LESSONS LEARNED FROM COVID-19

POLICY PAPER

MAY 2022

medicines for europe

better access. better health.

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Introduction

After years of crisis, we can discern some of the key lessons learned from COVID-19 for the future of pharmaceutical policy in Europe. The COVID-19 outbreak in Europe has catalysed some long-standing issues in the functioning of pharmaceutical and medicines manufacturing policies, as well as the impact these can have on patient access and hospital and pharmacy supply.

Throughout the crisis, the off-patent medicines industry mobilised, in collaboration with the European Institutions, to ensure medicines continued to be developed, transported, and supplied. Our industry notably massively scaled up production and put in place cooperation mechanisms to tackle the colossal surge in demand for medicine.

Lessons learned

Industry manufacturing contingency plans enabled a dramatic increase in supply during COVID-19.

Government pandemic (and crisis in general) planning should exempt medicine manufacturing and logistics from lockdowns and other control measures.

Avoiding shortages during a crisis requires cooperation with industry and demands visibility and close cooperation between governments/regulators and industry for regulatory flexibility.

EU and national coordination to ensure equitable supply of medicines is important for industry. Hoarding and other restrictions undermine our ability to supply patients in need.

Disruptions to global supply chains did not cause any critical shortages during COVID-19 because Europe has a robust medicines and API manufacturing sector. The off-patent sector should be strengthened to increase Europe's manufacturing competitiveness and resilience.

Repurposing of medicines was essential in securing treatment options in a crisis. A fit for purpose regulatory and market framework is needed to encourage future repurposing developments.

This document outlines the Medicines for Europe vision for a robust generic, biosimilar and value added medicines industry in Europe, that delivers on equitable access in normal and crisis circumstances through more resilient and sustainable healthcare systems and enables EU industry to remain a strong global player.

Improving pandemic preparedness

The EU was too slow at the start of the pandemic, in the period from January to March 2020. Although health systems adapted to the influx of COVID-19 patients, both the European Union (EU) and Member States were slow to prepare for the outbreak including enacting effective control measures such as testing and contact tracing. This happened despite the WHO warning early on that there was a risk of COVID-19 spreading beyond Asia. Member States also adopted different and poorly coordinated measures which increased the difficulties to track and monitor the outbreak. Panic also set in regarding ICU medicine supplies which led many countries to hoard medicines at the expense of European solidarity and the efficient delivery of medicines to patients in need.

This shows the need for an EU pandemic preparedness plan, which should integrate lessons learned from COVID-19. An EU pandemic preparedness plan should address country coordination of confinement measures, including border closures and travel restrictions. The fragmentation in these measures in the early stages of COVID-19 – and to a lesser extent over the following months - led to major internal market disruptions, which challenged the manufacturing, packaging, testing and distribution of urgently needed medicines.

The recognition of pharmaceutical manufacturing as essential production was critical for our industry response to the surge in demand for medicines brought on by COVID-19. Medicines for Europe members successfully implemented contingency production plans that reduced supply chain risks and enabled them to scale up production output during the outbreak. In some cases, border closures and heavy-handed state interventions undermined supply capabilities and limited industry efforts. Commission efforts and outreach to tackle these challenges were important to move medicines to where they were needed. A more rapid and coordinated approach to medicine demand and supply planning at Member State and European level would also reduce panic in hospitals and Member States that led to a lot of hoarding within and across countries to the detriment of equitable access to medicine.

Recommendations:

- Maintain the integrity of the internal market so that critical manufacturing and logistics for medicine supply can continue during a health crisis. The Regulation on Single Market Emergency Instrument (SMEI) should incorporate COVID-19 lessons learned and avoid future disfunctions of the Single Market that can create bottlenecks to the supply chain.
- Develop an EU epidemic/pandemic /crisis preparedness plan to be implemented, where appropriate, for future communicable disease risks or other crises (such as a war), led by the European Commission, with input from industry, with the technical support of the European Medicines Agency (EMA), HERA, European Centre for Disease Control (ECDC), and in coordination with Member States. Industry input would cover supply chain risks and how to plan for sudden demand surges, including logistical challenges requiring support.
- Share best practices between EU countries on how to lower risks and to best treat patients during a pandemic/crisis.
- Foresee measures to ensure continuity of care/treatment for all patients during a pandemic, as well as continuing screening and diagnostic procedures. This is important to avoid disease worsening for chronically ill patients.

