European Parliament
2019-2024

Committee on the Environment, Public Health and Food Safety

2021/2013(INI)

26.4.2021

DRAFT REPORT

on a pharmaceutical strategy for Europe
(2021/2013(INI))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Dolors Montserrat

Rapporteur for the opinion (*):
Marc Botenga, Committee on Industry, Research and Energy

(*) Associated committees – Rule 57 of the Rules of Procedure

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MOTION FOR A EUROPEAN PARLIAMENT RESOLUTION

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The European Parliament,

– having regard to Article 168 of the Treaty on the Functioning of the European Union,

– having regard to the Commission communication of 11 November 2020 entitled 'Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats' (COM(2020)0724) and accompanying legislative proposals[1],

– having regard to the Commission communication of 25 November 2020 on a Pharmaceutical Strategy for Europe (COM(2020)0761),

– having regard to the Commission communication of 17 June 2020 on an EU Strategy for COVID-19 vaccines (COM(2020)0245),

– having regard to the Commission communication of 3 February 2021 on Europe's Beating Cancer Plan (COM(2021)0044),

– having regard to the Council conclusions of 18 December 2020 on COVID-19 lessons learned in health[2],

– having regard to its resolution of 17 September 2020 entitled 'the shortage of medicines – how to address an emerging problem'[3],

– having regard to its resolution of 17 September 2020 on a strategic approach to pharmaceuticals in the environment[4],

– having regard to Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019 amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products[5],

– having regard to Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation

[1] Proposal for a regulation of the European Parliament and of the Council of 11 November 2020 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (COM(2020)0725); proposal for a regulation of the European Parliament and of the Council of 11 November 2020 amending Regulation (EC) No 851/2004 establishing a European Centre for disease prevention and control (COM(2020)0726); proposal for a Regulation of the European Parliament and of the Council of 11 November 2020 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (COM(2020)0727).
[2] OJ C 450, 28.12.2020, p. 1.
[3] Texts adopted, P9_TA(2020)0228.
[4] Texts adopted, P9_TA(2020)0226.
[5] OJ L 153, 11.6.2019, p. 1.

(EU) No 282/2014[6],

– having regard to Regulation (EU) 2021/XXX of the European Parliament and of the Council of xx xxxx 2021 entitled ‘establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination’[7],

– having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[8],

– having regard to Rule 54 of its Rules of Procedure,

– having regard to the opinions of the Committee on Industry, Research and Energy and the Committee on Legal Affairs,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety (A9-0000/2021),

A. whereas health is fundamental to the well-being of Europeans and equitable access to healthcare is a pillar of the EU; whereas safe, affordable medicines are needed to combat all diseases; whereas patients should be at the centre of all health policies, alongside investment and research;

B. whereas COVID-19 has had an impact on people’s health and on the economy; whereas it has highlighted both the EU’s strengths and weaknesses; whereas in order to strengthen the resilience of our national health systems to cross-border threats, more European integration is necessary; whereas a European Health Union, which contributes to an increasingly social Union, is key in this process;

C. whereas the pharmaceutical strategy covers the full cycle of medicines, including research, testing, authorisation, consumption and disposal, and contributes to meeting the objectives of the European Green Deal, the digital transformation and climate neutrality;

Putting patients at the centre of all health policies

1. Stresses that investment in research into and the development of innovative medicines and treatments, as well as access to safe, effective and high-quality medicines, are essential for making progress in the prevention and treatment of diseases;

2. Considers that investment in research has not been sufficient to meet the therapeutic needs of patients with rare diseases, paediatric cancers and neurodegenerative diseases or to deal with antimicrobial resistance (AMR);

3. Considers it imperative that a common EU therapeutic guide for antimicrobials be introduced and that communication campaigns on AMR be coordinated through a single

[6] OJ L 107, 26.3.2021, p. 1.
[7] Reference to be inserted following publication.
[8] OJ L 311, 28.11.2001, p. 67.

calendar at EU level;

4. Calls on the Commission to incorporate new criteria into the system of incentives for research into and the development of new medicines for unmet therapeutic needs, prioritising projects promoted by the pharmaceutical industry combating rare diseases, paediatric cancers, neurodegenerative diseases and AMR, with the aim of finding more therapeutic options and meeting the needs of patients and health systems; calls on the Commission to promote the creation of an EU framework to guide and regularly evaluate the implementation of national plans to fight these diseases;

5. Calls on the Commission to promote dialogue with the Member States and stakeholders to assess new criteria for national pricing, such as whether a product is 'Made in Europe', whether the EU invested in the product to support research, or whether prices should be adapted to the value of the therapeutic benefit of the medicine, and the primary and broader needs of the population;

