European Parliament
2019-2024

TEXTS ADOPTED

P9_TA(2021)0470

A Pharmaceutical Strategy for Europe

European Parliament resolution of 24 November 2021 on a pharmaceutical strategy for Europe (2021/2013(INI))

The European Parliament,

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

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

– having regard to Article 6 of the Treaty on European Union and Article 35 of the Charter of Fundamental Rights of the European Union (the Charter) on the right to preventive healthcare for all European citizens,

– having regard to its resolution of 2 March 2017 on EU options for improving access to medicines[1],

– having regards to its resolution of 13 September 2018 on a European One Health Action Plan against Antimicrobial Resistance[2],

– having regard to its resolution of 15 January 2020 on the European Green Deal[3],

– having regard to its resolution of 10 July 2020 on the EU's public health strategy post-COVID-19[4], calling for an EU action plan on rare and neglected diseases,

– having regard to its resolution of 17 September 2020 entitled 'The shortage of medicines – how to address an emerging problem'[5],

– having regard to its resolution of 17 September 2020 on a strategic approach to pharmaceuticals in the environment[6],

---

1 OJ C 263, 25.7.2018, p. 4.
2 OJ C 433, 23.12.2019, p. 153.
3 OJ C 270, 7.7.2021, p. 2.
4 Texts adopted, P9_TA(2020)0205.
5 Texts adopted, P9_TA(2020)0228.
6 Texts adopted, P9_TA(2020)0226.

– having regard to the Doha Declaration on the Agreement on Trade-Related Aspects of Intellectual Property Rights and Public Health (TRIPS Agreement) and to the decision of the General Council of the World Trade Organization (WTO) of 30 August 2003 on the implementation of Paragraph 6 of the Doha Declaration,

– having regard to the 72nd World Health Assembly resolution of May 2019 on improving the transparency of markets for medicines, vaccines, and other health products,

– having regard to Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products[1],

– 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[2],

– having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[3],

– having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use[4],

– having regard to Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes[5],

– having regard to 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[6],

– 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[7],

– 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 (EU) No 282/2014[8],

---

1 OJ L 18, 22.1.2000, p. 1.
2 OJ L 311, 28.11.2001, p. 67.
3 OJ L 136, 30.4.2004, p. 1.
4 OJ L 378, 27.12.2006, p. 1.
5 OJ L 276, 20.10.2010, p. 33.
6 OJ L 158, 27.5.2014, p. 1.
7 OJ L 153, 11.6.2019, p. 1.
8 OJ L 107, 26.3.2021, p. 1.

– having regard to Regulation (EU) 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination[1],

– having regard to the Commission communication of 11 December 2019 on the European Green Deal (COM(2019)0640),

– having regard to the Commission communication of 10 March 2020 entitled 'A New Industrial Strategy for Europe' (COM(2020)0102),

– 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[2] ,

– 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 Commission's Strategic Agenda for Medical Ionising Applications (SAMIRA) Action Plan of 5 February 2021 in support of the European Beating Cancer Plan,

– having regard to the Commission communication of 5 May 2021 entitled 'Updating the 2020 New Industrial Strategy: Building a stronger Single Market for Europe's recovery' (COM(2021)0350),

– having regard to the Commission communication of 15 June 2021 on drawing the early lessons from the COVID-19 pandemic (COM(2021)0380),

– having regard to the Commission communication of 16 September 2021 introducing HERA, the European Health Emergency preparedness and Response Authority, the next step towards completing the European Health Union (COM(2021)0576),

---

1 OJ L 170, 12.5.2021, p. 1.

2 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).

– having regard to the proposal for a regulation of the European Parliament and of the Council of 31 January 2018 on health technology assessment (COM(2018)0051) and the work of EUNetHTA Joint Actions,

– having regard to the joint evaluation of Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (SWD(2020)0163),

– having regard to the Council conclusions of 1 December 2014 on innovation for the benefit of patients,

– 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 the Council conclusions of 18 December 2020 on COVID-19 lessons learned in health[1],

– 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 (A9-0317/2021),

A. whereas health is fundamental to the well-being of Europeans and equitable access to healthcare is a cornerstone of the EU and Member States' national health policies; whereas the Charter recognises the fundamental right of citizens to health, a high quality of life and medical treatment; whereas public health systems are crucial to guaranteeing equitable access to healthcare and safe, effective and affordable medicines; whereas ensuring patient access to medicines is one of the core objectives of the EU and the World Health Organization, and of Sustainable Development Goal 3;

B. whereas one of the 20 principles of the European Pillar of Social Rights, reinforced by the Porto Declaration, establishes that everyone has the right to timely access to affordable, preventive and curative healthcare of good quality;

C. whereas patients should be at the centre of all health policies and involved throughout the regulatory pathway for medicines; whereas access inequalities exist between and within Member States and special attention should be paid to people in vulnerable situations with specific health risks, including women, with a particular focus on pregnant women, children, the elderly, persons with disabilities, patients with chronic conditions and comorbidities, patients in intensive care units (ICU) and persons on long-term medication;

D. whereas the increasing burden of chronic diseases and the health needs of aging populations, combined with high and rising prices of medicinal products and an increase in the societal cost of providing care, pose budgetary and affordability constraints and

---

[1] OJ C 450, 28.12.2020, p. 1.

serious threats to the sustainability of European health systems; whereas the adoption of integrated models of care for chronic and other long-term conditions, underpinned by a person-centred and multi-disciplinary approach to healthcare, is essential to delivering high-quality health services;

E. whereas a competitive, trusted, innovative and resilient European research-based pharmaceutical industry is more responsive to patients' needs and to strategic interests in terms of public health, economic growth, jobs, trade, and scientific and technological progress;

F. whereas the new European pharmaceutical strategy should be welcomed as a new opportunity;

G. whereas medicine producers in the EU made a significant contribution to research investment in 2019, standing at over EUR 37 billion; whereas the sector provides 800 000 direct jobs and a EUR 109,4 billion trade surplus; whereas the sector generates about three times more employment indirectly – upstream and downstream – than it does directly; regrets that there are no aggregated data on the overall amount of public financing for the pharmaceutical sector in the EU;

H. whereas there are differences in healthcare systems, national regulation, the implementation of EU legislation, pricing and authorisation processes in the different Member States; whereas these differences are a result of Member States' competences in the area of health; whereas the differences can lead to fragmentation and unpredictable circumstances for actors in the pharmaceutical sector who operate outside their own country; whereas it is important to recognise that cooperation is required between the Commission and Member States so as to set out ambitious implementation agendas with clear timelines and the necessary long-term financing to implement concrete actions that follow on from the pharmaceutical strategy for Europe;

I. whereas the overall consumption of pharmaceuticals continues to grow both globally and in the EU; whereas a number of pharmaceuticals continue to be prescribed, dispensed, sold or used inappropriately; whereas such misuse of pharmaceuticals means a waste of precious resources and can lead to health and environmental hazards;

J. whereas 40 % of medicinal end products marketed in the EU originate in non-EU countries, while 60 % to 80 % of active pharmaceutical ingredients are produced in China and India; whereas this delocalisation of part of the production of essential components of medicines, vaccines and medical devices has direct consequences on treatment follow-up for patients;

K. whereas the transfer of production to third countries tends to be motivated by an attempt to reduce production costs; whereas these savings are mainly the result of more lax environmental, safety and labour law standards;

L. whereas the strategy recognises the key role that generic and biosimilar medicines play in hugely increasing equitable access for patients and for the sustainability of healthcare systems and that their entry into the market after exclusivity expiry should not be delayed;

M. whereas biosimilar medicines create opportunities beyond access to medicines, such as benefit sharing across healthcare, and thus provide better healthcare and services to patients;