Coordination between the EU institutions and industry

Coordination between European institutions and Agencies, including particularly the European Commission, the HERA, the EMA, Member States, and the ECDC, is vital during a pandemic. Each

institution/agency has a critical role to play in the coordination of a public health crisis, and open and transparent discourse with all stakeholders is essential. Sustained partnership between the institutions and industry is needed beyond the pandemic to ensure focused policies for off-patent medicines that deliver for public health, in times of and beyond a pandemic.

The European Commission

The European Commission adopted a series of essential measures including:

- Considering pharmaceutical manufacturing critical under lockdowns, for cross-border workers and for logistics.
- Addressing internal and external restrictions to medicines allocation.
- Establishing green lanes for transport and calling for priority treatment for air cargo for medicines.
- Enabling industry cooperation under special competition and health law rules to avoid shortages of essential medicines.
- Engaging in continuous dialogue with Member States to coordinate, where necessary, policies for equitable access to medicine and solidarity.

European Health Emergency Preparedness and Response Authority (HERA)

HERA is a central agency to enable the European Union to plan and respond more effectively to major health crises while strengthening the European Health Union with better EU preparedness and response to serious cross-border health threats. HERA is expected to enable rapid availability, access and distribution of needed countermeasures. HERA is equipped with an advisory forum of technical experts from Member States. Within this framework, a 'Joint Industrial Cooperation Forum' of the representatives of the industry and Member States will also be set up. A priority of HERA should be to agree on risk scenarios with the industry

The European Medicines Agency

The coordination role of the EMA is important to address demand surges or supply chain risks. This coordination was crucial for the early adoption of essential measures such as regulatory flexibility and industry dialogue to manage potential supply risks.

However, during the Covid outbreak, the EMA was not equipped to address demand surges which were the root cause of many acute shortage announcements for hospital ICU medicines across Europe. Consequently, Medicines for Europe set up a Hospital Medicines ICU project to assess the demand/supply balance specifically for Europe. The European Commission was supportive of this project and adopted written competition law guidance and a comfort letter for this project. The EMA SPOC and ISPOC consultations were good initiatives by the agency to collect more information on supply problems caused by demand surges. In future, the SPOC and ISPOC should be merged into a single, simplified and harmonised data system for shortage collection based on SPOR. This can be achieved by standardising the definition of a shortage based on criticality and requiring all agencies to collect the information via a digital tool with common data sets. This could then be consolidated at European level to assess where problems lie.

The Commission, together with the European Parliament and Council, has extended the EMA's mandate by including a harmonised and interoperable medicine shortages monitoring system by the establishment of the:

- EU monitoring platform for shortage reporting: based on harmonised data fields, existing IT systems, interoperability by design that according to the legislation must avoid duplication and be based on SPOR, financed by EU4Health and subject to the Commission's evaluation
- possibility to share aggregated data with stakeholders for shortage mitigation and the harmonised data fields for reporting across MS
- provision to consult the industry regarding the list of critical medicines

The European Centre for Disease Control

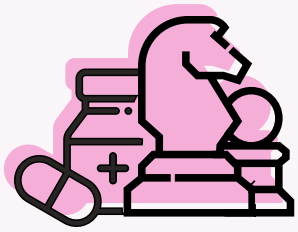
The ECDC plays a vital role in understanding the risks of pandemic outbreaks, and helps stakeholders react through the provision of robust epidemiological data on infection rates. With this data, the ECDC should be able to rapidly generate preliminary epidemic forecasts on

demand needs and communicate them to the industry. For industry to adapt its production capacity, it is necessary to provide forecasts of demand needs, which will inform the decision of how much additional production is required. While modelling is uncertain, upscaling or repurposing of manufacturing capacity needs to be data driven to ensure that it is proportionate to actual needs (avoiding unnecessary disruption to the manufacturing of other medicines that other patients need). Regrettably, ECDC data was only shared with industry on 27 May 2020 (at the end of the 1st wave of the outbreak in Europe) and only 15-day projections were shared. This is not sufficient for industrial planning.

