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Committee on Petitions

2016/2057(INI)

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