FEAM
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FEAM STATEMENT

Shortages of Medicines

FEAM Statement on Shortages of Medicines

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Executive Summary

Shortages of medicines are a growing concern for healthcare systems, drug manufacturers, healthcare professionals, veterinarians, and especially for patients. Shortages have a wide range of impacts, ultimately leading to lower quality care and patient treatment disruption. Depending on the context, the underlying causes of the problem can be identified in two groups: demand- or supply-led shortages. Due to a sudden exponential demand, the COVID-19 crisis has put shortages of critical medicines and protective equipment in the spotlight. However, these particular types of shortages do not necessarily reflect structural and long-term features of recurrent supply disruptions, mainly caused by active pharmaceutical ingredient shortages or low profitable generic production and distribution.

The multi-factorial nature of shortages amplifies the difficulty to assess and define them, contributing, until recently, to little policy attention at national and European levels. The definition of a drug shortage may vary depending on the political level and scale to be considered (i.e. local, national, European, international), the frequency baseline to report shortages (i.e. in terms of hours, days or weeks) and the different perspectives of the stakeholders being affected by this problem (e.g. industry, patients). European and national actions are greatly needed to tackle this pressing issue.

Therefore, FEAM and its Member Academies recommend the following:

1. **Promote a European approach to shortages of medicines** to harmonise data collection throughout Europe and encourage multi-disciplinary and encompassing discussions to find broad solutions.
2. **Take actions at EU level based on a commonly agreed definition of shortages as a result of an informed consultation process.** The forthcoming EU legislation on the matter should take into consideration inputs from a wide range of actors and findings of the external study mapping root causes and assessing existing legislative frameworks. Initiatives put in place to respond to the immediate consequences of the pandemic should also be acknowledged and replicated if relevant.
3. **Foster cooperation at multiple policy levels, including national, European and international**. Strong national commitments would play a key role in enhancing European capacity to deal with drug shortages. EU Agencies' mandates should be revised and reinforced concomitantly with increasing resources in terms of staff and budget.
4. **Reinforce domestic production of certain medicines by relocating manufacturing units and ensure a good spread of supply sources to avoid over-reliance and dependency**. Defining a list of critical medicines would be a step forward to prioritise which drugs should receive greater attention.

Shortages of medicines: a growing problem at EU level

While the COVID-19 crisis has put shortages of medicines in the spotlight, this problem largely preceded the pandemic. Shortages affect patients, as well as healthcare workers and healthcare systems in Europe and worldwide. A wide and complex set of factors can lead to shortages of medicines and a better understanding of these is an essential prerequisite to much needed action.

According to a March 2020 Commission note to the Pharmaceutical Committee, shortages of medicines occur "when supply of an already marketed medicine does not meet demand at a national level from healthcare professionals or patients in response to clinical needs"[1]. While shortages of medicines in Europe are mostly tackled at national level, the European Union has also increasingly attempted to address this issue. For instance, the European Medicines Agency (EMA) is involved in cases when a medicine shortage is linked to a safety concern or affects several Member States. EMA considers that "a shortage of a medicinal product for human or veterinary use occurs when supply does not meet demand at a national level" [2]. Cooperation between regulatory authorities within and outside Europe is crucial to prevent shortages and to limit their impact whenever they occur. In the United States, the Food and Drug Administration (FDA) considers drug shortages as "a period when the demand or projected demand for a drug within the United States exceeds the supply of the drug"[3].

Back in 2013, a group of European stakeholders, composed of patient and healthcare professional stakeholder groups, published a common position paper outlining potential causes of shortages and proposing measures to prevent and manage supply shortages of medicines within the existing regulatory framework. Shortages of medicine were defined as "a situation in which the total supply of an authorised medicine or of a medicine used on a compassionate basis is inadequate to meet the current or projected demand at the patient level. The shortage may be local, national, European or international"[4].

