

AN OPEN MEMO TO THE HEALTH INDUSTRY

9 April 2020

Dear Health Industry Representatives,

We are living in extremely challenging times. The COVID-19 Pandemic is forcing us to rethink everything we do. As you are aware, patients with chronic diseases – numbering at least 150 million in the EU – are among the most vulnerable, as many are at much higher risk of serious illness and death from COVID-19. Patients with long term conditions are also directly exposed to any disruptions in healthcare provision. The huge economic impact of the crisis is likely to affect, disproportionately, these patients, widening existing inequalities.

This is a defining moment for all health stakeholders to demonstrate collective leadership and to make the right choices.

For this reason, we are reaching out to you, alongside other institutions and actors from different sectors to request your continued commitment to ensure the best possible outcomes for patients and citizens in Europe and worldwide. More than ever, we need strong commitment from you to provide the most advanced science and expertise, valued partnerships and transparent and ethical behaviour.

We see many very concrete supportive actions undertaken by companies in the wake of the crisis, at local, national and regional level and we welcome these strongly.

We also know, from our member organisations, that many patients are really worried about shortages of medicines and technologies. This is not a new issue, but highly exacerbated by the current situation, the huge surge in demand, and the focus on COVID-19. We are counting on industry to continue to deliver for patients, despite the enormous pressures.

The on-going collaborative, pre-competitive efforts to develop new diagnostics, vaccines, medical technologies and treatments swiftly to respond to COVID-19 is vital, and equitable access equally so. We hope and expect principles of fairness and justice to be applied, echoing EPF's statement on value and pricing. Availability and affordability of innovative technologies have never been more important.



The current situation has forced some clinical trials to halt, others to be conducted differently. It is very important that patients receive clear and timely information, support and where needed, continuing treatment.

We hope that our cumulative work in the area of patient engagement in the life cycle of medicines and technologies, from the earliest stages and throughout, continues to be a beacon. Patients and citizens play an essential role in ensuring treatments and therapies respond as closely as possible to their critical needs.

Finally, we count on your support, alongside other stakeholders, in ensuring we all learn from this pandemic, and apply those learnings in building resilient people-centred health systems for the future.

I look forward to receiving a response as soon as possible, that we can share with our communities.

Best wishes

Marco Greco

EPF President



Mr Marco GRECO EPF President Chaussée d'Etterbeek, 180 1040 Brussels

Brussels, 9 April 2020

Dear Mr Greco, dear Marco,

Thank you for reaching out at this difficult time. We recognize the impact that the coronavirus outbreak is having on the 150 million Europeans living with long-term conditions. We stand shoulder to shoulder with the patient community, citizens, the EU Institutions and Member States in the fight against this pandemic. Last week, EFPIA published <u>our commitment</u> to that fight, focused on ensuring the safe supply of medicines to the patients who need them, finding diagnostics, vaccines and treatments for use against COVID-19 and supporting health systems and organisations on the ground.

EFPIA member companies are working around the clock to increase capacity and ensure the supply of critical medicines to patients in the face of the significant challenges caused by the pandemic. The increased demand, unilateral export bans by countries, requirements to stockpile at national level or forcing manufacturers to produce only for a local market first, all put pressure on a supply system designed to function across borders and are exacerbated by the logistical challenges. As an industry, we will continue to do everything we can to work with EU Institutions, Member States, Regulators and other actors in the medicines supply chain to continue to ensure the supply of medicines to the patients that need them.

The industry research response has been rapid, collaborative and significant. Around 30 antiviral medicines in various stages of development or use are currently being explored by member companies to see if they are effective in treating patients with COVID-19. Since its launch in March, 13 companies have responded to IMI Call 21, sharing compounds and assets from their libraries in a collaborative bid to accelerate the development of therapeutics and diagnostics. In addition, there are multiple collaborative research initiatives to find a vaccine to tackle this and future outbreaks. Companies are expanding their manufacturing capabilities and sharing available capacity to ramp up production once a successful medicine or vaccine is developed. We will work closely with governments and health systems to ensure that when new treatments and vaccines are approved they are available and affordable.