Recommendations:

- High level dialogue between European institutions and industry is critical to manage demand surges and any other access and supply issues.
- Creation of a permanent Supply Committee at EU level (representatives of Member States and National extended EMA mandate (including industry)
- Competent Authorities and industry coordinated by DG SANTE (or technically by EMA) to respond to major supply disruptions.
- The European Commission should ensure a timely implementation of the European Shortages monitoring platform (ESMP) as indicated in the EMA regulation extended mandate.
- Open discussion and collaboration with EU institutions and Member States for epidemiological forecasting to enable industry to scale up manufacturing accordingly.
- EMA should collect information from medical societies and hospital pharmacists on pandemic treatment protocols so that industry can plan for future demand surges for these products.
- Under HERA, The European Commission must ensure that the joint procurement system should not create distortions into the internal market.

Recognise the public health role of off-patent medicines in future industrial and pharmaceutical strategies



The pandemic showcased the essential role that off-patent medicines play in a large public health crisis, as the majority of medicine needs were covered by our industry. For example, in Germany, 97% of the medicines needed for Covid19 had a generic medicine option available on the market. Our industry was also able to massively scale up supply to meet the large-scale demand surge for medicines used in Covid19. This Covid19 experience typifies the central role of our industry in public health.

Recommendations:

The implementation of the pharmaceutical or industrial policy strategies should take the following elements into consideration:

- The generic, biosimilar and value added medicines industry is vital for public health in terms of access and sustainability (between 70% and 90% of ICU medicines were off-patent medicines). The crisis notably underlined the value of maintaining a strong medicines manufacturing sector that was able to adapt to major global supply chain disruption and a massive demand surge to serve European patients.
- Forward looking policies should be adopted to stimulate investments in:
  - a resilient and diversified manufacturing chain including a strong medicine manufacturing sector in Europe. This will improve rapid production scale-up together with an efficient and flexible regulatory framework to respond to demand surges.
  - sustainable policies that encourage companies to have resilient supply chains with mature quality, safety, environmental and supply chain reliability.

> better planning and commitment from Member States on equitable access to medicines based on solidarity.

Recommendations:

- Resilience criteria in medicines procurement rather than price only, rewarding companies that invest in green and digital manufacturing, and state aid or EU funds to strengthen European manufacturing and better integrate API in the regulation of medicines.
- An EU Recovery Fund should provide investment in key value chains crucial for our future resilience, such as the medicines sector. In this context, the EU Green Deal and Digital Transformation can help to boost resilience.
- Measures to stimulate investments in R&D need to be targeted and focused, with clear objectives to be achieved and factoring in competition and equitable access policies.
- In addition, European health initiatives on communicable and non-communicable diseases should all encompass a dedicated set of policy interventions to ensure uptake of generic and biosimilar medicines as essential pillars of the treatment of a number of conditions, as well as policy interventions fostering innovation and repurposing of existing medicines and the emergence of value added medicines to fill healthcare gaps and tackle unmet needs.

Modernising regulatory systems

Regulatory flexibility

The COVID-19 pandemic posed unprecedented challenges to the continuity of medicines supplies. Therefore, targeted regulatory flexibility measures were needed to minimise shortages risks by, for example, permitting companies to swiftly source starting materials, reagents, intermediates or active substances from alternative suppliers, or add new manufacturing sites for scale-up, among other measures.
In a crisis situation and/or where there is a major shortage risk, the movement of medicines within and to the EU should be facilitated to ensure availability in the Member States where they are needed the most. In such circumstances, regulatory flexibilities are needed to accept the product information in another language or preferably in electronic/digital formats (especially for hospital products).

In general, simplified regulatory processes were required to ensure access to medicines. This practical experience should serve to simplify and harmonise processes for authorities and industry also in peace time. Clearly simplified processes to move a medicine from one EU country to another during a crisis, such as packaging or licensing issues, can be introduced in the future. For example, the crisis has once again highlighted the benefits of moving from a paper to a digital leaflet. From good experience with virtual inspections, electronic documents only shall be incorporated to “new normal” regulatory practices.

Recommendations:

- Pragmatic solutions to react faster on patient needs should apply not only in a crisis situation but also in case of any risk of major supply challenges:
- More frequent use of 0 Day Repeat Use Procedure (RUP)
- More flexibility on medicinal product labelling.
- Notification process via database instead of the traditional variation process for some registration file changes.
- More electronic reporting/ digital tools for regulatory activities. It is high time to progress on the digitalisation of the regulatory system which has been delayed for far too long in Europe.
- Single global development for generic medicines, leveraged by acceptance of comparator product from jurisdictions outside the EU.

