AFFORDABLE MEDICINES EUROPE
WORKING IN PARALLEL FOR A BETTER DEAL

VAD
German Association of Pharmaceutical Parallel Distributors

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INFORMATION FROM THE PARALLEL TRADE INDUSTRY

PHARMACEUTICAL & HEALTH CARE POLITICS

The problem of medicines shortages – OECD delivers its long-waited analysis on supply vulnerabilities in the pharma market

Even in the wealthiest economies, access to medicines can be hindered by increasing supply interruptions and shortages. In the attempt to develop a more comprehensive picture of the issue, OECD recently unveiled its final report on shortages of medicines in OECD countries. By analysing pre-pandemic trends, the Paper presents insights into the scale of the issue and explores some possible root causes. Finally, the survey reports on the several policy measures taken by countries and provides some recommendations.

Assessing the magnitude of the problem, and investigating its main drivers

As reported by OECD, the number of shortage notifications increased by 60% between 2017 and 2019 across the 14 OECD countries considered. According to the analysis, shortages mostly affected older, off-patent molecules and, in about 60% of the cases, were due to manufacturing and quality issues. However, commercial factors, as well as regulation and reimbursement policies can also have a role in exacerbating supply vulnerabilities. When it comes to the drivers of shortages, the report also explains that there is no obvious relationship between the rise of shortages and trends in parallel trade, despite the fact that the sector has often wrongfully been cited as a possible cause of increasing shortages in Europe. Likewise, as mentioned in the Paper, the review conducted by the European Healthcare Distribution Association (GIRP) of the websites of 12 national medicines agency found that parallel trade was not explicitly mentioned in any of the reviewed databases as a possible driver of shortages.

Addressing medicine shortages

In order to tackle shortages, many countries have been pursuing a mix of individual policy measures going from regulatory actions to the introduction of stockpiling requirements. Additionally, to protect national supply, several Member States have introduced provisions to ban or limit the export of medicines. However, the report notes how trade restrictions can actually increase medicines scarcity and the risk of vulnerabilities, and overall stressed that shortages represent a complex problem, which would require greater harmonisation and a more coordinated approach.

In conclusion, while an in-depth assessment of the reasons of shortages in OECD countries remains challenging based on the current available information, fact is that more than half of all cases trace back to issues related to quality and manufacturing, which are, therefore, the main culprit in relation to shortages. In light of this and notwithstanding with other contributing factors, addressing production deficiencies and reducing manufacturing concentration will certainly help reduce the overall vulnerability of medicines' supply. ■

EDITORIAL

Dear Readers,

long awaited and recently delivered – the final report on shortages of medicines in OECD countries. With a broad view on the situation before the pandemic, the analysis shows that mostly older off-patent pharmaceuticals are short and that manufacturing problems and quality issues play the main role in shortages.

Often accused by Big Pharma, the report shows no connection between increasing shortages and trends of parallel trade of pharmaceuticals. With these findings and awareness we deeply hope to switch the focus on the main aim and effects of parallel trade – creating competition and leading to significant savings as well as solving shortages by importing medicines in shortage. The latter point is highlighted as a solution in the report, and we invite policymakers to consider this.

Furthermore we would like to put your focus on the debate on the future of the pharmaceutical sector which was part of our first general assembly in Brussels after 2 years of corona crisis. Read what experts from DG SANTE, GIRP, AESGP put in discussion about the implementation of a new pharmaceutical strategy **(page 3)**

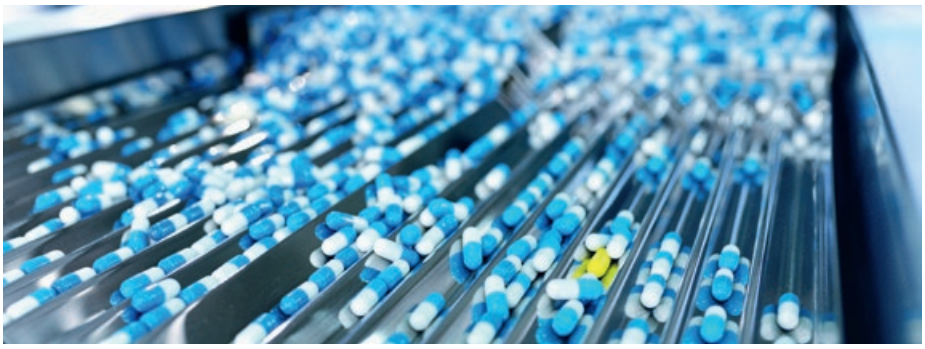
May you discover many informative insights as you read this 78th edition of our Pharmaceutical Dialogue.

