# Christoph Stoller â?? President & Adrian van den Hoven â?? Director General, Medicines for Europe

I am calling on the European Commission and its newly elected President Ursula von der Leyen to take action on sustainable access to medicines for patients

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08.10.2019

Tags:

Europe, Medicines for Europe, Generics, Shortages,

*Christoph Stoller, the recently appointed president of Medicines for Europe, outlines the mission of his presidency, how the association and its members are working to tackle the issue of drug shortages across the continent, and the crucial importance of establishing a high-level dialogue between industry and governments. Adrian van den Hoven, the organizationâ??s director general, adds his take on the major challenges facing the generics industry today.*

**What is the mission of your presidency?**

Christoph Stoller (CS): For high-quality medicines to be in the hands of patients when they need them. Over the coming two years, I will focus on sustainable access to generics, biosimilars and value-added medicines and the prevention of medicine shortages. I plan to do this by optimising the regulatory framework, fostering a sustainable and responsive industry, securing European leadership in medicines and API manufacturing, and incentivising the digital transformation of our healthcare systems.

Taking shortages of essential medicines as an example, in the last couple of days, an elderly woman wrote me a letter. Her husband, who is an epilepsy patient, was unable to get his drug in the pharmacy and she reached out to me for support. This illustrates that the level of shortages is unacceptable and something we need to fix. We need to make sure that healthcare gets a seat at the top table.

We as an industry need to partner with governments to rapidly enact policy reforms. Therefore, I am calling on the European Commission and its newly elected President Ursula von der Leyen to take action on sustainable access to medicines for patients. I strongly believe that, after ten years, the time has come to launch an action-focused high-level pharmaceutical forum and strive for a clear consensus and strategic roadmap by addressing policy failures that hinder investments in medicine manufacturing and supply.

**What is the partnership model you would like to establish between the generics industry and European governments?**

CS: We need to ensure that we have a sustainable system that works for all and that the focus is on value rather than costs. That is exactly what we will discuss in the high-level political healthcare forum.

To draw on a specific example, in Germany an industry-government dialogue was initiated by the Ministry of Health, which included all stakeholders and very specific action items were defined and, later, executed. We are so essential for a functioning system that we need to ensure our industry is sustainable going forward.

**How hopeful are you of establishing this dialogue at a time when there is increasing scrutiny and concern from the general public around conflicts of interest?**

Our members account for roughly 70 percent of the medicines sold in Europe and that is expected to grow, given the ageing population and the way healthcare systems in the continent are developing. I believe that governments are increasingly cognizant of this fact and, as the current level of shortages is unacceptably high, I am very positive that we will succeed in establishing this high-level pharmaceutical forum.

**How serious is the issue of medicine shortages in Europe and what needs to be done to address it?**

CS: The level of shortages is unacceptable and we as an industry need to fix the holes in the supply chain. We are now taking action to make our supply chain more secure and less vulnerable by ensuring that, as much as possible, we do not rely on single suppliers and that we have backups. We are also putting much more focus on essential medicines.

However, we cannot solve this problem alone. That is why I am calling for the establishment of a high-level forum. We need to collaborate with all key stakeholders to fix this issue. It is no longer about mitigating the issue, but about fixing the root causes. There are many areas we can look at in terms of the regulatory framework and certain cost-containment measures.

**What are some of the major challenges facing your members today?**

Adrian van den Hoven (AvdH): In the last two years, our industry has made some of the biggest investments in manufacturing in its history. Obviously, beyond GMP, which we have been dealing with for many years, for many of our members have been investing in sterile manufacturing. This requires near-constant upgrading to maintain and adapt to GMP.

Additionally, the introduction of serialization with the Falsified Medicines Directive has been a challenge. This was not just a costly exercise â?? it cost the industry EUR one billion â?? but it was also extremely complex as it required alignment between contract manufacturers and manufacturers. Beyond the cost of equipment and machinery, you need IT engineers to support these systems and maintain them.

Brexit is another key issue, which has required our industry to review 20 percent of all of its licenses and make them compliant with a possible exit of the UK from the EU. Furthermore, we have had to rebuild laboratory capacity for batch testing.

These are all massive regulatory costs with a high level of complexity that have been introduced concurrently over the last two years in Europe.

Governments have toughened the hospital procurement market conditions by creating more single-winner tenders and more consolidated- or bulk-buying. France is a good example. It is extremely difficult for even very large-scale manufacturers to respond to this, as there is a need for huge production lines. This, in turn creates a lot of uncertainty for manufacturers at a time when, because of certain difficulties in other countries, our industry has had to re-invest in manufacturing capacity. Those investments have to have a return. It takes five years to build and have a factory approved by regulators, so a long-term perspective is needed.

**Do you see European governments as appreciative of the industryâ??s struggles?**

AvdH: It is not clear to us that governments currently share our long-term perspective. Therefore, we need this dialogue at the EU level â?? manufacturing is either for Europe or global. There are no more country-specific manufacturing plants. These are very big factors and there is a big mismatch between the regulatory costs and complexities of manufacturing, which are going up, and the pressure from procurers or payers to push generic prices down. This creates shortages and sometimes unavailability of drugs where companies simply cannot take the risk of participating in some markets.

In many cases in the hospital procurement market, the monetary fine for not being able to supply the medicines is a multiple of a companyâ??s total volume of sales, not just their profits. Therefore, if a

company wants to bid in a tender, they need to ensure that they are absolutely able to supply. In countries like France and Italy, in 15-20 percent of hospital tenders no-one bids, which is an indication of a major problem and a reason why we need to have a dialogue to rebuild an understanding.

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