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The difficulties faced by the generic and biosimilar pharmaceutical industry and the economic unsustainability of many of its medicines are reflected in the high number of medicines shortages

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Erstwhile 21-year CEO of leading Portuguese generics group Tecnimede, Maria do Carmo Neves today serves as president of her countryâ??s generics industry association, APOGEN. She outlines the highly challenging market situation facing generics, biosimilar, and value-added medicine producers in Portugal today; how this situation reflects Europe-wide trends; and the solutions that APOGEN is proposing to resolve it, thereby creating a more economically sustainable and accessible Portuguese healthcare system.

Could you begin by giving our audience a brief refresher on what APOGEN is, the organisations it represents, and the key issues that it advocates for?

The Portuguese Association of Generics and Biosimilars Medicines (APOGEN) is a national, non-profit, democratically governed organization, independent of the State, public administration and professional or religious organizations. Founded on 26 May 2003 by a group of nine companies, APOGEN is made up of pharmaceutical companies present in the Portuguese market and dedicated to the research, development, production and/or marketing of generics and biosimilars.

APOGEN has been involved in establishing a dialogue with various stakeholders and the health community, namely the government and policy makers, in order to provide information and collective

global solutions capable of promoting a more competitive pharmaceutical market, increasing Portuguese citizensâ?? access to high quality, safe and effective medicines, promoting more and better healthcare for users and contributing to the sustainability of the National Health Service.

APOGENâ??s mission is to disseminate the concepts of generic and biosimilar medicines, actively contributing to the development of these market segments in Portugal, making medicines more accessible in a sustainable healthcare system, and allowing funds to be allocated to more healthcare and new healthcare technologies.

In fulfilling our mission, we are guided by our values: Ethics and Integrity, Quality, Partnership, Fairness and Sustainability. APOGEN currently has 15 member companies, representing around 90 per cent of the generics market. 11 are foreign multinationals, 4 are Portuguese companies and 7 have manufacturing facilities in Portugal.

APOGENâ??s main activity is to:

â?? represent and defend the legitimate economic, professional, social, and commercial interests and rights of our members before national and European authorities, our affiliated associations and public opinion.

â?? contribute to the understanding of the needs of the generic and biosimilar medicines market by collecting and disseminating specific information for the knowledge and use of our members.

â?? cooperate and intervene with the competent authorities and official bodies in the study, drafting and implementation of measures aimed at the appropriate regulation of the generic and biosimilar medicines market and the activities of our members.

â?? disseminate ethical and quality principles and practices among our members, ensuring their professional prestige and promoting mutual understanding and support among member companies for a better and more effective exercise of common rights and obligations.

The homepage of the APOGEN website has a live totalizer calculating the savings made through the dispensations of generic medicines in outpatient clinics. Do you feel that stakeholders in Portugal are sufficiently aware of the importance of a thriving generics industry?

The awareness about the impact of generic and biosimilar medicines on the sustainability of the health system has been increased. However, the introduction of unsustainable cost containment measures such as clawbacks (in Portugal we have a pharmaceutical industry contribution that has been in force since 2015) and inefficient procurement mechanisms to reduce pharmaceutical expenditure has led to withdrawals of products and companies from the market.

In recent years, the European Commission has emphasized that pharmaceutical pricing policies that solely contain expenditure and do not allow for price adjustments to reflect changes in cost of goods, manufacturing, regulatory procedures, and distribution have a negative effect on supply reliability.

So, in answer to your question, our role is crucial for access to more affordable medicines and for health system sustainability, but stakeholders are not sufficiently aware of the risks of our industry becoming unsustainable.

What are the roadblocks to greater generic penetration in Portugal and how can they be overcome?

Generics penetration in Portugal stands at 51 percent in units and 64.7 percent in the competitive market. These data is from Infarmed (our national competent authority) and are related to June of this year. Nevertheless, almost 70 percent of dispensed medicines in Europe are generics. So, Portugal still has a significant potential to grow.

