**European Parliament**
2019-2024

**TEXTS ADOPTED**

# P9_TA(2020)0228

## Shortage of medicines - how to address an emerging problem

**European Parliament resolution of 17 September 2020 on the shortage of medicines – how to address an emerging problem (2020/2071(INI))**

*The European Parliament,*

– having regard to Article 3 of the Treaty on European Union (TEU),

– having regard to Article 6(1) TEU and Article 35 of the Charter of Fundamental Rights of the European Union on the right to preventive healthcare for all European citizens,

– having regard to Article 14 of the Treaty on the Functioning of the European Union (TFEU) and Article 36 of the Charter of Fundamental Rights of the European Union,

– having regard to Articles 101 and 102 TFEU and the Protocol (No 27) on the internal market and competition,

– having regard to the provisions of Articles 107 and 108 TFEU regarding State aid,

– having regard to Article 168 TFEU, which states that a high level of human health protection must be ensured in the definition and implementation of all Union policies and activities,

– 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[1], and the obligations set out in Article 81 thereof concerning an appropriate and uninterrupted supply of medicinal products, and Article 23a thereof on notifying the competent authority if a product ceases to be placed on the market on a temporary or permanent basis,

– having regard to the assessment report from the Commission to the European Parliament and the Council in accordance with Article 59(4) of 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 (COM(2017)0135),

– having regard to the Council conclusions of 8 June 2010 on ‘Equity and Health in All

[1] OJ L 311, 28.11.2001, p. 67.

Policies: Solidarity in Health',

– having regard to 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[1],

– 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[2],

– having regard to Council Regulation (EU) 2015/1589 of 13 July 2015 laying down detailed rules for the application of Article 108 of the Treaty on the Functioning of the European Union[3],

– having regard to Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use[4],

– having regard to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC[5],

– having regard to Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions[6],

– having regard to Regulation (EU) 2019/5 of the European Parliament and of the Council of 11 December 2018 amending Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, Regulation (EC) No 1901/2006 on medicinal products for paediatric use and Directive 2001/83/EC on the Community code relating to medicinal products for human use[7],

– having regard to the proposal for a regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU (COM(2018)0051), and to Parliament's position at first reading of 14 February 2019 on that proposal,

– having regard to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and to the Doha Declaration on the TRIPS Agreement and Public Health,

– having regard to the Commission communication of 8 April 2020 entitled 'Guidelines

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1 OJ L 94, 28.3.2014, p. 65.
2 OJ L 158, 27.5.2014, p. 1.
3 OJ L 248, 24.9.2015, p. 9.
4 OJ L 32, 9.2.2016, p. 1.
5 OJ L 117, 5.5.2017, p. 1.
6 OJ L 130, 24.4.2020, p. 18.
7 OJ L 4, 7.1.2019, p. 24.

on the optimal and rational supply of medicines to avoid shortages during the COVID-19 outbreak' (C(2020)2272),

– having regard to the Commission communication of 27 May 2020 on 'Europe's moment: Repair and Prepare for the Next Generation' (COM(2020)0456),

– having regard to the Commission communication of 27 May 2020 on 'The EU budget powering the recovery plan for Europe' (COM(2020)0442),

– 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 20 May 2020 on the EU Biodiversity Strategy for 2030 (COM(2020)0380),

– having regard to its resolution of 17 April 2020 on EU coordinated action to combat the COVID-19 pandemic and its consequences[1],

– having regard to its resolution of 18 December 2019 on enabling the digital transformation of health and care in the Digital Single Market: empowering citizens and building a healthier society[2],

– having regard to its resolution of 2 March 2017 on EU options for improving access to medicines[3],

– having regard to the guidelines of the Task Force on the availability of authorised medicinal products for human and veterinary use, bringing together the European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA), in particular those of 1 July 2019 entitled 'Guidance on detection and notification of shortages of medicinal products for Marketing Authorisation Holders (MAHs) in the Union (EEA)' (EMA/674304/2018) and those of 4 July 2019 on 'Good practice guidance for communication to the public on medicines: availability issues' (EMA/632473/2018),

– having regard to the newly created platforms in the light of the current COVID-19 crisis, such as EMA's Industry Single Point of Contact (I-SPOC) system, which is streamlining the process of reporting potential medicine shortages in order to prevent them and to flag these shortages as early as possible; having regard to the fact that these platforms have enabled and facilitated a dialogue on shortages between stakeholders in the pharmaceutical supply chain and regulators,

– having regard to the report of the World Health Organization (WHO) entitled 'The selection of essential medicines. Report of a WHO Expert Committee [meeting in Geneva from 17 to 21 October 1977]' (WHO Technical Report Series, No 615), the report by the WHO Secretariat of 7 December 2001 entitled 'WHO medicines strategy: revised procedure for updating WHO's Model List of Essential Drugs' (EB109/8), the WHO report of March 2015 entitled 'Access to new medicines in Europe', and the WHO report of 9 July 2013 entitled 'Priority Medicines for Europe and the World',

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1 Texts adopted, P9_TA(2020)0054.
2 Texts adopted, P9_TA(2019)0105.
3 OJ C 263, 25.7.2018, p. 4.

– having regard to the WHO's 'One World, One Health' philosophy,

– having regard to UN Sustainable Development Goal No 3, 'Ensure healthy lives and promote wellbeing for all at all ages',

– having regard to Report No 737 of the French Senate of 27 September 2018 on shortages of medicines and vaccines – focusing more closely on public health issues in the medicine supply chain, drawn up by Jean-Pierre Decool on behalf of the Senate's fact-finding mission on the shortage of medicines and vaccines,

– having regard to the Commission Guidance concerning foreign direct investment and free movement of capital from third countries, and the protection of Europe's strategic assets in the context of the COVID-19 emergency, ahead of the application of Regulation (EU) 2019/452 (the FDI Screening Regulation), which will be fully operational as from 11 October 2020,

– having regard to the conclusions of the meeting of the Employment, Social Policy, Health and Consumer Policy Council of 9 and 10 December 2019,

– having regard to the 2016 Report of the UN Secretary-General's High-Level Panel on Access to Medicines entitled 'Promoting innovation and access to health technologies',

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

– having regard to its resolution of 15 January 2020 on the European Green Deal[1],

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

– having regard to the opinions of the Committee on Industry, Research and Energy, the Committee on Development, the Committee on International Trade, the Committee on Transport and Tourism and the Committee on Legal Affairs,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety (A9-0142/2020),

A. whereas the longstanding problem of shortages of medicines within the EU has worsened exponentially in recent years; whereas the increase in global demand, as well as the COVID-19 pandemic, have further aggravated shortages of medicines, undermining health services in the Member States and entailing considerable risks for the health and care of patients, including disease progression and/or worsening of symptoms, increased delays or interruption in care or therapy, longer hospitalisations, increased exposure to falsified medicines, medication errors or adverse events occurring when the missing medicine is substituted by another, avoidable transmission of infectious diseases, significant psychological distress, and increased expenditure for the healthcare system; whereas the Member States have a duty to find swift and effective solutions, including through common European coordination and action;

B. whereas the Treaties and the Charter of Fundamental Rights of the European Union state that everyone shall have access to preventive healthcare and the right to benefit

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[1] Texts adopted, P9_TA(2020)0005.

from medical treatment under the conditions established by national laws and practices; whereas this right should be enforced for all citizens, including those living in the smaller Member States and in the most peripheral areas of the Union; whereas shortage of medicines is a growing public health threat with a serious impact on healthcare systems and the right of every patient in the EU to access appropriate medical treatment;

C. whereas ensuring patient access to essential medicines is one of the core objectives of the EU and the WHO, and of Sustainable Development Goal 3; whereas universal access to medicines depends on their timely availability and their affordability for everyone, without any geographical discrimination;

