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DRAFT REPORT

on the shortage of medicines - how to deal with an emerging problem
(2020/0000(INI))

Committee on the Environment, Public Health and Food Safety

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MOTION FOR A EUROPEAN PARLIAMENT RESOLUTION

on the shortage of medicines - how to deal with an emerging problem (2020/0000(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 health care 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 and Article 81 thereof concerning an adequate and uninterrupted supply of medicinal products,

– 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,

– 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,

– 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,

– 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,

– 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,

– 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),

– having regard to the Commission communication of 8 April 2020 entitled ‘Guidelines on the optimal and rational supply of medicines to avoid shortages during the COVID-19 outbreak’ (C(2020)2272),

– having regard to the communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions of 10 March 2020 entitled 'A New Industrial Strategy for Europe' (COM(2020)0102),

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

– 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 (2019/2804(RSP)),

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

– 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 World Health Organization (WHO) report 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’,

– having regard to the WHO ‘One World, One Health’ philosophy,

– having regard to UN Sustainable Development Goal No 3: ‘Ensure healthy lives and promote well-being for all at all ages’,

– having regard to Report No 737 of 27 September 2018 entitled ‘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 French Senate fact-finding

mission on the shortage of medicines and vaccines,

– 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 Rule 54 of its Rules of Procedure,

– having regard to the opinions of the Committee on International Trade, the Committee on Employment and Social Affairs, the Committee on Industry, Research and Energy, 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 (A9-0000/2020),

A. whereas medicine shortages are a growing public health threat with a serious impact on health care systems and public health;

B. whereas medicine shortages can lead to possible delays in patients' treatment, to the need to switch to alternative therapies that could be less effective, to adverse effects and adherence problems or even life threat when a shortage concerns essential medicines;

A. whereas the increase in global demand has aggravated shortages of medicines in the EU, undermining health services in the Member States and exposing patients to considerable risks; whereas the Member States have a duty to find swift and effective solutions through closer European integration;

B. whereas medicines to treat cancer, infections and disorders of the nervous system account for more than half of those in short supply;

C. whereas the loss of European sovereignty and 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 the only way to save money is to rely heavily on subcontractors to produce pharmaceutical raw materials in Asia, where labour costs and environmental standards are lower, with the result that 80% of active ingredients are manufactured outside the EU, mainly in China and India;

D. whereas the consequence of growing demand coupled with price suppression is the concentration of supply, a reduction in the number of chemicals manufacturers and a lack of alternative solutions should problems arise;

E. whereas stocks of 'strategic' medicines are inadequate, with chemicals that are cheap and easy to produce and mature medicines being in particularly short supply; whereas pharmaceutical firms operate on a just-in-time basis;

F. whereas there are no price harmonisation arrangements to facilitate 'parallel exports' to countries where the medicine in question is more expensive;

G. whereas, in the absence of a regulatory authority, stockpiling in some Member States is leading to a market imbalance;

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

I. whereas profit-oriented decision making on the part of the pharmaceutical industry such as products' discontinuations and withdrawals from particular (less profitable) Member States' markets is often the reason for medicine shortages;

I. whereas the greater number, geographical spread and impact of epidemics is partly attributable to climate change, in combination with globalisation and increased travel;

J. whereas the destruction of biodiversity, the proliferation of man-made habitats and damage to natural areas densely populated by humans are facilitating the propagation of zoonoses, i.e. the transmission to humans and rapid spread of animal pathogens;

1. Stresses the geostrategic imperative that the Union regain its sovereignty and independence with regard to health care and secure its supply of medicines and medical equipment;

2. Points out that, while public health policies are a Member State matter, it is incumbent upon the EU to coordinate and complement national measures to guarantee affordable and high-quality health services for European citizens;

3. Stresses the need for health policies to focus on patients' interests and for closer cooperation between Member States;

Securing supplies in the interests of patients and restoring health sovereignty

4. Calls on the Commission and the Member States to take whatever action is needed to restore European health sovereignty and local pharmaceutical manufacturing, giving priority to essential and strategic medicines; calls on the Commission to map out potential production sites in the EU;

5. Calls on the Commission to address in its next pharmaceutical and industrial strategies issues relating to the availability and accessibility of medicines and manufacturers' dependence on third countries;

6. Urges the Commission and the Member States to introduce tax and financial incentives in return for appropriate commitments and to authorise state aid to encourage producers to locate their operations in Europe, from compound manufacturing to packaging and distribution; emphasises the strategic significance of this sector and the importance of investing in European companies, in the interests of resource diversification; ***observes that all incentives should incorporate pro-public safeguards, such as transparency regarding public contributions and clauses on accessibility and affordability of manufactured medicines to ensure they are equally available at a fair price;***