According to market research performed by GfK in 2021 the population doesnâ??t have any issue with generics â?? 85 percent of the population above 55 years have already used them and the results were identical to the reference medicines, 96 percent of the pharmacists recommend the use of generics, yet percent of doctors have doubts about their quality and efficacy, which is a barrier for generic entry. The health authorities should invest in literacy programs about generic and biosimilar medicines for health professionals and patients.

Another barrier to generic entry is the P&R system in Portugal. The generic price can be 50 percent to 80 percent less than the reference medicine which is not attractive taking into consideration that Portugal is a peripheric small country with very low prices.

During the last 20 years the price of medicines in Portugal were affected by continuous price cuts, only this year the medicines with more low prices, until EUR 15 had a price increase â?? 5 percent for medicines below EUR 10 and 2 percent for medicines up to EUR 15. Our recommendation is that every year the generic and biosimilar medicines prices should be updated according to the inflation rate.

In the hospital market generics and biosimilar medicines are obliged to a pharmaceutical industrial contribution of 14.3 percent over sales which is equal for innovative products and off-patent medicines. This is a real roadblock for more generic and biosimilar entries in the market. In retail market generics had a positive discrimination and the tax is 2.5 percent. APOGENâ??s recommendation is to harmonize the pharmaceutical industrial contribution to 2.5 percent.

The procurement system in Portugal is also a barrier to the entry of off-patent medicines.

Generic manufacturers across Europe are worried about system sustainability, with some tenders becoming so uneconomical that there are almost no participation incentives. Is there enough planning and reward to make supply sustainable in Portugal?

In Portugal, conditions have not been established to guarantee the creation of value and the sustainability and attractiveness of the generic and biosimilar medicines value chain.

The difficulties faced by the generic and biosimilar pharmaceutical industry and the economic unsustainability of many of its medicines are reflected in the high number of medicines shortages. In the hospital market, there are no official figures on shortages. However, it is very common for hospital tenders to be deserted. There is an urgent need to implement several procedures that will help keeping generic and biosimilar medicines on the market and contribute to the sustainability of the healthcare system by creating efficiencies for the NHS. These include:

Awarding contracts to more than one supplier

This allows the competitive market to remain healthy; avoids situations of market disruption, which is particularly important in the case of life-saving medicines; and ensures that patients can be treated

without the need for exceptional use of medicines or the preparation of other procurement processes, thereby avoiding additional costs.

We recommend guaranteeing sustainable competition, an analysis of the market should be made and the number of procurements winning manufacturers should be selected according to the different characteristics of the market. Multi-winner tenders should be preferential to guarantee multiple manufacturers in the market and prevent medicine shortages.

Launching new tenders once a year to:

â?? ensure that sufficient time is allowed for the introduction of new off-patent medicines and the switching of patients to biosimilars, respecting the recommended minimum duration of use of the originator product of 6 months.

â?? plan stocks in time to ensure normal supply of medicines.

â?? increase the efficiency of the NHS by encouraging competition.

Using extended lead times that guarantee a predictable supply of medicines to patients

Aiming to comply with the current short lead times in case of award, manufacturers often hold stock in anticipation. However, if the procurement application fails, the manufacturer is left with an excess of stock which generally has a shelf life of only 10-12 months. Therefore, the manufacturer has to destroy their stock, which is very costly, or faces increased pressure to win the next procurement process, which might disrupt competition and lead to market dumping at unsustainable low prices (sale price or sometimes even below the level of the cost of goods). Lead times can vary across countries.

On average, the minimum lead time needed for a manufacturer to supply a generic medicine is around six months, whereas this might be even longer for biosimilar and complex generic medicines due to the more sophisticated manufacturing processes. Therefore, lead times should be adapted to the product characteristics as well as the requested volumes to be supplied, to guarantee a predictable supply.

Furthermore, it is important to highlight that the process of extending lead times is not onerous for authorities, and this measure can significantly reduce waste and improve efficiency.

Establishing most economically advantageous tender rule criteria

Procurement criteria should be designed to ensure a secure and continuous supply of medicines to patients. For this reason, the focus should not only be on the lowest price of the medicine, but a holistic view should be adopted, and additional relevant criteria considered that do not undermine access to generic and biosimilar medicines. These criteria should ensure the best value for money for the benefit of patients and healthcare systems.