D. whereas patients should have access to the healthcare and treatment options of their choice and preference;

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

F. whereas medicine shortages have multifactorial and complex root causes; whereas some decision-making by the pharmaceutical industry, such as discontinuations of products and withdrawals from less profitable Member States' markets, is also often a reason for medicine shortages;

G. whereas it is imperative to prevent medicine shortages and to mitigate their effects should they occur;

H. whereas an efficient strategy should cover measures to mitigate medicine shortages, but also to prevent them from happening, looking at the multiple root causes of shortages;

I. whereas there are no harmonised definitions between Member States of 'shortage', 'tensions', 'supply disruptions', 'stock-out' and 'overstocking'; whereas a distinction should be made between 'medicinal products of major therapeutic interest' (MITMs) and 'medicines of health and strategic interest' (MISSs);

J. whereas medicine shortages impose significant costs on both public and private health stakeholders;

K. whereas pharmaceuticals are one of the pillars of healthcare, and whereas insufficient access to essential medicinal products and high prices of innovative medicines pose a serious threat to the population's health and to the sustainability of national healthcare systems;

L. whereas in many cases the prices of new medicines, notably cancer treatments, have increased during the past few decades to the point of being unaffordable for many EU citizens;

M. whereas the generic and biosimilar medicines industry supplies the majority of medicines to EU patients (almost 70 % of dispensed pharmaceuticals);

N. whereas the entry of generics and biosimilars into the market is an important mechanism for increasing competition, reducing prices and ensuring the sustainability of healthcare systems; whereas their market entry should not be delayed;

O. whereas the EU-based manufacturers of generics have an important role to play in satisfying the growth in demand for affordable medicines in the Member States;

P. whereas medicines to treat cancer, diabetes, infections and disorders of the nervous system account for more than half of those in short supply; whereas injectable specialities appear to be the most vulnerable to the risk of shortage due to the complexity of their manufacturing process;

Q. whereas medicine shortages could pose a risk to the success of Union and Member State health initiatives, such as Europe's Beating Cancer Plan;

R. whereas in Member States with small markets the medicines to treat rare diseases are often not available or are available only at substantially higher prices than in larger markets;

S. whereas the COVID-19 pandemic has highlighted the importance of a well-functioning internal market and robust supply chains for medicines and medical equipment; whereas a European dialogue on how to ensure this is needed;

T. whereas uncoordinated initiatives at national level, such as stockpiling and penalties, are not the right solution and could lead to an increased risk of medicine shortages;

U. whereas the loss of European independence in the health sector is linked to the relocation of production, with 40 % of medicinal end products marketed in the EU now originating in third countries; whereas while Europe has a strong manufacturing footprint, the supply chain still relies heavily on subcontractors to produce pharmaceutical raw materials outside the EU, where labour costs and environmental standards are often lower, with the result that 60 % to 80 % of chemical active ingredients are manufactured outside the EU, mainly in China and India; whereas this proportion was 20 % 30 years ago; whereas those two countries reportedly produce 60 % of the world's paracetamol, 90 % of its penicillin and 50 % of its ibuprofen; whereas, to date, no label or labelling visible to patients and customers is required for medicinal products and active pharmaceutical ingredients (APIs) concerning their origin and country of manufacturing; whereas limited access to APIs required for the production of generic medicines poses a particular challenge; whereas the disruption of the global supply chain ensuing from the COVID-19 pandemic has highlighted even more the EU's dependency on third countries in the health sector; whereas the novel coronavirus pandemic has also revealed shortages of medical devices, medical products and protective equipment;

V. whereas the EU continues to have a strong pharmaceutical manufacturing sector, particularly in the innovative sector, and is the world's largest exporter of pharmaceutical products, as part of a global trade in pharmaceuticals; whereas the supply of generic medicines at a lower cost involving manufacturing outside the EU enables the affordability of medicines, impacting Member States' healthcare budgets and patients' access;

W. whereas as a consequence of the COVID-19 health crisis, the EU will be facing an economic crisis that will impact on shortages of medicines and the competitiveness of its pharmaceutical industry;

X. whereas it is equally important to protect and foster the existing production sites in the EU and strengthen the European research landscape;

Y. whereas the consequences of growing demand coupled with price pressure include the concentration of supply of APIs, a reduction in the number of chemicals manufacturers and a lack of alternative solutions should problems arise, as shown in the case of the current COVID-19 crisis;

Z. whereas stocks of medicinal products of major therapeutic interest and of health and strategic importance are insufficient, APIs are cheap and easy to produce, and mature medicines, which are essential for public health, are in particularly short supply; whereas pharmaceutical firms operate according to the just-in-time method, which can leave manufacturers vulnerable to supply shocks where there are unanticipated production and supply chain interruptions and fluctuations in market demand;

AA. whereas differential pricing between Member States facilitates 'parallel exports' to countries where the medicine in question is more expensive; whereas parallel exports can in some cases have the unintended consequence of creating disruptions in supply across Member States, thereby contributing to market imbalances; whereas in its resolution of 2 March 2017 Parliament called on the Commission and the Council to assess the impact of the parallel trade and supply quotas;

AB. whereas in the absence of effective coordination at EU level, inappropriate stockpiling in some Member States is leading to a market imbalance, exacerbating medicine shortages and reducing access to treatment for patients across the EU;

AC. whereas uncoordinated measures at national level have proven to be ineffective in fighting the COVID-19 crisis, while pan-European coordination and dialogue are needed;

AD. whereas the COVID-19 pandemic has highlighted how coordination among EU institutions, regulators and pharmaceutical supply chain experts is vital to respond to health crises and to supply disruptions such as shortages of medicines; whereas it has also demonstrated the importance of coordination between EU policies and services in order to react promptly and efficiently to emergencies as well as to prevent medicine shortages, and to mitigate them should they occur;

AE. whereas an increasing number of Member States are seeking to establish national stockpiles of medical supplies, and the subsequent increase in demand as a result of this would exceed current demand forecasts based on epidemiological need; whereas sudden large spikes in demand can place considerable strain on suppliers and, as a result, lead to challenges in meeting demand in other countries;

AF. whereas the 2009 financial crisis forced European countries to introduce unsustainable cost containment measures such as clawbacks and inefficient procurement mechanisms in order to reduce pharmaceutical expenditure, which has led to withdrawals of products and companies from the market;

AG. whereas the movement of medicines within the single market is being hampered by the lack of harmonised rules between Member States;

AH. whereas the COVID-19 emergency has highlighted the increased risk of attempts to

acquire healthcare capacities via foreign direct investment and the need to preserve and enhance the sharing of such precious capacities within the single market;

AI. whereas a strong, innovative and competitive pharmaceutical industry in Europe is in the vital interest of the EU and its Member States;

AJ. whereas the pharmaceutical industry needs the right legal framework to undertake research, development and production for pharmaceuticals within the EU;

AK. whereas patent protection creates a legal framework, which is important for pharmaceutical innovation as it provides companies with financial incentives to cover the research and development (R&D) costs of new medicines;

AL. whereas Member States are free to determine further grounds for granting compulsory licences, and to determine what constitutes a national emergency;

AM. whereas medicine shortage notification mechanisms for supply chain operators and pharmacists in particular are currently very fragmented in the Member States; whereas this could prevent adequate monitoring and communication between Member State authorities regarding medicine shortages;

AN. whereas Article 81 of Directive 2001/83/EC calls for measures to prevent shortages of medicinal products or distributional issues regarding them in Member States; whereas the Commission has issued guidelines for an optimal and rational supply of medicines in order to avoid shortages during the COVID-19 pandemic; whereas in these guidelines the Commission recognises that no country is self-sufficient in raw materials, APIs or intermediate products, or in finished medicines that are needed for the proper functioning of the health system;