In early 2017, the medicines supply chain stakeholders issued a joint statement on information and medicinal products shortages. Using a patient-centered definition of 'suspected medicine shortage' as "the inability for a community or hospital pharmacy, as a result of factors beyond their control, to supply a medicinal product to a patient within a defined period, for example 72 hours"[5], the document called for greater

[1] https://ec.europa.eu/health/sites/default/files/files/committee/ev_20200312_792_en.pdf

[2] https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guidance-detection-notification-shortages-medicinal-products-marketing-authorisation-holders-mahs_en.pdf

[3] https://www.fda.gov/media/131130/download

[4] https://www.eahp.eu/sites/default/files/european_patient_organisations_position_on_shortages_medicinal_products_1.pdf

[5] Association of the European Self-Medication Industry (AESGP), European Association of Euro-Pharmaceutical Companies (EAEPC), European Association of Hospital Pharmacists (EAHP), European Industrial Pharmacists Group (EIPG), European Federation of Pharmaceutical Industries and Associations (EFPIA), European Healthcare Distribution Association (GIRP), Medicines for Europe (formerly EGA), Pharmaceutical Group of the European Union (PGEU).

transparency and availability of medicines shortage data, early detection and assessment of potential shortages, consistency of reporting, increased access to the information available across all parts of the supply chain, improved data infrastructure, and collaborative governance processes.

In May 2019, the European Association of Hospital Pharmacists (EAHP) together with 30 national and European associations of patients, consumers, healthcare professionals and public health advocates approached the European Commission with the request to start an investigation into the factors leading to medicines shortages[6]. In September, the initiative reached out to the Environment, Public Health and Food Safety (ENVI) committee of the European Parliament. In a letter addressed to the ENVI committee's chair, its vice chairs and the group coordinators, the initiative highlighted their growing concern about medicines shortages and called upon the ENVI committee to act[7].

As a result of the growing mobilisation on this issue, the European Parliament adopted a Resolution entitled "Shortage of medicines - how to address an emerging problem" and called for co-legislators to jointly address this problem[8]. Shortly afterwards, several associations put together a list of actions to be prioritised, among which was the call for carrying out a study to better delineate and understand the issue at stake, the compliance with market authorisation obligations and the creation of a platform to report any shortages in Europe[9].

Finding solutions to address shortages of medicines has become a key priority at EU and national level. Currently, as shown by the above-mentioned definitions, even an agreement on a common definition at EU level to help characterise the problem, its causes and hence facilitate finding concrete solutions is lacking. As the definition of shortages of medicines slightly differs on the political level and scale to be considered (i.e. local, national, European, international), the frequency baseline to report shortages (i.e. in terms of hours, days or weeks) and the supply or demand sides based on which the shortage is perceived, all these aspects should be addressed to better define the problem and find suitable solutions to address it.

As highlighted by the March 2020 Commission note to the Pharmaceutical Committee, shortages of medicines belong to the wider problem of access, affordability and availability of medicines[10]. Current discussions on a pharmaceutical strategy for Europe provide important momentum for addressing this issue, learning from the COVID-19 crisis and preparing for the future.

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http://www.eahp.eu/sites/default/files/170201e_supply_chain_statement_on_information_on_med_short.pdf

[6] https://www.eahp.eu/sites/default/files/request_to_start_an_investigation_into_the_factors_leading_to_medicines_shortages.pdf

[7] https://www.eahp.eu/sites/default/files/medicines_shortages_letter_mep_canfin.pdf

[8] https://www.europarl.europa.eu/doceo/document/TA-9-2020-0228_EN.html

[9] https://www.eahp.eu/sites/default/files/common_note_ep_report_on_shortages.pdf

[10] https://ec.europa.eu/health/sites/default/files/files/committee/ev_20200312_792_en.pdf

Against this background, FEAM has been working with the French Academy of Pharmaceutical Sciences and in collaboration with other national member academies since 2019 to gather more information about each European country experience on shortages of medicines, including through a survey. A few insights from the survey are mentioned below (see section *FEAM's and its Member Academies' position on shortages of medicine*). Gathering precise and comprehensive data about the severity of this problem, including the number of medicines affected by shortages and other indicators was a difficult task and this finding also evidenced the requirement for more cooperation at EU level, including the need to compile systematic and comprehensive data.

Healthcare and patients' communities impacted by shortages of medicines

Shortages of medicines are a serious problem threatening patients and putting burdens on healthcare workers, hospitals and pharmacists. As essential components of patient care, medicines must be accessible in a timely manner. For some groups, including patients with chronic conditions, significant clinical consequences might follow if doses are missed. This is the case, for instance, of anti-psychotics, anti-epileptics, immunosuppressives and anti-cancer drugs[11]. Managing shortages and ensuring the continuity of supply can also absorb significant amounts of the time and attention of pharmacists (hospital as well as community pharmacists), time which is taken away from other important tasks necessary for high quality, safe and efficacious care[12]. Shortages can also have negative impacts on health systems, including leading to higher expenses, as systems faced with a shortage often need to rely on a costlier or even less effective alternative.

