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Given that seven out of ten prescriptions in Europe are for generics, it is in everybodyâ??s interest to have a thriving generic industry

12.12.2023

Tags:

Europe, Spain, Medicines for Europe, Association, Generics, Biosimilars, Manufacturing

The COVID-19 pandemic and subsequent shortages of essential medicines and APIs laid bare Europeâ??s reliance on suppliers outside its borders. To combat this issue and ensure that Europe is better prepared for future health crises, the Spanish Presidency of the EU is advocating for a focus on â??strategic autonomyâ?? up to 2030. In conversation with PharmaBoardroom, Elisabeth Stampa of Medicines for Europe, which advocates for the generic, biosimilar and value-added medicine industry, unpacks what this concept means for European companies and governments. Stampa highlights why efficient, green, and digitalized production processes must be further incentivised; gives her take on the shortcomings of stockpiling; and calls for urgent reform of pricing, tendering, and procurement processes to ensure that her industry can continue to invest in Europe.

Medicines for Europe has made the concept of â??strategic autonomyâ?? one of its key agenda priorities; how would you define it?

This is a topic that we have long advocated for, but the COVID-19 pandemic and subsequent medicine shortages reinforced its importance and increased public awareness. Production of many high-volume products has shifted to lower cost regions outside of Europeâ??s borders in recent years, given the pressure on costs here, which led to shortages during the surge in demand that COVID brought about. At the end of the day, there is labour involved in manufacturing active pharmaceutical ingredients (APIs) and medicines, and other geographies are able to be much more

competitive than Europe on costs.

The Spanish Presidency of the EU has created a document around strategic autonomy, laying out what countries should be working on up to 2030. The document highlights APIs as a point of concern for which production needs to be increased, although Europe is already a strong producer of these products. It is the third-biggest supplier of APIs to the US, for example, behind only India and China, and there is a significant network of companies here producing them.

However, most producers in Europe are currently concentrating on more complex and higher value molecules, despite generics counting for 70 percent of the prescriptions in Europe. These are usually older, high-volume therapies for chronic conditions like hypertension, diabetes, CNS, and cardiovascular diseases, and are now produced outside of the continent.

What needs to change for more essential medicine and ingredient manufacturing to take place in Europe?

All producers in Europe, whether of APIs or finished products, are heavily investing in green technologies to comply with the EUâ??s restrictive legal requirements. Moreover, European producers are shifting towards more sophisticated and efficient production processes, especially in terms of digitalisation, electronic batch records, electronic lab notes, and biocatalytic processes.

These trends are already leading to reshoring and, while reshoring all production to Europe is unrealistic, there are more products once more being manufactured in Europe. In some cases, this is because companies have found more efficient ways of manufacturing. In others, it is because tender customers in regions like the Nordics are favouring products that are manufactured according to European environmental rules. This something we would really like to see extended towards other countries. Moving forward, we would like to see more state aid and mechanisms to incentivise companies to go even further on efficient, green, and digitalised production technologies.

How much of an investment incentive can this shift towards green technology really be without significant changes to how low-margin generic products are priced?

Both factors are important. Some companies have already invested heavily in producing antibiotics in a greener way. However, we are operating with razor thin margins because of the price containment measures that exist in most European countries. We are not talking about increasing prices systematically, but at least being able to adapt the prices to inflation. A product that was priced at three euros ten years ago, is likely to cost almost exactly the same today, which does not reflect inflation at all. Maybe the price has even gone further down.

There have already been some measures taken in certain European markets. In Portugal, depending on the price of the product, the price can be increased by ten percent, and there have been similar measures in Greece. Nevertheless, there is still no unanimous move for all countries in the EU to allow prices of generics to be inflation-adjusted. My own country of Spain is a prime example of a market where things stay the same for far longer than they should.

A recent FT article reported on discussions about a â??voluntary solidarity mechanismâ?• whereby EU member states could access an EU-funded medicine stockpile to avoid

shortages. Might stockpiling and other reallocations of existing resources help alleviate shortages more effectively than constructing big new manufacturing facilities in Europe?

Perhaps, but the challenge would be deciding which products to stockpile. There is no unified list of essential medicines in the EU; individual member states have listed, as do organisations like HERA, the WHO and the US FDA, but these differ. While some heavily used medicines, or those for life-threatening diseases could broadly be agreed to be â??essential,â?• the definition is somewhat vague.

