Amendment 1
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on behalf of the ENF Group

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

Motion for a resolution (Rule 170(3) of the Rules of Procedure) replacing non-legislative motion for a resolution A8-0040/2017

European Parliament resolution on EU options for improving access to medicines

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 systems¹,

– 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 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 (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

¹ OJ C 24, 22.1.2016, p. 119.
10 April 2014¹,

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

– 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 (A8-0000/2017),

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

A. whereas the Charter of Fundamental Rights of the European Union recognises the fundamental right of citizens to health and medical treatment²; whereas the cost of care for migrants and undocumented immigrants, including the free delivery of medicines, represents an increasing burden on Member State budgets;

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;

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 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 about 80 % of the active substances of generics are imported from third countries such as India and China, where the concentration of plants and effluents leads to environmental pollution and antimicrobial resistance, posing a major threat to global health and to the national health sovereignty of Member States in the event of a shortage

² 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.
of active substances;

H. 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; whereas being a member of the European Union leads to healthcare budget cuts and prevents Member States from taking sovereign decisions on their national health care systems;

I. 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;

J. 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;

K. 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;

L. whereas the EU has failed to introduce incentives to promote research in areas such as rare diseases and paediatric diseases; whereas the Orphan Medicinal Products Regulation has provided a framework for promoting research on orphan medicines, but there are concerns about its implementation;

M. 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;

N. 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);

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

P. 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;

Q. 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 highlighting the EU’s incapacity to solve the problems caused by its own policy, such as relocations;

R. 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;

S. whereas the aim of intellectual property is to benefit society and promote innovation, as well as to protect companies and inventors’ investments, and whereas there is concern about the abuse/misuse thereof;

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

U. 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;

V. 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; whereas counterfeit medicines are mostly produced in third countries and can easily be dispatched across the EU thanks to the lack of border controls between Member States;

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

X. 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 pricing is set with respect to the indications mentioned in the original marketing authorisations, which define a precise market size;

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

1. 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 but that this right does not imply that access to care systems shall be free of charge;

2. 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;

3. 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;

4. Stresses that the issue of access to medicines in the developing world must be seen in a broader context;

5. 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 national regulatory frameworks must facilitate the best possible outcome for patients and public interest;

6. 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;

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

8. Underlines the role of European research projects and SMEs in improving access to medicines at the EU level;

9. Recalls that the European pharmaceutical industry is one of the most competitive industries in the world; 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;

10. 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;
11. 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;

12. 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;

13. 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;

14. 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;

15. 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

16. 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;

17. 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;

18. 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; stresses that delivery of authorisation for biosimilar medicines is currently a task of the EMA, and that the future of this Agency is somewhat uncertain;

19. 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;

20. 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

21. 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;

22. 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;

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

24. 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;

25. 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;

26. 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;

27. 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;

28. 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;

29. Believes that the real therapeutic added value of a medicine, the social impact, the cost benefit, the budget impact, the efforts made during research and development and
testing to remove tests on animals and vivisection, and the efficiency for the public health system, all need to be taken into account when determining the pricing and reimbursement procedures for medicines;

30. 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 Member States to support sustainable or organic food production, and to take all necessary initiatives to promote healthy and safe habits such as healthy nutrition;

**Member States cooperation**

31. 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;

32. 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;

33. Highlights the EU procedure for joint procurement of medicines used for the acquisition of vaccines in accordance with Decision No 1082/2013/EU; encourages Member States to make full use of this tool;

34. 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;

35. 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;

36. 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**

37. Calls for national 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 national 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; calls for respect of any sovereign national measures, such as those giving priority to reimbursement of care and medicines to national or documented citizens;
38. Notes that the repurposing of existing drugs for new indications can be accompanied by a price increase; invites the Member States and companies to consider that any new authorised indication ought to lead to a revaluation of the original pricing, taking into account the cost of R&D efforts and the increase in the targeted market;

39. 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;

40. Invites 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;

41. Highlights the threat of growing antimicrobial resistance and the urgency of the threats of AMR recently recognised by the UN; underlines that a growing number of infections may be left untreated due to the increase in antimicrobial resistance; calls on the Commission to increase its actions to combat AMR, to undertake a comprehensive analysis of the causes of the said increase in antimicrobial resistance and to promote public and private R&D in this area, with a particular focus on finding new antimicrobial agents and on alternative and innovative therapeutic approaches, such as the ongoing research projects on phage therapies, and to present a new and comprehensive EU Action Plan based on the ‘One Health’ approach;

42. 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;

43. 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;

44. Invites the Member States to analyse the overall impact of IP on innovation on, and on patient access to, medicines, by means of a thorough and objective study 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;

45. Invites the Member States to improve national pharmacovigilance systems, and to guarantee post-authorisation assessments of the effectiveness and adverse effects of medicines;

46. Invites the Member States 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;

47. Invites the Member States to evaluate the promotion of domestic production of generic and biosimilar medicines, for instance through financial incentives such as selective reimbursements;
48. Invites the Member States 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;

49. Invites the Member States to increase cooperation 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;

50. Invites 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,

51. Invites the Member States to promote rational use of medicines, with the goal of avoiding overconsumption, in particular of antibiotics;

52. 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;

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

54. Invites the Member States to recommend measures to improve the rate of approval of novel therapies and the supply of these to patients;

55. Invites the Member States to establish a mechanism whereby medicine shortages across the EU can be reported upon on an annual basis;

56. Insists that it is essential for Member States to maintain their domestic medicine agencies so as to ensure an adequate level of scientific expertise in every Member State;

57. 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;

58. 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;

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

59. 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;

60. 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;

61. Notes that compulsory licensing should be allowed only for a limited period of time and restricted to exceptional circumstances such as a public health crisis, and that the generic medicine produced through such licensing should be strictly similar to the patented versions, namely with respect to the adjuvants;

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

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