OPINION

of the Committee on Industry, Research and Energy

for the Committee on the Environment, Public Health and Food Safety

on shortage of medicines - how to address an emerging problem
(2020/0071(INI))

Rapporteur for opinion (*): Joëlle Mélin

(*) Associated committee – Rule 57 of the Rules of Procedure
SUGGESTIONS

The Committee on Industry, Research and Energy calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following suggestions into its motion for a resolution:

A. whereas the coronavirus pandemic has exacerbated the longstanding and growing problem of medicine shortages across the EU; whereas the ensuing disruption of the global supply chain has highlighted the EU’s dependency on third countries for medicines, active pharmaceutical ingredients (APIs), starting materials and other components entering into medicines manufacturing; whereas the EU’s reliance on imports in this area and the lack of diversification create additional threats to the EU’s capacity to provide a prompt and adequate response to health emergencies and result in the vulnerability of the EU health systems; whereas the novel coronavirus pandemic has also revealed shortages of medical devices, medical products and protective equipment; whereas 60% to 80% of APIs are manufactured outside Europe, mainly in China and India; whereas this proportion was 20% 30 years ago; whereas, to date, no label or labelling visible to patients and customers is required for medicinal products and 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, finally, during the COVID-19 outbreak many national governments of Member States have been victims of fraud and have been supplied with defective medical equipment and supplies coming from companies located in third countries;

B. whereas the manufacturing of medicines and other medical products are challenging and require highly sophisticated facilities and procedures and highly trained staff to ensure labour and environmental standards and the safety and efficiency of medicines; whereas the quality of medicines and other medical products must conform to strict EU regulatory standards, which are amongst the highest worldwide; whereas there is a high level of control in force in the EU over the quality of drug production; whereas purchasers, in particular hospital pharmacies, are subject to budgetary restrictions which very often require them to consider only financial criteria and not quality or origin; whereas production of chemical raw and starting materials and APIs in the EU has been affected by the tendering system based on the criterion of lowest price; whereas this incentivises the outsourcing of such production to third countries, thus harming European companies with higher standards; whereas some facilities in these third countries often lack the capacity to enforce standards of sustainable and ethical production of these materials and ingredients that can comply with EU standards;

C. whereas a cooperation mechanism to coordinate European and national policies is needed to address medicine shortages that have multi-factorial and complex root causes, including economic aspects such as lack of market predictability, the often monopolistic nature of the pharmaceutical markets, single winner tender systems, parallel trade, export bans, overstocking, regulatory burdens, unforeseen surges in demand, supply chain disruption, complexity and interdependency, including on third countries, and challenges and complexity of manufacturing, storing, distributing and dispensing medicines; whereas the early detection, monitoring, and reporting of medicine shortages should be improved and underpinned by more transparent and accessible data on such
shortages;

D. whereas medicine shortages pose a serious threat to patients and undermine the resilience and efficiency of public healthcare systems across the Union; whereas it is of the utmost importance to prevent shortages of medicines, as well as to mitigate them should they occur; whereas Article 81 of Directive 2001/83/EC\(^1\) 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, intermediate products or finished medicines needed for the proper functioning of the health system;

E. whereas the coronavirus pandemic has demonstrated that coordination, cooperation and close dialogue among all actors are needed to fight health threats, as opposed to individual and uncoordinated measures at national level; whereas effective coordination at EU level at times of crisis is essential to avoid unilateral border closures and export bans, which exacerbate medicine shortages and jeopardise the resilience of supply chains and distribution channels;

F. whereas, following the coronavirus pandemic, the EU will have to face an economic crisis which will challenge even further equitable access to medicines and the competitiveness of the European pharmaceutical industry; whereas that industry employs 765,000 people directly and supports another 2.7 million jobs indirectly in Europe; whereas existing tax mechanisms and incentives can be implemented at European and Member State level for strategic industrial sectors;

G. 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 made 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;

H. whereas the European Parliament in its resolution of 8 March 2011 and the Council in its conclusions of 13 September 2010 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 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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Agreement of participating Member States;

I. whereas the Treaties and the European Charter of Fundamental Rights state that everyone shall have access to preventive healthcare and the right to benefit 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 access to medicines is a growing problem within the EU, and is usually associated with the high price of medicines;

J. whereas the Commission has announced its intention to publish, by the end of 2020, recommendations for a future EU Pharmaceutical Strategy;

Definitions and monitoring tools

1. Calls on the Commission to introduce a reinforced, centralised and harmonised definition of medicine shortages for the reporting and monitoring of manufacturing authorisation holders (MAHs), as proposed by the joint task force of the European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA) in 2019; notes that a clear definition of ‘risk of shortage’ is essential to support the notification process; stresses the need to establish a definition of ‘essential’ medicinal products and to give them priority when addressing shortages; calls furthermore for an assessment of the possibility of using the European Medicines Verification System (EMVS) data repositories at aggregate level as a tool for overseeing shortages; notes that a more appropriate use of EMVS repository data to obtain a serialisation of each box of medicines could also ensure the reliability of the entire chain of manufacture, packaging and distribution; invites the Commission, therefore, to assess the possibility of allowing manufacturers, on a voluntary basis and with no additional burden for them, to introduce a system of labelling - visible to and identifiable by patients/customers - concerning the origin and place of production of medicinal products and active ingredients;