While there are important gaps in evidence on shortages of medicines, which the EU Commission is currently addressing in a broad study conducted by Technopolis mapping the root causes of medicines' shortages, several organisations at EU level, have gathered information on the extent of the problem, including:

- Several surveys by European Association of Hospital Pharmacists (EAHP) on shortages of medicines in the hospital sector demonstrated its prevalence, nature and impacts for patient care. The most recent survey collected data between November 2019 and mid-January 2020 and was published on 7 April 2020. The survey found that the problem has continued to worsen; hospital pharmacists reporting shortages to be an issue in terms of delivering the best care to patients amounted to 95% of respondents, compared to 91.8% in 2018. The EAHP recommends additional efforts to combat medicines shortages.
- The Pharmaceutical Group of the European Union (PGEU) Medicine Shortages Survey 2020 gathered feedbacks from PGEU pharmacists' members covering 26 EU Member states between 9 November 2020 until 11 January 2021. For 65% of them, the situation with medicine shortages has gotten worse. The problem persists throughout Europe, with more severe consequences in specific countries with 8 countries reporting that more than 400 medicines had been unavailable. This has major consequences on patients as distress and inconvenience for 96% of them, as well as leading to interrupted treatments for 80% of the countries covered by the survey, and an

[11] https://www.eahp.eu/practice-and-policy/medicines-shortages

[12] https://www.eahp.eu/practice-and-policy/medicines-shortages and https://www.pgeu.eu/wp-content/uploads/2019/03/190514E-PGEU-Position-Paper-on-Medicine-Shortages.pdf

indication that pharmacy staff spend 6.3 hours per week on average dealing with these issues[13].

For the past two decades, shortages have been repeatedly flagged up as a major concern for healthcare and patient communities. For the problem to be solved, root causes must be mapped in order to provide plausible and effective responses.

A multi-factorial problem requiring comprehensive solutions

Shortages are fundamentally a problem of mismatch between the supply and demand of medicines. Its causes however are multiple and complex. The French Academy of Pharmacy report on "Unavailability of drugs" identified three main reasons behind shortages, namely economic, industrial and regulatory explanations. Economic causes comprise profit margins that are too low for industry, notably for generic medicines, which leads to a halt in the commercialization due to unprofitable sales. Industrial explanations refer to supply chain disruptions as a consequence of outsourced active pharmaceutical ingredients (API), location of manufacturing capacities outside the EU which therefore increase reliance on non-EU actors upon which controls are limited. Finally, shortages would be partially due to regulatory measures and an increased administrative burden in particular with growing binding compliance with lots of Good Manufacturing Practices (GMP) and environmental norms, but also the complex process of modification post-Marketing Authorization Application (MAA) induces considerable authorization delays up to 5 years[14].

The report recommends that, in the short-term, regulatory enforcement measures at the level of marketing authorizations and good manufacturing practices (GMP) inspections should be enforced, with a revision of the European guidelines for the case of small production and the provision for a system of support and dialogue with industry. Also, a review of the pricing of essential medicines is considered necessary and, at hospital level, procurement procedures should be corrected to facilitate the multiplicity of providers, and a better forecast of necessary quantity of drugs to enable pharmaceutical companies to anticipate the manufacturing campaign. On the medium- to long- term plan, it is advised to adopt measures on governance with the creation of a strategic committee at EU Commission level, as well as economic measures to relocate the synthesis of active substances to Europe to achieve European independence for essential medicine. Furthermore, the report suggests regulatory measures in order to encourage the EU Commission and the EMA to be involved in an international harmonization of a shared framework for evaluating

[13] https://www.pgeu.eu/wp-content/uploads/2019/03/2020-PGEU-Medicine-Shortages-Survey-Results-v2.pdf
[14] https://www.acadpharm.org/dos_public/2018_06_20_AnP_RAPPORT_INDISPONIBILITE_MED_VF1.pdf

modification requests post-MAA. Finally, the report recommends that a clear public catalogue of validated sources of active substances' supply should be made accessible on the EMA website in order to facilitate the problem's monitoring.

After convening a dedicated Task Force, a 2019 Drug Shortages Report of the United States Food and Drug Administration (FDA) concluded that "economic forces are the root causes of drug shortages", mainly due to the lack of incentives for manufacturers to produce low-priced medicines, including low advantages to keep up with high quality management of supply chains. However, this is not reflected in the end price and therefore poor application of GMP brings additional supply disruptions. Furthermore, regulatory barriers remain and impede speedy recovery after market disruptions [15].