7. 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 in Article 67 of Directive 2014/24/EU; proposes that investments in the manufacture of active ingredients and medicinal end products in the EU should also be a criterion;

8. Notes that procurement procedures with only one successful tenderer may exacerbate vulnerability should supplies be disrupted; calls on the Commission and the Member States to introduce procurement procedures under which contracts may be awarded to a number of successful tenderers, in order to maintain market competition and reduce the risk of shortages, while guaranteeing high-quality treatment for patients;

9. Notes that procurement practices focusing solely on the price have resulted in manufacturers pulling out of national markets leading to market consolidation and an increasing risk of medicines shortages; calls on the Commission and Member States to engage in a structured exchange to apply other criteria than price in tendering procedures such as reliability of supply and the number and location of production sites;

9. Calls on the Commission and the Member States to create one or more European non-profit pharmaceutical undertakings which operate in the public interest to manufacture priority medicines of strategic importance for health care; stresses the key contribution that can be made by new technologies and artificial intelligence in enabling European laboratory researchers to form networks and share their objectives and findings;

10. Calls for links to be established between the pharmaceutical industry and other production sectors, such as farming, 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;

11. Stresses the importance of research and innovation, and calls for the establishment of a genuine European network, given that the price of relocation must not be a deterioration in the quality of medical research;

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

12. Recommends the introduction of centralised management ***under the leadership of the European Medicines Agency (EMA)*** to bring about greater transparency in the distribution chain and the creation of a European supply management unit tasked with developing a European strategy to prevent and resolve breaks in supply;

13. Calls on the Commission to develop European health strategies on the basis of a common basket of drugs for the treatment of cancer and infections whose prices are harmonised, in a bid to counter recurrent shortages and ensure that patients have access to treatment;

14. Calls on the Commission to create a European contingency reserve of medicines of strategic importance for health care, supplies of which are critical, along the lines of the 'RescEU' mechanism, in order to alleviate shortages outside crisis periods;

15. Calls on the Commission and the Member States to adopt a joint definition of ***'medicine shortages' relevant for all stakeholders,*** 'medicines of strategic importance for health care' and of 'criticality', emphasising the value of these medicines for public health, the lack of alternatives and the vulnerability of the production chain; calls for a European

regulatory authority to be designated to carry out the task of setting quotas for the allocation of medicines from that reserve to the Member States;

16. Calls on the Commission and Member States to develop innovative and coordinated strategies and to step up exchanges of good practice in the area of stock management; ***recognizes the European Medicines Agency (EMA) the body best suited to take the responsibility of the European response to medicines shortages;*** considers that the European Medicines Agency (EMA) ~~could~~ ***should*** be designated as the regulatory authority ***coordinating and monitoring medicines shortages at EU level during emergencies and beyond*** ~~tasked with preventing shortages of essential medicines~~, with a correspondingly ***stronger mandate and better infrastructure; notes that EMA should be entirely publicly funded as a prerequisite to its independence;*** ~~wider remit and more staff;~~

17. Calls for further invitations to tender to be issued at European level in an effort to counter shortages, as has been done following the onset of the COVID-19 virus, with simplified procedures in the interests of improved response times;

18. Calls on the Commission to publish new EU guidance on the possibility to temporarily ban parallel trade to prevent and address medicine shortages and on the possibility to restrict free movement of medicines without an infringement of the principles of free trade and movement of goods within the EU.

Closer cooperation between Member States

18. Calls on the Commission to set up an innovative centralised digital platform for sharing information provided by national agencies and all stakeholders regarding shortages of medicines and medical equipment; welcomes the introduction by the EMA of the SPOC and i-SPOC systems; calls for existing information systems to be improved so as to provide a clear overview of problems, shortages and requirements in each Member State, with a view to preventing stockpiling; ***calls on the Commission and Member States to establish a standardized, early warning system at national and EU level enhancing pharmaceutical companies' obligations to immediately notify any interruptions of supply of medicines;***

19. Notes that current legislation does not ensure the stable supply of medicines; calls on the Commission to clarify the marketing authorisation holder's obligations under the Directive 2001/83/EC and develop an enforcement mechanism including sanctions to hold companies accountable.

