reimbursement decision-making, with the involvement of patients and their representative organisations;

85. Calls on the Commission and the Member States to promote major public-funded investment in research based on unmet medical needs, to ensure the public a health return on public investment, and to introduce conditional funding based on non-exclusive licencing and affordable medicines;

86. Calls on the Council to promote rational use of medicines across the EU, promoting campaigns and educational programmes aimed at making citizens aware of the rational use of medicines, with the goal of avoiding overconsumption, in particular of antibiotics, and promoting the use of prescriptions by active principles by healthcare professionals and the generic medicines administration;

87. Calls on the Member States to ensure accessibility of pharmacies, including their density in both urban and rural areas, professional staff number, appropriate opening hours, qualitative advice and counselling service;

88. Calls on the Commission and the Council to develop measures that ensure affordable patient access to medicines, and benefit to society, whilst avoiding any unacceptable impact on healthcare budgets, to employ different measures, such as horizon scanning, early dialogue, innovative pricing models, voluntary joint procurements and voluntary

cooperation in price negotiations, as is the case in the initiative between the Benelux countries and Austria, and to explore the numerous tools based on delinkage mechanisms for neglected areas of research such as AMR and poverty-related diseases;

89. Calls on the Commission to define with all relevant stakeholders how the most advantageous economic tender (MEAT) criterion – as described in the Public Procurement Directive, and which does not imply only the lower cost criteria – could best apply to medicines tenders in hospitals at national level, in order to enable a sustainable and responsible supply of medicines; encourages the Member States to transpose into their national legislation, in the best way, the most economic advantageous tender criterion for medicinal products;

90. Calls on the Commission and the Member States to launch a high-level strategic dialogue with all the relevant stakeholders, together with representatives of the Commission, Parliament, the Member States, patient organisations, paying agencies, healthcare professionals, and representatives from the academic and scientific world as well as from industry, on current and future developments in the pharmaceutical system in the EU, with the aim of establishing short-, medium- and long-term holistic strategies for ensuring access to medicines and for the sustainability of healthcare systems and a competitive pharmaceutical industry, leading to affordable prices and faster access to medicines for patients;

91. Calls on the Commission and the Council to define clear rules on incompatibility, conflicts of interest and transparency in the EU institutions and for experts involved in issues related to medicines; calls on the experts involved in the authorisation process to publish their CVs and to sign declarations of absence of conflict of interest;

92. Calls on the Commission and national antitrust authorities to monitor unfair practices with a view to protecting consumers from artificially high prices on medicines;

93. Calls on the Commission and the Court of Justice of the European Union to clarify, in accordance with Article 102 TFEU, what constitutes an abuse of a dominant position by charging high prices;

94. Calls on the Commission and the Member States to make use of the flexibilities under the WTO TRIPS agreement and to coordinate and clarify their use when necessary;

95. Calls on the Council and the Commission fully to safeguard the practicability of biomedical innovation models other than patent-based intellectual property regimes in international trade negotiations;

96. Calls on the Commission to submit a report, at least every five years, to the Council and to Parliament on access to medicines in the EU, and to report more regularly in cases of exceptional problems regarding access to medicines;

97. Calls on the Commission to recommend measures to improve the rate of approval of novel therapies and the supply of these to patients;

98. Calls on the Commission to promote the importance of having the same medicine composition across the EU;

99. Calls on the Commission and the Council to formulate a better definition of the concept – and analyse the causes – of shortages of medicines, and, in this regard, to assess the impact of parallel trade and supply quotas, to establish and update together with the Member States, the EMA and relevant stakeholders a list of essential medicines which are short of supply, using the WHO list as a reference, to monitor compliance with Article 81 of Directive 2001/83/EU on shortages of supply, to explore mechanisms to address the withdrawal of effective medicines from the market purely for commercial reasons, and to take actions to remedy these shortages;

100. Calls on the Commission and Council to establish a mechanism whereby medicine shortages across the EU can be reported upon on an annual basis;

101. Calls on the Commission and Council to review the statutory basis of the EMA, and to give consideration to enhancing its remit to coordinate pan-European activity aiming at tackling medicines shortages in the Member States;

102. Stresses that building strong surveillance and delivery systems at all levels, from community to district, provincial and national, and supported by high-quality laboratory services and strong logistical systems, could make access to medicines more feasible, while the transfer of health-related technologies (through licence agreements, and the provision of information, know-how and performance skills to technical materials and equipment) to developing countries can enable recipient countries to produce the product locally, and may result in increased access to the product and improved health;

103. Calls on the Commission and the Member States to develop a single eHealth and mHealth road map, including, in particular, the development and valorisation of pilot projects at national level, the modernisation of the reimbursement models stimulating a shift towards health outcomes-driven healthcare systems and the definition of incentives to stimulate the healthcare community to engage in this digital revolution, and to enhance education of healthcare professionals, patients and all relevant stakeholders in order to enable their empowerment;

