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DRAFT 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	3
EXPLANATORY STATEMENT	8

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 systems¹,
 - having regard to the final report of the Commission's Pharmaceutical Sector Inquiry (SEC(2009)0952),
 - having regard to the Commission's 6th Report on the Monitoring of Patent Settlements in the pharmaceutical sector,
 - having regard to the antitrust procedure, Case AT.39612 – Perindopril (Servier), and to paragraphs 249 and 250 of the judgment of the Court of Justice of 14 February 1978 in Case 27/76 on excessive prices,
 - 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 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 Employment and Social Affairs, the Committee on Legal Affairs and the Committee on Petitions (A8-0000/2016),
- A. whereas the Charter of Fundamental Rights of the European Union recognises the fundamental right of citizens to health and medical treatment²;
- B. whereas public health systems are crucial to guarantee universal access to health care;
- C. whereas the prices of new medicines have increased during the past few decades to the point of being unaffordable for many European citizens;
- D. whereas in addition to high prices, other barriers to access to medicines include shortages of essential medicines, the poor connection between clinical needs and research, unjustified administrative procedures, rigid patent rules and budget restrictions;
- E. whereas the aim of intellectual property is to benefit society, guaranteeing investment returns to promote innovation, and whereas there is concern about the abuse/misuse

¹ OJ C 24, 22.1.2016, p. 119.

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.

thereof;

- F. whereas the Commission has had to introduce incentives to promote research in areas such as rare diseases, and whereas 25 000 people die each year in the EU owing to lack of access to adequate antimicrobial drugs;
- G. whereas the prices of medicines are usually negotiated by means of bilateral and confidential negotiations between the pharmaceutical industry and Member States;
- H. whereas the majority of Member States have their own health care assessment agencies with their own standards;
- I. whereas the entry of generics onto the market is an important mechanism to reduce prices, and whereas there are clear concerns about the strategies to delay this entry;
- J. whereas under Article 168 of the Treaty on the Functioning of the European Union (TFEU), Parliament and the Council can, in order to meet common safety concerns, adopt measures setting high standards of quality and safety for medicinal products;

Pharmaceutical market

- 1. Recalls that the EU pharmaceutical industry is one of the most competitive industries in Europe and that quality innovation is key to improving its competitiveness;
- 2. Regrets that the research priorities of the pharmaceutical industry are profit-oriented rather than patient-oriented;
- 3. Stresses that transparency of the cost of development and clinical trials is crucial in order to set a fair price;
- 4. Stresses that the interests of the pharmaceutical industry favour short trials and fast access to the market;

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

- 5. Recalls that IP rights allow a legal monopoly, which needs to be carefully regulated to avoid conflict with the right to health protection and to promote quality of innovation and competitiveness;
- 6. Emphasises that most medicines are not examples of genuine innovation, but often ‘me-too’ or ‘evergreening’ products, which are permitted notably by complementary patent extensions;
- 7. Stresses that the high level of public funds used for R&D is not reflected in the pricing;

Competition

- 8. Deplores the large number of litigation cases aiming to delay generic entry;
- 9. Stresses that better regulation will promote competitiveness; also recognises the importance and effectiveness of antitrust tools against anti-competitive behaviours such

as the abuse or misuse of patent systems and of the system for authorisation of medicines, in violation of Articles 101 and/or 102 of the TFEU;

Pricing and transparency

10. Stresses that most national assessment agencies are already using clinical, economic and social benefit criteria to assess new drugs in terms of pricing and reimbursement;
11. Stresses the importance of assessing the real therapeutic evidence-based added value of new medicines compared to the best available alternative;
12. Believes that the real therapeutic added value of a medicine, the social impact, the cost benefit, the budget impact and efficiency for the public health system all need to be taken into account when determining the pricing and reimbursement procedures for medicines;
13. Believes that a fair price should cover the cost of the drug development and production, plus a margin of profit;

EU competences and cooperation

14. Welcomes initiatives such as the Innovative Medicines Initiative (IMI), but regrets that only a few of them are entirely public;
15. Recalls that transparency in all EU and national institutions and agencies is crucial, and that experts involved in the authorisation process should have no conflicts of interest;
16. Highlights the European procedure for joint procurement of medicines used for the acquisition of vaccines in accordance with Decision No 1082/2013/EU;

Recommendations

17. Calls for EU-wide measures to guarantee the right of patients to universal, affordable, effective, safe and timely access to essential and innovative therapies, and to guarantee the sustainability of EU public health care systems;
18. Calls for EU-wide measures on the pharmaceutical market to reinforce the negotiation capacities of Member States in order to achieve fair prices for medicines;
19. Calls on the Commission to promote R&D driven by patients' needs, while fostering social responsibility in the pharmaceutical sector, by setting up an EU public platform for R&D funded by contributions from profits made by the pharmaceutical industry through sales to public health systems; calls for transparency on the costs of R&D;
20. Calls on the Commission to analyse the overall impact of IP in promoting innovation, especially the impact of supplementary protection certificates (SPCs), data exclusivity or market exclusivity on competitiveness and quality of innovation, and to set strict limits on these practices;
21. Calls on the Commission to promote open data in private research, especially where public funding is involved, and to establish conditions such as affordable pricing and

non-exclusivity, or co-ownership of IP for projects funded by EU public grants such as Horizon 2020;

22. Calls on the Commission to review the regulatory framework for orphan medicines, to define clearly the concept of unmet medical needs, to assess the impact of incentives to develop effective, safe and affordable drugs compared to the best available alternative and to promote the European register of rare diseases and reference centres;
23. Calls on the Commission to guarantee safety and efficacy in any fast-track approval process and to introduce the concept of conditional authorisation based on effectiveness;
24. Calls on the Commission to set up a framework to promote, guarantee and reinforce the competitiveness of generic medicines, guaranteeing their faster entry onto the market and monitoring unfair practices in accordance with Articles 101 and 102 of the TFEU, and to present a biannual report in this regard;
25. Calls on the Commission to propose legislation on a European system for health technology assessment as soon as possible, and to assess added-value medicines compared with the best available alternative; also calls on the Commission to harmonise pricing and reimbursement criteria to take into account the level of innovation and the social and economic cost-benefit analysis, and to put in place a European classification on the added value level of medicines;
26. Calls on the Commission and the Member States to promote major publicly funded investment in research based on medical needs, and to introduce conditional funding based on affordable end pricing and non-exclusive licencing;
27. Calls on the Council to increase cooperation between the Member States as regards price-setting procedures, in order to share information about prices, reimbursement, negotiation agreements and good practices and to avoid unnecessary administrative requirements and delays;
28. Calls on the Council to promote rational use of medicines across the EU;
29. Calls on the Commission and the Council to explore new measures to control prices, such as horizontal scanning and coordinating joint procurements;
30. 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;
31. 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;
32. Calls on the Commission and the Court of Justice of the European Union to clarify, in accordance with Article 102 of the TFEU, what constitutes an abuse of a dominant position due to high prices;
33. 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;

34. Calls on the Commission to examine and compare the prices of medicines in the EU and to present an annual report to Parliament in this regard;
35. Calls for the creation of a European Parliament task force to monitor the prices of medicines;
36. Calls on the Commission to analyse the causes of shortages, to establish a list of essential medicines and monitor compliance with Article 81 of Directive 2001/83/EU on shortages of supply, and to promote the supply of generics;
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37. 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 multidisciplinary nature 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.