N. whereas many innovations in the pharmaceutical industry do not really offer breakthrough improvements for patients, but are either so-called ‘me-too’ pharmaceuticals, which are simply another substance used for the same therapeutic purposes but without major benefits, or only offer minor improvements at a significantly higher cost; whereas it would be beneficial for patients if the framework for the pharmaceutical industry in Europe were to better incentivise real breakthrough innovations;

O. whereas there is convincing evidence that pharmaceuticals leach into the environment, in particular soil and water; whereas their presence can have adverse effects on wild animals such as fish, birds and insects and, as a result, broader impacts on the stability of individual ecosystems; whereas these medicines also appear in drinking water at lower concentrations; whereas the European Green Deal must encourage the development of a vibrant, dynamic, sustainable and clean pharmaceutical industry within the EU;

P. whereas action is required throughout the lifecycle of medicines to reduce resource use, emissions, and levels of pharmaceutical waste and residues in the environment;

Q. whereas COVID-19 has had an impact on people’s physical and mental 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, as well as greater sharing of epidemiological and health data at EU level; whereas a European Health Union should contribute to and foster closer cooperation, coordination and knowledge sharing on health among Member States and relevant stakeholders and increase the EU’s capacity to combat cross-border health threats;

R. whereas the disruption of the global supply chain ensuing from the COVID-19 pandemic has highlighted the EU’s dependency on third countries in the health sector; whereas understanding the root causes of medicine shortages is crucial for building an appropriate European response and tackling this long-standing challenge; whereas the EU’s open strategic autonomy and security of supply should be ensured through the diversification of supply chains for essential medicines and medicinal products, including European manufacturing sites, as well as by applying public procurement rules that do not consider price to be the sole criterion;

S. whereas during the COVID-19 pandemic, uncoordinated actions at national level, such as hoarding and extreme stockpiling, undermined equitable supply in all markets; whereas lessons should be drawn from this experience in order to prevent it from happening again in any future crisis situation;

T. whereas the COVID-19 experience also demonstrated the resilience of the European pharmaceutical industry and manufacturers and that they had contingency plans in place to limit disruption for critical products; whereas this was also possible thanks to the bilateral dialogue and two-way communication established, demand visibility and close

cooperation between governments/regulators and actors, a practice which should be maintained and continued on a regular basis;

U. whereas for the pharmaceutical strategy to be fully effective it must incorporate lessons learnt from the COVID-19 crisis and take into consideration the resilience demonstrated by the off-patent medicines industry during the COVID-19 outbreak, so as to build on existing European manufacturing capacity;

V. whereas the pandemic has brought to the fore a number of pre-existing problems in the global production and supply of pharmaceuticals, such as the limited capacity of least-developed and middle-income countries to produce vaccines, the lack of essential medicines and an unevenly functioning supply chain; whereas the EU vaccine strategy is proving successful in delivering vaccines to all citizens in the EU; whereas the EU has been at the forefront of global vaccine delivery by continuing to export vaccines and by setting up and financing COVAX; stresses that more needs to be done to fully vaccinate low- and middle-income countries;

W. whereas innovative R&D projects such as VACCELERATE have proven their worth during the pandemic and should be made sustainable in the long term;

X. whereas gene and cell therapies, personalised medicine, nanotechnology, next-generation vaccines, e-health and the '1+ Million Genomes' initiative can bring benefits in relation to the prevention, diagnosis and treatment of all diseases, and care for the patients affected, provided that they are effective, safe, affordable and accessible to all patients who need them;

Y. whereas, in the spirit of the 'One Health' approach, the pharmaceutical strategy covers the full lifecycle of medicines and medical devices, including the collection and production of starting material, research, testing, manufacturing, authorisation, pre-and post-marketing pharmacovigilance, consumption and disposal, and contributes to meeting the objectives of the European Green Deal, Europe's Beating Cancer Plan, the digital transformation, the circular economy and the industrial strategy, and climate neutrality;

Z. whereas to secure the Union's leading position in pharmaceutical development, the strategy must focus on strengthening the innovative potential of European pharmaceutical research, fulfilling patients' needs, and acknowledging and reinforcing the link with the EU industrial strategy, the small and medium-sized enterprise (SME) strategy and the European Health Data Space;

Putting patients at the centre of all health policies

1. Recalls that healthcare is a human right enshrined in the Universal Declaration of Human Rights; regrets the disparities in access to high-quality healthcare services, including access to medicinal products, among Member States and also among different regions within Member States; calls for national and EU measures, including legislative measures where appropriate, to address these disparities and guarantee the right of patients to universal, affordable, effective, safe and timely access to essential and innovative medicines;

2. Points out that given that the Union is responsible for pharmaceutical legislation, as well as complementing public health policies, it should strive to coordinate national measures to guarantee access to affordable and high-quality health services for all EU citizens and residents;

3. Stresses the geostrategic imperative for the Union to regain its independence with regard to healthcare, and its need for a diversified supply chain in order to secure its supply of medicines, medical equipment, medical devices, active substances, diagnostic tools and vaccines rapidly, affordably and efficiently and to prevent shortages thereof, thus prioritising the interest and safety of patients;

4. Underlines that COVID-19 has brought about unprecedented challenges for health systems and their sustainability, but has also had a dramatic impact on patients, including those suffering from chronic conditions, and their ability to access treatments and care; calls on the Commission and Member States to assess and address the overall impact of the pandemic on patients and on the resilience of healthcare systems and to work collaboratively to ensure that no patient is left behind and that continuity of care is guaranteed even during emergency situations;

5. Underlines that public investment in research should aim to strengthen public health and address unmet medical needs, especially those in areas not covered by the private sector, defined with the involvement of regulators, academia, healthcare professionals, patients and payers at the early stages of R&D, so as to ensure that research priorities respond to societal needs; points out that embedding meaningful patient involvement and dialogue throughout the entire lifecycle of medicines and other therapies is an indispensable requirement for achieving high-value innovation and the overall success of the pharmaceutical strategy, which also requires the adequate consultation of consumer and patient representatives throughout the implementation of the strategy;

6. Calls on the Commission to start the process of defining unmet medical needs, under the coordination of the European Medicines Agency (EMA), in order to establish a commonly accepted definition that would help to better orientate research needs and prevent the use of various definitions for unmet medical needs which, at an early stage, lead to exorbitant pricing in the marketing of medicines;

7. Calls on the Commission to leverage and coordinate the pharmaceutical, industrial, digital strategies, the renewed EU trade policy and other relevant policies to promote European competitiveness and ensure that the EU is capable of competing with challenger regions;

8. Stresses that public and private investment in research into and the development of innovative diagnostics, as well as access to safe, affordable, effective and high-quality medicines and treatments, are essential for making progress in the prevention, diagnosis and treatment of diseases and the quality of life of patients;

9. Recalls that public and private investments should be aligned with the necessary regulatory and legislative measures in order to meet the therapeutic and diagnostic needs of patients, including for rare and chronic diseases, rare adult cancers and paediatric cancers, and neurodegenerative diseases, and tackle antimicrobial resistance (AMR);

10. Welcomes the Commission's intention to assess and review the existing incentive framework; calls on the Commission to stimulate competition by adapting its regulatory framework and stimulating investments in off-patent orphan and paediatric medicines, including for oncology, paediatric cancers and neurological diseases;

Pharmaceuticals and antimicrobial resistance

11. Highlights the serious and constantly increasing risks of AMR to public health, the environment, food production and economic growth; recognises the value of public health campaigns aimed at the prevention of infections through vaccination;

12. Considers that AMR constitutes a serious threat to public health; calls on the Commission and Member States to fund projects aimed at improving diagnostics and developing new antibiotics, as well as developing a protocol for the prudent use of antibiotics and an awareness campaign for health professionals to encourage more targeted treatment based on patients' actual needs;

