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Medicines For Europe Highlights Sector Challenges As It Celebrates Milestone Anniversary

European And Irish Associations Provide Perspectives At 30th Annual Conference In Dublin

by David Wallace

At Medicines for Europe's 30th annual conference in Dublin last week, the European association and its Irish counterpart provided an overview of the challenges and opportunities facing the European off-patent industry.

Four days of meetings in Dublin last week saw Medicines for Europe set out the key challenges facing the European off-patent industry, as well as offering its views on some of the possible solutions and opportunities on the horizon.

At the association's landmark 30th annual conference – preceded earlier in the week by its 18th legal affairs conference – Medicines for Europe highlighted the significance of the current review of European pharmaceutical legislation for the industry, calling for "EU-wide solutions to tackle medicines shortages, clearer laws to allow patients to access generic and biosimilar medicines after patent expiry, and strong incentives for affordable value added medicines innovation and repurposing."

Meanwhile, on supply-chain security, the industry group called for a future EU Critical Medicines Act that would "encourage more investment in essential medicines and active pharmaceutical ingredient manufacturing and implement security of supply criteria into procurement and other market policies."

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> *"30 years has brought a whole host of achievements, but we cannot stand still. We're really here to discuss the future of our industry."*

Acknowledging the huge progress made over the past three decades by Medicines for Europe, Medicines for Europe president Elisabeth Stampa nevertheless said "our 30th anniversary is not just a celebration of our past achievements but a testament to our unwavering commitment to the future of healthcare in Europe."

"We are proud of the role we have played so far," Stampa said, "but our journey is far from over and we are dedicated to continuing our work towards delivering solutions."

Underlining the continuing need for action from the off-patent industry to address the challenges that lay ahead, Stampa told delegates that "30 years has brought a whole host of achievements, but we cannot stand still. We're really here to discuss the future of our industry."

"We are doing business in a framework that sometimes overlooks the value we bring, that has not adapted regulatory and market policies to managing medicines shortages and supply chain challenges," Stampa pointed out, as well as lamenting "a system that does not yet adequately support off patent medicines innovation, nor allows [us] to adjust the price of generic and biosimilar medicines to [reflect] cost of living increases."

And commenting on the importance of maintaining the secure supply of medicines, the association president said this issue "has never been more apparent or urgent," suggesting that "the challenges posed by global disruptions have emphasized the need to strengthen our supply chains and ultimately prevent and mitigate medicine shortages."

However, Stampa pointed to "progress we've made at the EU level on this topic," adding that "with the recent launch of the EU Critical Medicines Alliance (*see sidebar*), there's an important step toward a dedicated Critical Medicines Act, which would

Industry Body Calls For Action In Response To EU Initiatives

By Adam Zamecnik

05 Jun 2024

Medicines for Europe has responded to two EU initiatives linked to biosimilars and generic drugs in quick succession, calling for action in reaction to drug shortages.

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concretely back our industry, help reduce medicine shortages and support manufacturing in Europe."

"We need the next health commissioner and the next internal market commissioner to make this a reality," she urged.

Emphasizing that the association conference was "not just a forum for discussion," Stampa called for "action on reducing medicines shortages; action on working towards a more sustainable industry; action in helping those who need our support; action on better solutions for patients." And "we cannot expect only the authorities to move. We ourselves, our companies, and as a civil society need to push for the changes we believe that European patients deserve."

Day-One Launch Is A Key Priority

Speaking on the sidelines of the conference, Stampa elaborated further on some of the challenges facing the off-patent sector.

"We believe that one of the key topics here is to how to make it possible for generics and biosimilars to launch exactly on the day after patent expiry," she highlighted. "We have seen that the average delay is of five months after a patent expires," she noted, with such delays limiting patient access and preventing healthcare systems from benefiting from lower prices.

Meanwhile, greater digitalization was also a key goal, with Stampa urging the EU authorities to "move more towards the use of digital technologies, in two senses: one is how we can monitor and control demand, because this has an impact on shortages; but also how we can improve the delivery, for example, with the electronic patient leaflet."

"So our clear message here towards the next parliament and commission is to finish the [EU pharma] legislation so these changes can be implemented."

Local manufacturing was also a key concern for Medicines for Europe, Stampa outlined. "We have a very strong industry in Europe still, which continues to invest in both APIs in medicines and biologics. But at the same time, a lot of this production has moved outside Europe. And we think that the Critical Medicines Alliance – which we would like to move into a Critical Medicines Act, similar to what has been done with the microchips industry – could help to build a stronger and more reliant resilient manufacturing in Europe."

Procurement policies were also an important area of focus, Stampa explained, urging procurement mechanisms to "include some security of supply criteria and not only [...] the lowest price possible."