19. ***Observes that doctors must have access to up-to-date information to be able to adequately respond to arising and existing shortages. Early awareness of a supply problem and early identification of potential therapeutic alternatives may mitigate the possibility for adverse reactions endangering patient safety;*** considers it essential to improve communication with healthcare professionals and patients on medicine availability through the use of innovative digital tools providing real-time data on the availability, location, quantity and price of a given medicine, in compliance with data protection legislation;

20. Calls for an electronic information notice to be drawn up in all the Union languages for

every medicine on the EU market, in order to facilitate sales of medicines between Member States; recommends the provision of more comprehensive information on the origin of medicines;

21. 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: acceptance of different packaging formats, reuse procedure to enable marketing authorisation holders to obtain approval in another Member State, longer expiry periods, use of veterinary medicinal products, etc.; calls on the Commission to monitor strictly the use of these arrangements and to keep them available in the event of problems or shortages;

22. Takes the view that the introduction of stress tests to assess the resilience of health systems in emergencies would provide an effective means of countering shortages in the event of pandemics and of identifying structural risk factors which go to create shortages;

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

EXPLANATORY STATEMENT

The highly sensitive issue of medicine shortages is not a recent development. The sudden exponential increase in global demand triggered by the COVID-19 health crisis has merely served to highlight the recurring problem of shortages of medicines and medical equipment in Europe, a situation with which health workers and some particularly vulnerable patients are all too familiar.

Cheap chemicals that are easy to manufacture and 'mature' medicines are in particularly short supply as stocks become depleted. **The number of shortages increased 20-fold between 2000 and 2018, and has increased 12-fold since 2008, putting patients at considerable risk and undermining health services in the Member States.**

Cancer treatments, antibiotics, vaccines, anaesthetics and medication for hypertension, heart disease and disorders of the nervous system are in particularly short supply. In fact, medicines for the treatment of **cancer (chemotherapy), infections (vaccines) and disorders of the nervous system (epilepsy, Parkinson's disease) alone account for over half of those in short supply.**

The COVID 19 health crisis has also highlighted the EU's increasing dependence on third countries, mainly China and India.

While these shortages may be attributed to numerous factors (manufacturing problems, quality issues, unexpected spikes in demand following sudden viral epidemics or natural disasters, supply chain problems, etc.), there is no disputing the fact that the relocation of plants producing active ingredients and end products has considerably weakened the sovereignty of the Member States. According to the EMA, 40% of medicinal end products marketed in the EU originate in third countries, while 80% of active pharmaceutical ingredients are produced in China and India. Indeed, the only way to save money is to rely heavily on subcontractors in Asia, where labour costs and environmental standards are significantly lower.

Price suppression and soaring demand have effectively led to a concentration of supply, with many compounds now being obtainable from only two or three suppliers in Asia. Production problems will inevitably cause supplies to be disrupted if no alternative source is available.

Public health has become a geostrategic weapon that can bring a continent to its knees. Our loss of sovereignty was thrown into sharp relief with the onset of the current pandemic. While health care is a Member State matter, under Article 168 TFEU **it is incumbent on the European Union to coordinate and complement national measures** in a bid to guarantee high-quality health services for European citizens, protect them from threats to their health, improve surveillance measures and levels of preparedness for epidemics and bioterrorism and strengthen capacity to meet new health challenges, such as climate change.

Closer cooperation and more concerted action is needed to step up efficiency and improve response times in line with the needs of European citizens. Cooperation of this kind began to emerge at the peak of the epidemic, particularly with the transfer of patients between Member States as certain hospitals were filled to capacity. These arrangements must now be placed on a permanent, structured footing in a bid to counter shortages.

The European response to the shortage of medicines must be based on three pillars: a return to health sovereignty by securing supplies, stepping up European action to better coordinate and supplement Member State health policies, and enhancing cooperation between them.

Return to health sovereignty through closer European integration.

Above all, this calls for **relocation back to the European Union of plants producing active ingredients and medicinal end products of strategic importance for health care, given that breaks in** supply put at grave and immediate risk patients with serious conditions who are unable to obtain officially recommended alternative treatments.

With this goal in mind, the following major steps should be taken:

- Measures to foster relocation activities and authorisation of **state aid** (tax concessions and funding), in order to encourage firms to operate in Europe, from the compound manufacturing to the packaging and distribution stages, with the precise locations of possible production sites in the European Union to be mapped out.

- Making **security of supply a priority criterion in tendering procedures** with the Commission recommending the best offer to the Member States.

- The **creation of one or more non-profit European pharmaceutical undertakings** capable of producing certain medicines of strategic importance for health care in emergencies (vulnerable production chain with either a single production line or an ingredient that is particularly difficult to obtain or no longer profitable for pharmaceutical companies to manufacture).

- **Making our continent a world leader in the development of innovative treatments for tomorrow**. European research programmes are among the best in the world and must receive stronger support from the European Union, in terms of funding and coordination, the pooling of results and access to essential information. The European research programmes for the development of COVID-19 treatments and vaccines are an example of what the European Union will need to do in the future, that is to say carry out more joint research, covering a wider range of sectors. The European Union has the tools, infrastructure and researchers needed to take the lead in medical research and innovation for the development of treatments and medical equipment. **By diversifying our resources, learning once again to produce active ingredients in the European Union, and investing heavily in research, innovation, the bioeconomy and biotechnology, it will be possible to develop and manufacture the medicinal products of the future.**

More vigorous action at European level to better coordinate and supplement Member State health policies

- Anticipating difficulties and crises in the health sector through the creation of **a European reserve of medicines of strategic importance for health care** along the lines of the 'RescEU' mechanism set up by the Commission. The aim here is to develop a number of health strategies at European level, with a joint reserve of priority medicines and vaccines, with harmonised prices, to enable Member States to deal with supply

problems.

