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Subject: Time for a new medicine security contract for Europe

The purpose of Medicines for Europe members is to improve access to medicines and provide a better availability and supply security for European patients. However, the current situation is challenging our ability to fulfil this objective.

Last year, we have repeatedly warned the EU that the current high inflation and geopolitically disrupted environment could increase the risk of essential medicines shortages in Europe. All input costs for medicine manufacturing such as energy, raw materials, packaging, transport, and logistics have increased dramatically in

2022 and 2023.[1] Yet, generic medicines continue to be subject to strict price caps in market policies which make it impossible to adjust for this cost inflation. This is exacerbating the already dramatic consolidation of suppliers of most essential medicines including the medicines currently in short supply for infections. IQVIA data shows that the markets of two of the most common antibiotics, namely amoxicillin and amoxiclav, are heavily consolidated in most EU countries due to low pricing and procurement policies. This is a repetition of the market consolidation we are seeing in other therapy areas, like oncology and many other therapies across the generic sector.

While the current medicines in shortage were triggered by an earlier than expected infectious surge across Europe, there are deeper structural causes that must be addressed. Given the huge stress on global supply chains and the extreme consolidation of generic medicine production, there are significant risks of more medicine shortages in 2023. We propose an agreement with the EU and Member States with solutions, based on concrete policy reforms and industry commitments to reduce these risks.

1. Market consolidation: the structural cause of shortages and supply chain risk

The structural root cause of shortages is the economic model for generic medicines in Europe. Generic medicines play a fundamental role in healthcare by bringing price competition and thereby enabling much greater access to medicines and by pushing the originator industry to innovate in new molecules. Since the 2009 financial crisis, governments have based the generic medicines market model exclusively on cost-containment. Member States have used pricing and reimbursement or procurement policies to lower generic medicines prices as much as possible. For example, in Germany average generic prices were reduce by two thirds over that period and most medicines cost only a few cents a day.[2] Through price referencing, all other EU countries followed the cost-containment model, applying lowest-price referencing, mandatory price reductions, clawback taxes, procurement price ceilings and many other tools designed to reduce prices to the lowest level.

To adapt, the generic medicines industry has consolidated manufacturing supply chains, optimized capacity, and looked for lower cost inputs, often outside of Europe. Factories in the supply chain are run at maximum utilisation rates to remain profitable as GMP rules require continuous investment in manufacturing plant upgrades. Consequently, ***there is no spare capacity in manufacturing supply chains*** to deal with demand surges caused by illness or when one manufacturer in the supply chain has a manufacturing problem. This is why the industry is challenged to quickly ramp up production in a shortage. These issues are exacerbated for small volume medicines with long supply chains as was acknowledge in the Commission's research to support the production of critical APIs, key intermediates and medicines to reduce the vulnerability of supply chains causing shortages.

Over this same period, the Commission introduced more stringent regulations on the pharmaceutical industry, often for good regulatory reasons such as fighting against falsified medicines. When adopting and implementing these regulations, the Commission does account for the additional costs of implementation and the impact on the margins of low-price essential medicines. These regulations, which may be necessary, further consolidate supply chains and generic markets and, in some cases, can be a source of medicine stock outs (temporary shortages that disrupt the market).

[1] For a detailed analysis of inflation impacts, see: https://www.nomisma.it/la-stagione-dellincertezza-dati-e-riflessioni-sul-sistema-dei-farmaci-generici-in-italia/

[2] Average generic daily dose prices declined from €0.17 to €0.06.

Over the past few years, other external factors outside of our control have put more stress on supply chains. Brexit required the severing of a major market from the EU and special rules to supply Northern Ireland. Covid-19 required our industry to introduce costly new hygiene measures while massively ramping up production to respond to the emergency. The Russian invasion of Ukraine exacerbated cost inflation which our industry cannot pass on due to capped pricing in the EU market.[3] China's zero Covid policy has disrupted all industrial supply chains, including the generic medicines industry. Our industry has absorbed the costs of these major events because EU medicines prices are capped for the generic industry. This has resulted in further consolidation.

