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**Sent:** vendredi 27 mars 2020 15:59  
**To:** KYRIAKIDES Stella (CAB-KYRIAKIDES); BRETON Thierry (CAB-BRETON); LENARCIC Janez (CAB-LENARCIC)  
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**Subject:** Week 3: EFPIA & Vaccines Europe follow-up to videocall on COVID-19 with 3 Commissioners of 27.03.2020  
**Attachments:** COVID-19 EFPIA & Vaccines Europe Situational Assessment 27032020.docx

Dear Commissioners Kyriakides, Breton and Lenarčič,

With sincere thanks for today's call on COVID-19, please find attached as promised, the detailed answers to the questions that you had posed ahead of the meeting on behalf of both **EFPIA** and **Vaccines Europe**.

The attached document also includes important complementary information regarding urgent needs of the innovative industry to continue to operate and supply treatments as well as an update on the most recent treatment developments as requested.

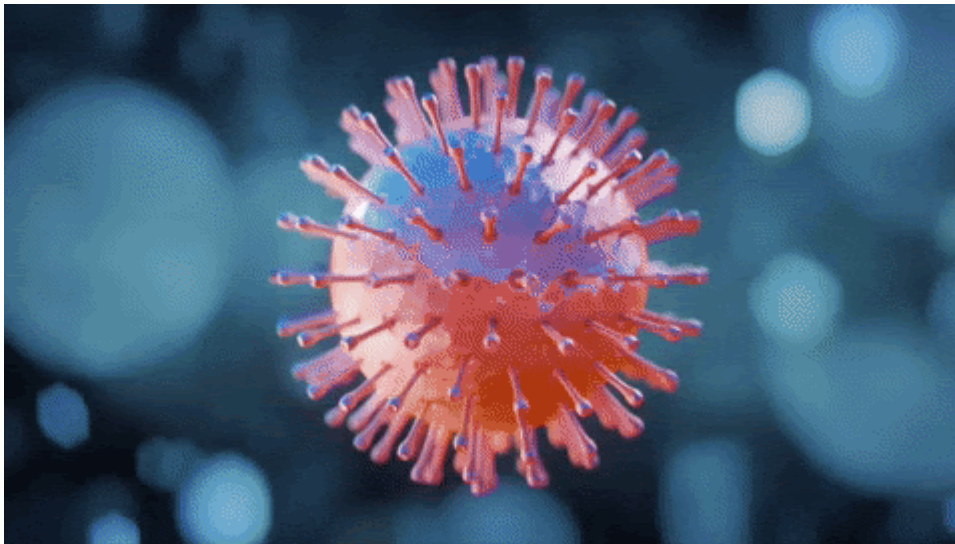
N.B. In the attached document, we have noted **in red** any additional requests that come on top of those already shared with you after last week's call. We have kept any previously communicated information and requests that continue to be relevant today, in black, for ease of reference.

As always, my Colleagues and I remain at your entire disposal for any further information you might require.

With very best wishes and thanks,

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For more information related to COVID-19 see: <https://efpia.eu/news-events/the-efpia-view/statements-press-releases/european-pharmaceutical-industry-response-to-coronavirus/>

On Fri, 20 Mar 2020 at 17:04, [REDACTED] <[\[REDACTED\]@efpia.eu](mailto:[REDACTED]@efpia.eu)> wrote:

Dear Commissioners Kyriakides, Breton and Lenarčič,

With sincere thanks for today's call on COVID-19, please find attached as promised, the detailed answers to the questions that you had posed ahead of the meeting.

The attached document also includes important complementary information regarding urgent needs of the innovative industry to continue to operate and supply treatments as well as an update on the most recent treatment developments as requested.

N.B. In the attached document, we have noted **in red** any additional requests that come on top of those already shared with you after last week's call. We have kept any previously communicated information and requests that continue to be relevant today, in black, for ease of reference.

