INTERNATIONAL PHARMACEUTICAL POLICY

Special edition on the ABDA conference "Medicine shortages: Giving up? Finding solutions!"

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EUROPEAN CONFERENCE “MEDICINE SHORTAGES: GIVING UP? FINDING SOLUTIONS!“

ABDA – Federal Union of German Associations of Pharmacists invites politicians, pharmacists, managers, journalists, economists, civil servants and other stakeholders from across Europe to the conference “Medicine Shortages: Giving up? Finding solutions!“ on December 1, 2020.

Medicine shortages have been part of everyday life in Europe for several years. The underlying reasons are complex and relate to a highly globalized and specialized drug manufacturing process. Currently, only a small number of manufacturers worldwide produce certain active ingredients. Production stoppages or quality problems in a single plant can be sufficient to endanger the supply of pharmaceuticals to patients across Europe.

The outbreak of the COVID-19 pandemic has now exacerbated this situation and sparked a new discussion at EU level. One focus of the German EU Council Presidency is to ensure a continuous supply of medicines to Europe and to collaborate closely with the European Commission to develop a European pharmaceutical strategy.

Together with a high-level panel consisting of members of the European Parliament, the European Commission and representatives from international pharmacists' associations and the pharmaceutical industry, ABDA will shed a light on the challenges surrounding this problem and discuss possible solutions.

“Pharmapolitik International” is an internal ABDA newsletter issued in German on international topics concerning pharmacies and the health care industry. This issue of “Pharmapolitik International” is a special edition in English on the ABDA conference "Medicine shortages: Giving up? Finding solutions!" and focuses on medicine supply shortages in Europe.

EU-LEVEL COOPERATION

EUROPE – EMA: SHORTAGES CATALOGUE AND COORDINATION DURING THE CORONA PANDEMIC

Prior to the introduction of medicines in the European market, pharmaceutical companies need to apply for market authorization by the European Medicines Agency (EMA). EMA has its headquarters in Amsterdam and ensures the scientific evaluation, supervision and safety review of medicines for human and veterinary use in the EU. After the provision of authorization by EMA, medicines are authorized for marketing throughout the EU and the European Economic Area (EEA).

EMA also publishes information on medicine shortages that affect or are likely to affect more than one Member State of the EU in a shortages catalogue. This catalogue assesses the shortages and provides information on affected Member States and the expected duration of the shortage. Furthermore, EMA publishes a list of all existing national registers in EU/EEA that monitor shortages and provide information on shortages on country level. The list of ongoing and resolved shortages can be found here, an overview of national shortage registers can be found here.

At the beginning of the Corona pandemic, EMA together with European Medicines Regulatory Network published measures in order to prevent and reduce evolving medicine supply shortages in the EU during the pandemic. Especially during the pandemic, supply disruptions or medicine shortages may occur due to export bans, temporary discontinuation of manufacturing, closures of borders and their effects on trade, generally rising demand for medicines used to treat COVID-19 patients, as well as stockpiling by hospitals, individuals or Member States.

The established shortages monitoring system (launched on April 17, 2020) focusses on crucial medicines used for treating COVID-19 patients. Generally, pharmaceutical companies report all (expected) shortages of COVID-19 critical medicines to EMA. EMA then compiles and shares the bundled information to Member States.

Apart from the ongoing Corona pandemic, EMA and Heads of Medicines Agencies (HMA), of which EMA is a member, created a taskforce on the Availability of Authorised Medicines for Human and Veterinary Use in December 2016. Its purpose is minimizing supply disruptions, avoiding medicine supply shortages, developing strategies to prevent shortages caused by supply chain disruptions and promoting stakeholder collaboration.

EUROPE – EUROPEAN PARLIAMENT ON MEDICINE SHORTAGES

In September 2020, the European Parliament published a press release stating that the EU must step up in the efforts to tackle medicine shortages in view of COVID-19. According to the Parliament, EU should ensure the availability of affordable medical treatments at any time. The Parliament also requests to strengthen the independence of the EU in the health sector. This includes fostering domestic production of essential medicines and setting up a comprehensive screening of Foreign Direct Investments (FDI) in pharmaceutical manufacturing plants, which are part of Europe's critical health infrastructure. In addition, financial incentives should be provided to pharmaceutical companies to relocate parts of the active pharmaceutical ingredients and medicine production to the EU in order to reduce dependence on non-EU production sites. Further on, the Parliament demands Member States to increase the EU-wide coordination in health strategies and the creation of an equal access to European reserves of essential medicines functioning as "an emergency European pharmacy" intended to minimizing shortages.