The structural root cause of shortages is increasingly evident in studies such as the Technopolis Study on medicines shortages or the study on medicines procurement. Both identify the absence of supply security in market policies as a major risk for the EU. We therefore propose solutions for medicines security in Europe.

2. Short term measures to mitigate the risk of shortages in 2023

Our industry cannot undo the consolidation caused by more than ten years of continuous cost-containment measures overnight. However, we can take action together, as we did successfully in 2020 to address demand surges, to reduce the risk of shortages this year. We propose the following short-term measures:

a. **Introduce regulatory flexibility** for packaging (especially for patient information leaflet) to allow manufacturers to rapidly reallocate medicines across internal EU borders. There should also be a process to facilitate rapid variations to mitigate a shortage, as was done during Covid-19 to enable manufacturers to rapidly make a change in case of a production problem in the supply chain. The Commission can also provide implementation flexibility for any new regulations that may cause a stock out such as the revised GMP annex 1, clearer thresholds for nitrosamines and avoiding new regulations that have disproportionate impact on low margin medicines. Member States can take additional measures related to shelf life and local flexibilities.

b. Engage in a **dialogue with the generic industry and with Member States on immediate measures to tackle the cost of inflation** on generic medicines. Member States are pursuing totally contradictory policies on this issue. While countries like Germany and Portugal are revising their laws to adapt prices to inflation, countries like France and the UK are reducing prices (in a shortage!) though hidden price reductions in the form of clawback taxes. The Commission can help solve this by encouraging best practices and implementing the MEAT security of supply criteria in the Public Procurement directive.

c. **Improve demand predictability by sharing more aggregate data and analysis with the generic industry** about demand surge risks. For example, there could be a dialogue between the EMA/HMA shortage working group and our industry to warn of shortage risks earlier to adapt supply chains. There could also be more sharing of information about epidemiological risks in the EU such as expected timing of the infectious/flu season and other infectious risks since many of them are increasing globally or important changes to prescribing guidelines that increase volume demand. The Commission should also consider how to better use data – such as EMVS – to understand demand and supply dynamics for shortage prevention.

[3] Despite this pressure, our industry has been a leading donator of 1200 trucks of medicines – including ICU and antibiotics – to support Ukraine.

3. Medium term measures to encourage more generic medicines supply and supply chain resilience by 2025

The EU can help coordinate a strategy to improve supply chain resilience with clear policies to encourage more manufacturers to invest in diversified supply chains and to improve the efficiency of supply across EU Member States in the context of EU legislation and policies.

a. **Fast track the regulatory efficiency and harmonisation measures in the EU Pharmaceutical Strategy**, especially the replacement of paper patient leaflets with electronic patient information (ePI) as this would dramatically reduce complexity, stock outs and misallocation across countries. There are also critical measures related to the reduction of variations, the management of API sources and the harmonisation of packs and requirements at national level that will dramatically improve supply chain efficiency. The backbone of these reforms will rely on a genuine EU commitment to digitalise the medicines regulatory network and to make better use of big data. This will be essential to understand heavily consolidated supply chains through IDMP-SPOR, to introduce ePI in a standardised format across the EU and to collect better surge data from the EMVS for the shortage prevention platform called ESMP. All these digital projects are behind schedule, lack scale and interoperability and do not promote the automated collection and aggregation of industry data. Without this, there can be no use of big data to analyse shortage or supply chain risks and to prevent them. There should be a single high level person in the Commission nominated to put these projects back on track.

b. Strengthen **security of supply criteria in generic medicines markets**. The Commission can introduce a legal guidance on the implementation of this criteria which exists in the Public Procurement Directive, but which is not used for generic medicine tendering.[4] The Commission could also discuss with the Transparency Committee how certain aspects of the Transparency Directive could be re-interpreted from the security of supply perspective. For example, Canada applies a ladder reference pricing system that increases prices when there are few suppliers and reduces prices when there are many suppliers. This is a good way to adapt a regulated pricing market for security of supply and would be well suited for many EU Member States. Germany is reforming its Generic Law to empower the medicines agency to adjust pricing policies when supply chains are too consolidated. Other Member States should also empower their agencies to act against consolidation.