104. Encourages the Member States to evaluate healthcare pathways and policies with a view to improving patient outcomes and the financial sustainability of the system, in particular by fostering digital solutions to improve healthcare delivery to patients and to identify waste of resources;

105. Urges the EU to step up efforts to improve developing countries' capacities and help them design working health systems that aim at improving access to services, particularly for vulnerable communities;

106. Stresses that the ongoing REFIT review of the EU Tiered Pricing Regulation should aim at further promoting lower prices in developing countries, and calls on the EU to open a broader and transparent discussion on pricing regulation and strategies that ensure access to quality and affordable medicines; recalls that tiered pricing does not necessarily lead to affordability, and that it is contrary to experience showing that robust generic competition and technology transfers result in lower prices;

107. Urges the EU to step up its support of global programmes and initiatives promoting access to medicines in developing countries, as these programmes have been

instrumental in advancing health goals and greatly improved access to medicines and vaccines;

Intellectual Property (IP) and Research and Development (R&D)

108. Recalls that IP rights allow a period of exclusivity that needs carefully and effectively to be regulated, monitored and implemented by the competent authorities with a view to avoiding conflict with the fundamental human right to health protection while promoting quality innovation and competitiveness; emphasises that the European Patent Office (EPO) and the Member States should only grant patents on medicinal products that strictly fulfil the patentability requirements of novelty, inventive step and industrial applicability, as enshrined in the European Patent Convention;

109. Emphasises that, while some new medicines are examples of breakthrough innovations, other new medicines demonstrate insufficient therapeutic added value to be deemed genuine innovations; emphasises that the repurposing and reformulation of known molecules, and the development of new medicines for the same indication ("me-too" substances), should be assessed carefully, especially as regards their added therapeutic value; measurable benefits should be demonstrated and the patentability requirements of novelty, inventive step and industrial applicability should be strictly fulfilled; warns against the potential misuse of IP protection rules allowing the ‘evergreening’ of patent rights and avoidance of competition;

110. Acknowledges the positive impact of Regulation 141/2000/EC on the development of orphan medicines, which has enabled a number of innovative products for patients deprived of treatment to be placed on the market; notes the concerns surrounding the possible incorrect application of orphan medicinal products designation criteria and the possible effect of this on the growing number of orphan medicines authorisations; recognises that orphan medicines may also be used off-label, or repurposed and authorised for additional indications allowing for increased sales; calls on the Commission to ensure balanced incentives without discouraging innovation in this area; stresses that the provisions in the orphan medicinal products regulation should only be applicable if all the relevant criteria are fulfilled;

111. Notes the fact that the WTO TRIPS agreement provides flexibilities to patent rights, such as compulsory licensing, which have effectively brought prices down; notes that these flexibilities can be used as an effective tool in exceptional circumstances established by the law of each WTO member to address public health problems, in order to be able to provide essential medicines at affordable prices under domestic public health programmes and to protect and promote public health;

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112. Instructs its President to forward this resolution to the Council, the Commission, and the governments and parliaments of the Member States.

EXPLANATORY STATEMENT

The pharmaceutical system we currently have in the developed world dates back to the 1970s, when it was set up with the principal aim of improving and ensuring patients' health care safety. This was following the 'thalidomide tragedy', one of the deciding factors behind the creation of the EU's pharmacovigilance system.

In the development of the current pharmaceutical market, the World Trade Organisation greatly encouraged the inclusion of medicines in the patent system and the protection of intellectual property rights in the industrial sector in connection with the development of new drugs.

Intellectual property rights are recognised by Article 17 of the Charter of Fundamental Rights, which aims to guarantee investors/researchers a return on their investments, thus safeguarding, promoting and stimulating innovation and research for the benefit of society.

The protection of intellectual property and the inclusion of medicines in the patent system gave rise to changes in the pharmaceutical market which, in recent decades, has become one of the most lucrative in the world, accounting for 1.5% of the GDP of OECD countries.

However, the pharmaceutical market differs significantly from other markets in that medicines cannot be considered in the same way as other products, since the protection of intellectual property in this market could conflict with the fundamental right to health protection whereby governments must guarantee access to medicines.

Article 35 of the Charter of Fundamental Rights on 'Health protection' provides that 'everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices'. It also provides that a high level of human health protection must be ensured in the definition and implementation of all EU policies and activities.

A number of parliamentary resolutions and Council conclusions have drawn attention to the specific nature of the pharmaceutical market, highlighting the need for debate and for measures to be taken in this regard.

The pharmaceutical market in Europe has generally faced high levels of safety regulation but looser control over financial matters and innovation quality. This can be seen in the way the pharmaceutical industry decides which research areas to prioritise: it bases its decisions on the size of the market, whilst setting the price based on the market value, and choosing the market according to the highest price that the buyer is willing to pay and on the greatest financial gain possible.

This practice has called into question the sustainability of health care systems and provoked a reaction from health care authorities, which are advocating the rebalancing of public and private interests.