Similarly, a group of European patients', consumers and healthcare professionals' organizations published a joint position on shortages of medicinal products, highlighting that medicines disruption could be the result of several factors[16]:

- Medical or regulatory: when demand fluctuates provoking sales' perturbations;
- Economic: too much reliability on very few manufacturing facilities, speculation, pricing leading selling strategies;
- Manufacturing: global supply chain weaknesses, quality standards, critical access to raw materials;
- In relation to the organization of the pharmaceutical market: demand growth, stockpiling, regulatory burden.

The World Health Organisation (WHO) has also been increasingly involved in finding solutions at the global level. Regarding the supply-side problems, the "just-in-time" supply practice to avoid too much stockpiling, results in tight stocks and possible supply difficulties. In addition, an increased demand for medicines coming from low- and middle- income countries (LMIC) has been documented, leading to higher pressure in API provision[17].

As a recurrent pattern, an increase in the number of generic drugs, after the expiration of patents, appears to have had an impact on lowering price setting, which has resulted in increased generic drug shortages due to the lack of profitability for pharmaceutical companies[18].

Medicines' shortages can be seen as a much broader concern on the international stage. Working in an interdependent and highly connected market, pharmaceutical companies greatly rely on different parts of the world for raw materials supply,

[15] https://www.fda.gov/media/131130/download

[16] https://www.eahp.eu/sites/default/files/files/European%20patient%20organisations%20position%20on%20shortages%20medicinal%20products.pdf

[17] https://www.who.int/medicines/areas/access/Medicines_Shortages.pdf?ua=1

[18] https://www.who.int/medicines/areas/access/Medicines_Shortages.pdf?ua=1 and https://www.fda.gov/media/131130/download

manufacturing, production and distribution. Consequently, many relocations of production units took place due to low prices in Europe, mainly in Asia where 60% to 80% of active pharmaceutical ingredients come from[19]. The provision of medicines for the EU market highly depends on variables occurring outside the European Economic Area, upon which controls remain low.

In January 2018, the World Health Assembly agreed on the need to find common ground for coordinated actions at global level[20]. From the WHO perspective, shortages are partially demand-driven due to an expanded demand from LMICs, putting the broader question of access to medicines under the spotlight. This introduces an additional complexity, highlighted for instance in a report from the Access to Medicines Foundation on access to and shortages of antibiotics in relation to the growing concern regarding anti-microbial resistance (AMR)[21]. With global antibiotic consumption increasing by 65% from 2000 to 2015[22], due to scarcity some patients are given antibiotics even though these are not the most appropriate drugs to treat their diseases. This leads to less optimal care delivery, inequalities in access, as well as increasing the risk of AMR.

[19] https://www.europarl.europa.eu/doceo/document/TA-9-2020-09-17_EN.html

[20] https://apps.who.int/gb/ebwha/pdf_files/EB142/B142_13-en.pdf

[21] https://accesstomedicinefoundation.org/media/uploads/downloads/5d848ddd0b2ac_Antibiotic-Shortages-Stockouts-and-Scarcity_Access-to-Medicine-Foundation_31-May-2018.pdf

[22] in, E. Y., et al. Global increase and geographic convergence in antibiotic consumption between 2000 and 2015. Proc. Natl. Acad. Sci. U. S. A. 115, E3463–E3470 (2018).

In search of solutions for shortages of medicines at EU level

Against this background, European institutions have included the problem of shortages of medicines among the top priorities of the current EU Commission[23].

With a view towards minimizing the impact of medicine shortages on patients, the European Medicine Agency (EMA) has mainly focused its work on: (1) communications on shortages in line with the Heads of Medicines Agencies (HMA)/EMA good practice guidance on communicating shortages to the public and EMA's discussion paper on supply shortages of medicinal products; and (2) EU-level coordination on medicines availability: a task force set up by the EMA and the HMA has been looking at availability of medicines, including those that are authorised but not marketed, and at supply chain disruptions, to improve continuity of supply of human and veterinary medicines across Europe since 2016[24].