2. Insists that the Commission urgently launches a multi-stakeholder consultation and market research in order to identify evidence-based drivers, within the supply chain and beyond, that directly cause or increase the risk of drug shortages, as well as initiatives to mitigate risks to supply chains; calls for a permanent, concrete and action-oriented dialogue with the EMA, National Competent Authorities (NCAs), Member States, the pharmaceutical industry, patients’ and pharmacists’ organisations, and all actors in the pharmaceutical supply chain; calls for effective European policy cooperation to prevent shortages in the long term by sharing information, reporting anticipated shortages and improving the transparency of the supply chain; 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;

3. Calls on the Commission to publish the EU Pharmaceutical Strategy, which will identify root causes of medicine shortages; urges the Commission to propose ambitious and specific regulatory measures with the objective of making medicines available,
affordable, sustainable and equally accessible, and which will also put transparency measures into practice; notes with concern market failures in several Member States where patients’ access to effective and affordable medicines and medical devices remains threatened by very high and often unsustainable price levels; recognises that access to medicines and medical devices in Member States with smaller markets requires particular consideration; emphasises that the design of an emergency EU stock inventory system, handled by the EMA and in collaboration with national competent authorities, should also be part of the planned Pharmaceutical Strategy and should include how the keeping of inventories can be kept in line with medical developments;

4. Calls on the Commission to promote measures which will increase the security of supply of medicines in the EU and reduce dependency on third countries; calls on the Commission also to include in the planned Pharmaceutical Strategy measures to cope with any disruption in global value chains; notes in this respect the importance of the industry having the capacity to increase its production in order to be able to meet sudden surges in demand arising from critical situations; calls, therefore, for a plan, coordinated and concerted with the Member States, as well as for financial incentives in line with state aid rules and sustainable policies, to protect the EU’s strong pharmaceutical industrial base, to initiate negotiations with stakeholders on the creation of an API alliance, and to support in the meantime the relocation to Europe from third countries of production of those medicines and APIs deemed essential for security of supply;

5. 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 (IP) system under the forthcoming EU 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;

**Early warnings and reporting**

6. Calls for an overhaul of the cooperative reporting and notification early warning system in order to establish a real-time, interconnected, responsive and easily activated system that would provide a comprehensive picture and issue regular and timely alerts on potential shortages of medicines so that, in the future, countries facing this problem can react and turn to other markets if necessary; calls for a more central role for the EMA in an EU-wide early warning system that includes, in addition to the aforementioned stakeholders, hospital pharmacists and patient organisations; furthermore, considers that the European Centre for Disease Control (ECDC) should share modelling of the likely progression of a pandemic with the competent national authorities of each Member State, so as to anticipate demand and adjust the manufacturing capacity and distribution channels accordingly in order to supply those medicines needed to the right regions at the right time;

7. Insists that, within this system, all stakeholders in the supply chain, including parallel traders and wholesalers, should comply with the legal obligation to report, in a timely
manner and, in line with Article 23a, paragraph 2 of Directive 2001/83/EC\(^3\), at least two months in advance; considers that the EMA and the Commission should work closely with the national competent authorities of the Member States in order to ensure a timely and well-coordinated response to reported imminent shortages and temporary or permanent disruptions in the supply and distribution of medicinal products; calls for the initial focus of the system to be on the pan-European critical list of products covering both centralised and national marketing authorisations; calls on the Commission to temporarily restrict parallel trade until the corresponding shortage is restored; calls on the Commission and the Member States to carry out stress tests on the availability and production capacity of medicines and active ingredients in order to protect against future pandemic health crises;

**Cooperation and coordination**

8. Calls on the Commission to establish a cooperation mechanism to coordinate European and national policies to address medicine shortages and to ensure the right of patients to sustainable, universal, equitable, affordable, effective, safe and timely access to essential medicines so as to guarantee the sustainability of the EU public healthcare systems, with the EMA, the National Competent Authorities (NCAs), Member States, the pharmaceutical industry, patients’ and pharmacists’ organisations and all actors in the pharmaceutical supply chain;

**Free movement of goods**

9. Calls on the Commission, in close collaboration with Member States, to prepare and adopt a European pandemic preparedness plan in order to ensure a coordinated and effective European pandemic response; emphasises that this plan should include measures ensuring open borders for pharmaceutical or medical companies, in particular through greenways, in order to protect the free movement of goods and avoid possible shortages of medicines; 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;

**Procurement**

10. Urges the Commission, in the context of the EU Public Procurement Directive 2014/24/EU\(^4\), to develop guidelines to support sustainable public procurement practices in the pharmaceutical field, in particular with regard to the implementation of the criteria of the most economically advantageous tender (MEAT), aimed at ensuring long-term sustainability, competition and security of supply and stimulating investment in manufacturing; calls for remedies against single-winner, price-only tenders that cause severe price erosion, reducing the number of suppliers on the market and often resulting in short lead times and penalties being applied to companies, which in turn increases the risk of shortages of medical products; calls on the Member States to review tendering