AO. whereas, as stated by the Commission, Member States' response to the COVID-19 pandemic crisis has required a significant increase in the production of both APIs and medicinal products in the EU, necessitating a reorganisation of supply chains and production lines; whereas in her statements during a meeting of 22 April 2020 with the members of the European Parliament's Committee on the Environment, Public Health and Food Safety (ENVI), Commissioner Stella Kyriakides highlighted the need to increase the production of medicines and the level of innovation within the EU; whereas all small and medium-sized pharmaceutical laboratories constitute an asset to be preserved and a breeding ground for research and discoveries that is to be supported, as they can participate in the prevention of drug shortages;

AP. whereas Parliament, in its resolution of 8 March 2011[1], and the Council, in its conclusions of 13 September 2010, both stressed the need to introduce a common procedure for the joint procurement of medical countermeasures, and in particular of pandemic vaccines; whereas Decision No 1082/2013/EU of the European Parliament and of the Council[2] encourages Member States to take advantage of joint procurement procedures provided that such procedures are preceded by a Joint Procurement

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1 European Parliament resolution of 8 March 2011 on evaluation of the management of H1N1 influenza in 2009-2010 in the EU (OJ C 199 E, 7.7.2012, p. 7).

2 Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

Agreement of participating Member States;

AQ. whereas the Commission has announced its intention to publish, by the end of 2020, recommendations for a future EU pharmaceutical strategy;

AR. whereas transport and logistics management are of crucial importance for the supply of medicines, pharmaceutical products, medical equipment, personal protective equipment, other medical supplies and raw materials, not least given the increasing degree of complexity of the transport chain; whereas it is important to have efficient 'green lane' border crossings with fast-track lanes in order to ensure the unobstructed flow of medicines, reducing administrative barriers and easing access to transport services;

AS. whereas high safety standards and the preservation of decent working conditions for workers should be guaranteed; whereas pharmaceutical regulation should ensure the quality, quantity, safety and efficiency of the supply of medicines between Member States;

AT. whereas patients rely on equitable and efficient access to medicines based on a sustainable, competitive, multi-source and well-functioning single market, which includes the Single European Transport Area;

AU. whereas the COVID-19 outbreak has highlighted the fact that the intra-EU and extra-EU circulation of medicines is key to overcoming existing constraints and prioritising the circulation of essential goods;

AV. whereas it is necessary to prevent the COVID-19 outbreak from worsening the socio-economic situation and living conditions of vulnerable citizens;

AW. whereas the greater number, geographical spread and impact of epidemics is partly attributable to climate change, in combination with globalisation, urbanisation and increased travel; whereas European surveillance has been strengthened on vector-borne diseases such as malaria, dengue, chikungunya, Zika and the West Nile virus;

AX. whereas there is an increased correlation between the destruction of biodiversity, the illegal trade in wildlife, the proliferation of human-made habitats and damage to natural areas densely populated by humans, as well as unsustainable food production methods and zoonosis propagation, i.e. the transmission to humans and rapid spread of animal pathogens; whereas biodiversity is an important source for existing medicines and potential future drug development;

1. Stresses the geostrategic imperative for the Union to regain its independence with regard to healthcare, to secure rapidly and efficiently its supply of affordable medicines, medical equipment, medical devices, active substances, diagnostic tools and vaccines, and to prevent shortages thereof, prioritising the interest and safety of patients; stresses the importance of ensuring that all Member States have fair access to the supply chain; highlights, to that end, 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 their supply chain;

2. Points out that while the Member States are responsible for the definition and organisation of their health policies, the Union is responsible for the pharmaceutical legislation as well as various public health policies and it is incumbent on the EU to

coordinate and complement national measures to guarantee access to affordable and high-quality health services for all EU citizens and residents;

3. Stresses the importance of always putting the interests and safety of patients at the heart of health policies without allowing any discrimination in the access to medicines and treatments, and the need for closer cooperation and coordination between Member States and to facilitate the exchange of good practices; highlights the potential harm to patients from shortages of medicines and medical devices; calls on the Commission and the Member States to coordinate closely to protect the resilience and sustainability of the healthcare supply chain and ensure the continuous availability of medicines;

4. Stresses that the shortage of medicines is a serious threat to the right to essential medical treatment for patients in the EU, generating inequalities between patients depending on their country of residence and creating a possible disruption of the single market;

5. Stresses the importance of a harmonised definition at EU level of 'shortage', 'tension', 'supply disruptions', 'stock-out' and 'overstocking'; calls on the Commission to work towards these harmonised definitions in close cooperation with the Member States and all the relevant stakeholders, including patient organisations; calls on the Commission, in particular, to reinforce the definition of 'shortage' proposed by the European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA) joint Task Force in 2019; calls on the Commission to draw a distinction between 'medicinal products of major therapeutic interest' (MITMs), i.e. medicines for which an interruption of treatment is likely to jeopardise the vital prognosis of patients in the short or medium term or significantly diminishes the patient's chances with regard to the progressive potential of the disease, or for which there are no suitable therapeutic alternatives available in sufficient quantity, and 'medicinal products of health and strategic importance' (MISSs), for which the interruption of treatment causes an immediate threat to the patient's life;

6. Deems it essential that the multifactorial root causes of medicine shortages be assessed and addressed; welcomes, in that context, the call for tender launched by the Commission for a study on the causes of shortage of medicines in the Union and calls for the study to be published by the end of the year; calls, however, for another study to be carried out on the impacts of medicine shortages on patient care, treatment and health;

7. Calls on the Commission to propose ambitious and concrete actions to address these issues in its planned pharmaceutical strategy; calls on the Commission to incorporate measures for the pharmaceutical sector into the 2021 due diligence law proposal for companies;

8. Welcomes the Commission's proposal for a new European health programme (EU4Health) and the fact that one of its stated objectives is to promote the availability and accessibility of medicines and medical equipment; calls for a joint action on the prevention of shortage of medicines, to be funded by the future health programme,

9. Recalls that the shortage of medicines is a global challenge; stresses that developing countries, such as a number of African countries, are the most affected by these shortages; urges that access to medicines in developing countries be tackled in a wider

context in the WHO framework; calls on the Commission and the Member States to increase their support to developing countries, in particular through the RescEU strategic reserve;

10. Underlines the fundamental right of all persons to a standard of living adequate for the health and well-being of themselves and of their families, as enshrined in Article 25 of the Universal Declaration of Human Rights; recalls in this regard that the EU is committed to ensuring a high level of protection of human health in all its policies and activities, in accordance with Article 208 of the Treaty on the Functioning of the European Union and the principle of Policy Coherence for Development, in full compliance with international commitments, notably Agenda 2030 for Sustainable Development and Sustainable Development Goal 3 'Ensure healthy lives and promote well-being for all at all ages';

***Securing supplies in the interests of patients, ensuring access to medical treatment for all patients, and restoring the EU's health independence***

11. Recalls that medicine shortages have a direct impact on patients' health and safety and the continuation of their treatment; stresses that for patients, the consequences of drug shortages include: progression of the disease and/or worsening of symptoms due to a delay in treatment, avoidable transmission of infectious diseases, increased risk of exposure to falsified medicines, and significant psychological distress for patients and their families; recalls that no Member State is self-sufficient with regard to the raw materials, intermediates, APIs and finished medicines necessary to guarantee the proper functioning of its health system;

12. Notes that the risks are particularly high among vulnerable people such as children, the elderly, pregnant women, persons with disabilities, patients with chronic diseases or cancer, or those in an intensive care unit (ICU);

13. Recalls the shortages of female hormonal drugs used for contraception and hormone replacement therapy (HRT); notes with concern the threats posed by such shortages to women's and girls' sexual and reproductive health and rights; stresses the importance of enhancing the control and management of the manufacturing, stockpiling and marketing of those medicines to ensure continuity in supply chains, fair pricing and availability for women;