In September 2020 the European Parliament adopted a Resolution marking progress in recognizing the importance of the problem, by detailing the multiple adverse effects currently occurring and calling co-legislators to take rapid and consistent actions on the matter. This stance has been rapidly followed by the EU Council conclusion adopted in October 2020, inviting the EU Commission "to identify strategic dependencies, particularly in the most sensitive industrial ecosystems such as for health, and to propose measures to reduce these dependencies, including by diversifying production and supply chains, ensuring strategic stockpiling, as well as fostering production and investment in Europe"[25].

While shortages of medicine were happening before, the COVID-19 crisis has emphasized the supply instability, encouraging European authorities to legislate rapidly on the matter. Shortly after the beginning of the COVID-19 pandemic in Europe, the supply of medical disposable items, medical devices and medicines to treat COVID-19 patients was disrupted. In an official address on 8 April 2020, European Commission President Ursula van der Leyen quickly reacted by issuing guidelines to ensure supply and availability of medicines. The plan comprised the following urgent measures concerning medicines: lift export ban within the European territory, stop stockpiling, increase production, limit online sales and guarantee transparent information[26].

The swift shift in demand exacerbated shortages. Indeed, pharmaceutical companies were incapable of planning and had to respond with their existing stock and manufacturing capabilities. Lockdown measures and transport restrictions added an

[23] https://ec.europa.eu/commission/commissioners/sites/default/files/commissioner_mission_letters/mission-letter-stella-kyriakides_en.pdf
[24] https://www.hma.eu/522.html
[25] https://www.consilium.europa.eu/media/45910/021020-euco-final-conclusions.pdf
[26] https://audiovisual.ec.europa.eu/en/video/I-188695

extra pressure on the delivery of medicines. In response to this, the legislative proposal to extend EMA's mandate stated that "during the COVID-19 crisis, *ad hoc* solutions needed to be found to contain the risk of shortages of medicines and medical devices such as ventilators, surgical masks and COVID-19 test kits. […] This has in some cases required the Commission and the Agency to take on tasks requiring *ad hoc* working methods. For these solutions to become efficient and predictable, the respective roles and obligations of the different entities should be clarified and anchored in the relevant legislative framework".[27]

The European Medicines Agency took a leading role at European level to mitigate and remediate these shortages through the following activities[28]:

- The creation of the EU Executive Steering Group on Shortages of Medicines caused by major event in March 2020 compounded by EMA representatives, the EU Commission, Heads of Medicines Agencies, coordination groups for mutual recognition and decentralized procedures for human and veterinary medicines and risk communication specialists. Its objectives are to provide with a platform to exchange and coordinate actions and to foster data exchange among Member States on medicines stock level and possible shortages;
- Enhanced monitoring system for medicines used for treating COVID-19 patients;
- Monitoring of supply chains;
- Issuing guidelines on the optimal and rational supply of medicines to avoid shortages during the COVID-19 outbreak[29].

The parliamentary resolution and Council conclusion formed the bedrock for the EU Commission to act on that matter. The EU Pharmaceutical Strategy, released on 25 November 2020, is a part of the legislative package to build up a European Health Union and is the first piece of legislation moving forward on this topic, endorsing a proactive stance to tackle the issue of medicine shortages. Indeed, in addition to the current ongoing study to map root causes and assess the existing legislative framework, several flagship initiatives were announced such as a revision of the pharmaceutical legislation and new policy measures to address any existing gaps in the supply chain. Furthermore, the proposal to extend the mandate of the European Medicines Agency (EMA) foresees a new domain of action for the agency that is the monitoring and mitigating shortages of critical medicinal products and of critical

[27] Explanatory Memorandum of the Proposal for a Regulation of the European Parliament and of the Council on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020PC0725&from=EN

[28] https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/availability-medicines-during-covid-19-pandemic

[29] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020XC0408(03)&from=EN

medical devices (Chapter II and IV)[30]. A stronger role on that issue is therefore expected from the regulatory drug agency. In the proposal, it is not clear if EMA will monitor shortage situations on a regular basis, outside health emergency times and other major events.

As part of the EU Health Union, the forthcoming plan to create a new EU Health Emergency and Preparedness Authority (HERA) is expected to improve EU preparation and response to cross-border health threats. However, as underlined in a joint Wellcome and FEAM report on the topic, its role in addressing shortages of medicine still needs to be determined and should first and foremost be well-coordinated, complementary and supportive with other EU initiatives' work, such as the EMA and the planned legislative proposal on shortages, but also with the European Directorate for the Quality of Medicines & HealthCare (EDQM) of the Council of Europe, to avoid any duplication[31].

