efpia
European Federation of Pharmaceutical Industries and Associations

FIGHTING COVID-19

REGULATORY ROAD TO INNOVATION IN THE FIGHT AGAINST COVID-19

While governments contend with implementing appropriate public health measures and health systems are treating unprecedented numbers of patients requiring intensive care, Europe's regulatory system is showing its resilience to adapt to these unprecedented challenges. EFPIA and its members are ready to work together with regulators to make safe and high quality COVID-19 diagnostics, vaccines and treatments available to patients, as fast as possible.

ADAPTING TO NEW CHALLENGES

The pandemic is unique in recent history and as a result is placing unprecedented demands on global supply chains for healthcare products, ongoing clinical research and the regulatory infrastructure. In these exceptional circumstances, all stakeholders need to consider how to simplify and accelerate procedures while keeping patient safety paramount. Industry and regulators are currently in dialogue to secure the following:

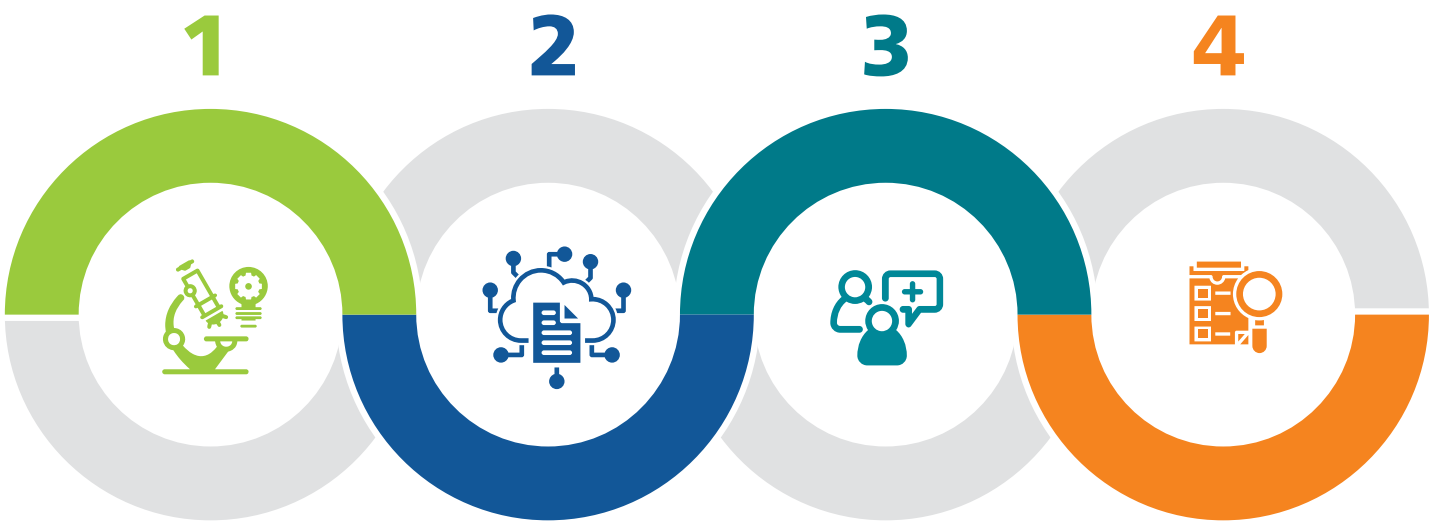
- **The supply of vaccines, medicines and other healthcare products to enable the continued treatment of patients;**
- **Research into effective treatments and vaccines to address COVID-19, while preserving their quality and safety;**
- **Ongoing clinical trials;**
- **Concerted, harmonised approaches to tackle this pandemic, and future outbreaks, more effectively.**

EVOLVING THE SYSTEM CAN HELP US DELIVER MORE FOR PATIENTS

To meet today's challenges, industry needs to work with the multiple partners in the healthcare system to evolve and adapt the regulatory system **within the existing legislation** to utilise the opportunities science is offering to help Europe face this emergency.