13. Invites the Innovative Medicines Initiative and the European Investment Bank to play a more active role in financing innovative initiatives in the field of AMR; stresses the importance of implementing the joint action plan on AMR and health infections; notes the need to facilitate access to new antibiotics while maintaining access to old ones;

14. Considers it imperative that a common EU therapeutic guide for antimicrobials be introduced, setting up traceable antimicrobial use reduction targets at EU level, and that communication campaigns on AMR be coordinated through a single calendar at EU level to create more awareness of AMR, resistant variants and the consequences thereof;

15. Underlines that the 'One Health' approach should guide the reduction and use optimisation of antimicrobials, as well as the development of new medicines, including antimicrobial agents; calls on the Commission and Member States to assess the existing legislative framework related to AMR and, where appropriate, come forward with a proposal to revise it;

Research in pharmaceuticals

16. Calls on the Commission to assess, and revise where appropriate, the system of incentives to promote research into and the development of new medicines for unmet diagnostic and therapeutic needs, prioritising public interests and patient safety when assessing projects promoted by the pharmaceutical industry to combat cancers, including paediatric cancers, in particular to incentivise first-in-child development of paediatric anticancer medicines, rare diseases, neurodegenerative and mental illnesses, and AMR, with the aim of finding more therapeutic options and meeting the needs of patients and health systems;

17. 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, and calls on the Member States to support R&D that focuses on unmet medical needs; stresses that a system based solely on research incentives will not achieve the necessary objectives in the fight against rare diseases;

18. Calls on the Commission to provide public research funding to investigate the use of repurposed, off-label and off-patent products that can be used safely and effectively in

patients; stresses that medicines resulting from publicly funded research must be equally available across the Union for a fair and affordable price and that, where appropriate, the marketing authorisation holder (MAH) may consider voluntary non-exclusive licensing for these products; emphasises that EU funding should be steered towards projects where research is needed the most;

19. Stresses the importance of continuous innovation, including in the off-patent segment, to address patients' unmet needs; calls on the Commission to design a fit-for-purpose regulatory framework that will enable the development of value added medicines, as well as recognise this category of affordable innovation, through appropriate incentives, for its value for healthcare systems;

20. Welcomes the initiative to launch a pilot project seeking to test the framework provisions on new indications for off-patent medicines and the basis for possible regulatory action; stresses, in this regard, the necessity and importance of input from industry and academia and their involvement;

21. Calls on the Commission, in dialogue with the Member States, to work on a framework for pharmaceutical legislation and a reimbursement system that favours meaningful innovation for patients and incentivises fewer 'me-too' pharmaceuticals which have no added value or highly expensive pharmaceuticals that offer only minor improvements for patients;

22. Calls on the Commission to revise Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006 ; calls for an assessment of the effectiveness of funding and of public-private partnership projects, especially with a view to improving the relationship between local health authorities, universities and industry; recognises that further improvements are needed to address the needs of the patients that these regulations aim to cover and calls on the Commission to allow for measures targeting important underserved areas in order to streamline, simplify and adjust regulatory procedures;

23. Highlights the fact that scientifically recognised integrative medicine approved by public health authorities can bring benefits to patients in relation to the parallel effects of several diseases, such as cancer, and their treatment; stresses the importance of developing a holistic, integrative and patient-centric approach and encouraging, where appropriate, the complementary use of these therapies under the supervision of healthcare professionals;

24. Calls on the Commission to support additional research in underrepresented populations, such as the elderly, children, women and patients with comorbidities, including obesity as a primary morbidity, as well as where it exists as a gateway chronic disease to other non-communicable diseases; stresses the need to take gender into account in research, diagnosis and treatment and in the impact of medicines and therapeutics, as women across their lifespan remain underrepresented in biomedical and health research and data; underlines that consequently, the evidence base is weaker for women, as well as for older people, leading to many conditions being underdiagnosed in women, such as cardiovascular disease;

25. Calls on the Commission to build on the work of Europe's Beating Cancer Plan and ensure that Europe becomes the worldwide centre of excellence for R&D in emerging, innovative fields of medicine; underlines that state-of-the art technologies, such as

nanomedicines, stand to provide solutions to current treatment challenges in areas such as cancer and cardiovascular diseases; highlights that these innovative fields of medicine should be authorised by the centralised approval framework for nanomedicines;

26. Calls on the Commission to ensure that EU funding for biomedical research and development is made conditional on the full transparency and traceability of investments, on ensuring supply in all Member States, and on facilitating the best outcome for patients, including in terms of the accessibility and affordability of manufactured medicines;

27. Emphasises that research into and the production and use of medicines should follow ethical principles that guarantee the right to life, dignity and the integrity of the person;

28. Calls on the Commission to promote the development of research in the field of pain therapy drugs;

29. Welcomes the Commission's publication on 5 February 2021 of the SAMIRA Action Plan; calls on the Commission, when revising pharmaceutical legislation, to draw up a regulatory framework geared to the deployment of radiological and nuclear technologies for therapeutic, and not solely diagnostic, purposes;

30. Calls for an important project of common European interest (IPCEI) to be launched in the pharmaceutical sector with a view to identifying targeted diseases or technologies in advance;

31. Points out that a range of EU programmes can be used to fund pharmaceutical research projects, such as Horizon Europe, InvestEU, EU4Health, cohesion policy and the Digital Europe programme for projects focusing on the deployment of artificial intelligence (AI);

32. Calls for the EU pharmaceutical strategy to give deeper and greater attention to all aspects of gender-specific medicine; underlines the need to reflect the diversity of society and gender-specific issues in physiology when conducting research on medicines to support research and development in gender-specific medicine and to ensure that these issues are taken into account when granting market authorisation;

Pricing and costs of pharmaceuticals

33. Calls on the Commission to promote dialogue with the Member States and all relevant stakeholders to promote 'Made in Europe' pharmaceuticals by strengthening manufacturing and supply resilience, by assessing additional criteria for national pricing, at no additional cost to patients and without prejudice to the sustainability of the health system; stresses that these criteria should include high environmental manufacturing standards, robust supply chain management and investment in innovation and research;

34. Further recommends that the Commission and Member States ensure that pricing also reflects whether any type of public funding was used to support innovation, manufacturing and research, the value of the therapeutic benefit of the medicine, whether the medicine in question is generic or biosimilar, and the primary and broader needs of the population;

35. Underlines that such dialogue should further encourage cooperation in pricing negotiations and, where appropriate, joint procurement; recalls that national pricing should be based on the transparency of factors such as public and private research, development costs and added therapeutic value; calls on the Commission to promote information sharing among Member States on net medicine prices through the European Integrated Price Information Database (EURIPID) collaboration;

36. Calls on the Commission to explore the possibility of establishing, subject to conditionalities, an EU fund, co-financed by the Member States, for negotiating and purchasing orphan medicines and other new, personalised medicines, so as to guarantee equal access for patients from different Member States to effective therapeutics and treatments and prevent individual healthcare units from having to bear excessive costs when treating rare diseases;

37. Calls on the Commission to work with Member States to introduce measures to increase transparency in the area of research into and the development and production of medicinal products; calls for greater price transparency and invites Member States to continue to share their best pricing practices on a voluntary basis; stresses that pricing should remain a national competence, taking account of diversity across the EU;

38. Calls on the Commission to periodically evaluate and review the incentive system, increase price transparency, and highlight the factors limiting affordability and patient access to medicinal products; further calls on the Commission to address the root causes of shortages of pharmaceuticals and propose sustainable solutions that also promote on- and off-patent competition and the timely entry into the market of generic and biosimilar medicines;