In turn, other problems have been detected in the market which call the current system into question. Some of the most serious problems are the shortages of essential medicines both outside and within the EU; the fact that the research priorities are profit-oriented rather than patient-oriented; and the high cost of 'innovative' medicines, which, paradoxically, for the most

part fail to produce a real added value and are in fact merely modifications of molecules that already exist.

The prices of new medicines have increased during the past few decades to the point of being unaffordable for many European citizens and of creating an unsustainable situation for health care systems. This can be seen in the fact that, in Europe, 20% of Member States' average health budgets is spent on medicines.

Another factor distorting the drugs market—and one which must be addressed—is generic entry, since these drugs are one of the main ways of increasing competitiveness. However, misusing and abusing the system of intellectual property leads to a large number of litigation cases which delay a generic drug's entry onto the market, as well as many strategies and ploys whereby companies reach agreements aimed at achieving this purpose.

Concerning the impact of intellectual property on innovation, there is still not much information available. Nonetheless, the flexibility of complementary patent extensions allows small changes made to the product to be patented in order to extend the protection of the drug to the detriment of the search for new products. In turn, this kind of incentive has led to the promotion of research into rare diseases, with more medicines being authorised with no evidence-based added value or proven efficiency but which are normally accompanied by high prices.

The individual Member States and the Commission have taken timid measures without any kind of coordination, which has fragmented the market even more and generated inequality in access to medicines for European citizens. Likewise, they have missed the opportunity to achieve greater efficiency.

In this context, the ageing population, the emergence of new and expensive technologies and the threat posed by the economic crisis to the sustainability of health care systems, which have failed to guarantee access to medicines such as Sovaldi for hepatitis C in many countries in Europe, call for EU-wide debate and a corresponding parliamentary initiative.

The pharmaceutical industry is one of the most competitive sectors in Europe with a 20% return on investment, generating 800 000 jobs and producing an output of approximately EUR 200 billion each year. However, it is up against big competitors like the USA and the Asian market, which calls for the implementation of strategies—innovation being a key one—to improve its competitiveness.

Thus, after being in place for four decades, the system needs to be reviewed, as does its regulation, to strike a balance between public and private interests, the sustainability of health care systems and the right everyone has to health protection, guaranteeing research incentives as well as individuals' interests and their right to better health care standards.

Given the multidisciplinarity of the subject and the diversity of the bodies responsible, there needs to be a review at a global level, since while the price-setting procedures and reimbursement systems are managed by the Member States, it is, for the most part, the EU institutions that are responsible for authorisation, competition law and research support.

Under this review, and with the aim of improving the system and guaranteeing access to medicines, a 'quality' standard should be applied, to guarantee innovation with a clear clinical,

social and economic added value, with quantifiable social and ethical limits and with active monitoring of competition.

Studying the impact of the intellectual property system as an incentive for innovation; greater transparency of research data and costs; greater public investment in research; improved regulation and mechanisms to monitor conflicts of interest; and patient-oriented research priorities, are other areas that need to be discussed and addressed at a European level.

Lastly, the fact should not be overlooked that the 21st century is characterised by the 'technological revolution' and research should be considered as the solution to society's problems and challenges and not as an obstacle, and definitely not as the root of new inequalities. All the Member States and EU institutions, as well as the private sector directly involved, should be aware of the role they have to play.

9.11.2016

OPINION OF THE COMMITTEE ON DEVELOPMENT

for the Committee on the Environment, Public Health and Food Safety

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

Rapporteur: Ignazio Corrao

SUGGESTIONS

The Committee on Development calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following suggestions into its motion for a resolution:

1. Notes that Article 25 of the Universal Declaration of Human Rights (UDHR) recognises the right of every person to a 'standard of living adequate for the health and well-being of himself and of his family' and that the Constitution of the World Health Organisation (WHO) states that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition; recalls, moreover, that Article 168 of the **Treaty on the Functioning of the European Union** (TFEU) states that a high level of human health protection must be ensured in the definition and implementation of all Union policies and activities;

2. Recalls the 2030 Agenda for Sustainable Development and Sustainable Development Goal (SDG) No 3 thereof entitled 'Ensure healthy lives and promote well-being for all at all ages' under which target 3b is to 'support research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries' and 'provide access to affordable essential medicines and vaccines'; considers that lifesaving medicines are not just consumer goods, and thus, should not be regulated as such; underlines that, each year, an estimated 100 million people fall into poverty because of health costs which are disproportionate to their incomes, and that target 3b cannot be achieved without efficient and effective investment in new improved prevention, treatment and diagnostic tools; emphasises that, according to the WHO, over one third of the world's population, with over 50 % in Africa, does not have access to safe, effective and affordable medicines, and that an increasing number of sick people in developing countries, especially in Central and South America, are forced to defend their claim to health rights through the courts;