14. Underlines that in several Member States, a higher price of the substitute medicine proposed to the patient, a lower reimbursement rate or lack of reimbursement constitute major obstacles to access to medicines for people on low incomes or those with chronic conditions; calls on the Member States to guarantee access to a substitute medicine at an equivalent price or subject to a similar reimbursement in the event of a supply shortage;

15. Calls on the Commission to include in the EU Statistics on Income and Living Conditions (EU-SILC) data on self-reported unmet needs regarding access to medicines, as access to medicines in not measured in the EU-SILC at present;

16. Calls on the Commission and the Member States to take the rapid necessary action to ensure security of supply of medical products, reduce the EU's dependence on third countries and support local pharmaceutical manufacturing, for medicines of major therapeutic interest, giving priority to medicinal products of health and strategic

importance in close cooperation with the Member States; calls on the Commission and the Member States to draw up, with the help of the relevant stakeholders, a map of EU production sites in third countries and an evolving map, to be used as a reference, of the existing and potential production sites in the EU, in order to be able to sustain, modernise and strengthen their capacities, where necessary, possible and viable; stresses the importance for the pharmaceutical industry to have the capacity to address sudden increases in demand in critical situations;

17. Calls on the Commission to address in its upcoming pharmaceutical and industrial strategies issues relating to the availability, accessibility and affordability of medicines, to cooperation between national regulatory authorities, and to the EU's dependence on third countries for manufacturing capacity, the supply of APIs and starting materials; believes that these strategies must include regulatory measures and encourage the production of essential APIs and medicines in Europe with the aim of making medicines available, affordable, sustainable and equally accessible;

18. Calls on the Commission to make the shortage of medicines one of the pillars of the upcoming pharmaceutical strategy and to create a pharmaceutical forum, supervised by EMA, bringing together policymakers, regulators, payers, patient and consumer organisations, industry representatives and other relevant stakeholders in the healthcare supply chain in order to prevent shortages, address pharmaceutical sustainability issues and ensure the competitiveness of the European pharmaceutical industry; calls in particular on the Commission to further strengthen dialogue with the relevant stakeholders and with international actors to assess new treatments and vaccines and with EMA in order to find ways to rapidly align scientific assessments between national agencies, including on collaboration in the pre-assessment phase prior to the availability of critical clinical data, on the alignment of post-approval data generation, and on flexible approaches to upscaling manufacturing of treatments and vaccines;

19. Calls on the Commission to ensure that its pharmaceutical strategy is guaranteed to combat inadmissible business practices anywhere on the medicines circuit that might undermine transparency and balanced relations between the various public and private entities directly or indirectly involved in fulfilling the essential public service of ensuring access to medicines;

20. Urges the Commission and the Member States, if needed for the public interest, to consider the introduction of measures as well as financial incentives in line with State aid rules and sustainable policies in return for commitments, to protect Europe's strong pharmaceutical industrial base and to encourage the industry to locate its operations in the EU, from the production of APIs to medicine manufacturing, packaging and distribution; urges the Member States to secure existing operations, for example by rewarding investments in the quality of medicines and in the security of supply; 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 must be made conditional on the full transparency and traceability of investments, on supply obligations on the European market, and on facilitating the best outcome for patients, including in terms of accessibility and affordability of manufactured medicines;

21. Urges the Commission and the Member States to put the right economic framework in

place to secure and modernise existing manufacturing capabilities of medicines, technology and APIs in Europe, for example by rewarding investments in the quality of medicines and in the security of supply;

22. Stresses that the pharmaceutical sector remains an important industrial pillar as well as a driving force in terms of job creation;

23. 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;

24. Underlines that a complete repatriation of medical supply chains might not be feasible in a global economy; calls on the Commission, the Member States and the EU's multilateral partners, in particular the WHO and WTO, to establish an international framework to ensure the quality and integrity of global supply chains in order to limit the use of damaging protectionist measures, while upholding the highest labour and environmental standards in production worldwide; calls on the Commission, in that context, to include measures in the new pharmaceutical strategy to cope with any disruption in the global supply chains; calls on the Commission to address the issues relating to the supply of medicines, including in the context of the forthcoming trade policy review;

25. Notes that for certain biological medicinal products such as those derived from blood and plasma, enabling Europe to increase its capacity to collect blood and plasma will be key to reducing its dependence on plasma imports from third countries; calls on the Commission to accelerate the revision of the blood, tissues and cells legislation (Directive 2002/98/EC[1] and Directive 2004/23/EC[2]) in order to reduce the risk of shortages of these essential life-saving medicinal products;

26. Recalls that Articles 81 and 23a of Directive 2001/83/EC have laid down general obligations for the supply of medicinal products to be borne by marketing authorisation holders (MAHs) and distributors, as well as a notification obligation in the event of a temporary or permanent supply interruption; regrets, however, the disparities observed by the Commission in the transposition of these obligations into national legislations; calls 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 ensure appropriate and continued supplies of medicines; calls on the Commission to further clarify the obligations for MAHs under Directive 2001/83/EC and highlights the need to ensure that they 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;

27. Calls on the Commission and the Member States to consider the establishment of

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1 Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (OJ L 33, 8.2.2003, p. 30).

2 Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (OJ L 102, 7.4.2004, p. 48).

harmonised shortage prevention and management plans requiring producers to identify medicines of major therapeutic interest for which preventive and corrective measures should be taken in order to avoid or alleviate any disruption in supplies; points out that such plans should include solutions for the strategic storage of medicines in order to ensure supply for a reasonable period of time and transparent and permanent communication mechanisms through which patients and healthcare professionals can report and anticipate shortages; urges the Commission to develop guidance to ensure that national initiatives on stockpiling are proportionate to need and do not create unintended consequences in other Member States;

28. Notes that security of supply is an essential factor in combating shortages and must be used as a qualitative criterion in connection with the award of public pharmacy contracts and calls for tender for the supply of medicines, as recommended by Article 67 of Directive 2014/24/EU; emphasises the importance of diversified supplies and procurement practices for pharmaceuticals; urges the Commission, in the context of Directive 2014/24/EU, 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 only; proposes that investments in the manufacture of active ingredients and medicinal end products in the EU should also be retained as a 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;

29. Notes that procurement procedures with only one successful tenderer and/or only one production site of the basic substance may exacerbate vulnerability should supplies be disrupted; 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, by focusing on production in the EU and guaranteeing at least two different sources for the basic substance, in order to maintain market competition and reduce the risk of shortages, while guaranteeing high-quality and affordable treatment for patients; asks the Commission, to that end, to examine the possibility of creating a legislative framework encouraging and enabling healthcare systems to carry out tenders that reward pharmaceutical companies that guarantee the supply of pharmaceuticals in difficult circumstances;

30. Calls on the Commission and the Member States to examine the possibility of creating one or more European non-profit pharmaceutical undertakings which operate in the public interest to manufacture medicinal products of health and strategic importance for healthcare, in the absence of existing industrial production, in order to complete and guarantee security of supply and prevent possible shortages of medicines in cases of emergency; recalls the essential role that new technologies, digitalisation and artificial intelligence can play in enabling researchers from European laboratories to work in a network and share their objectives and their results, while fully respecting the European Data Protection Framework;

31. Calls on the Commission to carefully evaluate the positive contribution that artificial intelligence could make to the fast and reliable delivery of medical supplies;

32. Stresses the importance of public-private partnerships such as the European Innovative Medicines Initiative (IMI), in the framework of programmes for research and innovation; believes that the Commission should also consider the creation of a

European model of the US Biomedical Advanced Research and Development Authority;

33. Stresses that the urgent need for medicines and medical equipment must not mean compromising the quality, safety, efficacy and cost-effectiveness of medicines for human use and health products;