COVID-19 has been a catalyst in optimising research and development and streamlining regulatory processes. Some of the elements that in the context of COVID-19 have **simplified procedures, minimised non-value adding activities and accelerated delivery,** should be evaluated and tested to help us address health challenges in the post-COVID-19 world.

THIS IS THE REGULATORY ROAD TO INNOVATION.



Encourage the use of new types of clinical trials to help new medicines get to patients faster

Allow greater use of data from real world use of treatments

Allow ongoing dialogue and discussion about a medicine throughout development

Simplify how medicines and other healthcare products are regulated

1. INNOVATIVE CLINICAL TRIAL DESIGNS

ISSUE

Since participants' travel to clinical trial sites will be limited during the COVID-19 crisis, EU regulators should encourage innovative approaches to evaluate new medical products, such as through master protocols, adaptive studies, and decentralised trial designs.

This will allow **patients to continue to participate in trials and allow the researchers to evaluate treatments,** even in the setting of a public health emergency.

80% of EFPIA companies have already used **Innovative Trial Designs (ITD)** to collect clinical data[1].

RECOMMENDATIONS

EMA and the national authorities to lead a strategic initiative to broaden the appropriate use and acceptability of ITD, including the design of an IT platform for ITD application.

The European Commission to ensure the compatibility of ITD with the **EU Clinical Trial Regulation**.

2. REAL WORLD DATA (RWD) / REAL WORLD EVIDENCE (RWE)

ISSUE

Industry and regulators recognise the value of using good quality RWD/RWE as additional sources of evidence for decision-making, since they allow to **consider real-life impact of medicines,** instead of standard effects as considered in traditional clinical trials.

RWE is showing its value in tackling COVID-19. RWD on COVID-19 patients and treatments is being collected across global health systems as we speak. We can learn a lot about its quality and accessibility and how it translates into evidence.

RECOMMENDATION

EMA to develop and adopt guidance on a RWD/RWE framework with clear principles for data quality and interoperability, access, analysis and regulatory acceptance. This will also lead to important digital tools for collecting available evidence for the development of future vaccines and treatments.

3. DYNAMIC REGULATORY ASSESSMENT

ISSUE

To ensure novel treatments and vaccines for COVID-19 are developed as quickly and as efficiently as possible, there is a need for continuous dialogue between developers, regulators and other stakeholders so that there is mutual awareness, and agreed analysis of the merging data and a common understanding of what the data is showing.

This approach to development should help reduce the uncertainties and optimise the application process. This would allow **more rapid approval of medicines and faster access for patients to new treatments.**

RECOMMENDATIONS

EMA to design guidelines for a flexible regulatory pathway which includes an iterative process for seeking early and continuous dialogue on data, as they are generated.

The European Commission to accelerate the review of EMA recommendations for approval.

4.DRUG-DEVICE COMBINATIONS & BIOMARKER VALIDATION

ISSUE

1 in 4 medicines approved at EU level includes a *device* component. In the EU, while medicines are assessed by the EMA, diagnostic tools and medicines are currently evaluated by different authorities.

Diagnostics play a key role in identifying those who are impacted by COVID-19, and a **streamlined regulatory pathway** for assessing diagnostics and drug-device combinations can accelerate access to innovation.

For example, advances in personalised medicine require additional regulatory requirements, such as biomarker validation. Current biomarker qualification process lengthens already **cumbersome procedures** thus jeopardising access of patients to innovation.

RECOMMENDATIONS

EMA to adopt an integrated EU pathway for the assessment of drug-device combinations and in vitro diagnostics.

EMA to incorporate best practices in order to include additional regulatory requirements coming from advances in science, such as biomarker validation, without overburdening existing procedures.

#RegulatoryRoadToInnovation

@EFPIA

www.efpia.eu

[1] Internal EFPIA Survey, 2019.