39. Stresses the importance of striking the right balance between, on the one hand, offering incentives in medicine development, particularly where no treatment alternatives exist, and, on the other, safeguarding the public interest by preventing the distortion of competition and unintended effects and ensuring the affordability and availability of medicinal products;

40. Further calls on the Commission, especially its Directorate-General for Competition, and national competent authorities to be alert to anti-competitive conduct and investigate anti-competitive practices in the pharmaceutical industry;

41. Calls for maximum transparency in the use of public research and development funding and for easy public access to information regarding patenting/licensing conditions, the findings of clinical trials and public/private contributions;

42. Insists on the need to ensure equal access to affordable drugs within the EU; supports collective negotiation of the price of medicines with pharmaceutical industries, such as in the case of the Beneluxa Initiative and the Valetta Declaration; considers that pharmaceutical industries should respect conditionalities on the affordable price of medicines within the framework of publicly funded research;

Role of generic and biosimilar medicines

43. Points out that generic and biosimilar medicines increase patients' access to effective and safe treatment options, increase competition, offer accessible and affordable

treatments and contribute greatly to the budgetary sustainability of healthcare systems, generating costs savings, while maintaining the high quality of healthcare;

44. Stresses the importance of generic, biosimilar and value added medicines for consistently increasing equitable access for patients and making healthcare systems sustainable in a European Union where access is still uneven; calls on the Commission to ensure healthy competition at the expiry of intellectual property (IP) exclusivities as a matter of urgency by ensuring accessibility to biosimilar medicines from day one and by removing all barriers to access to competition, for example through patent linkage, by banning IP evergreening practices that unduly delay access to medicines and by allowing single global development;

45. Calls on the Commission to take measures to support the greater market presence of these medicines, and to harmonise at EU level the interpretation of the Bolar provision concerning possible exemptions from the legal framework for the Unitary Patent system for generic drug manufacturers;

46. Calls on the Commission to take action that promotes research, development and the production of generic and biosimilar medicines in the EU and to propose EU protocols for the interchangeability of biosimilar medicines, as defined by the EMA, with respect for individual patient needs and clinicians' freedom to prescribe the best treatment for each patient, while always keeping the patient informed and at the centre of all decision making;

47. Encourages Member States to evaluate measures to promote the use of financial savings generated in the national health system from the use of biosimilar medicines and reinvest them in a transparent and tangible way to improve the quality of care services; calls on the Commission to encourage Member States to support transparent practices with regard to biosimilar-related cost savings; calls on the Commission to facilitate arrangements such as gainsharing programmes;

48. Stresses the need for the Commission to continue preventing anti-competitive practices to ensure a competitive market in generic and biosimilar medicines;

49. Stresses the importance of improving education on biosimilar medicines; calls on the Commission to promote relevant educational and communication activities among healthcare professionals by setting up a dedicated Europe-wide online resource centre;

Delayed arrival of medicines on the market

50. 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; calls on the Commission to look at the huge differences across the EU of the average number of days between the approval of a medicine and the moment it become available to patients and to propose new ways to improve the regulatory process and its implementation and implement innovative solutions to reduce delays to the market entry of medicines;

51. Emphasises that any revision of the regulatory procedures and approaches to the assessment of scientific evidence must be undertaken cautiously in order to adequately take the benefit to patients and safety aspects into consideration;

52. Stresses the need to reduce medicine approval times, setting, where appropriate, a time limit for market access, and to align them with EMA decision-making times, in order to ensure rapid and equal access to medicines for everyone in the EU and prevent discrimination between EU citizens; recalls that MAH and distributors could also play a key role in the availability of medicinal products across the EU by avoiding the discontinuation of products and delays to arrival on the market due only to commercial factors;

Public-private partnerships and innovation

53. Highlights the benefits of public-private partnership tenders for national health systems in funding research into and the production of innovative medicines and research into medicine repurposing, and that academia-pharma cooperation is essential for the exchange of knowledge and information for the benefit of all patients across the Union;

54. Stresses that such collaboration must guarantee that research priorities are driven by patient and public health needs and that public funds are invested in a transparent manner, ensuring the availability and affordability of products resulting from these partnerships and public funds;

55. Calls on the Commission to ensure that the European Partnership for Health Innovation is driven by public interest considerations; calls on the Commission to adopt and implement a general policy on such conditionalities under Horizon Europe;

European Health Emergency Preparedness and Response Authority (HERA)

56. Welcomes the launch on 17 February 2021 of the HERA incubator focused on tackling variants of the COVID-19 virus;

57. Takes note of the Commission proposal to establish HERA; considers that the authority should identify health threats, initiate and support the development of innovation, establish at EU level a list of medicinal products of major therapeutic interest, facilitate their production within the EU, and promote the joint purchase and build up strategic stocks of such medicines;

58. Calls for the granting of sufficient resources and power autonomy to broadly address all the cross-borders threats to health that the EU could face in the medium term and beyond the COVID-19 pandemic, including resources for the development of new therapeutics against viral and bacterial pathogens;

59. Calls on the Commission to ensure that HERA is public-interest driven and contributes effectively to the development, availability and affordability of safe and effective medical countermeasures;

60. Reiterates its position that the Commission should consider the creation of a European version of the US Biomedical Advanced Research and Development Authority; welcomes the fact that the Commission has made a proposal for a European HERA but expresses its disappointment that Parliament has not been involved in its proper role as co-legislator;

Procurement practices

61. Stresses the importance of new joint EU public procurement contracts by the Commission and the Member States, especially for, but not limited to, emergency medicines and unmet therapeutic needs to improve their affordability and access to them at EU level; calls for exploration of such practices in areas such as rare diseases and cancer through clearly outlined milestones, objectives and commitments agreed by all parties involved; highlights the need to ensure high levels of transparency in these initiatives and to apply lessons learned from the joint procurement of COVID-19 products; stresses that joint procurement must not risk having a negative impact on supply flows by increasing the risk of shortages in the EU;

62. Underlines that joint procurement should be based on shared responsibilities and a fair approach, with rights and obligations for all parties involved; stresses that clear commitments should be made and respected, with manufacturers delivering the agreed production levels and the authorities purchasing the agreed reserved volumes;

63. Further underlines that where joint procurement is deployed, the awarding process should take into account qualitative criteria such as the ability of the manufacturer to ensure security of supply during a health crisis;

64. Highlights that joint public procurement should have a clearly defined scope, given the potential for new innovative antibiotics, vaccines, curative medicines and medicines for rare diseases, for example, while taking into consideration the need for more balanced public-private investment, clear liability for manufacturers, and sufficient flexibility for Member States in line with national specificities, while honouring the commitments undertaken;

65. Welcomes the reference in the strategy to the fact that actions in the area of public procurement can foster competition and improve access to medicines; urges the Commission, in the context of Directive 2014/24/EU[1], to swiftly propose guidelines for the Member States, notably on how to best implement the most economically advantageous tender (MEAT) criteria, looking beyond the lowest price criteria alone; emphasises that security of supply is an essential factor and must be used as a qualitative criterion in connection with the awarding of public pharmacy contracts and calls for tender for the supply of medicines; emphasises the importance of diversified supplies and sustainable procurement practices for pharmaceuticals; proposes that investments in the manufacture of active ingredients and medicinal end products in the EU should also be retained as an essential criterion, as well as the number and location of production sites, the reliability of supply, the reinvestment of profits into R&D, and the application of social, environmental, ethical and quality standards;

66. Considers that, in times of crisis, part of the Union's joint procurement could, where appropriate and upon request, be pre-allocated to low- and middle-income third countries, in a spirit of solidarity;

---

[1] Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC (OJ L 94, 28.3.2014, p. 65).