34. Calls on the Commission to take action against the spread of falsified medicines from unauthorised websites and vendors, which are presently raising concerns; considers that this practice can cause serious harm and lead to severe health problems or worsen the health conditions of EU citizens; stresses that EU coordination in mapping and combatting counterfeit medicines is essential;

35. Calls for an enhanced dialogue between the pharmaceutical industry and other production sectors, such as agriculture, horticulture and forestry, in a bid to develop the production of active ingredients in the EU; calls for efforts to counter over-specialisation in certain sectors and for substantial investment in research, the bioeconomy and biotechnology, for the purposes of resource diversification; considers that Europe's industrial recovery needs to prioritise the twin digital and ecological transformation of our societies and the building of resilience to external shocks;

36. Stresses the importance of high-quality medical research and innovation, including the off-patent segment; calls for the establishment of a genuine European network to support therapeutic and medical research and underlines that the price of relocation must not lead to a deterioration in the quality of medical research; emphasises that a stable research and development system can have a positive impact on production capacities and stability of supply;

37. Acknowledges that the research-based pharmaceutical industry is an essential sector and contributor to ensuring quality manufacturing and supply of medicines, to ensuring future innovation to address outstanding, unmet needs, and to supporting the resilience, responsiveness and readiness of healthcare systems to address future challenges including pandemics;

38. Calls on the Commission to provide an environment where the research-based pharmaceutical industry is incentivised to develop affordable solutions for unmet medical needs, such as the fight against antimicrobial resistance; calls on the Commission to maintain a robust European intellectual property system under the forthcoming pharmaceutical strategy, in order to encourage R&D and manufacturing in Europe and ensure that Europe remains an innovator and world leader, and, ultimately, to protect and strengthen Europe's strategic autonomy in the field of public health;

39. Urges the Commission to propose measures to incentivise the greater inclusion of EU small and medium-sized enterprises (SMEs) in the medicine supply chain, given their key role in research and innovation and their inherent ability to quickly adapt their production focus with a view to coping better with unexpected shocks;

40. Calls on the Commission and the Member States to provide an environment that ensures that Europe continues to be an attractive location for R&D investment, in order to preserve an active and competitive research-based pharmaceutical industry underpinned by more investment in R&D capabilities and infrastructure, including universities,

taking into account the fact that the EU remains by far the leading region in the world for the manufacture of active ingredients for patent medicines; calls on the Commission to provide adequate financial resources, under Horizon Europe and other EU programmes, to strengthen the Union's research and investment (R&I) activities supporting manufacturing in key industrial sectors including the pharmaceutical industry, while ensuring geographical balance and the participation of low-R&I-performing Member States in collaborative EU projects and programmes while upholding the principle of excellence;

41. Highlights the fact that Horizon 2020 has already financed a significant number of health-related research and innovation activities; underlines that the funding of coronavirus-related research should not affect other health priorities of Horizon 2020; calls for more funding to be provided through Horizon Europe to create and support medicine-focused research and innovation ecosystems that are medically oriented, including public-private partnerships and support for public research in high added value and innovative sectors; stresses that a leading medical research ecosystem requires skills, networks and academic connections, health data infrastructure, a functioning regulatory framework, and intellectual property policies that foster innovation; calls for a review of the incentives put in place to encourage research on 'orphan medicines' in order to determine whether they are successful, and calls for new incentives should this not be the case; underlines that Horizon Europe and other EU programmes need to support rare diseases and that research, best practices, clinical trials and medication pertaining to rare diseases must be made accessible to the benefit of citizens of all Member States; recalls the importance that non-exclusive licensing can have in mitigating shortages and in stabilising prices of medicines, especially in times of health emergency;

42. Calls on the Commission to take stock of the impact of the coronavirus on industry and SMEs, and to present a renewed EU industrial strategy which would prioritise the twin digital and ecological transformation of our societies and the building of resilience to external shocks; urges the Commission to enable the Member States to make every necessary effort to ensure that small and medium-sized pharmaceutical companies continue or resume their research activities and help ensure the diversity of our production and the maintenance of the jobs that go with it, while also stressing the importance of sustainable, ethical and quality manufacturing for jobs, growth and competitiveness;

43. Stresses that patient associations should be more involved in defining research strategies for public and private clinical trials in order to ensure that they satisfy the unmet needs of European patients;

44. Calls on the Commission to promote transparency of public investments for the R&D costs of medicines in order to reflect these investments in the availability and price setting for the general public; recalls its position on Directive 89/105/EC[1] and asks the Commission to take appropriate measures in the upcoming pharmaceutical strategy in

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[1] European Parliament position of 6 February 2013 on the proposal for a directive of the European Parliament and of the Council relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems (Texts adopted, P7_TA(2013)0039).

that regard, including considering a revision of the directive;

45. Calls on the Commission and the Member States to screen foreign direct investment in pharmaceutical manufacturing plants, which are part of Europe's critical health infrastructure;

46. Stresses the need to ensure that health professionals and the general public have access to safe, effective and good-quality medicines and health products by monitoring and regulating continued compliance with good clinical practice regarding the authorisation of clinical trials and the conduct thereof, in line with the highest health protection standards;

47. Calls for the market for European medicines to be strengthened in order to speed up patients' access to medicines, make care more affordable, maximise savings in national health budgets and avoid administrative burdens for pharmaceutical companies;

48. Points out that generic and biosimilar medicines enable increased competition, reduced prices and savings for healthcare systems, thus helping to improve access to medicines for patients;

49. Stresses that the added value and economic impact of biosimilar medicines on the sustainability of healthcare systems should be analysed, their market entry should not be delayed, and, where necessary, measures to support their introduction to the market should be examined;

50. Deplores the litigation cases aimed at delaying generic entry; calls on the Commission to ensure that the end of the innovator's period of commercial exclusivity is respected;

51. Is concerned about the possible negative impact of the UK's withdrawal from the EU on the supply of medicines, particularly for Ireland; calls for the inclusion in the future relationship agreement with the UK of targeted provisions, such as mutual recognition agreements, allowing both sides to respond to emerging health threats and ensuring continued and rapid access to safe medicines and medical devices for patients and for contingency plans in the case of 'no deal';

***More vigorous action at European level to better coordinate and supplement Member States' health policies***

52. Recommends that the Commission, the Member States and the industry, under the leadership of EMA, work together to introduce greater transparency in the production and distribution chain of medicines and to create a European unit for preventing and managing shortages;

53. Calls on the Member States, in close collaboration with the Commission and other affected stakeholders, to simultaneously explore alternative approaches to ensuring adequate stocks, such as the effective enforcement of existing regulatory requirements on all actors in the supply chain at national level, along with measures to increase transparency within the supply chain;

54. Calls on the Commission to develop European health strategies on the basis of a common basket of drugs for the treatment of cancer, infections, rare diseases and other areas particularly affected by shortages to ensure that patients have access to treatment,

taking into account the differences in clinical approaches across the Member States; calls on the Commission to also examine the possibility of harmonised pricing criteria to make these medicines affordable in a bid to counter recurrent shortages, taking into account purchasing power parity in all Member States;

55. Calls on the Commission to place the issue of the shortage of cancer medicines at the centre of the treatment part of the forthcoming Europe's Beating Cancer Plan;

56. Calls for the introduction of a specific statute for certain mature medicines which would be accompanied by incentives for manufacturers to maintain their marketing on the European market and ensure diversification of European production;

57. Calls on the Commission to create a European contingency reserve for medicinal products of health and strategic importance (MISSs) that are at high risk of shortage, along the lines of the 'RescEU' mechanism, in order to alleviate recurrent shortages and create an emergency European pharmacy; insists that this reserve must be proportionate to its objective and should be used in a manner that is transparent, accountable and fair for all Member States; emphasises that such a mechanism should be managed carefully with particular regard to shelf life and avoiding waste;

