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Stampa Urges Investment In European Manufacturing

New Medicines For Europe President Also Warns Over Pricing And Cost Pressures

by David Wallace

Fresh from being named as the new president of Medicines for Europe, Medichem CEO Elisabeth Stampa sets out the association's priorities around investment in European manufacturing, as well as identifying key obstacles that must be overcome to create a sustainable environment for off-patent medicines, in an exclusive interview with *Generics Bulletin*.

In the wake of her appointment as president of European off-patent industry association Medicines for Europe, Medichem CEO Elisabeth Stampa has elaborated on the importance of investing in European manufacturing – as well as offering warnings over current price and cost pressures – in an exclusive interview with *Generics Bulletin*.

"We've been working on three priorities," Stampa outlined, as she set out three key objectives for Medicines for Europe under her presidency.

"The first one is to have an economically sustainable off-patent sector." While "seven out of every 10 drugs prescribed or dispensed in Europe are generics," healthcare costs were also on the rise, she cautioned, particularly with an ageing population.

"We have to be a substantial part of those healthcare systems," she insisted. But

Medichem's Stampa Takes Lead At Medicines For Europe

By David Wallace

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Medichem CEO Elisabeth Stampa has been

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"driving prices down is certainly not helping to sustain our sector."

Second among the association's priorities was "to aim for a strong manufacturing footprint in Europe," Stampa explained.

Referring to a study carried out by German industry association Pro Generika, she said there were "93 or 94 active pharmaceutical ingredients registered with the European pharmacopeia where there is no European producer. And if we look at finished dosage forms, shortages have multiplied in the past 10 years twelve times."

named as the new president of Medicines for Europe, setting out policy priorities that include bolstering the European API sector and supporting a "green transformation" for manufacturing.

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"For both APIs and finished dosage forms, we are seeing that there is increased consumption of products that are not produced in Europe. So we think we have to aim for incentives there; to be able also to access the European recovery funds; to have an intellectual property situation which helps to continue developing our industry; and we are also aiming to attract and retain the talent we need for our industry, which is highly specialized."

Finally, she said, Medicines for Europe also wanted to "support the European authorities in their green ambitions and to make them compatible with our industry and what needs to be done to continue manufacturing APIs and finished dosage forms. So we want to engage in a dialog with the authorities to make that compatible."

'Still Recovering' From Pandemic As Price And Cost Pressures Mount

Asked whether generics and biosimilars were now sufficiently established as a key component of Europe's continuing recovery from the COVID-19 pandemic – and whether the off-patent industry was now moving into a post-pandemic era, with fewer disruptions than had been seen over the past two years – Stampa said "I think the industry is still recovering."

"There are lots of fluctuations in demand," she outlined. Moreover, "we are coping with increasing inflation and transportation costs at the same time, while governments are still focusing very much on austerity measures and the lowest possible price."

"There is definitely an urgency in stopping those downward pricing pressures," Stampa maintained, "because they are only making the problem worse than it already is."

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> *"API producers are trying to do their best, and are continuing to invest, and trying to maintain supply, but it is not easy."*

"But at the same time, COVID shed a lot of light on the dependence on other geographies," providing industry with "good momentum to establish and to keep a dialog with the European authorities" around the importance of European manufacturing.

On the question of API supply and demand specifically, she acknowledged that "it is still a fragile area of the supply chain." Supplier validation and switching between suppliers were adding complications to API supply, while "the different ways in which different variants of COVID affected different geographies at different times is also not helping."

Meanwhile, "demand is still unstable, and the transportation costs and scarcity of containers – plus the increase in inflation, which most probably will only continue – is not contributing."

"So API producers are trying to do their best, and are continuing to invest, and trying to maintain supply, but it is not easy."

Europe Could Do More To Incentivize Investment

In terms of investment in European manufacturing – both for APIs and finished dosage forms – Stampa was clear that more could be done at a European level to incentivize this.

"We have recorded several investments by our member companies," she pointed out. "But what we believe is that the European authorities that have access to the funds could help much more to increase those investments in both APIs and finished dosage forms, and expanding capacity or adapting to greener technologies or new technologies, to incentivize and attract more investment in Europe." (Also see "*EU Must Stop Offshoring Of Essential Medicines, Say Trade Groups*" - Generics Bulletin, 26 Nov, 2021.)

Asked whether EU rules on state aid were still proving an obstacle (*see sidebar*), she acknowledged that "it is still a barrier, but we are having a good dialog with the EU Commission, so we are very confident we will reach a solution there."