Europe has become the worldâ??s leading region for biosimilars uptake, but what is the situation in Portugal and what are some of the challenges to fostering wider biosimilar use?

Biologic medicines take up an important part of the pharmaceutical budget, and a growing number of new pharmaceutical therapies are biological molecules. Biosimilar medicines have offered patients increased access to these life-altering biologic therapies.

Portugal has implemented a set of measures that have facilitated the entry of biosimilar medicines. Several Orientations were published by National Commission of Pharmacy and Therapeutics from 2016 to 2022. In 2021 the Orientation was published that allows the interchangeability between biologic and biosimilar medicines.

In 2016 the gain-sharing program for 2017 was defined which included performance indicators associated with the uptake of biosimilars, taking as reference a minimum share of biosimilars of 20 percent.

Infarmed has promoted several conferences, in 2013, 2015, 2016 and 2022 with the support of APOGEN about the challenges and opportunities of biosimilars.

Analyses about uptake are disseminated on a monthly basis and analyses about the potential savings on an annual basis.

An important tool is the hospital benchmarking which compares the biosimilar uptake in each public hospital. In June the biosimilar market share in public hospitals was 70.8 percent and in the retail market the range is from 23.6 percent, for insulin glargine, to 68.3 percent for follitropin.

In comparison to the European market Portugal is well positioned in terms of biosimilar uptake, however we have concerns about some measures that are mentioned on the report related to the proposal of Budget Law for 2024 which can compromise the maintenance and the launch of new biosimilars in Portugal. We are in discussion with the competent authorities about the impact that such measures would have on access to biological therapy and the sustainability of the NHS.

The new EU Pharma Package has been broadly welcomed by the generics industry as a means to foster greater access to medicines, including via shortening the IP window for innovative drugs and allowing earlier access of generic competition to the market. What has been APOGENâ??s membersâ?? reaction and what are your hopes for how this topic will evolve?

The recent proposal of the Commission to amend the Pharmaceutical Directive and Regulation is a positive first step towards reforming EU pharmaceutical policy for access, availability and sustainability. Building on this proposal and to fully unlock the potential of off-patent medicines, the following changes should be introduced into the legislation:

Predictability and legal certainty to deliver on equitable access

The co-legislators can support generic, biosimilar, and value-added medicines uptake policies and timely competition by ensuring that the modulation of incentives provides legal certainty for generic and biosimilar medicines applications.

The modulation aims to reward originators for fulfilling key public health objectives such as ensuring equitable access or addressing unmet medical need

Failure to deliver on those objectives should lead to earlier generic or biosimilar medicine competition and access to medicines. Thus, the EU should modulate the market protection rather than data protection. In this way, in case the originator manufacturer does not fulfil the requirement to supply their products to all EU markets, the generic or biosimilar medicines would be approved in time to supply the underserved market. Since the EU already has the longest data protection period in the world, the cumulative data protection and market protection period should not be extended

beyond the current system (8+2+1=11 years).

Removing barriers to off-patent medicines competition at loss of protection

The EU should ban the artificial and unlawful barriers to the day-1 entry of generic and biosimilar medicines by clarifying the Bolar provision in the Pharmaceutical Directive. This should include the supply of EU produced active pharmaceutical ingredients (APIs) for obtaining marketing authorizations and conducting studies as well administrative actions needed for pricing and reimbursement and tender procedures.

Rejecting transferable exclusivity vouchers (TEV) for novel antimicrobials that will massively increase costs for healthcare budgets, reduce predictability for off patent medicines producers and delay access to medicines in critical therapy areas like oncology

The TEV undermines the fundamental tenant of EU innovation policy by delinking the reward from innovation and research and by effectively creating a market to purchase monopoly extensions for most expensive blockbuster drugs. To encourage equitable access to novel and established reserve antibiotics, the EU should establish push and pull incentives scheme, such as for instance: market entry rewards, â??play or payâ?• fees or subscription payment mechanisms.