3. Stresses that some of the barriers to accessing medicines in developing countries include the lack of proper national legislation, limited infrastructure, poor quality pharmaceuticals (which are harmful and foster drug resistance) and counterfeit pharmaceuticals (which are a crime against human safety), the lack of accurate diagnoses, resource constraints, weak pharmaceutical policies, poorly managed distribution and supply chains, insufficiently trained and a shortage of healthcare workers, unaffordable pricing, a lack of public healthcare systems and limited access to social protection schemes, lower education levels, lower incomes and limited access to information, as well as the difficulty in reaching access points in rural areas;

4. Considers that the lack of access to healthcare is the result of both a problem in access to care and access to treatment;

5. Stresses the need for consistency between all EU policies (global public health, development, research and trade) and underlines therefore that the issue of access to medicines in the developing world has to be seen in a broader context;

6. Urges the EU to step up efforts to improve developing countries' capacities and help them design working health systems that aim at improving access to services, particularly for vulnerable communities;

7. Stresses that building strong surveillance and delivery systems at all levels, from community to district, provincial and national, supported by high-quality laboratory services and strong logistical systems could make access to medicines more feasible, while the transfer of health-related technologies (through licence agreements, provision of information, know-how and performance skills, to technical materials and equipment) to developing countries can enable recipient countries to produce the product locally and may result in increased access to the product and improved health;

8. Highlights the fact that investment in health is a major driver of economic development and a key factor in social cohesion;

9. Observes that the EU's current biomedical R&D system based on intellectual property monopolies has revealed some limits to delivering accessibility for life saving medicines in the developing world and has not offered sufficient incentives for research and possibilities for knowledge transfer; notes with concern that, regarding medicines for diseases where there is no profitable market, patents are among the factors that hinder innovation; observes, moreover, that the EU has not received sufficient return on its public investment in biomedical R&D with regard to ownership of the outcome of research; calls therefore for the EU biomedical R&D system to be restructured in order for it to be capable of developing efficient policies on access to medicines, within the framework of the EU's development policy;

10. Underlines the key role played by public investments in R&D and highlights the importance of implementing measures to ensure a public health return on investments when EU funds are financing biomedical R&D, including the provision of conditions relating to public R&D funding that ensure biomedical research results in suitable and affordable medicines; calls on the EU to actively invest in R&D and to promote innovative practices and financing models in the pharmaceutical sector allowing access-oriented pricing strategies in developing countries; stresses that medical research should

focus on neglected and poverty-related diseases for which safe, effective, appropriate, affordable and easy-to-use medicines and vaccines should be developed and placed on the market;

11. Highlights the critical need to develop local capacities in developing countries in terms of pharmaceutical research in order to bridge the persisting research gap and medicines production through product-development public-private partnerships and the creation of open centres of research and production;

12. Recalls that the least developed countries (LDC) are the most affected by poverty-related diseases, especially HIV/AIDS, malaria, tuberculosis, diseases of the reproductive organs and infectious and skin diseases;

13. Acknowledges that the intellectual property system contributes to the development of new medicines and is therefore a tool to improve the availability of medicines; takes the view that the international intellectual property system must be consistent with international human rights law, public international law and public health requirements, and reflect in a balanced way the concerns of the least developed countries regarding access to medicines;

14. Draws attention to the Declaration on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and Public Health, adopted on 14 November 2001, which states that the TRIPS Agreement should be implemented and interpreted in a way that is good for public health – encouraging both access to existing medicines and the development of new ones; takes note in this regard of the decision of 6 November 2015 of the WTO TRIPS Council to extend the drug patent exemption for LDCs until January 2033;

15. Insists that international trade and investment agreements do not include provisions that interfere with a government's obligation to fulfil the right to health or that undermine the right of government to use TRIPS flexibilities in the WTO framework;

16. Welcomes among other tools, the option for voluntary licensing that allows the production of generic drugs with allowances and adapted remuneration for the originator at reduced prices; recalls that TRIPS allow compulsory licensing which enable developing countries to produce generics without consent of the originator, particularly in the event of a national emergency or other circumstances of extreme urgency;

17. Recognises the importance of, and supports competition in, generic medicines which can contribute to a broader access to medicines in low- and middle-income countries (LMICs) and makes for savings in the health sector; calls, in particular, for the EU and the Member States to support governments actively to protect and promote public health, as well as the public-private partnerships in their initiatives to promote access to medicines, in particular in developing countries, that use the available legal measures, including TRIPS safeguards and flexibilities (such as compulsory licencing provisions and parallel imports), in order to be able to provide essential medicines at affordable prices under their domestic public health programmes and to protect and promote public health;

18. Stresses that, without basic transparency of research and development costs for originator companies and information on the actual prices paid for medicines across the EU, fair pricing is difficult to determine; stresses equally that the results of clinical trials should be

accessible to researchers and the public; recalls the Commission's commitment to transparency of EU positions, specific legal proposals, and negotiating texts in the TTIP negotiations;

19. Stresses that the ongoing REFIT review of the EU Tiered Pricing Regulation should aim at further promoting lower prices in developing countries and calls on the EU to open a broader and transparent discussion on pricing regulation and strategies that ensure access to quality and affordable medicines; recalls that tiered pricing does not necessarily lead to affordability and is contrary to experience that shows that robust generic competition and technology transfers result in lower prices;