European Industry Urges State Aid Changes To Allow COVID Recovery

By David Wallace

But a significant change in the global manufacturing environment for the off-patent industry

would take time, she acknowledged, even with other geographies around the world also pursuing similar localization initiatives. (Also see "*Pandemic Perspectives: Cracks In Global Supply Chain Lead To Localization Trend*" - Generics Bulletin, 15 Mar, 2021.)

"I believe it's going to be a gradual shift," Stampa said. "It's very difficult to shift all the dependency we currently have on APIs into Europe, or even into the US or other developed countries. I think that's not going to happen overnight for sure."

18 Nov 2021
A five-year period of temporary relief from EU state aid rules should be introduced for countries willing to invest in API and medicine production, Medicines for Europe has urged, insisting that current restrictions do not allow the investment necessary to bolster the supply chain in the wake of COVID-19.

Read the full article here

To shift this dependency, would there need to be a shift in the focus on price as the sole or deciding factor in European procurement processes? "Having other factors beside cost is going to enable [this], like environmental, like compliance, like quality but also regulatory flexibility and digitalization," Stampa said, also calling for "a harmonized Bolar within all the European countries to stop the evergreening divisional patent system which still exists in Europe."

German Tamoxifen Shortage Provides Cautionary Example

Touching on the recent supply issues around breast cancer treatment tamoxifen in Germany (*see sidebar*), Stampa was clear on how similar situations could be avoided in future.

"It's a matter of price, of not putting all the pressure on price," she summarized. "It's a matter of tenders with multiple winners [and] implementing the Most Economically Advantageous Tender (MEAT) system with other considerations than strictly price."

Asked whether the political will existed to shift away from the focus on price, she conceded that "it will be very difficult to move away. The population is only going to get older, which is only going to cost more money. And at the same time there are new fantastic therapies which have to be covered. So we need to find a way of

German Tamoxifen Shortage Shows Consequences Of Cost Containment

By David Wallace

17 Feb 2022
Supply issues around breast cancer treatment tamoxifen in Germany demonstrate the damaging effects of European cost-containment measures, Medicines for Europe has warned, citing an "urgent need to revise unsustainable pricing and tendering policies."

Read the full article here

moving forward with the healthcare systems that everyone wins."

Nevertheless, she said, examples such as the Germany tamoxifen shortage "will help to change minds, because it is definitely creating awareness."

"That's one example. Another example is that in France, production of paracetamol will start, and that was only after awareness was created that there was not production of paracetamol in Europe."

> *"It's a matter of price, of not putting all the pressure on price."*

Citing a growing awareness of these issues at a European level, Medicines for Europe has noted that a forthcoming study by the European Commission could be used to justify future legislative changes as part of the reform of medicines procurement of medicines across Europe. Expected to be published by the end of the year, the study is seen by the association as a "big step" that could help to push important reforms.

Moreover, Stampa noted, "the structural dialog is already a positive sign." (Also see "*EU 'Structured Dialog' Offers Opportunity To Secure Supply*" - Generics Bulletin, 3 Mar, 2021.) "It's the first time that there is a dialog, in that sense, with the industry, where the industry can put forward the problems and propose solutions. I think the [European Commission] study has come after the structural dialog started, probably to confirm what the industry was saying." But while this dialog was working well so far, Stampa acknowledged, "we have no direct conclusions yet."

However, Medicines for Europe believes that already available conclusions from industry stakeholders show a strong consensus, particularly around the reform of procurement for generics.

"In some countries like Denmark, environmental rules and compliance is already starting to be taken into account," Stampa noted. "We also think that quality compliance should be take into account for tenders, and the flexibility to supply."

Medicines For Europe Calls For Security Of Supply Legislation

By Chloe Kent

01 Dec 2021
Medicines for Europe has urged the European Commission to enshrine security of supply considerations for essential medicines into

Asked whether the potential of steep penalties for failure to supply was a concern, she agreed "it is, and that is a reason why having only one winner to a tender is extremely dangerous, because if that company fails the penalties can be huge – but at the same time, no-one else may be prepared to supply, because they lost the tender, so they don't have the API or vials or capsules that they need to supply."

legislature. Without these, additional cost containment measures for off-patent medicines under consideration by member states may ultimately threaten access by making production unsustainable for manufacturers.

Read the full article here

Medicines for Europe has also warned of the potential for confusion at the EU level between these procurement penalties and separate fines for failure to report shortages to medicines agencies. These were "two very different things and in fact very few companies fail to report manufacturing issues, this is very rare; but there is confusion at European level over these two issues and mixing them is not a good idea."