Beyond the supply of existing medicines and search for the new vaccines and treatments, EFPIA members are committing millions of euros to provide financial support and in-kind donations to organisations at the front line of the fight against COVID-19. From donating personal protective equipment (PPE) to repurposing factories to make, and then donate hand-sanitizer to health-systems, companies are utilising their world-leading science, people and resources to tackle this outbreak.

Both industry and the regulators recognise the need for harmonised EU wide approaches to minimise the negative impact on clinical research caused by COVID-19 pandemic and the need to provide timely and accurate information to patients. EFPIA is in constant dialogue with regulators to find pragmatic solutions that put patients first.

We support the need for a multi-stakeholder dialogue to learn the lessons from the coronavirus pandemic. We need to ensure that Europe has the research-ecosystem and people-centred, resilient health-systems it needs to respond to future health threats and challenges.

We understand what an extremely difficult time this is for patient communities and patient organisations alike and we are committed to working collaboratively with EPF and all patient organisations so that you can keep supporting your communities and help address the challenges they face during this difficult period.

Very best wishes,

Nathalie Moll Director General









Open response to the European Patients' Forum on COVID-19

14 April 2020

MEDICINES FOR EUROPE'S COMMITMENT TO PATIENTS DURING THE COVID-19 OUTBREAK

Patient access to medicines is not only our mission, it is our utmost priority during this crisis.

Medicines for Europe members supply almost 70% of dispensed medicines in Europe to treat major chronic and acute conditions such as cancer, auto-immune and infectious diseases. The supply of these medicines, along with tackling the COVID-19 outbreak, is of utmost priority for our members. Mindful of the risk profile of people with underlying conditions who contract COVID-19, a secure supply of medicines has never been more important.

Medicines for Europe members have been working around the clock to ensure the supply of medicines to patients, hospitals and pharmacies all across Europe since the outbreak of COVID-19. For this, we need to keep manufacturing and supplying all the medicines that patients rely on every day. Chronic and life-threatening conditions are unfortunately a part of life for many during this difficult time. The ongoing supply of medicines that our members provide is crucial to help support healthcare systems as they battle COVID-19. Our members have been supporting health systems by ramping up manufacturing, donating medicines to EU countries, supporting at-risk communities and investigative clinical trials. To ensure supply, day and night our members are continuously assessing portfolios, forecasts and supply to best meet these increasing demands.

In addition to our overarching commitment to supply medicines to all patients, the Medicines for Europe response to COVID-19 specifically has been focused on the following key areas:



PARTNERSHIP

Work with the healthcare community to help address public health needs



MEDICINES SUPPLY

Secure supply of affordable medicines to ensure equitable access for all patients

- We cannot address COVID-19 issues alone. We have been in constant contact with the entire healthcare community to understand and identify the needs of our partners.
- → This includes patients and their advocates, medical societies, Intensive Care Unit specialists, pharmacists, nurses, and institutional partners from the European Commission, Parliament, Council, Member States and the World Health Organisation.
- → Our members are working day and night to ensure access to medicines used in COVID-19 patients and the wider patient community.
- → This is our mission that motivates us to make unprecedented efforts for our healthcare partners.



PHARMACEUTICAL WORKFORCE

Essential employees keep working to make critical medicines



TRANSPORT

Keep medicines moving to where they are needed most



- → Our members are ramping up pharmaceutical manufacturing, keeping factories open and running at all times to ensure supply.
- → Key pharmaceutical employees continue to go to work to produce medicines while the rest of us work from home.
- → No one country or health system has the capacity to supply all essential medicines for all patient needs. We have been working to continue transport by road and plane to keep medicines moving to hospitals, pharmacies and patients all around Europe.

These are unprecedent times and the facts identified in the EPF open letter reflect many of the challenges that we are trying our best to address daily.