67. Calls on the Commission and the Member States to consider introducing procurement procedures under which contracts may be awarded to a number of successful tenderers, including joint tenderers;

Access to medicines in the EU

68. Is concerned that the accessibility and affordability of medicines remain a challenge for national health systems, and that innovative medicines are expensive or in certain Member States not even brought to the market for commercial reasons;

69. Calls on the Commission to look into policy options that help guarantee that centrally authorised medicines are marketed in all Member States and not just in those that are commercially interesting; stresses the need to ensure that any form of incentive at EU level leads to the fair and affordable pricing of pharmaceuticals, particularly innovative ones, across all Member States;

70. Welcomes the Commission's intention to review pharmaceutical legislation to promote robust and fair competition, to support the Member States in stabilising and balancing national drug pricing systems, to promote fair national drug pricing systems and to ensure equal access to medicines and medical products across the Member States; highlights that decisions on the pricing of medicines and reimbursement of the cost of medicines are the purview of Member States;

71. Stresses that commercial withdrawals can have serious consequences in terms of the availability of medicines and thus hamper patients' access to timely, equitable and high-quality treatment; underlines that commercial withdrawals of essential medicines should take place in situations where substitute and equivalent treatments are available for patients and should be subject to extended early notification obligations for MAHs and distributors, to ensure that Member State authorities are able to manage the situation of MAHs and distributors in the interest of patients;

72. Calls on the Commission to consider new processes for promoting the repurposing of medicinal products; calls on the Commission to facilitate broader off-label use of medicines, including less expensive medicines and medicines used for rare cancers, among others, whenever there is strong scientific evidence of efficacy and safety for patients; highlights, in addition, the opportunity for a new framework to support the marketing and use of drugs with new approved indications in order to make drug repurposing more attractive in the EU;

73. Calls on the Commission to develop European health strategies on the basis of a common basket of medicines for the treatment of cancer, infections and rare diseases and in other areas particularly affected by shortages; calls on the Commission to consider the option of common pricing criteria to make such medicines affordable; believes that facilitating faster access, without compromising safety, would be especially beneficial for patients with severe chronic diseases; suggests accordingly that patients be allowed to take part in decisions on risk-benefit, from early access to new and innovative medicines and treatment;

74. Encourages the inclusion of disease-based communities in the EMA's scientific advice processes, for rare cancers and diseases, so that they can provide regulators with their expertise on the disease concerned and factor in its rarity and unmet needs;

Supporting a transparent, competitive and innovative EU pharmaceutical industry to respond to public health needs

75. Insists that a competitive, self-sufficient and sustainable EU pharmaceutical industry is of strategic importance for the Union as it fosters innovation, research and high-quality employment and is more responsive to patients' needs; points out that the industry needs a stable and predictable regulatory environment, but one which limits the administrative burden and safeguards the principle of prevention and the availability of safe, effective and high-quality medicines on the EU market; underlines that the marketing authorisation system should build on the existing legislative framework and prevent duplication and any additional administrative burden;

76. Welcomes the strong focus and several initiatives included in the pharmaceutical strategy on the need to optimise and modernise the existing regulatory framework, such as through revision of the variations legislation, more digitalised and efficient regulatory processes, implementation of electronic product information (ePI), streamlined active pharmaceutical ingredient (API) assessment, and better good manufacturing processes (GMPs)/manufacturing management and resources; urges the Commission to make swift progress on this agenda, making the best use of existing digital tools at EU level (telematics);

77. Urges the Commission and the Member States to introduce financial incentives, where appropriate, to preserve and expand the EU's pharmaceutical industrial base, from the production of active pharmaceutical ingredients to medicine manufacturing, packaging and distribution; emphasises the strategic significance of this sector and the importance of investing in European companies in order to diversify resources and encourage the development of innovative production technologies capable of enhancing the responsiveness of entire production lines; recalls that all public funding should facilitate the best outcomes for patients, including in terms of the accessibility of manufactured medicines, by respecting transparency, traceability and supply obligation conditionalities;

78. Recalls the Commission communication of 5 May 2021 entitled 'Updating the 2020 New Industrial Strategy: Building a stronger Single Market for Europe's recovery', which analyses the EU's strategic dependencies, including the production of active pharmaceutical ingredients and other health-related products, which could lead to vulnerabilities for the EU and affect its core interests, and which refers to the pharmaceutical strategy as a means to address these issues;

79. Recalls the critical need for global health and for global supply chains to develop local production and distribution capacities in the EU and in developing countries, notably in terms of pharmaceutical research, development and production and always in accordance with social standards and industry due diligence; calls on the Commission to use the industrial, intellectual property and pharmaceutical strategies to facilitate bridging the persisting gap in research and medicine production through product-development partnerships and the creation of open centres for research and production;

80. Considers that pharmaceutical manufacturing plants are part of Europe's critical health infrastructure; calls therefore on the Commission and the Member States to monitor foreign direct investment in the sector; suggests applying the European Programme for Critical Infrastructure Protection to the health infrastructure sector;

81. Points out that developing new mutual recognition agreements on GMP certificates and extending the scope of existing ones (most importantly on inspections and batch testing) with more countries who have high manufacturing standards could make it easier to include sites in non-EU countries in a production supply chain without giving up European standards, which would allow for higher production capacity in times of crisis;

82. Urges the Commission to propose the inclusion of environmental standards, especially on waste and wastewater management, in the Good Manufacturing Practice guidelines at international level;

83. Highlights the need for up-skilling, re-skilling and out-skilling of workers for healthcare careers in order to be better prepared for potential emergency and crisis situations; calls for due consideration to be given to the further training and retraining of workers involved at all stages of the value chain and to broadening the range of training opportunities for STEM specialists;

84. Highlights the latest evolution of pharmaceutical products towards disease and patient-specific therapeutics, involving scrupulous manufacturing steps and the need to take into account the high sensitivity to environmental and transport conditions and complicating supply chain logistics; invites the Commission to maximise synergies between European funds and other EU instruments and policies in order to support the design and operation of robust manufacturing processes and distribution networks ensuring agile, responsive and reproducible manufacturing;

85. Calls on the Commission to expand the role of the EMA in the assessment of drug-device/diagnostic combination products to simplify the fragmented supervisory framework; believes that greater regulatory agility and efficiency can be achieved by adopting a more expertise-driven scientific assessment of marketing authorisations within the EMA;

86. Believes that fostering and building on an attractive European industrial eco-system for the pharmaceutical sector is one of the key conditions for continuing to foster the relocation of production facilities back to the EU; further believes that relocation of this kind can help to make European healthcare systems more independent from third countries and more resilient to disruptions, given that breaks in supply put patients at risk when they are not able to obtain recommended alternative treatments;

87. Calls on the Commission to include in the EU Statistics on Income and Living Conditions (EU-SILC) data on self-reported lack of access to medicines, as so far access to medicines is not measured in the EU-SILC;

88. Supports the adaptation of existing frameworks for the acceptability in decision making and adoption of AI technologies so as to provide a pathway through which AI can be developed, adopted and implemented in healthcare systems through inclusivity, capacity-building and trust; reiterates that, as with all AI-based technologies, human oversight must be guaranteed at all times; believes that legislation should not lag behind innovation; calls on the Commission to introduce a degree of regulatory flexibility in order to be able to respond more rapidly and effectively to new requirements and products, while respecting safety and ethical criteria;

89. Calls on the Commission to facilitate assessment processes that allow for early and iterative dialogue on data and evidence as they are generated; calls on the EMA and national medicine agencies to prioritise the submission of data from randomised controlled clinical trials that compare investigational medicines according to the EMA definition against the standard treatment;