Regulation Not Keeping Pace

Digitalization is also a key objective for the European off-patent industry, with Stampa acknowledging that regulators are not making enough progress in this area, "and not at the pace we would like."

"We think having a digital platform would help with all the regulatory agencies," she outlined, aiding interoperability and reducing the administrative burden "both for the regulatory agencies but also for the companies. I think it would make the system flexible and agile."

It was also important for European regulators to maintain the region's leading position in biosimilars, Stampa suggested.

"I was looking at the data and [as of] August 2020 there were 72 biosimilars approved in Europe versus 28 in the US. I think it's one of the areas where Europe is pioneering and we should try to keep that."

EU Industry Renews Call For Digital Regulatory Infrastructure

By David Wallace

19 Feb 2021

Medicines for Europe has renewed its call for a modern digital regulatory infrastructure in the wake of the COVID-19 pandemic to bolster communication and preparedness for future health crises, insisting that there is "no further excuse to delay."

Read the full article here

“That can be kept by also improving the uptake in different countries,” she suggested, pointing to a wide variety of market environments for biosimilars across Europe, with some offering much potential for improved uptake.

Asked about the expected launch of the first biosimilar with ophthalmic indications in Europe in mid-2022 – and the need for educational efforts in this area to lay a path for ophthalmic biosimilars (Also see "*How Samsung Bioepis Is Laying A Path For Ophthalmic Biosimilars*" - Generics Bulletin, 10 Dec, 2021.) – Stampa was clear that “companies still need to do those educational efforts, but at the same time countries have to incentivize the use of biosimilars.”

Touching also on value-added medicines, Stampa said this was an area where “we would like to see more emphasis.”

“We are encouraged by the establishment of working groups within the Italian and Spanish associations,” she said. “Together with some evidence like dexamethasone we believe it is going to move forward.” (Also see "*Dexamethasone Shows Potential Of Repurposed Generics Against COVID-19*" - Generics Bulletin, 18 Jun, 2020.)

Key goals were “to have a regulatory pathway and to enhance the repurposing of molecules which could be used for other indications,” with the US 505(b)(2) pathway offering a good model for Europe to emulate, despite the differing legal context.

A Number Of Upcoming Milestones In 2022

Forecasting a busy year ahead, Stampa said “we think the current pharmaceutical strategy, industrial strategy and IP action plan will definitely be milestones.”

“We are looking forward to the outcome of the structural dialog and the study that is being done, so that is another key milestone.”

Meanwhile, “in IP the most immediate would be the implementation of the SPC waiver from the start of July,” with it being important “to monitor that in every country [to ensure] that it works as designed.” (Also see "*Industry Prepares For Advent Of SPC Manufacturing Waiver*" - Generics Bulletin, 28 Jun, 2019.)

In general, Stampa said, “we are looking

EU Pharma Strategy Will Remove Barriers And Bolster Competition

By David Wallace

25 Nov 2020

The European Commission’s newly-published Pharmaceutical Strategy features a range of proposals related to generics and biosimilars, including “targeted policies” to improve competition, remove barriers and increase uptake.

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forward to engaging with other stakeholders – patient, hospital, warehousing associations, but also with our fellow industry groups – where we think we have to work in common, because we have common aspects in different projects," she highlighted.

And Medicines for Europe was "also looking forward to the start of the CEO committee within the IGBA, which for the first time has the CEOs of relevant companies from different geographies all together." (Also see "*IGBA Puts Together Global Leadership Alliance*" - Generics Bulletin, 7 Feb, 2022.)

"We are looking forward to by the end of June organizing our annual conference covering all of these issues," Stampa added, with Medicines for Europe planning its annual meeting in Barcelona, Spain, at the end of June, following on from its first post-pandemic in-person meeting in Athens, Greece last October. (Also see "*Off-Patent Industry Must Become 'Focal Point' For Health Systems Post-COVID*" - Generics Bulletin, 13 Oct, 2021.)

Finally, Stampa also acknowledged the ongoing efforts being made by the European off-patent industry in Ukraine against the backdrop of the ongoing conflict with Russia. (Also see "*Generics Industry Takes Action To Maintain Access In Ukraine*" - Generics Bulletin, 1 Mar, 2022.)

Emphasizing that the off-patent sector was doing its utmost to help people in Ukraine by identifying the need for and supplying essential medicines, Stampa confirmed that "companies are co-ordinating among them to make those donations possible. Competitors are trying all together to move that forward."