6. Calls on the Commission to review the incentive system, increase price transparency, highlight the causes limiting affordability and patient access to medicinal products, and propose sustainable solutions that also promote competition;

7. Stresses that generic and biosimilar medicines are accessible and affordable treatments and contribute greatly to the budgetary sustainability of healthcare systems; calls on the Commission to introduce measures to support a greater market presence of these medicines and to harmonise at EU level the interpretation of the so-called Bolar provision concerning possible exemptions from the legal framework for the Unitary Patent system for generic drug manufacturers; further calls on the Commission to design rules for the industry that promote research, development and the production of generic and biosimilar medicines in the EU and to propose EU protocols for the interchangeability of biosimilar medicines;

8. Welcomes the fact that the Commission will launch a pilot project to better understand the root causes of the delayed arrival of medicines on the market; further welcomes the fact that the Commission will continue to monitor mergers between pharmaceutical companies to avoid distortions of competition; stresses the need to reduce medicine approval times at national level and align them with European Medicines Agency (EMA) times, in order to ensure rapid and equal access to medicines for everyone in the EU;

9. Highlights the benefits of public-private partnership tenders for national health systems in funding research into and the production of innovative medicines;

10. Stresses the importance of new joint EU public procurement contracts by the Commission and the Member States, especially for emergency medicines and unmet therapeutic needs;

11. Is concerned that the affordability of medicines remains a challenge for national health systems, and that innovative medicines are expensive; welcomes the Commission's intention to review pharmaceutical legislation to promote robust competition and to stabilise and balance national drug pricing systems;

Supporting a competitive and innovative EU pharmaceutical industry

12. Insists that a competitive EU pharmaceutical industry is strategic and more responsive to patients' needs; points out that the industry needs a stable, flexible and agile regulatory environment; believes that it can thrive globally with a clear, robust and efficient intellectual property system; welcomes the initiative to build interoperable digital infrastructure for the European Health Data Space;

13. Calls on the Commission to revise the use of supplementary protection certificates based on technological and scientific advances to prevent generic and biosimilar medicines from becoming less competitive inside and outside the EU;

14. Stresses the importance of creating quality jobs in the EU along the entire pharmaceutical value chain, with the support of the NextGenerationEU instrument; calls on the Commission to propose measures to promote employment in the pharmaceutical sector, facilitating talent retention and mobility at EU level;

15. Highlights the fact that gene and cell therapies, personalised medicine, nanotechnology, next-generation vaccines, e-health and the 'Million plus genomes' initiative can bring enormous benefits in relation to the prevention, diagnosis, treatment and post-treatment of all diseases; urges the Commission to develop appropriate regulatory frameworks, to guide new business models, and to run information campaigns to raise awareness and encourage the use of these innovations;

16. Calls on the Commission to fully implement the Clinical Trials Regulation[9]; welcomes the revision of pharmaceutical legislation to adapt it to cutting-edge products, scientific advances and technological transformation; supports a new framework for the design of innovative trials and the pilot project to adopt a framework for the reuse of off-patent medicines; welcomes the launch of a vaccine platform to monitor vaccine efficacy and safety, supported by an EU-wide clinical trials network;

17. Urges the Commission, based on the experience with the authorisation of COVID-19 vaccines, to work with the EMA to consider extending the application of rolling reviews to other emergency medicines; further calls on the Commission to work with the EMA to develop the use of electronic product information for all medicines in the EU;

18. Calls on the Commission to reassess the system which leads from conditional marketing authorisation to standard marketing authorisation or to the exceptional renewal of the authorisation; calls on the EMA to thoroughly carry out the final evaluation and ensure the strict compliance by producers with all of the requirements for each medicine under conditional marketing authorisation in order to ensure the efficacy and safety of such medicine; asks for the time before the final evaluation to be reduced from five to three years;

Increasing resilience: secure supply chains, sustainable medicines, crisis preparedness and response mechanisms

[9] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, OJ L 158, 27.5.2014, p. 1.

19. Recalls that the EU's open strategic autonomy is linked to the constant and sufficient availability of medicines in all Member States; calls on the Commission to develop an early warning system for drug shortages, based on a European information network on supply problems, to increase public-private collaboration and to monitor the obligation on the part of industry to provide early and transparent information on the availability of medicines; calls on the Commission to develop a mechanism to safeguard transparency in production and supply chains in the event of emergencies;

20. Supports the Commission in its efforts to conduct a structured dialogue with players in the pharmaceutical value chain, public authorities, non-governmental patient and health organisations and the research community to address weaknesses in the global medicines manufacturing and supply chain;

21. Calls on the Commission to facilitate agreements between the EMA and non-EU regulatory agencies on preventing emergencies and coordinating responses to them; encourages the Commission to work with World Trade Organization members to facilitate trade in health products, increase resilience in global supply chains through stable access to raw materials, and contribute to an effective response in the event of a health emergency;