High time to introduce genuine telematics capabilities

During the crisis, digital submissions via Common European Submission Portal (CESP) were facilitated in Europe, including countries where CESP submission was not accepted before the crisis. This proves that digital process submissions can easily be introduced across Europe in the future.

To improve the use of digital submissions, teleworking modalities have underlined the need to equip Competent Authorities with telematics systems and a telematics strategy. For example, during the crisis, digital certificates for controlled substance management were accepted due to the lockdown but some countries continued to insist on the paper version (which could not physically be obtained due to lockdown) while other countries used a digital platform offered by the responsible UN agency. There is no excuse for countries to avoid secure digital platforms in the future.

The EU has delayed the implementation of its pharmaceutical telematics strategy for many years now. As a result, the telematics infrastructure was not ready to respond to the Covid19 pandemic for the assessment of critical medicine supplies among other issues. The EU must now prioritise the implementation of a digital telematics strategy based on European interoperability, such as Substance, Product, Organisation and Referentials (SPOR) data-system, electronic product information (ePI) and European Medicines Verification System (EMVS), to move into the digital age of medicines regulation. The goal of IDMP, to create an up to date central data repository of medicinal products that can be readily searched, understood and relied upon internationally, should become a reality for Europe.

Many Covid19 challenges could have been mitigated with a common repository for all medicines in Europe based on good quality data, improved data sharing and exchange of information between industry and competent authorities. This would have been possible with the full implementation of SPOR (Substance, Product, Organisation and Referential) data management services. In future, this data, supported by a Target Operating Model (TOM), can ensure data quality and consistency optimising the exchange of application data between regulators and applicants, paving the way for meaningful data-sharing across departmental, organisational and geographical borders. Accelerating the implementation of a common central repository for medicinal products and interconnection with EMVO-NMVs systems could also play a significant supportive role in the tracking and monitoring of potential supply disruptions by monitoring stock levels across member states.

Information on shortages caused by demand surges was difficult to obtain during Covid19. There is an urgent need to establish harmonised and accurate ways of reporting shortages. The ISPOC experience shows that data can be collected in a harmonised way across Europe based on real patient demand and criticality. As under the EMA extended mandate regulation, the creation of a web-based form will not be a digital revolution for the shortages reporting system, but will only introduce huge administrative burden on the Marketing authorisation holders (MAHs) without improving the quality of the data to be used by both agencies and industry to address shortages.

In addition, a two-way communication with MAHs will increase the capabilities of the EU to address and resolve shortages in a faster way. During COVID, cooperation with manufacturers has proved to be a key factor of success.

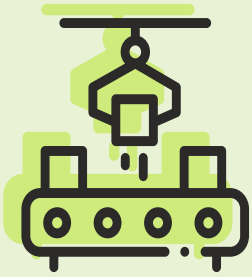
In addition, there were difficulties identifying the Qualified Person (QP) responsible for each product because the Article 57 database only includes the Qualified Person for pharmacovigilance (QPPV) contact. The EMA should have direct contact to QPs for shortage related matters in the future as was done for the ISPOC. The system can be improved only if agencies have access to the same data and use vocabulary for identification of medicinal products.

Recommendations:

- Prioritise the implementation of a common repository for all medicinal products via SPOR data management, supported by a Target Operating Model (TOM) to ensure

data-quality and faster decision-making in the EU Regulatory Network.
- Build appropriate interoperable IT network infrastructure to streamiline regulatory processes (i.e. variations to supply chain) and achieve an EU centralised mechanism to monitor the entire value chain through interconnection of SPOR and EMVO-NMVs as foreseen in the EMA extended mandate Regulation.
- Enhance two-way communication between Competent Authorities and Manufacturers to coordinate identification of medicine shortages or limited manufacturing supply capabilities that require collaboration across Europe.

Building resilient supply chains



The pandemic had a dramatic impact on demand surges that, in some cases, doubled or tripled relative to the normal annual consumption of medicines. Clearly no medicine stockpile could have covered these massive demand surges. Therefore, a key lesson of this crisis is the need to support the expansion of existing manufacturing capacity in finished dosage form and active pharmaceutical ingredients (APIs) during a crisis. This could be achieved with reform of market policies, implementing security of supply into national medicines procurement and purchasing policies, starting with the long-awaited Commission guidelines on medicines procurement most economically advantageous tender (MEAT) criteria. An important step would also be to define "investment in manufacturing security of supply" as a tax credit under EU state aid law.