- More systematic **joint procurement** to bring down the costs of certain medicines and items of equipment. It is easier to negotiate with suppliers when representing 446 million consumers.

- **Greater transparency in the distribution chain with the introduction of centralised management, obtaining more information from all stakeholders**, making pharmaceutical companies, manufacturers and distributors more accountable, alongside the management and marketing authorities. The results in terms of public health justify the imposition of special requirements by the authorities, particularly as regards 'strategic' medicine stocks, given that pharmaceutical firms generally operate on a 'just-in-time' basis.

Closer cooperation between Member States

- **Real-time management of medicine stocks in each Member State and prevention of stockpiling.** The Commissioner responsible for health should oversee a task force working in conjunction with the EMA, national agencies and manufacturers, in order to anticipate heavier demand on stocks and regulate the movement of medicines within the single market in accordance with the needs of each Member State. This is the kind of European solidarity and coordination that must now emerge.

- **The introduction of simplified legislation and more flexible regulatory measures in times of crisis** in order to alleviate shortages and facilitate the movement of medicines between Member States: acceptance of different packaging formats, a reuse procedure to enable marketing authorisation holders to obtain approval in another Member State, longer expiry periods, use of veterinary medicinal products and acceptance of a degree of coordination without this being regarded as a concerted practice, etc.

- **The introduction of innovative digital tools for the sharing of information** regarding shortages of medicines and medical equipment in the Member States.

A genuine industrial strategy must be developed for the pharmaceutical sector to enable the European Union to regain its health sovereignty and invest in the cutting-edge research needed to make Europe the world leader in innovation and excellence in the health sector.

ANNEX: LIST OF ORGANISATIONS OR INDIVIDUALS FROM WHICH THE RAPPORTEUR RECEIVED CONTRIBUTIONS

The following list has been drawn up on a purely voluntary basis under the exclusive responsibility of the rapporteur. The rapporteur has received input from the following organisations or individuals in the preparation of the report up to adoption thereof in committee:

Organisation and/or individual
Commission européenne, Stella Kyriakides, Commissaire santé
Commission européenne, Janez Lenarčič, Commissaire chargé de la gestion des crises
Agences du Médicament (EMA), Noel Wathion, Directeur exécutif adjoint
Centre européen de prévention et de contrôle des maladies (ECDC), Andrea Ammon, Directrice
Secrétariat général des affaires européennes, Sandrine Gaudin, Secrétaire générale
Sénat Français, Jean-Pierre Decool, Sénateur du Nord, Vice-Président de la Commission des Affaires Économiques, Rapporteur de la Mission d'information sur les pénuries de médicaments
Sénat Français, Sonia de la Provôté, Sénatrice du Calvados (Normandie), Vice-présidente de la Mission d'information sur les pénuries de médicaments
Jean Rottner, Président de la Région Grand-Est
Comité économique des produits de santé (CEPS), France Jean-Patrick Sales, Vice-président
Jacques Biot, ancien président de l'École polytechnique, en charge d'une mission auprès du

Premier Ministre français pour procéder à l’analyse des causes profondes de la situation de pénuries de médicament
Khalifé Khalifé, Chef du service de cardiologie, Président commission médicale du Centre Hospitalier Régional (CHR) Metz Thionville, Président collège médical GHT lorraine Nord, Président du Conseil Territorial de Santé Lorraine Nord, Conseiller Régional Grand-Est délégué à la Santé
Grégory Rondelot, Pharmacien-Gérant PUI de l'hôpital de Mercy et PUI de l'hôpital Bel-Air
Marianne Chacun-Colin, médecin gériatre /soins palliatifs en centre gériatrique
Jean-Marc Lupoglazoff, docteur en médecine et docteur en sciences (MD et PhD) praticien hospitalier (PH) à l'hôpital Robert Debré (APHP) en cardiologie pédiatrique
Bureau Européen des Unions de Consommateurs (BEUC)
European Organisation For Rare Diseases (EURORDIS)
European Federation of Pharmaceutical Industries and Associations (EFPIA)
Medicine for Europe
Groupement Pharmaceutique de l’Union européenne (PGEU)
European Healthcare Distribution Association (GIRP)
The European Chemical Industry Council (CEFIC)
European Society for Medical Oncology (ESMO)
Comité Permanent des Médecins Européens (CPME)
Les entreprises du médicament (LEEM)
Biogaran
Mylan
Teva Pharmaceutical
Novartis
Sanofi