58. Calls for a European regulatory authority to be designated to carry out, together with the Commission, the task of setting a mechanism for a fair allocation of medicines from the European contingency reserve to those Member States affected by disruptions or shortages of supply; calls on this designated European regulatory authority to plan independent and transparent reviews to make sure that all Member States are treated equally;

59. Calls on the Commission and the Member States to develop innovative and coordinated strategies and to step up exchanges of good practice in the area of stock management; considers EMA the best suited body to be designated as the regulatory authority tasked with preventing shortages of medicines at EU level during emergencies and beyond, for which it should be given a broader mandate and increased resources; calls on the Commission, therefore, to amend existing legislation in order to strengthen EMA's capacities; underlines that in the long term, EMA should be able to deliver marketing authorisations subject to the fulfilment of supply and accessibility requirements on the part of manufacturers, without such requirements leading to a shortage of medicines; hopes that the reinforcement of EMA's resources will enable it to maintain the current system of inspecting production sites established in third countries via coordination of the national inspectors;

60. Calls for Regulation (EC) No 141/2000 on orphan medicinal products[1] to be revised in order to reverse the burden of proof for the 10-year market exclusivity clause so that the holder of the market authorisation has to prove that the product is not sufficiently profitable to cover R&D costs;

61. Calls on the Commission to study and establish a fund for orphan medicines that would be financed by the Member States in order to procure collectively on behalf of the

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1 Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (OJ L 18, 22.1.2000, p. 1).

Member States the orphan medicines for all of the EU;

62. Calls for further EU joint procurement procedures to be launched at European level in an effort to counter shortages, especially in times of health crises, as has been done following the onset of the COVID-19 virus, with simplified and transparent procedures in the interests of improved response times; calls, in particular, for the establishment of EU joint procurement for medicines to treat rare diseases in order to ensure that these medicines are available in all Member States; calls on the Commission to conduct an urgent evaluation and possible revision by regulation of Decision No 1082/2013/EU on cross-border threats to health, which establishes the Joint Procurement Mechanism, in line with the Treaties;

63. Calls on the Commission and Member States to revisit the idea of transparency of net pricing and reimbursement of different treatments in order to put Member States on an equal footing when negotiating with pharmaceutical companies for treatments that are not jointly procured;

64. Calls on the Commission to increase its involvement in supporting critical health infrastructure protection in Member States and to start applying the European Programme for Critical Infrastructure Protection to the health infrastructure sector;

65. Calls for the full and rapid application of Regulation (EU) No 536/2014 on clinical trials for medicinal products for human use; considers that this regulation would facilitate the launch of large clinical trials carried out in a harmonised and coordinated manner at EU level;

66. Calls on the Commission and EMA to work with industry to ensure that medicines made available in one Member State are available in all other Member States, in particular smaller Member States;

67. Calls on the Commission to assess the impact of parallel trade on shortage of medicines 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; stresses the need, in this regard, to include the experiences of patients, consumer groups and health professionals;

68. Underlines the importance of patient empowerment and a patient-centred approach; urges the Commission and the Member States to improve patient representation and input in the decision-making process around addressing potential supply issues affecting their medicines;

69. Calls on the Member States to adopt a common position and start negotiations on the proposal for a regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU;

***Closer cooperation between Member States***

70. Calls on the Commission to set up an innovative, user-friendly, transparent and centralised digital platform for reporting and notifying harmonised information provided by national agencies and all stakeholders, including manufacturers, wholesalers and pharmacists, regarding available stocks and shortages of medicines and medical equipment, and for avoiding duplications; welcomes the work of the joint

EMA-HMA Task Force on the availability of medicines and the introduction by EMA of the Single Point of Contact (SPOC) and Industry Single Point of Contact (i-SPOC) systems; calls for existing information systems to be evaluated and improved so as to provide a clear overview of difficulties, shortages and requirements in each Member State with a view to preventing overstocking; encourages the Commission, in this context, to make use of and implement the digital and telematics tools at pan-European level, and to consider amending the Variations Regulation[1] and the Variations Classification Guidelines; calls on the Commission and the Member States to set up an early warning system both at national and European level in order to reinforce the obligation to notify pharmaceutical companies of any interruption or tension in the supply of medicines;

71. Considers it essential to improve early communication with healthcare professionals and patients on the availability of medicines through the use of innovative digital tools providing real-time and up-to-date data on the availability, location, quantity and price of a given medicine, in compliance with data protection legislation; recalls that healthcare professionals must have access to up-to-date information to be able to adequately respond to arising and existing shortages; stresses that early awareness of a supply problem and early identification of potential therapeutic alternatives may strengthen patient safety; recommends, therefore, the inclusion of information for healthcare professionals on available alternatives;

72. Considers that the Member States should share with all the actors involved information such as epidemiological forecasts to help them plan their activities better in the face of rising demand and respond better to needs at times of shortage;

73. Recalls that misinformation can lead to the inappropriate use of medicines and the creation of unnecessary stockpiling;

74. Notes in that vein that people are stockpiling medicines for fear of running out of supplies; calls on governments to counter these fears through education and reassurance in order to put an end to the excessive consumption of resources;

75. Calls for the paper information notice to be supplemented by an electronic product information leaflet notice, to be drawn up in all languages for all the countries where the medicine is marketed in order to facilitate the moving and sales of medicines within the single market and thus mitigate shortages; calls on the Commission to assess the possibility to allow manufacturers, on a voluntary basis and at no additional burden for them, to introduce a system of labelling – which should be visible and identifiable by patients and customers – concerning the origin and place of production of medicinal products and active ingredients;

76. Stresses the importance of ensuring the smooth functioning of the single market in order to eliminate barriers to access to medicines, medical devices and protective equipment for all citizens, especially those living in Member States that, due to their small size or remote location, rely heavily on imports and do not have easy access to the supply

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1 Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ L 334, 12.12.2008, p. 7).

chain;

77. Recommends the development of a catalogue of shortages in all Member States, which would allow EMA to easily update its public catalogue of shortages assessed by its Committee for Medicinal Products for Human Use (CHMP) and/or its Committee on Pharmacovigilance Risk Assessment (PRAC);

78. Highlights the importance of the Commission adopting all measures necessary to combat speculation, fraud and price abuses in the trade in essential medical substances;

79. Condemns the exploitation of shortages for criminal purposes; recalls that the counterfeiting or falsification of medicines and medical products exacerbates supply tensions; calls for the strengthening of measures to combat these practices by controlling online platforms that offer drugs, strengthening cooperation between the relevant EU and national agencies, and ensuring that victims' rights are respected;

***Preventing and responding to shortages in the event of health crises***

80. Highlights with concern the shortages of some medicines that have occurred during the COVID-19 crisis, including shortages of medicines used in intensive care; underlines the importance of maintaining the production, supply, distribution, development and equal access to high-quality medicines, coordinated by EMA; notes with concern the export bans placed on some medicines globally and welcomes the Commission's commitment to securing the supply of medicines; underlines that the experimental use of medicines to treat COVID-19 must not lead to shortages for patients with other conditions, who depend on these medicines;

81. Calls on the Commission, in close collaboration with the Member States, to adopt a European pandemic preparedness plan in order to ensure a coordinated and effective response; welcomes, in that regard, the creation by the Commission of a clearing house for medical equipment on COVID-19; reiterates the call it made in its resolution of 17 April 2020 for the creation of a European health response mechanism to respond to all types of health crises;

82. Emphasises that a European pandemic preparedness plan should include the coordination of information about the distribution and consumption of medicinal products in the Member States and the adequate definition of regulatory flexibilities to address supply tensions; considers that such a plan should also include the widespread use of cooperative EU-level crisis mechanisms targeting serious cross-border threats to health, such as RescEU and the Joint Procurement Agreement, in order to support the Member States' response capabilities effectively;