Supply chain resilience was challenged during COVID-19 by restrictions on exports from India and China but also by restrictions inside the EU by some member states. While it would be unrealistic to manufacture everything in the EU, steps can be taken to strengthen our manufacturing base in Europe. A new medicines trade policy agenda focused on regulatory cooperation and convergence could also reduce the risk of future trade disruptions in the global supply chain.

In the EU, several Member States have put in policies to ensure medicines supply for their own populations. Most national measures targeted parallel exports of medicines due to concerns that speculation could undermine supply to patients. In other more extreme cases, member states introduced restrictions to hoard medicines at the expense of their neighbours out of panic. These extreme measures disrupted European supply chains with no clear benefit for patients locally and should be avoided in the future. On a positive note, the EU guidance for the optimisation of supply for medicines, tackled disproportionate national stockpiles which were found to have no public health benefit.

Recommendations:

- Consider EU policies to encourage companies to build and maintain resilient (diverse, secure and sustainable) supply chains, with mature quality and EHS management systems.
- As EU and member states promote a greater focus on regional production, policy measures will be needed to help ensure long-term economic viability, as well as a "level playing field" due to economic incentives offered in other markets.
- National medicines stockpiles negatively impact supply and equitable access to medicines.
- Establish clear distinctions between normal medicines exports and parallel trade to ensure that medicines manufacturers can continue to operate when governments impose restrictions on parallel exports.
- National policies to ensure the plurality of suppliers active in their market.
- European and national communication and awareness raising campaigns towards HCPs on the availability of generic and biosimilar medicines options.

Ensuring equitable access to medicines and sustainability

Coordination and solidarity

The EU can and should play a key role to support equitable access to medicines. Several industry-led initiatives that were coordinated with the EU, such as the Medicines for Europe Hospital ICU medicines project, the distribution of hydroxychloroquine donations, direct financial support from the European Commission for medical equipment (Emergency Support Instrument), demonstrated that industry-EU cooperation can improve equitable access. Similar industry-government cooperation efforts were also critical to ensure the equity of medicines distribution inside Member States as regions and hospitals hoarded medicines out of panic. COVID-19 has demonstrated without doubt that industry-government cooperation is critical to solve challenges related to equitable access to medicines.

Countries and the EU should consider the impact of parallel trade on equitable access. The widespread introduction of restrictions on parallel exports demonstrates the clear concerns about its impact on availability. In turn, countries relying excessively on parallel imports due to quotas and other measures faced supply problems. There should be a rebalancing of parallel trade to address the concerns of exporting countries and the excessive reliance of some importing countries.

Sustainability and austerity

Almost all countries suspended measures that artificially lower generic medicine prices during the crisis. Most countries stopped the application of automatic generic medicines reference policies or amended clawback measures.

France removed artificial price caps on hospital medicines through free pricing tenders for ICU medicines. German payers were heavily criticised for continuing to apply single winner retail tenders in contradiction with federal government policy. During the crisis, governments clearly acknowledged the negative effect that these price control measures have on supply.

Looking ahead, as countries are expected to face major economic recessions and deep budget deficits, we need to remind the European Commission and Member States that there is a solid link between price cutting policies, manufacturing sustainability and supply. There are alternatives to price controls to achieve sustainability in pharmaceutical budgets.

Our industry can continue to deliver public health value, supplying essential medicines, if following conditions are respected:

- Pursue pharmaceutical cost-effectiveness by supporting multi-source market competition at patent expiry, rather than government mandated price cutting policies.
- Implement new pricing models for generic and off-patent medicines that ensure long-term market competition and prevent supply vulnerabilities.
- Introduce MEAT criteria and multi-winner procurement practices to ensure supply resilience and prevent over-reliance on a limited number of suppliers.

Tendering procedures should take account of factors that affect supply such as:

- encouraging a broader range of companies to participate in tender markets to ensure continuity of care to patients.
- Give payers a share of responsibility for security of supply along with medicine manufacturers and regulators. This will prevent payers from focusing exclusively on lowest price.
- Recognise that the risk/reward balance in a tender has an impact on continuity of supply. If the risk outweighs the reward, companies will exit the market which explains why so many older less expensive medicines are being withdrawn from European markets.