20. Urges the EU to step up its support to the global programmes and initiatives promoting access to medicines in developing countries, which have been instrumental in advancing health goals and greatly improved access to medicines and vaccines;

21. Highlights that women and children have less access to medicines in developing countries than adult men due to a lack of availability, accessibility, affordability and acceptability on account of discrimination based on cultural, religious or social factors, and poor-quality health facilities;

22. Recalls that healthcare systems and availability of medicines are subject to conflicts and emergencies and that the aim should be reaching people in need of health care when and where they need it; stresses the need for an international rapid emergency unit, coordinated between public and private actors to effectively prevent or respond to a possible outbreak;

23. Considering that tuberculosis has become the world's leading infectious killer and that the most dangerous form of the disease is the multi-drug resistant one, underlines the importance of tackling the emerging antimicrobial resistance crisis, including funding research and development for new tools for vaccines, diagnostics and treatment for tuberculosis, while ensuring sustainable and affordable access for those new tools to make sure no one is left behind;

RESULT OF FINAL VOTE IN COMMITTEE ASKED FOR OPINION

Date adopted	8.11.2016
Result of final vote	+: 22 –: 0 0: 2
Members present for the final vote	Nicolas Bay, Beatriz Becerra Basterrechea, Ignazio Corrao, Raymond Finch, Enrique Guerrero Salom, Maria Heubuch, György Hölvényi, Teresa Jiménez-Becerril Barrio, Arne Lietz, Linda McAvan, Norbert Neuser, Cristian Dan Preda, Elly Schlein, Eleni Theocharous, Paavo Väyrynen, Bogdan Brunon Wenta, Anna Záborská
Substitutes present for the final vote	Marina Albiol Guzmán, Agustín Díaz de Mera García Consuegra, Bernd Lucke, Paul Rübig, Judith Sargentini, Patrizia Toia
Substitutes under Rule 200(2) present for the final vote	Maria Grapini

18.11.2016

OPINION OF THE COMMITTEE ON LEGAL AFFAIRS

for the Committee on the Environment, Public Health and Food Safety

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

Rapporteur: Pascal Durand

SUGGESTIONS

The Committee on Legal Affairs calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following suggestions into its motion for a resolution:

A. whereas protection of health is a fundamental right enshrined in the European Convention on Human Rights and recognised in Article 35 of the Charter of Fundamental Rights of the European Union, under which everyone is guaranteed the right to access preventive and curative healthcare under the conditions established by national laws and practices; whereas, in accordance with Articles 6 and 168 of the Treaty on the Functioning of the European Union, promotion and protection of a high level of human health should be guaranteed in the definition and implementation of all EU policies and activities;

B. 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;

C. 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;

D. whereas, as a result inter alia of the economic crisis, EU Member States' public budgets, in particular for the sectors covering health expenditure, are under significant constraints;

E. whereas the WTO Doha Declaration on the TRIPS Agreement and Public Health recognises the important role of legal protection of intellectual property in the development of new medicines, while expressing concerns about its effects on prices;

F. whereas competition is an important factor in the overall balance of the pharmaceutical market and can lower costs, reduce expenditure on medicines and improve timely access for patients to affordable medicines, with higher quality standards being observed in the

research and development process;

G. 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;

H. 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;

I. 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;

J. 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;

1. Notes the fact that the WTO TRIPS Agreement provides flexibilities to patent rights, such as compulsory licensing, which have effectively brought prices down; notes that these flexibilities can be used as an effective tool in exceptional circumstances established by the law of each WTO member to address public health problems, and considers that, where duly justified, the mechanism for granting and issuing compulsory licences should be freed from discretionary judgement and bureaucratic constraints in order to encourage those countries that 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;

2. Considers that exclusive protection periods granted through patents are an important tool intended to promote innovation and the development of new medicines; acknowledges the importance of preventing cases of market abuse and disruption of drug trial periods, as well as the need to ensure access to necessary medicines at affordable prices and to guarantee the sustainability of national healthcare systems; observes, however, that when used abusively, the current EU biomedical R&D system based on exclusive protection periods granted to pharmaceuticals through patents or other mechanisms can hinder competition during those periods and lead to high prices;

3. Notes that awareness and monitoring are important functions of the competent authorities, and believes that improved awareness campaigns can serve as a tool to bring about better understanding of complex drug development processes on the part of both businesses and consumers;

4. Recalls that the Pharmaceutical Sector Inquiry Report carried out by the Commission in 2009 indicated that, among other factors, some companies' abusive practices in connection with patent claims have contributed to delays in the market entry of generic medicines and should be avoided;

5. Emphasises the importance of stronger competition law enforcement; asks the Commission to introduce tougher checks on possible cases of infringement of internal market and competition rules;

6. Calls on the Member States to cooperate fully and exchange information, expertise and best practices among themselves in order to prevent over-pricing of medicines and to ensure market access for generic products;