We are facing challenges such as increased demand and export restrictions in and between countries. Our call to action for the entire health community is to invest every effort to keep medicines moving, so that together we can overcome these challenges. This includes working with health care partners such as patient advocates, hospital representatives, medical societies, nurses and carers, pharmacists and industry, regulators like the EMA and their national counterparts and the EU and national institutions, the World Health Organisation, and others. In the spirit of partnership, we rely on all health stakeholders to support our mission to ensure secure supply and patient access to medicines.

As a proud partner of EPF, we support your call for affordable and equitable access to medicines. This is crucial for both COVID-19 and chronic disease patients, in these times of crisis but also beyond.

Our efforts will continue so that we deliver safe, affordable and timely medicines for the patients we serve.

Adrian van den Hoven,

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Director General, Medicines for Europe

About 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.



The Medical Technology Community Stands with Patients

Access to Medical Technologies and Services During the COVID-19 Pandemic

15 April 2020

These are difficult times for all of us. The scale of the COVID-19 pandemic is unlike any viral outbreak we have ever seen, and health and care systems are being tested like never before. Large parts of the world came to a standstill to stop the new coronavirus from spreading. On the other end, people who become infected, people who get acutely sick and people living with chronic conditions need effective care to continue.

We would like to reassure the patient communities that the priority of the medical technology manufacturers to serve patients has not shifted an inch. We hear well your worries and we want to reaffirm our commitment that we will get through this crisis together.

Providing the necessary medical supplies for patients and healthcare professionals

Since the very beginning of the outbreak, the medical technology community has been working around the clock to provide the needed medical technologies to fight COVID-19. Delivering new COVID-19 related tests, personal protective equipment, such as masks, gloves and gowns, respiratory equipment such as ventilators as well as many other equipment needed in 'Intensive Care Units' have been our core focus to allow the diagnosis and treatment of infected people.

Companies have been scaling up production as much as possible to meet the demand for medical supplies:

- Production facilities are kept open and operational. They are running maximum shifts, whilst workers
 practice remote working and social distancing in the manufacturing sites;
- Supply chains around the globe are being secured and strengthened as much as possible so that all
 materials, components and accessories are available, whilst working in the context of lockdowns in many
 countries:
- The distribution of equipment via land and air freights is being organised, whilst border restrictions are in place in many areas.

In a combined effort, we are mobilising everything we can to help save the lives of people that become infected and protect the lives of those who care for them.

Supporting vulnerable groups

Governments are being asked to take difficult decisions and shift priorities and resources to where they are most needed. In this uncertainty, it is important to also acknowledge that certain patient communities are



particularly vulnerable, such as those living with chronic or rare diseases. Those communities rely on medical technologies, medicines as well as on access to healthcare services on a regular basis. They must not be forgotten but be supported by all means.

Medical technologies manufacturers remain fully committed to do the utmost possible on their end to ease the difficulties that those patient communities might face in these challenging times and to ensure that needed medical technologies and services are available without disruptions.

It is important that people continue to reach out to their doctors and hospitals in order to seek treatment, when needed. Nevertheless, the medical technology community is also committed to strengthen digital solutions that support self-management, remote and home care. People and health care systems rely more than ever on these approaches in times of severe confinement measures.

Partnerships with international, European and regional actors

The medical technology industry works tirelessly to manufacture and distribute essential medical technologies. We will also continue to work diligently with the WHO, the European Institutions and national governments, to ensure that health systems are fortified to combat COVID-19. We encourage and support the efforts of the European Union to coordinate national activities of the member states. Together, we need to make sure that medical technologies are available and accessible where and when they are needed.

To that end, we emphasise that the existing dialogue between the patient community and the medical technology industry should continue and be deepened, so that critical questions are answered and we work together to manage these difficult weeks and months in the best way possible. Further on, we should jointly assess and draw lessons from this painful health crisis with the aim to come out of it strengthened and more resilient to face the future.

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

For more information on how the medical technology community engages in combatting the COVID-19 pandemic, please see MedTech Europe's Information Hub https://www.medtecheurope.org/covid-19-information-hub/