The Parliament also names some of the causes that – from its point of view – are responsible for medicine supply shortages and points out to solutions for reducing supply bottlenecks:

Causes of medicine shortages identified by the Parliament:

- manufacturing problems
- industry quotas
- legal parallel trade
- unexpected peaks in demand following epidemics or natural disasters
- increasing dependence on production sites in non-EU countries
- export bans
- stockpiling

Solutions proposed by the Parliament:

- introduction of financial incentives to encourage producers of active pharmaceutical ingredients to produce in Europe
- screening FDI in manufacturing plants
- creation of an EU contingency reserve of medicines of strategic importance
- exchange of best practices in stock management
- strengthening joint EU procurement of medicines
- facilitating the exchange of medicines between EU Member States
- setting minimum quality standards for healthcare
- fostering pharmaceutical production in Europe
- increasing traceability of research and development costs
- increasing public funding and market expenditure to make medicines more affordable

EUROPE – EUROPEAN PHARMACEUTICAL STRATEGY

The European Commission has issued a European Pharmaceutical Strategy, which was open for public consultation until the middle of September 2020. The upcoming strategy's aim is to address topics such as medicine availability and affordability across the EU.

In line with the new *Industrial Strategy for Europe* and the priorities outlined in the *European Green Deal*, *Europe's Beating Cancer Plan* and the *European Digital Strategy*, the European Pharmaceutical Strategy intends the following actions:

- equal access to safe and affordable therapies
- ensuring availability of medicines
- reducing medicine shortages
- increasing affordability of medicines
- promoting research and technologies that actually reach patients and fulfil their therapeutic needs
- taking advantage of digitalization
- reducing direct dependence on raw materials sourced from non-EU countries
- influencing other countries to harmonize international standards of quality and safety of medicines.

EUROPE – PGEU: 2019 REPORT ON SUPPLY SHORTAGES

The Pharmaceutical Group of the European Union (PGEU) conducted a survey regarding the impact of medicine shortages on European community pharmacists. For the year 2019, 24 European countries took part in the survey. The main results are briefly presented below:

All countries reported medicine supply shortages in pharmacies in the past 12 months, with 87% of respondents stating that the situation has worsened compared to 2018. At the time of the survey, more than 200 medicines were affected by supply shortages in 67% of European countries. All countries surveyed reported negative effects of medicine supply shortages on patients: 75% of the respondents stated treatment interruptions, 58% indicated increased co-payments to alternative medicines and 42% declared suboptimal treatment with limited efficacy or adverse effects as a consequence of medicine shortages.

Furthermore, the respondents identified undesirable effects related to shortages: 92% of the surveyed countries fear a loss of patient confidence, financial losses due to the time taken in case of unavailable drugs (82%) or a decrease in employee satisfaction (79%). Moreover, the overall time pharmacy staff has to spend each week on managing supply shortages has increased from an average of 5.6 hours in 2018 to 6.6 hours in 2019. 25% of the responding countries declared that there is no reporting system for medicine supply shortages for community pharmacists. Thus, pharmacists receive information on shortages from wholesalers (71%), medicines agencies (67%) and pharmacy organizations (42%).