Sincerely,

Prof. Edwin Kohl
Chairman
of VAD

Jörg Geller
President of AFFORDABLE
MEDICINES EUROPE

A step closer to the EU Pharma Revision – Main takeaways from the Technopolis 'Impact Assessment Workshop



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On April 25, Technopolis Group, together with the European Commission, held a workshop with stakeholders to discuss the initial findings of its work to help prepare the impact assessment on the upcoming EU pharma revision. The event also served as an opportunity to collect inputs from stakeholders, which will inform future policy changes. Most importantly, the workshop provided participants with the best available indication of where the Commission is headed with its revision based on several thematic areas which were explored during the different breakout sessions.

Ensuring access to affordable medicines for patients

One of the given goals of the EU Pharma Strategy is overcoming the significant inequalities that EU countries still experience when it comes to access to affordable medicines. In this context, the main battle of the revision will be ensuring an earlier introduction of generics into the market. While touching patent length is off the table, specific incentives for biosimilars, reduction of data exclusivity periods, as well as the extension of the Bolar exemption are currently being considered. On access, the main points include incentivising product launch in all EU Member States, as well as the introduction of specific obligations for MAHs to place CAPs on the market in a majority of Member States or include at least on small country when using MRP/DCP.

Enhancing the security of the supply of medicines and addressing shortages

A legislative revision of the pharmaceutical ecosystem could not omit to deliver on shortages, which represent a major problem for health systems and whose incidence could compromise the security of our supply chain. In this regard, discussions are currently focused on the following proposals: increasing shortage notification requirements to 6 months; adding shortage prevention and mitigation plans to GMP for all medicines; establishing additional stockpiling requirements for MAHs and wholesalers for critical medicines; introducing expanded requirements to diversify production; and increasing transparency of both supply and demand-side information.

Supporting a competitive and innovative European pharmaceutical industry

Building on the framework of the new EU's Industrial Strategy, the revision is not least also expected to foster the competitiveness of the pharmaceutical industry and provide a fertile environment for businesses to grow. According to the information available, this firstly implies striking a balance between competition and incentives to innovation while targeting specifically unmet medical needs and addressing antimicrobial resistance. Secondly, prerequisite for a modern pharmaceutical system is an increased regulatory efficiency. To accomplish this, the measures explored include inter alia the adaptation of the definition of a medicinal product, as well as more hardcore cutting of red tape. Finally, on the environment, the inclusion of the environmental risk of manufacturing within the Environmental Risk Assessment framework is currently under discussion.

Considering the various interests at stake, it is clear that turning these proposals into concrete action will not be an easy task for the Commission and the EU legislators, and this is only the very beginning of a process, which will likely be arduous and intricate. ■

NEWS IN BRIEF

Commission seeks views on the upcoming Single Market Emergency Instrument

The European Commission recently published a public consultation on a new Single Market Emergency Instrument, which remained open for feedback and inputs from stakeholders until May 11. In 2021, the Commission announced a new governance tool to increase transparency and guarantee the smooth functioning of the Single Market in times of crisis. The main policy objective of the initiative is therefore to provide adequate coordination and communication mechanisms between EU institutions, Member States, and stakeholders, and ensure the resilience of our internal market by safeguarding the free circulation of goods, services, and persons during emergencies. ■

