Christoph Stoller – President & Adrian van den Hoven – Director General, Medicines for Europe (July 2020)

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In the wake of the publication of Medicines for Europe's Lessons Learned from COVID-19 policy paper

, Christoph Stoller & Adrian van den Hoven outline the European generics, biosimilar and value-added-medicines industry's rapid and comprehensive response to the COVID-19 crisis as well as the potential long-term shifts in European pharmaceutical policy that may come from this tumultuous period.

What was the initial response of Medicines for Europe as the European industry association for generics, biosimilars and value-added-medicines (VAMs), to the COVID-19 pandemic?

Christoph Stoller (CS): A lot has happened in 2020, from the beginnings of the crisis in Europe in January and February, to the evolution in March and April, to where we are now in July. The dialogue established between the European Commission (EC), Medicines for Europe and other associations has been vital for exchanging views and discussing key challenges and solutions. The dialogue has been very action-oriented, with challenges discussed and solutions implemented shortly thereafter.

As an industry, we have been able to demonstrate the resilience of our supply chains. All our manufacturing sites have remained open, even during the most challenging times in March. For example, much of Europe's API manufacturing is in Northern Italy, at that point the epicentre of the crisis in Europe.

Thanks to dialogue with European governments, there has been a recognition that pharmaceuticals is part of critical infrastructure and essential to the supply of medicines in Europe – we supply around 70 percent of Europe's medicine after all – and our employees were allowed to go into the manufacturing and distribution sites.

Dialogue with the EC also led to the creation of so-called green lanes, allowing for international distribution at a time of border closures. At the beginning of the crisis, for example, trucks were having to wait at borders for 48 hours.

Aside from the EC, cooperation, collaboration and communication with other important stakeholders such as national governments and the European Medicines Agency (EMA) was put in place in a very short timeframe. Looking forward, we need to maintain these channels for the future so that problems can be solved quickly, and the system can be made more efficient.

Adrian van den Hoven (AvdH): Something that we documented in our Lessons Learned from COVID-19 policy paper is the difficulties that countries faced in estimating demand in hospitals. Many patients were put on ventilators and needed anaesthetics and neuromuscular-blocking drugs, but there was no visibility on hospital stocks and hospitals were not able to calculate what they needed.

Medicines for Europe led an important project to make this calculation where governmental institutions were unable to do so. As an industry we were surprised that this data was unavailable, so we created it with only a 10 percent margin of error.

However, this took a lot of work and we are not epidemiologists, so in future, these institutions need to develop these capabilities internally. Some of our proposals to facilitate this include having more data on what is going on in hospitals as well as using more digital tools to collect information. More interconnectivity between hospitals and countries at a European level will also be important to making better demand predictions.

To ensure that a second wave of COVID-19 does not have the same devastating effect as the first, what is your view on the shape and financing of contingency plans for

manufacturing and supply chain management in Europe? And who should be paying for it?

CS: We as an industry had contingency plans ready and went immediately into crisis mode to ensure that supply was maintained. That worked very well thanks to the fact that we were well prepared and had active pharmaceutical ingredients (APIs) and other key materials in stock.

However, governments also need to be well prepared for pandemics. At the beginning of the crisis, there was a somewhat chaotic rush for personal protective equipment (PPE) and intensive care unit (ICU) drugs exacerbated by border closures. Thankfully, EC intervention has improved that.

Now the question is, looking forward, how are we going to ensure these shortages do not happen again and who should pay for it? There needs to be a sustainable system to ensure the reliable supply of medicines in Europe. One way to do this is to engage in a dialogue with national government to secure necessary stock in every area, including hospitals, of key drugs. During the crisis, nobody had visibility on where these goods were on either a country or European level; that is something that we need to improve. Countries should use this time after the peak of the crisis to set up these systems.

Secondly, the European Centre for Disease Prevention and Control (ECDC) and EMA need to obtain better epidemiological data to ascertain the need for essential drugs in different areas.

Finally, we need to change the way that our systems work. Certain European countries cannot continue to maintain an unsustainable preference for the lowest-cost generic option. For example, there needs to be a move away from tenders run on price alone to begin to include other criteria such as supply security. This needs financial commitments from the member states to ensure equitable and sustainable access at all times.

We are not asking for anything new, but the COVID crisis has clearly shown that we cannot go on with the current way that our systems are organised. We need to reform our tender systems, implement sustainable pricing, and revamp the regulatory framework to be more cost-effective and digitalised.

This will also allow us to secure European manufacturing; our industry employs more than 190,000 people in this field. Despite the challenges on the demand side we have always been able to deliver our medicines to the patients who need them, however there is a long term trade-off between affordability and security of supply and we need to have this discussion now with the Commission, Member States, Regulators, and Payers.

How have you adapted to spikes in demand for some of your members' essential off-patent medicines?