90. Notes that decisions taken regarding the EU's pharmaceutical regulatory environment will have implications beyond EU borders, given that several third countries recognise and rely on EU requirements, particularly when it comes to facilitating exports and waiving requirements to test them in third countries when they come from the EU; therefore emphasises the importance of maintaining such mutual recognition agreements with third countries where possible and ensuring that they remain up to date;

91. Points out that the EU should focus on developing adequate capacity for the sustainable production of active substances, raw materials and medicines which reduce dependence on external sources; advocates greater legal certainty for drug developers;

Supplementary protection certificates

92. Calls on the Commission to evaluate the added value of the supplementary protection certificate (SPC) mechanism in order to prevent delays in access to generic medicines and improve the financial sustainability of healthcare systems;

93. Draws attention to differences in the validity of patents and SPCs in the various Member States; calls on the Commission to revise the use of SPCs on the basis of technological and scientific advances so as to enable generic and biosimilar medicines to become more competitive within and outside the EU;

94. Calls on the Commission to evaluate the impact that a proposal for a unitary SPC would have on the market entry of generic and biosimilar medicines and on equitable patient access to treatments, and on the basis of such an evaluation propose a unitary SPC where appropriate;

95. Underlines that the use of SPCs should be allowed only in exceptional and justified cases;

Innovative and new medicines

96. Stresses that R&D is key for the development of innovative medicines, therapies and diagnoses;

97. Highlights the fact that gene and cell therapies, personalised medicine, radionuclide therapy, nanotechnology, next-generation vaccines, including tmRNA derivatives, e-health and the '1+ Million Genomes' initiative can bring enormous benefits in relation to the prevention, diagnosis, treatment and post-treatment of all diseases if they prove their added value compared to existing health technologies; underlines the transformative potential of these novel therapies and technologies for patients as well as societies at large, for example by enabling a shift from chronic management and care to one-time treatment, thereby contributing to reducing costs for health systems, and strengthening their efficacy, sustainability and resilience; urges the Commission to promote sufficient expertise, develop appropriate regulatory frameworks, guide new

business models, consistently ensure high standards for safe products, and run information campaigns to raise awareness and ensure the uptake of these innovations; urges the Commission to propose adequate resources for the EMA to meet these objectives effectively;

98. Recognises that advanced therapy medicinal products (ATMPs) are fundamentally different from traditional pharmaceuticals as they address the root causes of disease, and that their fundamental durability and potential curative nature could allow them to be the future of medicine; acknowledges that regulatory bodies such as the EMA are set to review and approve dozens of ATMPs over the coming years, underlining the need for the Commission to establish, in addition to its ATMP Action Plan, a robust regulatory landscape that facilitates access for all eligible European patients, and to continue to build on Europe's position as a major player in ATMPs in order for Europe to remain globally competitive in ATMP development;

99. Calls on the Commission to ensure that the existing coordinating bodies will facilitate cross-border treatments based on ATMP and that patients across Europe enjoy equitable access to innovative therapies;

100. Urges the Commission to work with the EMA to create a one-stop shop for ATMP developers so as to provide them with guidance and a forum for communication on their applications;

101. Urges the Commission and the EMA to consider the full lifecycle of all innovative medicines and therapies, including gene and cell therapies, personalised medicine, nanotechnology and next-generation vaccines, and ensure a fit-for-purpose framework for off-patent competition at the time of loss of exclusivity; calls on the Commission to establish a regulatory framework for nanomedicines and nanosimilar medicines, and calls for these products to be approved through a compulsory centralised procedure;

102. Highlights that the take-up of new and innovative treatments, as well as their successful delivery to patients, depends on the knowledge, preparedness and technical base at the disposal of medical personnel; calls on the Commission and Member States to further cooperate with each other by sharing knowledge and best practices regarding emerging innovative medicines and treatments in order to better prepare their medical professionals;

Clinical trials

103. Calls on the Commission to fully implement the Clinical Trials Regulation[1] to facilitate the launch of large clinical trials carried out in a harmonised and coordinated manner at EU level; stresses that patient associations should be more involved in defining research strategies for public and private clinical trials, in order to ensure that they meet the unmet needs of European patients; welcomes the revision of pharmaceutical legislation to reduce red tape and to adapt it to cutting-edge products, scientific advances and technological transformation; supports clinical trials that are more patient-centred, as

---

[1] 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).

well as 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; urges the Commission to ensure more transparency in clinical trial results, with pharmaceutical companies sharing participant-level data, both positive and negative results, protocols and other trial documents in a timely manner;

104. Calls on the Commission to ensure continuous dialogue between the European Centre for Disease Control, the EMA and vaccine developers on the establishment and functioning of the vaccine platform to monitor vaccine efficacy and safety;

105. Calls for full implementation of the rules governing clinical trials in order to consolidate a clear and proportionate set of rules to ensure legal certainty for operators; calls on the Commission to improve the participation of public researchers in clinical trials and to allow clinical trials to be carried out in several Member States simultaneously for long-term research;

106. Stresses that R&D clinical drug trials are very rarely successfully completed and that the R&D therefore does not result in final drug approval;

Health technology assessment

107. Welcomes the agreement reached by Parliament and the Council on the forthcoming regulation on health technology assessment and calls for its swift adoption and thorough implementation so as to foster greater convergence between Member States on the evaluation of health technologies and to facilitate rapid access to innovative treatments for patients;

108. Points out that new health technologies should demonstrate their clinical added value and cost-effectiveness compared to what is already available on the market; emphasises that health technology assessment is a tool to support this analysis but that it is currently highly fragmented within the Union, although it can enable cooperation on clinical evidence requirements and clinical trial design and therefore support Member States' timely and evidence-based decision making on patient access to new medicines; reiterates that the Commission and Member States implement the regulation expeditiously in accordance with the agreed timeframe;

Current framework for authorisation

109. Urges the Commission, based on the experience of the authorisation of COVID-19 vaccines, to work with the EMA to consider extending the application of rolling reviews to other emergency medicines and evaluate if further regulatory flexibilities could contribute to a more efficient authorisation system, while safeguarding a high level of safety, quality and effectiveness;

110. Welcomes the fact that the strategy recognises that the better use of ePI will support the better delivery of information to patients and the wider availability of medicines, especially in critical situations;

111. Calls on the Commission to work with the EMA and the EU regulatory network, including industry and all relevant stakeholders, to develop and implement the use of

ePI for all medicines in the EU in all the languages of the Member States where the medicines are marketed;

112. 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, on the basis of robust clinical data; 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 where such measures are supported by sufficient clinical data;

113. Encourages the Commission, in cooperation with the EMA, to consider how established tools such as accelerated authorisation, early dialogue, the PRIME scheme and expanded guidance can be used to make medicine available to patients at a faster pace, especially medicine that has the potential to address an urgent public health threat or an unmet medical need; calls on the Commission to further the application of the EMA's PRIME scheme for life-saving medicines and to include a PRIME designation in the legislative framework, without affecting the safety of patients; recalls that accelerated schemes should not be misused where sufficient evidence on regular marketing authorisation is lacking;

114. Calls on the Commission, the EMA and the competent authorities to capitalise on all the pragmatic efforts made during the COVID-19 crisis, in particular as regards regulatory flexibility, with a view to effectively tackling medicine shortages, including in emergency situations;

115. Calls for long-term monitoring of medicines placed on the market in order to identify any harmful side effects and assess their cost-effectiveness as treatments;

SMEs and pharmaceuticals

116. Calls on the Commission to create an innovation ecosystem that facilitates the exchange of experience and access for SMEs and contributes to the EU's becoming a hub for global medical innovation; notes that the Commission should seek new advisory strategies to facilitate access to innovation funds for smaller companies; points out that bureaucratic hurdles and complexity make it difficult for SMEs and public research centres to take full advantage of European innovation programmes; underlines the need to promote access to funding lines to support the work of new start-ups and SMEs, while respecting the established conditions and criteria;