Meanwhile, Medicines for Europe was "also strongly advocating for prioritization of the

solidarity concept among the EU member states," calling out individual countries that were imposing stockpiling requirements on suppliers that could have negative consequences for other member states (*see sidebar*).

"We have two examples here, France and Germany, which have imposed stockpiling requirements on companies," she highlighted.

This not only "costs money to the companies, but at the same time, the demand of a country like Germany would equal the demand of 10 of the smaller European countries. So this would jeopardize the access to medicines or to those medicines for the patients of those smaller countries."

"So we are asking the next health commissioner to really prioritize solidarity towards the individual member states [over] stockpiling initiatives."

National Drug Stockpiles Create 'False Sense Of Security'

By Ian Schofield

22 Apr 2024

The generics and biosimilars industry body Medicines for Europe says disparate national stockpiling requirements are not a solution to shortages and can bring "significant risks" for the supply chain and access to medicines.

Read the full article here

Also speaking on the sidelines of the annual and legal conferences, Medicines for Europe director general Adrian van den Hoven pointed *Generics Bulletin* to certain legal obstacles that were taking their toll on the generics and biosimilars industry.

"We've worked on the SPC manufacturing waiver to put everybody, wherever you're manufacturing, on a level playing field," he recalled. (Also see "*Industry Prepares For Advent Of SPC Manufacturing Waiver*" - Generics Bulletin, 28 Jun, 2019.) But amid various lawsuits and misinterpretations of the waiver – outlined in detail at the legal conference – "sometimes it's working, sometimes it's not, unfortunately."

"The other thing we're seeing is a proliferation of secondary patents," van den Hoven highlighted, "a lot of patents around different uses, indications, production processes and things like this."

While "in many of the cases, these secondary patents are not innovative, so are found to be invalid, or they are irrelevant" – such as patents for production processes that are different to those used by off-patent manufacturers – van den Hoven said Medicines for Europe was still seeing "the originator industry using this huge number of secondary patents to tie the generic or biosimilar industry in knots."

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Ireland Is 'A Microcosm Of European Challenges'

As well as highlighting issues of European importance, the conference in Dublin also threw a spotlight on issues specifically affecting the Irish market.

While it was "very encouraging to see increasing penetration of generic medicines in Ireland in recent years," acknowledged Paul Neill, chair of Medicines for Ireland, "several influencing factors are causing Ireland to still lag behind our European counterparts, and these must be addressed."

Calling for "a market ecosystem that promotes fair competition and the availability of essential medicines into the future," he said that amid the "formidable challenges in Ireland's healthcare system, the role of a resilient and sustainable medicines industry cannot be overstated."

"I truly believe that Ireland's situation is a good example of the challenges we all face in making sure medicines are readily available and accessible across Europe," Neill summarized. "By encouraging the use of generic, biosimilar, and value-added medicines, we can alleviate the strain on our healthcare system and ensure that every patient has access to the medicines they need when they need them."

Irish Body Calls For Urgent Action To Tackle Drug Shortages

By Adam Zamecnik

30 May 2024
Medicines for Ireland has called for action that would alleviate drug shortages affecting every fifth patient in the country after recently urging strategic reform in the EU.

Read the full article here

Neill told delegates to the conference that Ireland was "a microcosm of the challenges we all face in providing sustainable supply and driving access for medicine across Europe."

"We stand on a crossroads where innovation, and policy shifts, and patient-centric approaches intersect. The delicate balance between patent protection and timely market entry shapes our industry. The EU commission proposal on pharmaceutical legislation underscores the need for robust patent policies that encourage innovation while at the same time ensuring affordable access for life-saving treatment."

And "Ireland's experience echoes those of other European states where generic, biosimilar and value added medicine manufacturers grapple with patent cliffs and the delicate dance of exclusivity periods," and with the COVID-19 pandemic having "brutally exposed the vulnerabilities in our medicine supply chain."

"Here in Ireland, we're proud to be a leading manufacturing hub for Europe, the US and beyond,"

Neill underlined, but “we need to do all that we can to safeguard the supply of medicines to and from Europe by helping to ensure supply chains remain secure and reliable.”

“We can’t do this alone,” he said. “It requires constructive and deep relationships and dialogue with government and policymakers. The off-patent industry needs, and in fact must have, a true seat at the table. If not, we are destined to repeat the mistakes of the past.”

“We cannot be called upon to try and help solve problems after the fact. We must have the opportunity to shape the future, not just to react as it unfolds.”

Look out for further coverage from the annual and legal conferences, discussing many of these issues in greater detail, over the coming days in Generics Bulletin.