

CALL FOR ACTION: HEADS OF STATE AND GOVERNMENT SHOULD PRIORITISE MEDICINES IN COVID-19 ACTIONS

Brussels, 25 March 2020

The EU must act now to support the production and supply of essential medicines – solidarity and coordination is key. Our 400 production sites across Europe are 24/7 at full capacity manufacturing finished products and active pharmaceutical ingredients (API) to respond to the COVID-19 outbreak in Europe. Our industry is operating with one mission: to ensure the supply of medicines to Europe. We need your support to succeed.

Europe needs to act to secure the emergency and the experimental medicines needed for this crisis. Regrettably, many countries around the world are introducing export restrictions (including some restrictions inside the EU) on manufacturers of medicines and their ingredients which undermines our ability to manufacture in Europe. European solidarity, as mandated by the EU treaties, and cooperation with our main international partners (India, US, China) is essential. Our industry also needs access to air freight and to optimise customs and other pharma-specific import procedures to accelerate the import key ingredients.

As we have requested in our <u>first letter dated 18 February to the European Medicines Agency</u>, we need effective coordination between manufacturers and authorities to manage this crisis. We deeply regret that this process is not yet fully operational at EU or at national level except in Italy. We therefore urge the EU and each member state to immediately establish a drug supply coordination centre with Medicines for Europe and the originator pharmaceutical industry at EU level and our national associations at national level.

At EU level, we should have a single point of contact in the Commission to coordinate all measures that impact medicines production and supply with authority to call on key directorates for rapid decisions or support: health, transport, industry, trade/diplomacy, home affairs, customs, competition and key EU agencies.

Our experience in Italy has shown that the crisis generates a massive surge in demand for medicines for patients in intensive care and experimental medicines for Covid-19 and for chronic patients as doctors extend their prescriptions to reduce their exposure to the risk of infection. EU and national coordination centres can manage these demand surges with manufacturers by:

 Aligning on <u>all necessary regulatory and other measures</u> to increase production output of critical hospital medicines based our list of critical medicine needs. There will be a large surge in demand for those medicines in all ICUs dealing with the outbreak so we must produce as much as possible and move it as quickly as possible to those ICUs.



- Using Europe's diplomatic services to keep international borders open and secure trade flows for medicines and the key ingredients for their manufacture notably with India, the US and China.
- Aligning on the off-label/experimental prescribing by doctors for infected patients (see critical list of medicines by Medicines for Europe). It is imperative to inform the industry of the required volumes because this medicine will not manufacture itself. This can be done by agreeing on national guidelines with both physicians and manufacturers. There must also be solutions for patients that currently take some of those medicines (Lupus, Rheumatology, HIV patients, etc). The EU should also develop *reasonable insurance plans* with manufacturers for these molecules in case of success in clinical trials. We should avoid unreasonable stockpiling at all levels which deliberately undermines EU solidarity.
- Ensuring that the **production and supply of chronic disease medicines continues normally to keep these patients healthy and out of hospitals**. This requires coordination on prescription extensions to avoid unmanageable surges. We have guidance on electronic prescribing to keep patients safe while enable shorter prescription extensions for such cases.

Medicines for Europe has issued multiple letters and guidances regarding medicines, production, regulation and transport/logistics. We ask the EU and the member states to enact and support those guidances and requests without delay. We ask that national medicines coordination centres are established to channel any problems with medicines supply to the EU level without delay.

Together, we will ensure the supply of medicines for Europe.

Yours sincerely,

Adrian van den Hoven

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Director General

Medicines for Europe

Medicines for Europe

Medicines for Europe represents the generic, biosimilar and value-added medicines industries across Europe. Its vision is to provide sustainable access to high quality medicines, based on 5 important pillars: patients, quality, value, sustainability and partnership. Its members directly employ 190,000 people at over 400 manufacturing and 126 R&D sites in Europe and invest up to 17% of their turnover in R&D investment. Medicines for Europe member companies across Europe are both increasing access to medicines and driving improved health outcomes. They play a key role in creating sustainable European healthcare systems by continuing to provide high quality, effective generic medicines, whilst also innovating to create new biosimilar medicines and bringing to market value added medicines, which deliver better health outcomes, greater efficiency and/or improved safety in the hospital setting for patients. For more information please follow us at www.medicinesforeurope.com and on Twitter @medicinesforEU.