Any form of joint procurement of off-patent medicines in the context of a health crisis should:

- Be transparent, open, and communicated to all possible suppliers
- Follow rules and principles in the Public Procurement Directive
- Include clear volume commitments
- Encourage generic and biosimilar medicines competition at market formation with streamlined development requirements in line with state-of-the-art regulatory science.
- Recognise the value of medicines repurposing in all therapeutic areas. Value added medicines can deliver equitable innovation with clear benefits for patients and sustainable costs for health systems.

Continuity of care

According to the World Health Organisation, COVID-19 severely disrupted the diagnosis and treatment of chronic diseases, including cardiac care, cancers, diabetes and respiratory ailments. The pandemic has severely disrupted the delivery of services to prevent and treat non-communicable diseases (NCDs) in almost 80% of countries surveyed by the WHO, including in Europe. This is particularly concerning as people with NCDs are also more vulnerable to COVID-19 infection, and/or their condition might be aggravated leading to serious health issues. Chronic disease care should resume promptly, in coordination with industry to ensure a stable supply of medicines.

Digital health technologies and their integration in European health care systems are now proven to be critical, including integrated medicines, connected to devices/apps. These systems enable patients to self-monitor and/or to exchange with their healthcare professionals, ensuring continuity of care and adherence for chronic disease management.

Recommendations:

- Industry-Government cooperation to ensure equitable access to medicines should continue beyond a pandemic situation. It is proven to deliver.
- Austerity measures negatively and disproportionately affect the supply of off-patent medicines. These should not be applied in the future.
- It is essential that countries resume NCD care, in coordination with industry, to ensure supply meets expected future demand when services resume.
- Digital health technologies offer a pragmatic solution for patient continuity of care and physician consultations in a crisis.

Evolving role of Intellectual Property (IP) protection

Intellectual property is an important component of drug development in the EU, and this will continue to be the case in the future. Regarding the concerns that are being raised that the patent protection of medicines or vaccines developed for COVID-19 limits the access to these medicines across Europe, voluntary licensing is a useful tool where appropriate to address these concerns, either on a bilateral basis or through the existing patent pooling mechanisms.

Compliance and Ethical Behaviour

Mastering rapid responses to issues and questions arising in a pandemic also presents immense ethical challenges to the pharmaceutical industry. The wildly shifting dynamic in the development, testing, sourcing, production, packaging, delivery, marketing, donation, and/or sale of pharmaceutical products, and innumerable requests for

items of medical utility and even normal office supplies such as disinfectant, gloves and masks places enormous stress on companies who have chosen to abide by Medicines for Europe's Code of Conduct and transparency requirements. In addition, controls arising from local laws and regulations as well as corporate policies and procedures are equally pressurised during such times.

During a pandemic, companies are faced with product shortages, delivery delays, logistical obstacles, restricted travel, and limited interactions with healthcare professionals. Consequently, companies and their business partners may feel justified in circumventing controls, ignoring policies, or diluting ethical standards to achieve immediate goals. This is unacceptable. The prominent public role of pharmaceutical companies in campaigns to fight a pandemic makes it even more important to clearly demonstrate the highest level of ethical behaviour. By complying with the Medicines for Europe Code of Conduct, relevant legislation, and corporate policies and procedures, we maintain the industry's standards while delivering on our promise to provide pharmaceutical products and support to patients in need.

Our members represent and account for:

medicines for europe
better access. better health.

generic medicines
better access. better health.

biosimilar medicines
better access. better health.

value added medicines
better access. better health.

190,000
Highly skilled direct **employees**

Over **400** **manufacturing sites**

126
Specialised **sites** for **R&D**

Over 10 years, increase in patient access by **100%** to treatments for illnesses such as diabetes, hypertension and epilepsy

Savings of up to **€18bn** possible through biosimilars since 2006 alone

2 billion patient days

Since 2006, biosimilar medicines have generated over 2 billion patient treatment days of clinical experience.

medicines for europe
better access better health

For more information, please find our factsheets below

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Medicines for Europe
Rue d'Arlon 50 - 1000 Brussels - Belgium
T: +32 (0)2 736 84 11 - F: +32 (0)2 736 74 38
info@medicinesforeurope.com
www.medicinesforeurope.com
@medicinesforEU