117. Supports the Commission's Intellectual Property Action Plan proposal to update a series of existing tools and make them fit for the digital age;

118. Calls for the intellectual property system to be made more effective for SMEs through measures to simplify intellectual property registration procedures, improve access to strategic intellectual property advice, and facilitate the use of intellectual property as a lever to access funding, for example through the Intellectual Property Rights Helpdesk for SMEs; highlights the need to allocate more resources at EU level to the fight against unfair and abusive practices in the market for medicines;

119. Points out that SMEs play a crucial role in the pharmaceutical value chain, often as first movers and drivers of innovation;

Increasing resilience: prevention of medicine shortages, secure supply chains, sustainable medicines, crisis preparedness and response mechanisms

120. Recalls that the EU's open strategic autonomy is linked to the constant and sufficient availability of medicines in all Member States; reiterates, in this regard, the recommendations stated in its resolution of 17 September 2020 on the shortage of medicines; calls on the Commission, the Member States and the EMA to develop an early warning system for medicine shortages, based on a European innovative, user-friendly, transparent and centralised digital platform to exchange information and data on shortages and focusing on supply problems; considers that such a system should be capable of determining the volume of existing medicine stock and demand and provide data capable of detecting, predicting and preventing shortages of medicinal products; calls on the Commission, moreover, to increase public-private collaboration and to monitor the obligation on the part of all relevant supply stakeholders to provide early and transparent information on the availability of medicines, demand for medicines, parallel trade activities, export bans and market distortions, without undue regulatory and administrative burdens;

121. Calls on the Commission to develop a mechanism to safeguard transparency in production and supply chains in the event of emergencies and beyond; stresses, in this regard, the importance of monitoring and fighting counterfeit pharmaceuticals;

122. Underlines that the pharmaceutical sector remains an important industrial pillar, as well as a driving force in terms of job creation; stresses the importance of creating high-quality jobs in the EU along the entire pharmaceutical value chain and in the medical field, including the health workforce, with the support of the Next Generation EU instrument; calls on the Commission to propose measures to promote employment and skill-building in the pharmaceutical and medical sectors in all Member States, facilitating geographical balance, talent retention and employment opportunities across the EU as a whole;

123. Calls on the Commission and the Member States to develop innovative and coordinated strategies and to step up the exchange of good practice in the area of stock management; takes the view that the EMA is the body best suited to be designated as the regulatory authority tasked with preventing shortages of medicines at EU level during emergencies and beyond;

124. Calls on the Commission to extend the mandate of the EMA further so as to allow it to monitor medicine shortages even beyond health crises and to ensure that it has the necessary resources;

125. Reiterates its call on the Commission and the Member States to ensure that MAHs and wholesale distributors comply with the requirements of Directive 2001/83/EC in order to secure appropriate and continued supplies of medicines, as well as respecting notification obligations in the event of temporary or permanent supply interruption, and to further clarify these obligations to ensure that MAHs report medicine shortages within the established timeframes; stresses the need to apply dissuasive and

proportionate sanctions in the event of non-compliance with these legal obligations, in line with the existing legislative framework;

126. Insists that the public service obligation established in Article 81 of Directive 2001/83/EC is not sufficient to ensure that the EU as a whole is adequately supplied; calls on the Commission to implement the recommendations of the EU Executive Steering Group on Shortages of Medicines Caused by Major Events in order to prevent and mitigate supply disruption during the pandemic and beyond;

127. Recalls that the root causes of medicine shortages should be addressed and tackled as a matter of urgency, taking into account the links between the supply chain and production challenges;

128. Calls on the Commission to therefore ensure that the revision of the general pharmaceutical legislation builds on a good understanding of the root causes of medicine shortages; highlights the need for the Union's pharmaceutical industry to have a diversified supply chain and a medicine shortage risk mitigation plan to cope with any vulnerabilities and risks to the supply chain; stresses, however, that sustainable systemic policies need to be put in place before resorting to disproportionate regulatory requirements, an obligation to supply, penalties or ill-conceived stockpiling fragmenting the single market or threatening products' economic sustainability, which may lead to further shortages;

129. Considers it important that the single market for medicines is safeguarded and that unjustified import and export restrictions, which can cause harm to the single market and decrease affordability, are avoided and addressed by the Commission if they occur; calls on the Commission to assess, and where necessary address, the impacts of parallel trade with regard to medicine shortages in the Member States and to tackle problems adequately by taking the necessary action to ensure that medicines reach all patients in the EU in a timely manner;

130. Calls on the Commission to use all the means at its disposal to prevent counterfeit medicinal products from entering the market, since such products are often of low quality and dangerous to health, and have a major economic impact;

131. Notes that technical assistance for the Member States is necessary for the proper implementation of the European Medicines Verification System;

132. Welcomes the fact that the Commission will continue to monitor mergers between pharmaceutical companies to prevent distortion of competition;

133. Calls on the Commission to consider creating a European contingency reserve for critical medicinal products that are at a high risk of shortage, along the lines of the RescEU mechanism, in order to alleviate recurrent shortages;

134. Recalls that medicine shortages have a direct impact on patients' health and safety and the continuation of their treatment, particularly for vulnerable populations such as children, the elderly, pregnant women, people with disabilities, patients with chronic diseases or cancer, and people in an ICU;

135. Calls on the Commission to draft a harmonised definition of ‘shortages’ and to standardise reporting requirements across Member States in order to enable closer cooperation and enhanced data exchange across Europe;

European Health Data Space, health data and GDPR

136. Welcomes the initiative of building interoperable digital infrastructure for the European Health Data Space, which will collate real-world data, to leverage the full potential of real-world data and access to rare therapies and to ensure fair, transparent and non-discriminatory access to data throughout Europe; underlines that the consistent application and enforcement of the General Data Protection Regulation[1] (GDPR) in all Member States is the foundation for such initiatives;

137. Requests that the Commission work with Member States to ensure the full and harmonised application of the GDPR with regard to conducting clinical research across the EU;

138. Highlights the need to promote the use of health data in full compliance with the GDPR; further believes that it is of the utmost importance to enable and promote trust and data innovation in digital health, which will be possible through education and capability building for regulators, industry and patients;

139. Highlights the need to promote both primary and secondary use of aggregated health data and the need in this regard for a clearer definition of secondary data use vs. primary data collection;

140. Stresses that, owing to the sensitive nature of health data, the Commission and all relevant agencies should safeguard and guarantee that its processing operations respect the data protection principles of lawfulness, fairness, transparency, purpose limitation, data minimisation, accuracy, storage limitation, integrity and confidentiality; further stresses that Member States and EU bodies should strictly respect the principles of data protection as set out in Article 4 of Regulation (EU) 2018/1725[2], while also determining appropriate technical and organisational security measures in accordance with Article 33 of that regulation;

141. Recalls the essential role that new technologies, digitalisation and AI can play in enabling researchers from European laboratories to work in a network and share their objectives and results, while fully respecting the European Data Protection Framework; calls on the Commission to support measures favouring open science in order to

---

1 Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (OJ L 119, 4.5.2016, p. 1).