INFORMATION SYSTEMS AND TRANSPARENCY

NETHERLANDS – REPORT ON SUPPLY SHORTAGES AND KNMP FARMANCO

Based on a survey from 2019, the handling of medicine supply shortages for pharmacists and pharmacy teams in the Netherlands takes approximately 17.5 hours per week (approx. 5.5 hours for the pharmacist and approx. 12 hours for the pharmacy team). This corresponds to 0.5 full-time equivalents. In order to alleviate the problem of medicine supply shortages, the Royal Dutch Pharmacists Association (Koninklijke Nederlandse Maatschappij ter bevordering der Pharmacie, KNMP) has developed a register in 2004 that records the status of medicine shortages and lists substitutes and therapy alternatives. The website KNMP Farmanco gives pharmacists a tool to receive up to date information on medicine shortages occurring in the Netherlands. A shortage of a product is included in the register if either it is not available nationwide or the manufacturer confirms that the medicine is not available for delivery for a total of 14 days. The website indicates all registered medicines that are not available and gives information on the cause of the shortage and the expected date on which the medicine becomes available again. Furthermore, KNMP Farmanco can be used by pharmacists to report their shortages through a special form. Manufacturers are required to report (imminent) shortages to the Government's Medicines Deficiencies and Defects Reporting Point since January 1, 2017. Manufacturers can also report their shortages to KNMP Farmanco on a voluntary basis.

FRANCE – SHORTAGE DECLARATION SYSTEM: DP-RUPTURES

In France, a shortage declaration system called “DP-Ruptures” is in place since 2015 with the aim to increase transparency and availability of information concerning medicine supply shortages. Since 2016, manufacturers of crucial medicines need to show an up to date plan for handling and avoiding medicine shortages at any time – otherwise financial and administrative penalties may be imposed. In France, a shortage is present whenever a pharmacist is not able to receive a medicine from two wholesalers for three consecutive days. DP-Ruptures is also used to communicate about expected or observed medicine shortages. Community pharmacists report supply disruptions via their business software. Pharmaceutical companies only receive notifications related to their own portfolio and respond to these shortage declarations with a personalized statement of availability of the respective product. Pharmacists are only able to look at their own notifications of shortages. DP-Ruptures furthermore allows quantifying supply shortages on national level.

SPAIN – CISMED-PROJECT

In Spain, a system for the early detection of medicine shortages called CISMED (Centro de Información sobre Suministros de Medicamentos, Medicines Supply Information Center) established by the Spanish General Pharmaceutical Council is in place. CISMED detects situations of irregular supply of medicines in real time, relying on by pharmacists transmitting the information on shortages directly to their regional pharmaceutical council. Authorities can use the data from CISMED to initiate appropriate measures in case of acute medicine shortages, as well as for preventative measures. CISMED provides information on the exact availability of medicines in pharmacies to actors within the Spanish supply chain, as well as to health authorities.

STOCKPILING

GREAT BRITAIN – STOCKPILING OF CRUCIAL MEDICINES DUE TO BREXIT AND THE CORONA PANDEMIC

In August 2020, the government advised pharmaceutical companies to create a six-weeks-worth stockpile of crucial medicines. According to the Department of Health, medicine reserve stocks should cushion disruptions caused after the Brexit transition period, which ends on December 31, 2020. The Department of Health fears that a disordered Brexit could severely disrupt existing global supply chains and thereby affect the supply of medicines to the National Health Service (NHS) in a serious way. Furthermore, crucial medicines may not be sufficiently available on the world market due to the pandemic. The Corona pandemic has led to a massive increase in demand for medicines and medical devices needed in intensive care. At the same time, the Corona measures imposed by governments have led to significant supply shortages due to factory closures, export bans and a drastic drop in airfreight. In June 2020, the pharmaceutical industry warned the government that all reserves of medicines used for the treatment of Corona patients have been used up in the UK. The pharmaceutical industry advised the government to maintain even larger stocks of a higher variety of crucial medicines.

FINLAND – MANDATORY RESERVE SUPPLY

In Finland, there is a legal basis for a mandatory reserve of medical supplies in order to prevent medicine shortages. The “Act on Mandatory Reserve Supplies” applies to pharmaceutical companies, importers of medical products, health care units and the National Institute for Health and Welfare. The government together with the Finnish Medicines Agency determines which medicines are of critical medical significance and therefore have to be kept in stock. In May 2020, the Finnish Medicines Agency confirmed a list of 1,398 medicinal products to have to be stocked as mandatory reserve supplies. The Finnish Medicines Agency and the National Emergency Supply Agency compensate pharmaceutical companies and importers of medicines for maintaining mandatory medicine reserves.