22. Stresses the need for the pharmaceutical industry to be environmentally friendly and climate-neutral throughout the life cycles of medicinal products; calls on the Commission to strengthen inspection and auditing throughout the production chain; urges the Commission to ensure quality environmental sustainability standards for active pharmaceutical ingredients imported from non-EU countries; calls on the Commission to address the problem of domestic pharmaceutical waste, with measures to reduce packaging and the size of containers to ensure they are no larger than necessary, and to bring medical prescriptions into line with real therapeutic needs;

The EU is leading the world in healthcare

23. Calls on the Commission to further facilitate access to global markets for the EU pharmaceutical industry, including small and medium-sized enterprises, through a level playing field and a regulatory framework facilitating trade agreements that prize innovation-based competitiveness, in order to make the pharmaceutical sector a strategic pillar of the EU;

24. Reiterates its commitment to continue working with the Commission and the World Health Organization to standardise effective, safe and sustainable regulatory frameworks for medicinal products;

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25. Instructs its President to forward this resolution to the Council and the Commission.

EXPLANATORY STATEMENT

The COVID-19 crisis has pushed health higher on the agenda of the European Union, but also on the list of top concerns of our citizens. A recent Eurobarometer on the Future of Europe (Special Eurobarometer 500) puts 'health-related risks' as the third main global challenge for the EU, just after 'climate change and environmental issues' and almost on a par with 'terrorism'. The rapporteur believes that a strong European Health Union is essential to strengthen our health systems and cope with future health crises.

Europe is leading the world in the fight against climate change and caring for the planet, and it is now, after COVID-19, that the opportunity arises to make Europe and its national public health systems with universal access world leaders in health care. During this year, the first pillars have been laid in the construction of the European Union of Health, with the COVID-19 vaccine strategy, the strengthening of the ECDC and the EMA, the creation of the HERA and its incubator, the new autonomous EU4health programme, the European Beating Cancer Plan, which together with this strategy start the decade of health and research in Europe, reinforcing not only the economic but also the social dimension of the European Union.

Europe has shown great resilience and strength during the health crisis, but the weaknesses of our health systems have also been exposed. Drawing on the lessons learned during the COVID-19 pandemic, the rapporteur calls on the Union to strengthen its health policy and security framework to increase preparedness and better meet the medical needs of the European citizens; the rapporteur stresses the need to put patients at the centre of all health policies and to ensure fair and equitable access to healthcare.

The European pharmaceutical strategy has four main objectives:

1. Ensure patient access to affordable medicines and address unmet medical needs, such as in the areas of antimicrobial resistance, cancer and rare diseases;

2. To promote the competitiveness, innovation and sustainability of the EU pharmaceutical industry and the development of high quality, safe, effective and greener medicines;

3. Improve crisis preparedness and response mechanisms and address security of supply;

4. Ensuring a strong EU voice in the world by promoting high standards of quality, effectiveness and safety.

The new pharmaceutical strategy is one of the pillars of the European Health Union and the rapporteur is convinced that it can respond, if fully implemented, to long-standing weaknesses in the field of medicines, such as affordability, access and shortages, support research aligned with the needs of patients and health systems, and it can strengthen and innovate the pharmaceutical industry. The new strategy can help build a future-proof and crisis-resilient EU pharmaceutical system; the vitality of the pharmaceutical sector is not only key for the Union's health and jobs, but is necessary to reinforce its strategic autonomy, especially in the wake of increased pandemic risks and fragile supply chains.

The rapporteur points out that patients can benefit from scientific advances and digital

transformation as they are fundamental to improve cutting-edge healthcare, and underlines that genetic and cellular therapies, personalized medicine, nanotechnologies, the latest generation of vaccines, as well as e-health with supercomputing, artificial intelligence and an interoperable structure for the European health data space with "More than a million genomes", will bring enormous benefits in research, prevention, early diagnosis, and treatments and post treatments of all diseases.

Although EU research programmes are among the best in the world, the rapporteur calls for more investment in research into rare diseases, paediatric cancers, neurodegenerative diseases and antimicrobial resistance.

The European Union has a legislative regulatory framework to address orphan drugs with the aim of stimulating research and development of medicines for rare diseases. The recent evaluation has identified a clear positive effect of the legislation; however, it also identified that there is room for improvement, as around 95% of rare diseases still have no treatment option. An example of this is that in 2019, the EMA authorised 103 orphan drugs, and only half of them reached the market, with an average delay time of two years. The rapporteur therefore calls for reducing and aligning the approval times of national agencies with EMA approval times and ensuring rapid and equal access to medicines across Europe.