2 Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

accelerate the sharing of data and research results within the scientific community in Europe and beyond;

142. Stresses the need to develop European federated data networks aiming to contribute to optimal research, development and healthcare delivery; underlines the importance of data sharing and data accessibility in deploying the full potential of AI in the field of healthcare, while putting in place robust ethical requirements and establishing clear liability rules; refuses the commercialisation of such data and notes the urgent need to act against the sale of such data to, among others, the pharmaceutical industry, health insurance providers, technology companies and employers;

143. Considers that the interconnection and interoperability of high-performance computing infrastructures with the European health data area would ensure the availability of large, high-quality health data sets, which are critically important for research and treatment of pathologies, especially rare diseases and paediatric conditions;

144. Supports the adaptation of existing frameworks for acceptability in decision-making and the adoption of AI technologies to provide a pathway through which AI can be developed, adopted and implemented in healthcare systems through inclusivity, capacity and trust;

Structured dialogue with stakeholders

145. Recognises the multiple drivers of shortages and therefore the importance of ensuring the involvement of manufacturers and other supply chain stakeholders to prevent and manage medicine shortages;

146. Supports the Commission in its efforts to conduct a structured dialogue with relevant actors in the pharmaceutical value chain, public authorities, non-governmental patient and health organisations, healthcare professionals, including pharmacists, and the research community as one of the tools to address the root causes of medicine shortages and the weaknesses in the global manufacturing and supply chain for critical medicines, pharmaceutical raw materials, intermediate products and active pharmaceutical ingredients, as well as identify opportunities for innovation; calls on the Commission to ensure the balanced representation of stakeholders;

147. Urges the Commission, the Member States and stakeholders to draw up, as soon as possible and on the basis of this structured dialogue, a clear and ambitious policy roadmap to secure and modernise Europe’s existing manufacturing capacity for medicines, technology and active pharmaceutical ingredients;

148. Believes that, in addition to the structured dialogue on manufacturing and supply chain, a wider political High Level Pharmaceutical Forum is also needed, bringing together policymakers, regulators, payers, patient organisations, industry representatives and other relevant stakeholders in the healthcare supply chain, in order to share the lessons learnt from the COVID-19 emergency situation and to establish an effective policy framework to prevent shortages in the long term, enable access to medicines for patients, reduce delays, and ensure competiveness and innovation;

149. Highlights the valuable role of community pharmacies and recognises their valuable contribution during the pandemic in continuously providing an essential and quality

service; stresses that pharmacists are an independent, reliable and trustworthy source of information; suggests that pharmacists play a more active role in pharmacovigilance activities to assess and monitor the effectiveness of medicines and invites Member States to include them in their health, care and research programmes; calls for greater recognition of pharmacies in rural areas, which enable such areas to retain their populations and ensure the well-being of citizens;

Sustainable and environmentally friendly medicines

150. Stresses the need for the pharmaceutical industry to be environmentally friendly and climate-neutral throughout the lifecycles of medicinal products, while ensuring access to safe and effective pharmaceutical treatments for patients; calls on the Commission to strengthen inspection and auditing throughout the production chain, particularly outside the EU; 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 pharmaceutical household waste, through measures to reduce packaging and the size of containers to ensure that they are no larger than necessary, while ensuring convenient and safe handling for patients or consumers with limited mobility, and to bring medical prescriptions into line with real therapeutic needs; encourages the Commission to consider the potential of e-leaflets as a measure complementary to the current paper information tools, in order to reduce the use of paper in packaging, while also maintaining equal access to important information; acknowledges the steps already taken by the pharmaceutical industry such as, for example, the Eco-Pharmaco-Stewardship initiative;

151. Considers that the European Green Deal constitutes a major opportunity to encourage pharmaceutical manufacturers to participate in the green recovery plan by producing in compliance with environmental and ecological standards;

152. Stresses that pharmaceutical waste should be handled in line with the objectives and targets of the circular economy; believes that the pharmaceutical industry should have the same requirements and standards for packaging and waste management as other sectors; calls on the Commission to create a uniform framework for packaging that takes into account user-friendliness and the characteristics of the industry;

153. Calls on the Commission to develop clear guidance on the role of procurement policy in promoting greener pharmaceuticals;

154. Calls on the Commission to respond to the demands made by Parliament in its resolution of 17 September 2020 on a strategic approach to pharmaceuticals in the environment[1], in particular that it revise the pharmaceutical legislation to strengthen the environmental risk assessment requirements and conditions for the approval and use of medicines, provided that marketing authorisations are not delayed or refused solely on the grounds of adverse environmental impacts; further calls on the Commission to speed up the catch-up procedure for environmental risk assessments of human medicines authorised before 2006, where they are not available;

---

1 OJ C 385, 22.9.2021, p. 59.

155. Recalls that information such as the impact of pharmaceuticals on water, environmental behaviour and degradability plays a key role in risk management and that this type of information should be transparent and made available to all relevant stakeholders; welcomes the Commission's efforts to address the problem of pharmaceuticals in the environment; stresses the need to continue and step up these efforts, in particular as regards investments in technologies providing more effective solutions for the removal of pharmaceuticals from waste water, the assessment of the environmental impact of veterinary medicines, the development of continuous monitoring, and data sharing on significant potential sources of this type of pollution;

156. Insists that the pharmaceutical strategy for Europe should consider the objectives of the Zero Pollution Action Plan for water, air and soil;

157. Supports the implementation of the 'polluter pays principle' to increase the responsibility of the pharmaceutical industry for the pollution it may generate;

158. Calls on the Member States and the Commission to support research, development and innovation in the field of pharmaceuticals that are equally effective for patients and intrinsically less harmful for the environment;

159. Stresses the importance of investment in finding new alternative, non-animal methodologies for drug development, without lowering the level of protection for human health and without prejudice to innovation in the field of pharmaceuticals;

The EU is leading the world in healthcare

160. Calls on the Commission to further facilitate access to global markets for the EU pharmaceutical industry, including SMEs, through a level playing field and a robust and clear regulatory framework promoting the highest standards of quality and safety at international level and facilitating trade agreements that prize innovation-based competitiveness, in order to make the pharmaceutical sector a strategic pillar of the EU; calls on the Commission to ensure that trade agreements contribute to improved access to safe, effective and affordable medicines in the EU and in third countries; highlights the importance of removing trade and non-tariff barriers in third countries, and ensuring fair access to international markets for companies operating in the EU;

161. Calls on the Commission to facilitate agreements between the EMA and non-EU regulatory agencies on preventing emergencies and coordinating responses to them with full respect for the highest EU standards of personal data protection; 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;

162. Reiterates its commitment to continue working with the Commission and the World Health Organization to standardise safe, effective and sustainable regulatory frameworks for medicinal products and improve access to and the affordability of medicines globally;

Patents and the TRIPs agreement

163. Notes that patent protection is a key incentive for companies to invest in innovation and produce new medicines; notes, at the same time, that the exclusionary effect of patents

may lead to limited market supply and reduced access to medicines and pharmaceutical products; stresses that a balance should be struck between encouraging innovation through the exclusionary effect of patents and ensuring access to medicines and protecting public health; recalls that a company that markets a medicine can enjoy data exclusivity for a period of eight years as of the first marketing authorisation pursuant to Article 14(11) of Regulation (EC) No 726/2004; calls on the Commission to propose a revision of that regulation to provide for the possibility of temporarily authorising the granting of compulsory licences in the event of a health crisis in order to allow for the production of generic versions of life-saving medicines; recalls that this is one of the public health flexibilities in the field of patent protection already included in the WTO's TRIPS Agreement, as further reaffirmed by the 2001 Doha Declaration; calls on the Commission to ensure that the implementation of EU free trade agreements (FTAs) does not interfere with the possibility of invoking flexibilities provided by the TRIPS Agreement and to provide guidance to Member States in order to encourage voluntary licensing over immediate compulsory licensing; stresses that FTAs should not focus exclusively on enforcing intellectual property standards in third countries, but should take into account the impact on generic and biosimilar medicines in the EU and in third countries, as well as ensure coordination of regulatory standards;

°

° °

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