FEAM's and its Member Academies' position on shortages of medicine

The French Academy of Pharmacy, a member of FEAM, set up a dedicated working group on «unavailability of drugs», and produced, in 2018, a report providing evidence-based analysis and expressing concern about the growing challenge of shortages of drugs[32]. The situation's urgency was highlighted, and recommendations were drawn to address the critical supply of active principal ingredients (API) and drugs availability more generally, while making sure patients can receive timely and qualitative drugs when needed. Additional recommendations are put forward for more coordinated and preventive action by European and the Member States[33].

FEAM is pleased to see this issue taken to the highest European decision-making level and welcomes the will of the European institutions to take concrete further steps. In previous statements, FEAM already expressed its support for enabling EU cooperation in "addressing shortages of medicines and vaccines as well as the EU's increasing dependence on medicines and active pharmaceutical ingredients manufactured in non-EU countries and enhancing timely and equal access to affordable medicines for patients"[34]. FEAM would like to emphasise that tackling drug shortages should be done in accordance with the continuation of a production of high-quality medicines, respectful of environmental, regulatory and social norms and standards.

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[30] Proposal for a Regulation of the European Parliament and of the Council on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020PC0725&from=EN

[31] https://www.feam.eu/eu-health-emergency-preparedness-and-response-authority-how-should-the-eu-prepare-and-respond-to-future-cross-border-health-threats/

[32] https://www.acadpharm.org/dos_public/2018_06_20_AnP_RAPPORT_INDISPONIBILITE_MED_VF1.pdf

[33] https://www.acadpharm.org/dos_public/ANP_RECO_COMPL_POUR_L_UE_INDISPO_MEDCTS_20_5_22_VF_EN_GB.PDF

[34] https://www.feam.eu/wp-content/uploads/FEAM-Board-Statement-EU-cooperation.pdf

Thanks to its membership, FEAM was able to gather feedback from its member academies through a preliminary survey, which enabled FEAM to gain knowledge on the shortages' national features, including the need for more precise and comprehensive data about the severity of this problem (e.g. number of medicines affected by shortages). Regarding the situation in France, the French Academy of Pharmacy noted that shortages become more and more frequent and amount to more than 1400 in 2019[35]. In addition, difficulties are encountered when transferring data from the UK to the EU and vice-versa and this could have implications for addressing medicines shortages. Lately, the adoption of the adequacy decision to allow transfers of personal data from the EU to the UK in the post-Brexit context[36] was a relief for the healthcare sector from both sides[37].

[35] https://www.acadpharm.org/dos_public/COMMUNIQUE_PLFSS_ANGLAIS_VF.PDF

[36] https://ec.europa.eu/transparency/comitology-register/screen/documents/074379/1/consult?lang=en

[37] https://www.feam.eu/wp-content/uploads/EHSG-Statement.-MS-vote-on-adequacy-decision-on-the-UK-data-protection-regime.docx-1.pdf

Recommendations

Therefore, FEAM and its Member Academies recommend the following:

Promote a European approach to shortages of medicines

- **Promote a pan-European approach to medicines shortages**. The current European situation on shortages of medicines is concerning and heterogeneous. Reliable information on shortages of medicines is lacking. Therefore, there is a striking need for a more uniform assessment for a pan-European approach to address shortages of medicines;
- **Recognise the multi-factorial nature of shortages of medicines** that requires multi-disciplinary and encompassing discussion to find broad solutions without creating negative unintended consequences.

Take action at EU level based on an informed consultation and on COVID-19 pandemic's lessons learned

- **Set up a consultation process to find a common definition to shortages of medicines by involving all stakeholders.** A common European definition of shortages is needed to be able to assess the problem in a similar way across Europe and to collect data that are comparable and interoperable, enabling a joint appreciation of shortages and possible solutions. However, caution is also important to consider views and interests from all stakeholders implicated along the whole chain from producers to patients[38] and provide a definition that should firstly consider best healthcare delivery and patient needs.
- **Ongoing investments and actions to address shortages such as the EMA-led EU Executive Steering Group on Shortages of Medicines Caused by Major Events that has been activated during the COVID-19 pandemic must be acknowledged.** In the complete revamping of EU health policies, shortages of medicine should be considered a top policy priority.
- **EU efforts should continue to map, assess, collect information and respond to shortages of medicines, and upcoming EU Commission legislation should build upon the Parliament and Council positions.** FEAM welcomes efforts by EU institutions in addressing this issue, noticeably the Resolution of the EU Parliament on 17 September 2020 on the shortage of medicines enjoining the EU Commission to take stock of the problem and propose actions. The EU Council has also underlined the need for limiting strategic dependencies, particularly regarding health-related products, and has

[38] https://www.eu-patient.eu/news/latest-epf-news/2021/extending-mandates-of-ema-ecdc/

asked the EU Commission to make sure the EU focuses on building stable supply chains.