83. Emphasises that the implementation of an open, free, fair, transparent and enforceable rules-based multilateral trading system is fundamental to ensuring the global availability of medical products and limiting our vulnerability in future emergencies;

84. Welcomes, following the onset of the COVID-19 crisis, the introduction of more flexible rules in a bid to mitigate shortages and facilitate the circulation of medicines between Member States, including the acceptance of different packaging formats, a reuse procedure to enable marketing authorisation holders to obtain approval in another Member State, extending the validity of good manufacturing practices certificates,

longer expiry periods, and the use of veterinary medicinal products, etc.; calls on the Commission to monitor strictly the use of these arrangements, to ensure that patient safety is not compromised and to keep them available in the event of difficulties or shortages; welcomes, in this regard, the temporary extension of the date of application of Regulation (EU) 2017/745 on medical devices; calls, to this end, for a specific approach for orphan medicinal products;

85. 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 as well as 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 to temporarily authorise the granting of compulsory licenses in the event of a health crisis in order to allow 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 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), as further reaffirmed by the 2001 Doha Declaration; calls on the Commission to ensure that the implementation of the EU free trade agreements (FTAs) does not interfere with the possibilities of invoking flexibilities provided by the TRIPS Agreement and to provide guidance to Member States in order to encourage voluntary licencing over immediate compulsory licencing;

86. Recalls that Regulation (EC) No 816/2006[1] harmonises the procedure for granting compulsory licences in relation to patents and supplementary protection certificates concerning the manufacture and sale of pharmaceutical products, when such products are intended for export to eligible importing countries in need of such products in order to address public health problems; calls on the Commission to consider, in the context of its upcoming pharmaceutical strategy, the possibility for harmonised rules on granting compulsory licensing of medicinal products, such as vaccines, which would allow Member States to respond faster and more effectively to future European public health crises;

87. Stresses that compulsory licensing schemes need to be part of wider EU action to address the issue of access to medicines; calls on the Commission to propose a European action plan in this regard;

88. Emphasises that patent protection and enforcement should have due regard for the interests of society, namely the safeguarding of human rights and public health priorities; recalls, in the same vein, that patent protection should not interfere with the right to health and should not serve to widen the gap between wealthier and poorer citizens when it comes to access to medicines; considers that the Union's approach to this question should ensure harmonisation and coherence among the different measures

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[1] Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems (OJ L 157, 9.6.2006, p. 1).

at the disposal of the Member States;

89. Emphasises that a broad network of fair and well-implemented FTAs with balanced intellectual property and regulatory cooperation provisions together with a fully functioning multilateral trading system, with the WTO and an operational Appellate Body at its core, constitute the best way of guaranteeing that multiple sources of manufacturing for essential medicines are available, and that regulatory standards converge globally, ensuring a strong global innovation framework complementing European production; emphasises the importance of having options to ensure the adequate availability of needed pharmaceuticals, including by readiness, if such a need arises, to authorise the import of medicines produced abroad under compulsory licenses; recalls that differences in regulatory frameworks and standards for medicinal products can create an unnecessary obstacle to trade; emphasises the importance of European quality and safety standards; encourages the adoption of international standards, and urges the Commission to ensure that all final or intermediate medicinal products destined for the European market fulfil applicable European quality and safety standards, and are not counterfeit; notes that another way to ensure the EU's strategic autonomy in health is by including the pharmaceutical production of certain products in the IPCEI programme (Important Projects of Common European Interest);

90. Strongly encourages all countries to join the WTO's Pharmaceutical Tariff Elimination Agreement; urges for its scope to be extended to all pharmaceutical and medicinal products while respecting all countries' policy space and ensuring their citizens' access to medicines; stresses that medical products and medicines, including in their intermediate forms, should at all times be exempted from retaliation in trade disputes, and be easily accessible; urges, furthermore, the immediate, unilateral and temporary elimination of tariffs on medical and pharmaceutical products to facilitate imports of these goods; stresses that the development of medical products has to be in line with international human rights standards, in compliance with the Paris Agreement, and that labour rights must comply with the ILO Core Conventions; takes note of the Commission's work on due diligence legislation;

91. Calls on the Commission and the Member States to ensure the swift and full implementation – and, if needed, revision – of the FDI Screening Regulation, in which healthcare should be included as a strategic sector;

92. Recalls that the COVID-19 crisis has tested the resilience of public health systems; takes the view that the introduction of stress tests to assess the resilience of public health systems in emergencies could help to identify structural risk factors and would provide an effective means of countering shortages in the event of pandemics; calls on the Commission and the Council, on the basis of the results of these tests, to draw up recommendations addressed to the Member States, in order to strengthen their health systems and to cover any essential needs that could arise in the event of a health emergency;

93. Believes that EU healthcare systems need more common standards and better interoperability in order to avoid medicine shortages and provide quality healthcare for all in society; calls on the Commission, therefore, to propose a directive setting minimum standards for quality healthcare systems, based on the findings of stress tests;

94. Considers that in the event of a health crisis, the closure of borders and customs controls

cannot constitute an obstacle to the cross-border movement of medicinal products of major interest within the Union; calls on the Commission and the Member States to set up secure and rapid procedures for checking products at the border during a health crisis in compliance with EU law;

95. Notes that the COVID-19 outbreak has highlighted the importance of cooperation and solidarity between the Member States and of the timely delivery of medicines in urgent and exceptional circumstances, which could occur again in the future; stresses, furthermore, that a new industrial and transport policy and R&D investments are key to ensuring that the pharmaceutical industry can respond to tomorrow's needs;

96. Emphasises the need for a more efficient and sustainable transport and logistics network and a reduction in the length of transport routes, which would lead to a reduction in emissions, mitigating the impact on the environment and on the climate, improving the functioning of the internal market and reducing administrative barriers;

97. Calls on the Member States to implement the 'green lanes' proposed by the Commission in its guidelines for border management measures to protect health and ensure the availability of goods and essential services in order to allow the smooth running of the transport not only of medicines but also of raw materials, intermediate products and related materials, including packaging; stress the need to maintain open borders via green lanes so they can be used to address future unexpected events;

98. Deems it necessary to remove bottlenecks and to tackle existing obstacles to a fully integrated and well-functioning Single European Transport Area for all modes of transport; stresses the need to boost intermodality – while favouring the shift to rail – finance the main hubs and ensure the uninterrupted delivery of various types of goods, including dangerous goods crucial for the production of the chemical and pharmaceutical industry; calls on the Member States to ensure that medical facilities and medical staff are reinforced in preparation for increasing traffic volumes resulting from the lifting of restrictions;

99. Highlights the importance of IT systems in facilitating the traceability, supervision and timely delivery of medicines and the exchange of information between the various actors involved in the transport logistics chain, including customs authorities;

100. Calls on the Commission to develop, in coordination with the Member States, mechanisms to ensure fast and safe transport and better oversight of transport and the stockpiling of medicines, namely the introduction of a contingency plan that ensures the unobstructed transport of medicines when the transport sector is disrupted, and unconventional distribution plans e.g. time-sensitive medicine deliveries via scheduled mixed traffic;

101. Notes the importance of guaranteeing non-discriminatory and high safety standards for both transport infrastructure and transport workers, making it possible to manage significant volumes in the supply chain without disruptions while allowing the competent authorities to take proportionate and adapted measures to minimise the risks to health; underlines the importance of preserving good working conditions for drivers;

102. Calls on the Commission and the Member States to ensure that healthcare workers are authorised to cross internal borders if they work in a neighbouring country;

103. Notes the importance of the careful management of ambient and cold-chain warehouse capacity in inbound and outbound transport infrastructure;