Make medicines available via a robust and digital supply chain and an efficient regulatory system

The proposal should include a European Strategy to prevent the risk of medicines shortages and address vulnerabilities in the global production chain by Improving the efficiency and digitalization of the Medicines Regulatory Network with:

A faster pan-European implementation of electronic product information

This will enable manufacturers to quickly respond to volatile market dynamics and move products more effectively from one EU country to another to address medicine shortages â?? 90 percent of which are limited to a single EU Member State according to the Commission study on shortages. Solidarity based allocation of medicines across the EU is one of the critical lessons learned from the Covid pandemic as the European Parliament has reiterated time and time again.

Improving supply chain transparency to enable pre-emptive measures against shortages

There are over 10 billion packs of medicine prescribed every year and there should be a way to improve the forecast demand and supply through access to existing regulatory and supply chain data, such as the European Medicines Verification System (EMVS), created under the Falsified Medicines Directive. The EU should not duplicate data that already exists in the EMVS by burdening manufacturers with additional reporting requirements.

Supporting a risk-based approach for shortages prevention plans (SPP), based on a single coherent list of critical medicines or essential medicines with no alternatives This will ensure that manufacturers and medicines agencies focus their limited resources on preventing and mitigating shortages rather than producing hundreds of thousands of burdensome reports and submissions that no one will ever have the time or human resources to read, let alone process.

â?? Similarly, the extension of shortages notifications from 2 to 6 months would massively increase shortage â??false alarmsâ?• as happened in Italy and in Canada. Manufacturers and regulators should focus resources on preventing and mitigating genuine shortage risks for patients by harmonizing and digitalizing the reporting of high risks of shortages and using EMVS data, as

mentioned above, to predict shortage risks.

â?? Develop a science driven, risk-based and efficient environmental risk assessment that successfully addresses â??Pharmaceuticals in the Environmentâ?• while fully maintaining patientsâ?? access to essential medicines. We urge extreme caution against any change to the notion of risk/benefit for pharmaceuticals in this context.

Affordable innovation that addresses patient needs

Supporting affordable innovation to address patient needs via a clear pathway for repurposed medicines (value added medicines). To encourage investment in affordable innovation, the co-legislators should include in the article devoted to repurposing all relevant changes which deliver significant benefit to patients, provided they are based on appropriate pre-clinical or clinical evidence. These include new indications, pharmaceutical forms, methods, or routes of administration as well as updates in posology, which can all bring meaningful improvements to health outcomes and help reduce the burden of disease for patients and healthcare systems.

Over the past two decades, Europe has moved away from essential medicine manufacturing, largely outsourcing such production to Asia while focusing on the most complex and profitable therapeutic niches at home. COVID-19 proved that this is a problematic system in times of crisis, where sovereign states safeguard their own populations as a priority, leading to shortages elsewhere. Why is bringing essential medicine manufacturing back to, and near to, Europe important, and what role might Portugal play in this EU-wide push?

Portugal has a high level of qualification of senior management, with highly skilled and specialized workers in the health sector. The labour costs in Portugal are attractive and competitive, compared to other European countries.

Portugal has a pole of production infrastructure of generic medicines competitive at international level, both from the technological and regulatory points of view. The technology available in Portugal is highly developed, allowing it to European pharmaceutical technological hubs.

Portugal is attractive for companies with international mobility programs given its stable social and political environment, comparing to other countries with equivalent production conditions.

The State must create mechanisms to make the sector more agile and attractive, through:

â?? Tax policies which aim to increase investment and change the tax burden of the sector.

â?? Pharmaceutical policies among others, incorporating the Pharmaceutical Strategy for Europe to strengthen the industryâ??s footprint in this context.

â?? Structural policies that promote the reindustrialization and the financial capacity of the sector.

According to a Deloitte Study on the strategic value of the generic and biosimilar medicines industry in Portugal our sector has created more than 16 331 jobs in Portugal, has an installed capacity to guarantee the supply of essential medicines in Portugal and exports EUR 625 million each year. Each EUR 100 million in exports corresponding to national production will have a full impact in the national economy of EUR 51.6 million in the GVA (gross value added), figure that is above the national average. The production of medicines, besides generating value for the country, increases national sovereignty in the medicine sector, and minimizes risks of disruption of supply chains.

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