- **Careful attention should be given to the findings of the external study commissioned by Health Directorate-General of the European Commission to investigate the root causes of shortages of medicines, which aims at feeding into the forthcoming EU Commission legislative proposal.** FEAM is looking forward to the full report requested by the EU Commission, forthcoming in 2021, to shed more light on causes and potential courses of action, more coordination at EU level, and to the planned impact assessment and legislative measures planned for 2022.
- **Expertise from well-informed actors working in the field should be taken into consideration when drafting EU legislative proposal.** Several stakeholders including the French Academy of Pharmacy, the European Association of Hospital Pharmacists (EAHP) and the Pharmaceutical Group of the European Union (PGEU) have already made short- and medium/long-term proposals to solve this problem through legislative, regulatory and economic measures. The European Commission should examine these various proposals.

Foster cooperation at multiple policy levels, including national, European and international

- **Federal and national agencies should be enjoined to cooperate among themselves, but also with the EMA and the EU Commission, to propose and implement solutions to tackle shortages of medicines.** Otherwise, the EMA and other EU initiatives could not achieve much on their own as they are extremely reliant on national support and investment.
- **FEAM encourages national agencies to increase their cooperation with the EMA and the European Directorate for the Quality of Medicines & HealthCare of the Council of Europe (European Pharmacopoeia) to make databases interoperable.** A first pilot project could be developed and initiated by these agencies, financed at European level in order to be rapidly operational. This is particularly important as EDQM is also a key stakeholder since they are issuing certificates for active ingredients and action should first come from national agencies, enabling EMA at a later stage to focus on mature products.
- **The EMA mandate should be reinforced, by extending its areas of work to the critical issue of monitoring and mitigating shortages of drugs during health emergencies, but also in-between major events**. FEAM supports the extension of the EMA mandate to include the monitoring and the mitigation of impacts of critical medicines supply shortages in its portfolio. A European system of shortages notifications, which should clearly define who to contact, when, and the information required when reporting, could be

monitored by the EMA. Coordinated action at EU level is much needed and EMA is a key actor to implement it. Sufficient staff and resources should be provided accordingly.

- **Foster European collaboration with regards to joint procurement of drugs and medical equipment's**. The signature of the Advanced Purchase Agreements (APA) by the European Commission on behalf of the 27 member states, to secure sufficient COVID-19 vaccines' doses, is the indisputable example of such success of a collective approach.
- **Promote equal health access globally and avoid any unintended consequences of action taken at EU level on other actors in the world.** While reducing occurrences of medicine shortages in Europe, this should not happen at the expense of other parts in the world and unintended consequences should be avoided. Diminishing health inequalities globally should remain a top priority and ensuring access to medicines to all is an important element of that.

Reinforce domestic production of certain medicines

- **Aligned with the new industrial strategy for Europe[39], relocation of some production in Europe seems critical.** Knowing that 80% of prescribed medicines in Europe come from India and China and that not all production can be relocated in Europe, therefore it is important to focus on a few medicines that are most relevant (i.e. producing essential/critical medicines). A European strategy to prevent shortages by disruption of supply chains would also be critical. A common database should be developed that would record API provenance and warn in case of monopoly or reliance on only a few producers.
- **A definition of critical and essential medicines should be thought through to make sure these are prioritised to secure a continuous sufficient production level and these production units should be relocated in priority.** A list of essential and critical medicines could be drawn up and updated continuously.

[39] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0102&from=EN

About the Federation of European Academies of Medicine (FEAM)

FEAM is the European platform of national Academies of Medicine, Pharmacy and Veterinary Science, or national Academies via their medical division. It brings together 23 national Academies within the WHO European region. FEAM's mission is to promote cooperation among them; to provide them with a platform to formulate and express their common position on European matters concerning human and animal medicine, biomedical research, education, and health; and to extend to the European authorities the advisory role that they exercise in their own countries on those matters.

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