Photo: Alexandros Michailidis/istock.com

Regulation on extended EMA mandate entered into force

The Regulation (EU) 2022/123 reinforcing EMA's role in crisis preparedness and management of medicinal products became applicable as of 1 March 2022. Based on this new mandate, EMA is now responsible for monitoring medicine shortages that might lead to a public health emergency, as well as reporting shortages of critical medicines during a crisis. The Regulation also foresees the development of an IT platform, the European Shortage Monitoring Platform (ESMP) to be used to facilitate the collection of information on shortages, supply, and demand for medicines including information on whether the medicinal product is placed or ceases to be placed on the market in a Member State. The work is already ongoing between EMA and stakeholders. ■

What does the future of pharma have in hold for Europe? A panel debate investigated what it is at stake.

Panel debate

In the framework of its General Assembly, Affordable Medicines Europe organised on May 19 a panel debate on the future of the pharmaceutical sector with representatives from the European Commission, the industry, and the wholesalers' community. The event served as an occasion to discuss the goals of the upcoming pharma revision and explore challenges and expectations related to the implementation of the new Pharmaceutical Strategy.

Is there a political momentum to move the tectonic plates of the pharmaceutical market?

Ms Olga Solomon, Head of Unit at DG SANTE, the European Commission's Directorate General responsible for health, kicked off the discussion by outlining how there is now an increased momentum to put forward an ambitious and targeted revision of the EU pharma rules, following a call from Member States. These words were echoed by Ms Monika Derecque-Pois, the Director General of the European Healthcare Distribution Association (GIRP), who underlined the importance of equipping the sector with new rules and strengthening it. Ms Jurate Svarcaite, the leader of the Association of the European Self-Care Industry (AESGP) emphasised the challenges posed by the lack of proper implementation of the current rules at Member States level.

Welcome speech of AME President Jörg Geller

Photos: Affordable Medicines Europe

A closer look at the Commission's goals and expectations from the healthcare community

The overall objective of the Commission will be incentivising innovation by improving the attractiveness of the ecosystem while ensuring that medicinal products are available, affordable and reach patients equally across the EU.

The debate firstly focused on the issue of availability of medicines. In this regard, the Commission is currently exploring options to address shortages, going from the introduction of additional stockpiling requirements to measures ensuring the smooth functioning of our Internal Market. A useful indication of how to increase the security of the supply came from the experience of the market of non-prescription medicines, where the high level of competition makes sure that OTC products are very rarely in shortage. In relation to specific tools to tackle availability, GIRP called for the facilitation of emergency import procedures as well as for a strengthening of the Public Service Obligation to ensure the right of wholesalers to be supplied by manufacturers. Moving to ensuring patients' access to affordable medicines, participants discussed the access gap across EU countries often linked to the market size as well as to the country's purchasing power. On this front, the Commission explained it is now looking into factors that influence access, such as delayed market launches, and underlined how overall an increased competition in the Single Market can represent a solution to both access and availability. Finally, to make our system fit for the future, some key suggestions from AESGP included increasing the flexibility of our regulatory framework and removing outdated requirements such as renewals and abolishing sunset clause.

Concerning the tools needed to achieve these goals and realize the above expectations, Ms Solomon concluded that the implementation of the pharma strategy would also require a mix of soft measures to facilitate exchange and cooperation between Member States and the EU and contribute together with the legislative revision to shaping the pharma market of the future. ■

NEWS IN BRIEF

Affordable Medicines Europe's General Assembly

On May 18-19, the General Assembly of Affordable Medicines Europe took place in Copenhagen with more than 100 members of the association representing the parallel distribution industry. The agenda included opening speeches from the DK Deputy Permanent Secretary of State for Health and the Director General at the DK Medicine Agency, as well as keynotes from IQVIA on European PI trends and EMA on metrics and commonly made mistakes during PD submissions. Finally, a panel debate on the future of pharma in the context of the upcoming revision of the EU legislation was held and entailed the participation of representatives from the European Commission, the industry, and the wholesalers' community. ■

Solidarity contributions of pharma and patients

According to the forecasts, the German statutory health insurance funds expecting a deficit of 17 billion euros for 2023. Nearly month after first announcement Federal Health Minister Karl Prof. Dr. Lauterbach finally presented "cornerstones" his draft for a financial reform.