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systems in order to reward sustainable, ethical and quality manufacturing;

11. States that facing unusual sanitary crises shows the need for increased cooperation on health, and, in the framework of the RescEU programme, for the joint procurement of vaccines, antiviral drugs and high-cost and essential medicines, as well as medical equipment and medical technologies; insists that such a joint response must be a priority post-pandemic, and must be easily accessible for citizens in every Member State, especially those which are particularly vulnerable from a public health and economic perspective owing to their remote location or small size;

12. Calls on the Commission to incentivise the pharmaceutical industry to ensure that its supply chain is diversified and sufficient at EU level, to put in place a medicine shortage risk mitigation plan to manage any vulnerabilities in and risks to the supply chain, and to submit such plans to the competent authorities; points out that such a plan should include solutions for the strategic storage of medicine in order to ensure supply for a reasonable period of time and transparent reporting mechanisms, with permanent communication channels through which patients and healthcare professionals can report and anticipate shortages of essential medicines;

Quotas

13. Acknowledges that supply quotas applied by marketing authorisation holders 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;

Industry and support to SMEs

14. Stresses the urgent need for the EU to protect its strong pharmaceutical industrial base while rethinking security of supply, and to reduce over-reliance on a small number of non-EU manufacturers and suppliers of key chemical raw and starting materials, intermediate materials and APIs; calls on the Commission to examine closely whether materials and ingredients entering the EU market are produced in accordance with adequate social and environmental standards; calls on stakeholders to diversify their supply chains in order to reduce their vulnerability; to this end, calls on the Commission to closely examine the impact of European import dependency, in particular concerning medical equipment, respiratory equipment, chemicals and raw materials;

15. Encourages the Commission to propose measures in its planned Pharmaceutical Strategy, including financial incentives and targeted guidelines on public procurement, with the aim of promoting investment in the sustainable, ethical and quality manufacturing, within the EU, of strategically important chemicals used in medicine production, particularly APIs and intermediates; urges the Commission also to propose measures to incentivise the greater inclusion of EU small and medium-sized enterprises 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;
16. Calls 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 research and development capabilities and infrastructure, including universities, taking into account that the European Union 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 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;

17. 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;

18. 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, also stressing the importance of sustainable, ethical and quality manufacturing for jobs, growth and competitiveness;

**Pricing**

19. Emphasises that pharmaceutical pricing policies that are solely containing 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;
**Parallel market**

20. Acknowledges that parallel trade may cause medicine shortages; calls on the Commission and the Member States to adequately tackle problems related to parallel trade in medicines in the EU, in order to prevent export shortages caused by large differences in the price of a medicinal product between Member States; highlights the importance of assessing the impact of parallel trade and export bans from the perspective of patient access; calls on the Commission to develop additional guidance as necessary for Member States on parallel exports; stresses the need to include the perspectives and experiences of patient and consumer groups;

21. Acknowledges that the movements of medicines throughout the Member States are not controlled only by the pharmaceutical companies, due to parallel trade; highlights that due to parallel trade there is a discrepancy between the volume which manufacturers release on a given market, the volume of exports and imports and the actual patients’ needs from the said market, which can give rise to shortages; highlights that parallel trade sometimes covers up to 80 or 90% of some Member States’ demand, which creates a fragile supply chain;

22. Calls for measures to discourage unfair practices and business strategies in the pharmaceutical sector, such as ‘pay for delay’, with a view to ensuring supply resilience across Member States’ markets; calls on the Commission to strengthen customs controls on the conformity of imported medicinal products or active ingredients with EU and national rules, particularly where such imports drive down internal market prices, distort competition, disincentivise sustainable, ethical and quality manufacturing and lead to the relocation of production lines outside the EU;

**Management of stockpiling**

23. Calls on the Commission to explore the possibilities of building up stocks at EU level in the framework of the RescEU programme; stresses that shortage of medicines is a national security matter; acknowledges that the issue of an inventory of important medicines and the possibility of increasing manufacturing readiness for a few particularly important medicines must be viewed from a longer-term perspective; calls on the Commission to assist Member States in developing stockpiles of important medicines as a shared public-private responsibility, in a coordinated approach so as to avoid shortages in all Member States and respond to patients’ needs, as well as developing measures to tackle the root causes of medicinal shortages in a joint and coordinated approach, in order to guarantee the resilience and perseverance of European societies in times of crisis and/or conflict;

**Regulatory requirements and quality**

24. 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 mean, nor 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);

25. 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;

26. Calls on the Commission and the relevant authorities to provide regulatory flexibility to mitigate drug shortages when they occur, by allowing targeted measures such as more flexibility for multilingual packaging, different pack sizes and electronic package leaflets, in order to ensure that patients have faster access to safe and high-quality medicines; calls on the Commission to amend the EC Variations Regulation and the Variations Classification Guidelines in order to modernise the current variations system and to reflect the evolution of technology and the regulatory needs of all actors involved.

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**INFORMATION ON ADOPTION IN COMMITTEE ASKED FOR OPINION**

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Key to symbols:
+ : in favour
- : against
0 : abstention