7. Calls on the Commission to assess the impact of intellectual-property-related incentives on biomedical innovation, to explore credible and effective alternatives to exclusive protections for the financing of medical R&D such as the numerous tools based on delinkage mechanisms; also calls on the Commission to assess the functioning of the applicable limitations to patent allocations and rights and to safeguard the right of countries to regulate and preserve policy space in order to guarantee universal access to medicines;

8. 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;

9. Calls on the Commission and the Member States to strike a balance between stimulating innovation, protecting innovators and ensuring that innovations are of maximum benefit to society;

10. Recalls that the European Patent Office (EPO) and the Member States should only 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, and should pay particular attention to 'evergreening' – the practice whereby slight modifications to existing products are patented as new inventions in order to perpetuate the patent and the privileges arising therefrom;

11. Calls on the Commission to ensure that all EU policies are consistent with, and beneficial for, access to affordable medicines in the EU and in low- and middle-income countries alike; asks the Commission, therefore, to encourage the 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 and anti-competitive practices;

12. Underlines the important role played by public investments in R&D, and calls on the Commission and the Member States 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 make a new proposal to amend Directive 89/105 in order to obtain more robust health systems based on transparent prices, to introduce best practices so as to encourage positive conditionality with the aim of promoting sharing and greater circulation of patents and, as provided by the law in force, to ensure public access to appropriate information on the safety and effectiveness of medicines;

13. 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.

RESULT OF FINAL VOTE IN COMMITTEE ASKED FOR OPINION

Date adopted	8.11.2016
Result of final vote	+: 20 –: 2 0: 0
Members present for the final vote	Joëlle Bergeron, Marie-Christine Boutonnet, Jean-Marie Cavada, Kostas Chrysogonos, Therese Comodini Cachia, Mady Delvaux, Rosa Estaràs Ferragut, Enrico Gasbarra, Mary Honeyball, Sajjad Karim, Gilles Lebreton, António Marinho e Pinto, Julia Reda, Evelyn Regner, Pavel Svoboda, Axel Voss, Tadeusz Zwiefka
Substitutes present for the final vote	Daniel Buda, Pascal Durand, Angel Dzhambazki, Stefano Maullu, Virginie Rozière

10.11.2016

OPINION OF THE COMMITTEE ON PETITIONS

for the Committee on the Environment, Public Health and Food Safety

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

Rapporteur: Eleonora Evi

SUGGESTIONS

The Committee on Petitions calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, on the basis of petitions received and in the light of the matters arising from them, to incorporate the following suggestions into its own-initiative report:

1. Believes that the opinions of European citizens voiced by petitioning the European Parliament are of fundamental importance and should be addressed by the European legislator as a matter of priority; points to the issues raised by the public concerning particularly the high cost, the lack of and restricted access to effective and affordable medicines, the impact of the economic crisis on patients' rights and Member States' healthcare systems owing to a significant increase in cuts to public investment in health, and the issues regarding marketing procedures, patents and intellectual property rights for medicinal products;

2. Calls on the Commission to make specific policy proposals and changes to EU legislation on intellectual property in order to step up EU competitiveness in regard to medicines through EU-manufactured or imported generic, affordable versions thereof;

3. Insists on the need for greater transparency concerning the cost of investment in pharmaceutical research, development and innovation, so as to know how much public money is invested in each research project and ensure that in the last analysis the public does not pay twice for the same product; urges the adoption of the measures needed to arrive at a model that will guarantee a return on this investment for public health services;

4. Points out that a high level of human health protection has to be ensured in the definition and implementation of all the Union's policies and activities, as required by Article 168 of the Treaty on the Functioning of the European Union (TFEU) and by Article 35 of the Charter of Fundamental Rights of the European Union; calls for

universal access to good quality, free public health services, equality, and for respect for the highest human rights standards to be ensured in the Member States' policies concerning healthcare systems and access to medicines, as a way of guaranteeing a high level of human health protection for the whole population;

5. Reiterates that the right to health is a human right recognised in both the Universal Declaration of Human Rights and the International Covenant on Economic, Social and Cultural Rights, and that this right concerns all Member States given that they have ratified international human rights treaties that recognise the right to health; points out that for this right to be guaranteed, access to medicine, among other factors, has to be ensured;

6. Recalls that Article 168(4) of the TFEU provides the EU with competences to guarantee that the authorisation of medicines ensures high standards of quality, safety and effectiveness; considers that the Commission should develop the principles of safety and efficiency to improve access to high quality medicines in a safe and equitable way;

7. Believes that a strategic breakthrough is needed in the area of disease prevention, as it can be considered a key factor in reducing the use of medicines and guaranteeing at the same time a high level of human health protection; calls on the EU and the Member States to reinforce legislation aimed at supporting sustainable food production and to take all necessary initiatives to promote healthy and safe habits such as healthy nutrition;