RELOCATION OF PRODUCTION

FRANCE – RELOCATION OF MEDICINE PRODUCTION

The French Ministries of Economy and Health announced that France plans to relocate the production of the entire French demand of paracetamol to France within the next three years. Paracetamol, like many other active pharmaceutical ingredients, is mainly produced in China and India. The national production of paracetamol will initially be implemented by the pharmaceutical companies Seqens, Sanofi and Upsa. The announcement came a few days after President Emmanuel Macron announced a series of measures to strengthen national health research and ensure the supply of medicines.

REFERENCES

EU-LEVEL COOPERATION

Europe – EMA shortages catalogue and coordination during the Corona pandemic
https://www.ema.europa.eu/en/human-regulatory/post-authorisation/availability-medicines/shortages-catalogue

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

https://www.ema.europa.eu/en/human-regulatory/post-authorisation/availability-medicines

Europe – European Parliament on medicine shortages
https://www.europarl.europa.eu/news/en/press-room/20200910IPR86823/covid-19-eu-must-step-up-efforts-to-tackle-medicine-shortages

https://www.europarl.europa.eu/news/en/headlines/society/20200709STO83006/medikamentenengpasse-in-der-eu-ursachen-und-losungen

Europe – European Pharmaceutical Strategy
https://ec.europa.eu/health/human-use/strategy_en

Europe – PGEU: 2019 report on supply shortages
https://www.pgeu.eu/wp-content/uploads/2019/03/PGEU-Medicine-Shortages-Survey-Results-2019-1.pdf

https://www.pgeu.eu/publications/press-release-pgeu-medicine-shortages-survey-2019-results/

https://www.pgeu.eu/wp-content/uploads/2020/01/PR-PGEU-publishes-results-of-Medicine-Shortages-Survey-2019-2.pdf

INFORMATION SYSTEMS AND TRANSPARENCY

Netherlands – Report on Supply Shortages and KNMP Farmanco
https://farmanco.knmp.nl/intro

https://www.knmp.nl/downloads/rapport-knmp-onderzoek-geneesmiddelentekorten-2019.pdf

France – shortage declaration system: DP-Ruptures
https://www.pgeu.eu/wp-content/uploads/2020/08/Pr%C3%A9sentation-DP-Ruptures-ANGLAIS-2019.pdf

http://www.ordre.pharmacien.fr/Le-Dossier-Pharmaceutique/Ruptures-d-approvisionnement-et-DP-Ruptures

Spain – CISMED-Project
https://www.portalfarma.com/Profesionales/organizacionfcolegial/memoriaactv/Documents/2018-resumen-memoria-cgcof-en.pdf

https://www.pgeu.eu/wp-content/uploads/2019/03/170201E-Supply-chain-Statement-on-Information-on-Med-Short.pdf

https://www.pgeu.eu/wp-content/uploads/2020/08/CISMED.pdf

https://www.portalfarma.com/Profesionales/medicamentos/CISMED/Paginas/default.aspx

STOCKPILING

Great Britain – stockpiling of crucial medicines due to Brexit and the Corona pandemic
https://www.bbc.com/news/business-53641803

https://www.theguardian.com/society/2020/oct/06/nhs-faces-drug-shortages-as-brexit-stockpile-used-in-covid-crisis

https://www.businessinsider.com/brexit-pharmaceutical-companies-stockpiling-medicine-for-northern-ireland-2020-10?r=DE&IR=T

Finland – mandatory reserve supply
https://www.fimea.fi/web/en/supervision/mandatory_reserve_supplies

https://www.fimea.fi/web/en/supervision/mandatory_reserve_supplies/list_of_products_to_be_stocked_as_mandatory_reserve_supplies

RELOCATION OF PRODUCTION

France – relocation of medicine production
https://medicalxpress.com/news/2020-06-france-aims-paracetamol-production-years.html

https://www.lemonde.fr/economie/article/2020/06/18/le-gouvernement-amorce-une-politique-de-relocalisation-des-medicaments_6043337_3234.html

https://www.ft.com/content/80a4836b-ca25-48e0-996d-458186e968dc