104. Stresses the need to eliminate barriers to access to medicines, medical devices and protective equipment for all citizens, especially those living in Member States that, due to their small size or remote location, rely heavily on imports and do not have easy access to the supply chain;

105. Stresses the importance of catering to specific transport needs at local and regional levels, particularly in peripheral, rural, mountain, sparsely populated and insular areas and outermost regions that are more difficult to access and involve higher delivery costs; believes that strategic plans to upgrade infrastructure in the Member States should include concrete actions for these regions; notes the importance of ensuring the digital transition reaches these areas and the need to accelerate the uptake of new solutions adapted to their needs, improving connectivity, accessibility and affordability; stresses that access to medicines in these areas should not be hampered in any way;

106. Calls on the Commission to provide organisational and financial support, including through the work programmes adopted within the 2021-2027 multiannual financial framework, to the Member States and to transport operators during emergency events, such as pandemics, and to give priority to and ensure reserved space in all cargo shipments for essential goods, such as medicines, APIs and medical equipment;

107. Calls for the implementation of fast-track and innovative solutions to mitigate the medicine shortage in a timely manner and to enable the safe transport of temperature-sensitive drugs, tracing the products through constant remote monitoring; calls on the Commission to extend the competences of the European Centre for Disease Prevention and Control (ECDC) in the area of public health and to promote the exchange of best practices;

108. Calls on the ECDC to release modelling data about the likely progression of the COVID-19 pandemic in each Member State as well as patient need data and hospital capacity data in the Member States in order to better anticipate demand and supply medicines where needed; considers that EMA should work in conjunction with ECDC to better prevent shortages of medicines and commonly used drugs in the light of possible future epidemics and pandemics;

109. Calls on the Commission, EMA and the national regulatory authorities to capitalise on all the pragmatic efforts made during the COVID-19 crisis and continue to allow regulatory flexibilities for MAHs, by for example covering procedures for changes in the suppliers of APIs, the designation of new manufacturing sites and faster import authorisations, with a view to better mitigating the shortage of medicines;

110. Acknowledges that supply quotas applied by MAHs on healthcare product distribution are set according to several parameters, including estimates of national patient needs; calls on the Commission to reflect, together with stakeholders from the pharmaceutical industry, on the volumes of stock of medicines available; recalls in this respect that the quotas of stock volumes put in place by distributors are often tight and cause slowdowns and shortages, and that a lack of stock transparency has been noticed in certain parts of the distribution chain;

111. Emphasises that pharmaceutical pricing policies that solely contain expenditure do not allow for price adjustments to reflect changes in cost of goods, manufacturing, regulatory procedures and distribution, and have a negative effect on supply reliability; notes with concern that increased product demand during medicine shortages could increase the risk of unfair pricing practices occurring in regions affected by the shortage, as well as in cases where alternative pharmaceutical products could replace those affected by the shortage;

112. Points to examples of shortages associated with the time needed to fulfil the regulatory requirements, including regulatory time lag and national requirements, but in the meantime stresses that the need for medicines and medical equipment cannot be at the expense of the quality, safety, efficacy and cost-effectiveness of medicines for human use and health products, including medical devices; recalls that compliance with the rules applicable to the authorisation of clinical trials of medicines, as well as the control of observance of good clinical practices in their performance, must continue to be regulated and supervised in accordance with the highest standards of public health protection; also recalls that priority should be given to optimising regulatory processes while maintaining high scientific standards, in order to enable simplified administrative tasks associated with maintaining medicinal products on the market by amending the existing Variations Regulation, improved access to information for patients and healthcare professionals, and simplified flow of medicines from one Member State to another in case of a shortage; encourages the Commission to make the best use of information technology for regulatory processes, including digital and telematics tools, in order to improve regulatory efficiency throughout the EU while upholding data privacy standards as set out in Regulation (EU) 2016/679 (the General Data Protection Regulation / GDPR)[1];

113. Urges the Commission, having regard to the European Strategy for Data and the digital transformation of healthcare and considering the vast potential that health data has for improving healthcare quality and patient outcomes, to encourage implementation of interoperable technologies in the Member States' health sectors which will facilitate delivery of innovative health solutions to patients; encourages the creation of a fully cooperative and operational European Health Data Space with a governance framework which fosters the creation of an innovative data-driven ecosystem, based on a secured and controlled exchange of information and critical data, among Member States; asks the Commission to promote next-generation standards, tools and infrastructure in order to store and process data suitable for research and the development of innovative products and services; underlines that personal health data may only be collected and processed on the legal grounds provided for in Article 6(1) of the GDPR, coupled with the conditions provided for in Article 9 of the GDPR; considers that in this context further processing of personal health data should be prohibited; reminds data controllers of the data protection principle of transparency and their obligations stemming therefrom towards patients and other data subjects;

114. Stresses the importance of ensuring universal access to vaccines and medical treatment, especially in emergencies and for new diseases for which no treatment exists, as in the case of COVID-19; urges close collaboration between the WHO and the WTO to ensure

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[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 (OJ L 119, 4.5.2016, p. 1).

the supply of the vaccine once it is found; calls on the Commission, at the same time, to strengthen its mechanisms for the joint procurement of medicines in order to guarantee universal access to treatment for all citizens regardless of their place of residence;

115. Insists that in preparation for the development and authorisation of a safe and efficacious vaccine or treatment against COVID-19, all steps must be taken to ensure that rapid production and distribution is possible in Europe and worldwide, ensuring fair and equal access to the vaccine or treatment;

116. Recognises that the COVID-19 epidemic has exacerbated the persisting problem of the shortage of medicines and protective equipment in the EU, while stressing that access to medicines and protective equipment is a matter of global concern which also has serious consequences in developing countries where poverty-related diseases are spreading and the availability of medicines is low; stresses the need for the EU to ensure coherence in its policies, particularly in the areas of development, trade, health, research and innovation, in order to help to safeguard the continuous access to essential medicines in the poorest countries and, in particular, in the least developed countries (LDCs);

117. Notes that the lack of access to medicines has severely affected the most vulnerable and marginalised groups, including women and children, people living with HIV and other chronic diseases, migrants, refugees and internally displaced persons, the elderly and persons with disabilities;

118. Calls on the Commission to exercise global leadership to ensure that developing countries have guaranteed access to and supply of essential medicines, especially in emergencies;

119. Highlights that the COVID-19 epidemic demonstrates the need to shorten existing supply chains as much as possible, notably to avoid reliance on long and fragile global supply chains for critical medical equipment and pharmaceuticals; urges the EU to help the developing world build local manufacturing, production and distribution capacity through technical support, critical knowledge and information, by incentivising technology transfer and fostering consistency in regulatory guidance, monitoring systems and the training of health professionals; underlines the need to create stronger health systems and well-operated supply chains; highlights the fact that developing countries, especially LDCs, are heavily reliant on international supply chains, which can lead to serious shortages when global demand rises and supply is limited;

120. Calls for a global collective response and welcomes the outcome of the Coronavirus Global Pledging event on 4 May 2020, where EUR 7,4 billion was pledged by donors from around the world to accelerate work on diagnostics, treatment and vaccine development; stresses that COVID-19 medical tools should be affordable, safe, effective, easy to administer and universally available to everyone everywhere and be considered ‘global public goods’; considers, therefore, that access and affordability should be an integral part of the entire R&D and manufacturing process; to this end, believes that strict conditions should be attached to public funding, notably in terms of collective governance, transparency, sharing of technology, technical know-how and clinical results, etc.; stresses that these conditions must be made public, as public finance cannot consist of blank cheques;

121. Stresses that the sharing of pathogen samples and sequence information is crucial for

the rapid development of diagnostics, therapies and vaccines; recalls the binding international obligations of fair and equitable benefit-sharing of the Convention on Biological Diversity and the Nagoya Protocol with regard to genetic material;

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