8. Deplores the fact that a large number of EU citizens do not have access to health care or medicines, meaning that their human rights are being violated; finds it intensely alarming that there are thousands of victims in the EU owing to lack of effective antibiotics, vaccines and treatments for rare diseases, and because they do not have access to or cannot pay the high cost of certain treatments; calls for a review of the incentives put in place to encourage research on 'orphan medicines' in order to determine whether they are successful, and calls for new incentives should this not be the case;

9. Calls on the Member States to implement Directive 2011/24/EU on the application of patients' rights in cross-border healthcare in a fair way, avoiding limitations to the application of the rules on reimbursement of cross-border healthcare, including the reimbursement of medicines, that could constitute a means of arbitrary discrimination or an unjustified obstacle to free movement;

10. Calls on the Commission to effectively monitor and assess the implementation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare in the Member States, and to plan and carry out a formal evaluation of this directive that includes complaints, infringements and all transposition measures;

11. Recognises as considerable obstacles to access to medicines the lack of affordability and availability of medicines, the impact of the financial crisis, the high price of medicines, the lack of research on certain diseases, the monopolies of companies in the market and all problems related to parallel trade in medicines in the EU;

12. Calls on the EU institutions and the Member States to take the utmost care to prevent parallel trade in pharmaceutical products in the most profitable markets, which is causing quotas to be established and a consequent shortage of many medicines, and thus creating extreme risks for the health of citizens, who in some cases are even forced to discontinue treatment;

13. Recalls the detrimentally high level of public dependency on the will of private companies to develop life-saving products, as highlighted in Petition No 0791/2009, where the Commission recalls in its reply that 'the pharmaceutical legislation of the EU foresees specific instruments as incentives for the development of innovative medicines, in particular data exclusivity for specific studies, or market exclusivity for certain medicinal products for rare diseases. Within this legal framework, pharmaceutical companies are free to choose which medicinal products they want to develop';

14. Highlights the negative impact of the austerity policies, which promote cuts in public investment and entail debt payment being given priority over all other items in national budgets; stresses that budgetary cuts invariably have negative health impacts on citizens and that action is therefore needed to ensure that no EU citizen, migrant or asylum seeker is prevented from being able to access medicines;

15. Calls on the Commission to continue assessing the functioning of the European pharmaceutical system in order to deliver data and proposals for solutions to ensure the sustainability of the European pharmaceutical system and Member States' health systems, as well as the development of new and innovative medicinal products;

16. Notes that austerity is undermining citizens' right to health in Europe, notably by Member States contravening the principle of non-regression with regard to their own health care policies and funding of health care systems;

17. Recognises the launch of the United Nations High-Level Panel on Access to Medicines as a global response to the need to address multifaceted issues in a holistic way;

18. Recognises the need to review patenting rules in order to improve access to medicines and incentivise research, including the possibility of adopting mandatory licences; recalls that the Innovative Medicines Initiative (IMI) contains no provision for the unpatentability of the results of publicly funded research; urges public policy makers to take proactive steps towards making generic and biosimilar medicines available in a timely manner to effectively lower costs and reduce overall expenditure on medicines, always taking into account the need to ensure the same beneficial effects, continuity of patient care and prevention of any risk of abuse or misuse of the regulatory framework;

19. Recalls that EU citizens finance at least 50 % of European pharmaceutical innovation through public participation in the Innovative Medicines Initiative (IMI);

20. Notes that Member States should enhance measures aimed at avoiding any conflicts of interest between producers and prescribers of medicines;

21. Calls on the Member States to support research and development (R&D) that focuses on the unmet medical needs of all citizens, and to guarantee non-exclusive licensing where

R&D is publicly funded and that access to medical advances in the European Union is non-discriminatory; emphasises the importance of further investments through the Horizon 2020 programme to develop innovative medicines and produce generic medicines at a price affordable for all European patients; calls on the Member States to make e-Health tools more effective, user-friendly and widely accepted;

22. Calls on the Commission to develop a European framework to provide reliable, timely, transparent, comparable and transferable information on the relative efficacy of health technologies to support Member States' decisions;

23. Believes that the EU must ensure that future international trade agreements do not undermine universal access to medicines and the principle of universal access to Member States' healthcare;

24. Invites the Member States, in cooperation with the Commission, to consider the possibility of the establishment of a pooled public platform for R&D financed by all Member States via a minimum contribution of 0.01 % of their GDP; considers that this platform should also be able to directly produce life-saving medicines in the EU in the event of a market failure being identified;

25. Emphasises that the Union has competence for taking action to support, coordinate and supplement the actions of the Member States to protect and improve human health;

26. Recognises the value of citizens' initiatives such as the European Charter of Patients' Rights, based on the Charter of Fundamental Rights of the European Union, and the European Patients' Rights Day celebrated every year on 18 April at local and national level in the Member States; invites the Commission to institutionalise the European Patients' Rights Day at EU level;

27. Calls for an emergency health recovery fund to be set up at EU level for people in the Member States who are suffering from pathologies such as hepatitis C or HIV/AIDS;