In order to increase research and development of medicines for unmet therapeutic needs, the rapporteur calls on the Commission to promote the creation of a European framework to guide the implementation of national plans and strategies to combat rare diseases, paediatric cancers, neurodegenerative diseases and antimicrobial resistance.

Misuse and overuse of antimicrobials are the main drivers for the development of drug-resistant pathogens. AMR is a major global health problem and a serious risk to the well-being of European citizens that will pose a major challenge to European health systems and societies. According to WHO figures, 33,000 people die each year in Europe because antibiotics are no longer effective. The WHO has declared AMR to be one of the top 10 global public health threats facing humanity. The rapporteur therefore calls on the EU to provide itself with a common therapeutic guide for antimicrobials.

The health crisis has also highlighted the growing threat of shortages of essential medicines, such as antimicrobials or muscle relaxants for intubation, which have been so necessary in the pandemic and which are mostly not produced in Europe, due to their low price, causing shortages, lack of access and tensions in the National Health Systems. As said, there are many factors responsible for these shortages, such as the great dependence on non-EU countries in terms of active pharmaceutical ingredients, chemical raw materials and medicines. The EU needs to increase its production capacity by encouraging its industry, but also to diversify its supply chain and ensure better coordination of national health strategies. The rapporteur appreciates the possibility of incentivising European production and adapting prices to the value of the therapeutic benefit of the medicine of primary and great need for the population.

The rapporteur calls on the Commission and the Member States to promote more joint European public procurement as has been done for Covid-19 vaccines, and innovative procurement procedures incorporating criteria such as: 'Made in Europe', timely delivery, organic production, security and continuity of supply, or as for example the Big Buyers initiative launched in the framework of the SME strategy, and the 'innovation partnership', which allows

public-private collaboration for the development, manufacture and purchase of medicines. This would facilitate increased market competitiveness and would be of particular interest for emergency medicines and unmet therapeutic needs. It is necessary to safeguard the transparency of production and supply chains in the event of a health crisis.

The quality and safety of medicines and medical devices are also crucial and, based on the lessons learned during the COVID-19 crisis, the rapporteur suggests that the European Medicines Agency (EMA) should consider extending the Rolling Review for authorisation to other emergency medicines as well, as it did for COVID-19 vaccines.

The rapporteur underlines the need to support clinical trials that are more patient-centred, as well as to ensure a framework that supports innovative clinical trials design. It is stressed that pragmatic trials, in which the treatment is used as standard practice, can improve patient engagement and tolerance to treatment by identifying the optimal dose and its uses with other treatments. We must therefore support initiatives to improve the regulatory knowledge of researchers and non-profit stakeholders, so that their research and evidence can be used for the repurposing of off-patent medicines for new therapeutic uses. As well as simplifying the requirements of legislation, so that bureaucracy is not a barrier to research..

The rapporteur stresses the need to analyse the emerging new manufacturing methods, which move from industrial manufacturing to “bedside” production, speed up production times, reduce costs, and facilitate greater access, creating new challenges in terms of quality, inspection and monitoring.

In recent decades, the prices of new and innovative medicines have risen to the point where they have become unaffordable for many, risking increasing inequality in access to health services and overburdening national health systems. The EU must continue to facilitate faster market access for generic and biosimilar medicines, as they can be an accessible and affordable option for many patients and relieve pressure on our healthcare systems. The rapporteur calls for a review of the legislation on pharmaceuticals in order to increase competition while stabilising and equilibrate the pricing system.

The EU pharmaceutical industry needs to maintain a strong European intellectual property system to encourage R&D and manufacturing in the European Union and to ensure that Europe remains innovative and a world leader. A thriving and technically advanced European healthcare industry and a competitive research community is vital. This requires an ambitious, clear and up-to-date regulatory framework for European companies, as well as dedicated resources for science and health research.

The pharmaceutical industry needs to be environmentally and climate friendly throughout the life cycle of the medicinal product. The rapporteur calls on the Commission to strengthen inspection and auditing along the production chain and to ensure high standards of quality and environmental sustainability of active pharmaceutical ingredients, including those imported from third countries. Pharmaceutical waste is also a serious concern that the Commission should address with measures to reduce wraps and packaging.

The rapporteur stresses the importance of creating quality jobs in the European Union, along the entire pharmaceutical value chain, by facilitating talent retention and mobility at EU level, with the support of NextGenerationEU.

To better prepare for future crises, the EMA and other extra-European regulatory agencies should co-operate to improve prevention and co-ordinate responses to emergencies. The Commission should also work with WTO members to facilitate trade in medical devices and with the WHO to contribute to more effective preparation and response to health emergencies.

In conclusion, this strategy aims to ensure that EU pharmaceutical policy remains at the service of public health by charting a course for its economically, environmentally and socially sustainable renewal, with a fundamental need for long-term commitment of resources and the involvement of all.