c. **The EU should invest in manufacturing diversification and greener technologies with a Medicines Security Act**. Our industry has re-invested in EU production of essential medicines and API in Austria, Greece, Italy, France, Germany, Portugal, Hungary, Romania, Spain, and Poland. Despite including our sector among the seven highly foreign dependent sectors in Europe along with raw materials, microchips, etc, *there has been almost no EU investment in our sector*. Our industry's attempts to participate in the RRF and other EU funds have been systematically rejected by the Commission's erroneous interpretation of state aid. We have underlined that for our industry to re-invest in the production of well-established API and medicines, we introduce innovative automation, more environmentally friendly processes and materials, manufacturing and chemistry processes which are necessary for production in the EU. This innovation, for example automation, contributes directly to supply chain resilience as it enables a more rapid production scale up. To achieve EU strategic autonomy, there should be a coherent EU strategy to

[4] According to a Commission study, only 24% of medicine tenders use this criterion – for the purchase of vaccines not generic medicines. https://op.europa.eu/en/publication-detail/-/publication/ca856a7f-7c37-11ed-9887-01aa75ed71a1/language-en/format-PDF/source-278040684

support the development of industrial infrastructure – critical to increase production capacities for both APIs and medicines in Europe.

We would caution the EU not to adopt knee-jerk and counter-productive policies that would exacerbate medicine shortages. **National stockpiling requirements** undermine EU solidarity, increase consolidation and costs, reduce medicines availability in other markets, and prevent industry for taking mitigation measures. In practice, stockpiling forces manufacturers and wholesalers to hold large volumes of stock in each member state to avoid fines. This prevents industry from moving medicines across internal EU borders to solve a shortage because they will be fined for doing so. Wholesalers will also hoard stocks to avoid similar fines so medicines will sit in warehouses while patients wait. The Commission's own shortage study[5] shows that 9 out of 10 shortages occur in only one member state so packaging harmonisation and the replacement of paper by digital information are the key to improving medicines availability and solving acute shortages. Our industry is open to working with **HERA on a European strategic reserve concept**. This could be based on rolling reserves as was the policy in the UK in the past (when they had a good policy to mitigate shortages) and which is the current policy in Australia. This model offers a high degree of security for patients, is flexible for manufacturers, and low cost for governments (or the EU).

As already experienced with the **failed joint procurement** for ICU medicines in 2020, we seriously question the use of joint procurement to address the demand for nationally licenced medicine like amoxicillin (which is mainly dispensed in community pharmacy), paracetamol and ibuprofen (which are mostly over the counter drugs). As there is no data on demand, there is no possibility to estimate the likely short term demand surges for these medicines at national level that would be required for a joint procurement. Moreover, the EU procurement process is too slow and cumbersome for generic medicines which have different national licences, dosing, and pack sizes. The joint procurement also presents a risk in further market consolidation and supply due to confusion over national stock levels as these medicines would need to be redistributed by Member States to 1000 wholesalers and well over 100 000 pharmacies across Europe. EU-wide procurement would decrease demand predictability at national level, destabilise existing local contracts and supply channels and further exacerbate the global surge in demand. Finally, joint procurement, unlike advanced purchase agreements, require bidders to build up stocks as a precondition to bid. This would mean that manufacturers would have to hold stocks and the associated costs of, for example, amoxicillin which means it could not be dispensed to a patient, to apply for the joint procurement. This would therefore further increase shortages almost everywhere across Europe.

Europe is facing major shortage risks this year. We want to work with you to make short- and medium-term changes to prevent medicine shortages in the future. We look forward to working with you on a new contract for medicines security in Europe.

[5] https://op.europa.eu/en/publication-detail/-/publication/1f8185d5-5325-11ec-91ac-01aa75ed71a1/language-en

Yours sincerely,

Signed

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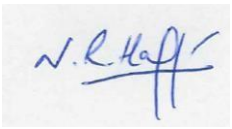

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