28. Emphasises its concern at the burgeoning increase in the price of medicines, for example 'Sovaldi' for the treatment of hepatitis C and medicines to treat rare and oncological diseases, recognising that this has been a determining factor for giving serious consideration to the real difficulty of guaranteeing access to medicines around the world, even in developed countries; notes with concern that the Commission's thematic analysis on health and health systems 2016 does not include any explicit recommendation on lowering the prices of medicines and strengthening the budgets for staff and infrastructure; calls on the Commission and the Member States to adopt measures based on the highest human rights standards in order to guarantee full availability and accessibility of all medicines; calls on the Commission to establish a plan to study and collect readily available and standardised data and statistics concerning access to medicines for EU citizens, focusing on the most vulnerable and disadvantaged social groups, including actions related to the early diagnosis, treatment and prevalence of hepatitis C in the EU;

29. Calls on the Member States to investigate the benefits of potential cooperation on lower costs of medicines for citizens; considers that an EU central purchasing body for

medicines needs to be set up in order to remove the differences that exist between Member States in terms of purchasing power when accessing medicines;

30. Supports the intention of the Member States to improve voluntary cooperation between the states and at EU level, especially in the area of pricing, reimbursements and information exchange;

31. Points to the conclusions of the informal Council meeting of healthcare ministers held in Milan on 22 and 23 September 2014 during the Italian Council Presidency, at which many Member States agreed on the need to make joint efforts to facilitate the sharing of best practices and enable swifter access for patients;

32. Calls on the Commission, in close cooperation with the Member States, to promote and facilitate greater public transparency, information and best practice sharing and cooperation in regard to pricing, reimbursement and procurement of medicines; calls for a new Transparency Directive to replace Directive 89/105/EEC with the aim of ensuring effective controls and full transparency on the procedures used to determine the prices and the reimbursement of medicinal products in the Member States;

33. Stresses that without full transparency of research and development costs to originator companies and information on the actual prices paid for medicines across Member States, any discussion on fair medicine prices remains highly problematic.

RESULT OF FINAL VOTE IN COMMITTEE ASKED FOR OPINION

Date adopted	9.11.2016
Result of final vote	+: 18 –: 10 0: 1
Members present for the final vote	Marina Albiol Guzmán, Margrete Auken, Beatriz Becerra Basterrechea, Soledad Cabezón Ruiz, Andrea Cozzolino, Pál Csáky, Miriam Dalli, Rosa Estaràs Ferragut, Eleonora Evi, Lidia Joanna Geringer de Oedenberg, Peter Jahr, Jude Kirton-Darling, Svetoslav Hristov Malinov, Notis Marias, Roberta Metsola, Marlene Mizzi, Julia Pitera, Sofia Sakorafa, Eleni Theocharous, Jarosław Wałęsa, Cecilia Wikström, Tatjana Ždanoka
Substitutes present for the final vote	Urszula Krupa, Demetris Papadakis, Ángela Vallina, Rainer Wieland
Substitutes under Rule 200(2) present for the final vote	Tiziana Beghin, Ernest Urtasun, Elżbieta Katarzyna Łukacijewska

RESULT OF FINAL VOTE IN COMMITTEE RESPONSIBLE

Date adopted	31.1.2017
Result of final vote	+: 59 –: 1 0: 2
Members present for the final vote	Marco Affronte, Margrete Auken, Zoltán Balczó, Simona Bonafè, Biljana Borzan, Paul Brannen, Soledad Cabezón Ruiz, Nessa Childers, Alberto Cirio, Mireille D'Ornano, Miriam Dalli, Angélique Delahaye, Mark Demesmaeker, Ian Duncan, Bas Eickhout, José Inácio Faria, Karl-Heinz Florenz, Francesc Gambús, Elisabetta Gardini, Gerben-Jan Gerbrandy, Jens Gieseke, Julie Girling, Sylvie Goddyn, Françoise Grossetête, Andrzej Grzyb, György Hölvényi, Anneli Jäätteenmäki, Benedek Jávor, Kateřina Konečná, Urszula Krupa, Giovanni La Via, Peter Liese, Norbert Lins, Valentinas Mazuronis, Susanne Melior, Miroslav Mikolášik, Gilles Pargneaux, Piernicola Pedicini, Pavel Poc, Julia Reid, Frédérique Ries, Daciana Octavia Sârbu, Renate Sommer, Claudiu Ciprian Tănăsescu, Estefanía Torres Martínez, Adina-Ioana Vălean, Jadwiga Wiśniewska, Damiano Zoffoli
Substitutes present for the final vote	Jørn Dohrmann, Herbert Dorfmann, Martin Häusling, Jan Huitema, Peter Jahr, Gesine Meissner, Gabriele Preuß, Christel Schaldemose, Bart Staes, Tibor Szanyi, Tiemo Wölken
Substitutes under Rule 200(2) present for the final vote	Inés Ayala Sender, Dieter-Lebrecht Koch, Inmaculada Rodríguez-Piñero Fernández