CS: These spikes in demand were a real stress test on the flexibility of our members' supply chains at the peak of the crisis in March and the first half of April. As an example, in March, demand for a certain molecule suddenly shot up by a factor of eight. However, thanks to the systems and contingency plans in place combined with a lot of hard work, demand was finally met.

AvdH: For certain ICU medicines demand rose incredibly and, contrary to what has been reported in certain media outlets, the industry delivered. Compared to April and May 2019 we multiplied supply in some areas by 800 percent. Can you name another industry with the capabilities to do that? To give another example, some companies – although not our members – had shortages in paracetamol. One of our big paracetamol producers increased their production by 300 percent to make up for these shortages. We want to emphasise the importance of looking at what happened across the crisis and not putting the blame on companies that multiplied production by 300 percent to save Europe from shortages as some authorities are currently doing.

There were 600 so-called reported shortages to the EMA – but not one led to a patient not getting medicine. These shortages are, therefore, merely small stock outages. We want to see facts and data rather than conjecture because the European generic industry delivered more than any other health industry; something that should be recognised.

In such a crisis, there is a temptation for countries to resort to nationalism, with a focus on sovereignty of supply. Do you think that, collectively, institutions have learned their lessons and are willing to listen to your message?

CS: After the initial reaction of panic, we brought this dialogue to the attention of the EC and to the national authorities in various member states. Medicines for Europe has been extremely active in mentioning challenges and proposing solutions. That has led to member states realising that our supply chains are interconnected, that border closures do not work, and that we cannot work in silos.

AvdH: One of the things we were confronted with, especially in Eastern Europe, was restrictions on parallel exports in the hope of avoiding medicines being parallel exported out of their country. This is understandable, but there was lack of clarity in the definition of these restrictions, leading to

some of our factories in the region becoming locked. We think the member states should clarify this – parallel trading is of course legal but there needs to be a discussion as to whether it is working optimally and it is creating a lot of confusion for companies like our member who are not engaged parallel trading.

The second thing we were confronted with is certain governments attempting to hoard APIs by purchasing their own APIs and compounding them in hospitals. This took APIs out of the market for normal manufacturers, meaning we had less available. Moreover, compounded APIs have a very short shelf life so most of this product will now have to be incinerated because it is not going to last long enough for a potential second wave.

We have advised the EU to have a very serious discussion about this kind of government intervention and the true meaning of European solidarity. Our industry was totally transparent that we would supply across borders with a fair allocation to all countries. We gave data and let each member state comment on it.

A potential COVID-19 vaccine dominates the headlines at the expense of off-patent medicines that could be used to treat the condition. What is your take on this?

CS: We all hope that it is possible to develop a vaccine that works, but in the very best-case scenario we may have something at the end of 2020. Drugs such as ribavirin, dexamethasone, and remdesivir are all potential treatments, which in the short-term are much more important.

Value Added Medicines (VAMs), known molecules which can be repurposed/reformulated, are one of Medicines for Europe’s three pillars, along with generics and biosimilars. To develop a totally new chemical entity and bring it to patients is an incredibly lengthy process, meaning that VAMs are key in the fight against COVID-19.

Digitalisation and its integration into European healthcare systems is also a critical point in VAMs. This encompasses telemedicine in terms of patients not being able to see their physicians or go to the pharmacy as well as drug-device combinations and patient self-monitoring.

We should not forget VAMs but instead continue to conduct research and development on known molecules; a process that should be incentivised. That is a challenge right now in Europe as there is no economic incentive for this kind of R&D effort.

What would these incentives that would enable VAMs to flourish look like?

CS: We need new pricing models across EU member states that reward innovation not only new molecules but also the repurposing of known molecules, enabling VAMS to be reimbursed at a price premium. There are some good examples in Europe where this is already possible, but there is nothing the EC can do as pricing is set at a national level. We are active in all the different member states, but we need to leverage this across Europe to ensure we have these new pricing models in place.

What influence will the COVID-19 experience have on sustainable change to European pharmaceutical policy?

CS: From our point of view, the key points are that we have demonstrated the resilience of our supply chain and that communication between stakeholders and solidarity are vital in such a crisis.

Now is the time to create sustainable systems by reforming tendering processes, creating new pricing models, and integrating digitalisation. We also need to maintain the manufacturing that we have in Europe, making sure all stakeholders understand that Medicines for Europe's members are a key part of the critical infrastructure, and ensure that the EU has a secure and resilient system for essential medicines in the medium- to long-term.

AvdH: Changes to pharmaceutical policy can be either beneficial or harmful, depending on how they are implemented. We share a lot of big-picture views with the EC but in the past, we have struggled in terms of practical planning, implementation, and follow up. During the COVID crisis, the close cooperation and dialogue we have had with the EC has been rather successful, solving a lot of problems and avoiding patient shortages.

We think going forward that all these changes, proposals and new policies should be discussed in a similar manner because implementation, setting clear plans, and achieving goals is an EU weak point. By working more closely with our industry, the EU can achieve the objectives of access equity, shortage avoidance, and more manufacturing jobs in Europe.

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