The guidelines of this reform are, among other things, the release of health insurance reserves (6,4 bn), a federal support/loan of 3 bn euros, as well as an increase in the supplementary contribution rate of 0.3 percentage points equally paid by employees and employers (4,8 bn).

A "solidarity contribution" of 1 bn has to be paid by big Pharma annualy for 2023/2024. 2 bn more of "efficiency reserves" coming from pharmacies, hospitals and doctors. Market wide critics rang the starting bell for hot summer discussions. ■

EXPERT OPINION

The EU pharma revision: Ensuring patients' access to evidence-based medicine

By Yannis Natsis, Director, European Social Insurance Platform (ESIP)

Photo: Yannis Natsis

Yannis Natsis

The EU general pharmaceuticals legislation revision offers an unparalleled opportunity to tackle the important evidence gaps in the approval of new drugs. We need to close the growing gap – the evidence gap – between the decreasing requirements of EU regulators for marketing authorisation and the increasing needs for comparative effectiveness by the payers and the HTA community.

To this end, the amendments to the EU legislation proposed by the European Social Insurance Platform (ESIP) and the Medicines Evaluation Committee (MEDEV) aim to strengthen the approvals system in Europe by guaranteeing stronger evidence on the added therapeutic benefit of new medicines at the time of marketing authorisation.

The hands-on experience of our members, the national statutory social security institutions, points to the fact that by reinforcing the evidentiary requirements and by reducing the uncertainty over the real added therapeutic benefit of a new product at the time of its approval, we will get to better informed decisions which will benefit patients, meet therapeutic needs, steer meaningful innovation, and offer the maximum value to society.

To this end, the use of regulatory fast-tracking mechanisms needs to be fully justified and limited to truly unmet therapeutic needs only. In other words, the proliferation of fast-track approvals is counterproductive. In this respect, we need to be pragmatic about the limitations and shortcomings of observational data in the generation of the necessary -missing comparative- evidence in the post-approval phase. We need to make sure that no-compliance with evidence generation requirements has consequences.

Patients deserve and expect much more than hype and false hope. In fact, stronger evidence at the time of the approval of a new product means moving closer to achieving the goal of faster access for patients to evidence-based medicine. Patients expect and demand solid information as to the medicines they take and how those work for them. Clinicians want to better understand what they are prescribing to their patients and my members as buyers need to know what we are buying and paying for.

Additionally, for the new EU HTA system to work, we absolutely need more information on the efficacy and the comparative effectiveness of new products. HTA & payers' needs should therefore be taken on board early in the regulatory approval process. This should be prioritised by the European Commission.

The EU pharma revision offers a once in 20 years opportunity to effectively mitigate the negative consequences of the growing weak evidence-high prices conundrum. Stronger evidence will lead to better deals, better priority-setting, better chances for the renegotiation of contracts, an expansion of competition and better targeted incentives. ■

CALENDAR

Meeting in Rome for the EU project MEDI-THEFT

On May 31, a meeting of MEDI-THEFT project took place in Rome. The recently launched EU funded initiative aims to counteract medicine theft through reporting and data sharing to develop an intelligence-based platform. The project is led by the Italian Medicines Agency and entails the participation of several institutions and organizations, including Affordable Medicines Europe. ■

EDQM Pharmacare Stakeholder Day

The European Directorate for the Quality of Medicines & HealthCare at the Council of Europe held its 2022 stakeholder day on May 31. The event saw the interventions of the PC Committee, focusing on pharmaceutical care in hospital and community pharmacy settings, and the CMED one, which is concerned about falsified medicines. Both committees provided an update about their ongoing activities. ■

EMA Industry Steering Group

The first meeting of the recently established EMA's Industry Steering Group took place on June 21. ISG will provide a forum to regularly exchange views, promote dialogue and receive feedback from industry stakeholders on issues of common interest related to human medicines within the European legal framework and will also focus on the implementation of EMA's extended mandate. ■

IMPRINT

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