There are a few main problems with the voluntary solidarity mechanism. The first is establishing which products should be included and deciding where they should be kept. The second is how to plan for a huge increase in demand, as we saw during the winter 2022/23 flu season. As there is no unified EU patient database, demand planning would be extremely challenging. Moreover, the entire production process takes at least six months or more â?? from sourcing raw materials to API production and final product creation â?? meaning that we would need to know in May how many cases there will be in November. Additionally, some products have a shelf life of only two or three years, while others last for five, so making sure that stockpiled medicines remain in date would be an issue.

Finally, simply increasing production as demand increases â?? which is sometimes called for by politicians and the media â?? is no easy task. All these products are produced under strict GMP regulations, meaning that a skilled and well-trained workforce is necessary. It is not like hiring more staff at a supermarket to deal with the Christmas rush.

Overall, it is a good idea, but it would not be straightforward to implement well.

Are these arguments being well received by government stakeholders in Europe?

They are, but governments have the unenviable task of dealing with a mountain of topics at the same time. They must tackle major sectors like energy, cars, batteries, and hydrogen on top of health; all of which have big repercussions for the workforce, consumers, and the public at large.

Dialogue with the authorities is very fluid: they understand where the problem lies, that we are not able to produce the amounts needed simply by increasing the number of shifts from one day to the other, and that this needs to be planned. However, we are still struggling to see the results of this good dialogue.

In this push for European strategic autonomy in pharmaceuticals, countries in the East and South of the continent that, unlike those in the West of Europe, have retained much of their essential medicine and API manufacturing capabilities may have a big opportunity. Do you see the East and South of Europe as the geographic hotspots on which the continentâ??s pharma future will depend?

I would not be quite so sure. In the API industry, for instance, Italy is the leading player in Europe, followed by Spain, then France and Germany. While Italy and Spain are indeed in southern Europe, France and Germany are more in the centre. Moreover, finished product manufacturing is spread throughout the entire continent and no one country hosts the entire supply chain to be completely autonomous.

Might North Africa become a more significant pharma manufacturing destination for Europe?

It might, but it has yet to happen. Some of the countries in that region have strong protectionist policies in place and most lack the tradition of fine chemistry that European countries like Switzerland, Germany, or Hungary possess.

While the idea of strategic autonomy in pharmaceuticals would be backed by most Europeans, there might be less eagerness for the building of large and potentially polluting factories near to where they live or work. How might a modern industrial footprint for Europe differ from what has gone before?

We must adopt a balanced approach. If we want medicine manufacturing in Europe, then we should accept that, in some industrial areas, medicines will be produced. In the same way that European governments are also investing in producing microchips in their own backyards, we will have to live with the reality of European ingredients and European medicines. However, the environmental restrictions are extremely stringent and finished product manufacturing is considered a clean industry.

The Spanish Presidency of the EU has touted the blocâ??s capacity to lead a new era of global prosperity. What does Medicines for Europe see as its role in contributing to the EUâ??s leadership on the global stage and how does this align with the EUâ??s vision for 2030?

Having a long-term vision and not only focusing on short-term issues is a very positive shift. This EU vision is fully aligned with what we are advocating for: i.e., investing more so that patients have the medicines they need. It is also contributing to health, one of the first rights within the welfare state.

Our industry contributes to health through the products it produces, but also to countriesâ?? economies through the jobs it generates, the tax revenues it pays, and the exports it makes, and the innovation it brings. The generics and biosimilars industry *is* innovative, as we have to produce products that are exactly as effective as those designed 30 years ago but utilising current technology. Moreover, we must comply with many more regulatory and safety restrictions and requirements than the originator did.

A lot of these topics are for the longer-term, but what will you be advocating for in the remainder of your two-year mandate as president of Medicines for Europe?

We are very much aligned with the 21 EU member states calling for a â??Critical Medicines Act,â?? creating an essential medicines list, solidarity mechanism, and industry incentives. However, my main advocacy priority will be the reform of the pricing, tendering, and procurement system for medicines throughout Europe. Price policies should allow for adjustments for inflation, and tenders should consider factors other than prices alone, both of which would make our industry more sustainable. Given that seven out of ten prescriptions in Europe are for generics, it is in everybodyâ??s interest to have a thriving generic industry. Our companies are businesses like any other and need some margins; without this, they will not continue to invest, and we will need to source these products from outside of our borders, exacerbating the supply issues we are already

facing.

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