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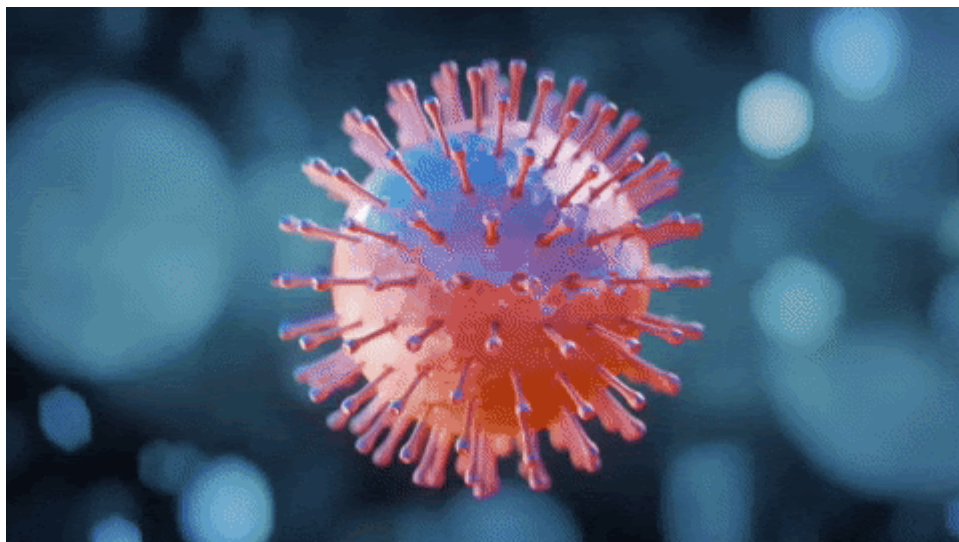
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On Fri, 13 Mar 2020 at 18:03, [REDACTED] [x@xxxxxx.xx](mailto:x@xxxxxx.xx) wrote:

Dear Commissioners Kyriakides, Breton and Lenarčič,

With sincere thanks for including EFPIA in the regular calls that you kicked-off today on the topic of COVID-19, please find attached as promised, the detailed answers to the questions that you had posed ahead of the meeting. The attached document also includes important complementary information regarding urgent needs of the innovative industry to continue to operate and supply treatments as well as an overview of the most recent treatment developments as requested.

We would very much appreciate also covering some key issues related to research during the next call, planned for 20 March 2020, if that were agreeable to you.

My Colleagues and I remain at your entire disposal for any further information you might require and send you our best wishes for this extremely complicated time,

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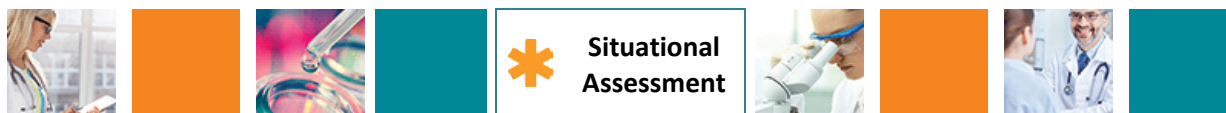
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## Potential impact of coronavirus (COVID-19) on the availability of medicinal products in Europe



BLACK = updates on 20 March 2020

RED = updates on 27 March 2020

### Overall assessment

Today, 27 March 2020, EFPIA is aware of **two** members forced to notify a shortage in Spain and Italy due to increased demand for **off-label use** of their medicines in order to treat COVID-19. The companies concerned is ramping up production, so this will be a temporary situation. Outside these specific examples, EFPIA does not have any knowledge of shortages for single source medicinal products or vaccines from among the EFPIA membership. Current stock levels and manufacturing cadence are maintained.

Within the European Union the situation is currently highly dynamic and everything will depend on the length of the current crisis as well as the overall level of cooperation and coordination among Member States to support our efforts to ensure continuity in manufacturing and distribution of medicines. EFPIA member companies have three immediate concerns in light of the past 3-day developments:

1. National stockpiling requirements – an increasing number of countries are requesting stockpiles, leading to potentially serious supply disruptions in this critical moment preventing other EU countries from getting access to the medicines and vaccines they need. **We ask the European Commission to urgently provide formal guidance to EU Member States to stop countries from stockpiling.** We would expect the EU Executive Steering Group on Shortages caused by major events to provide the Commission with a set of concrete recommendations in this respect.
2. Personal Protection Equipment (PPE): **we call upon Member States to ensure that pharmaceutical companies are listed on the priority list for distribution/supply of PPE at national level, and the prioritization of PPE for our sites is not hindered by, for example, government's measures to take control of the distribution or 'expropriation' of existing PPE supplies in the country.**
3. Logistics – **Shipments of medicines, vaccines and semi-finished products, as well as protective and sanitary equipment for our manufacturing sites, across Europe are becoming more and more difficult to organize.**



The EFPIA Secretariat monitors the situation closely with members and will report back any new developments as they arise. EFPIA together with AESGP, Medicines for Europe and Vaccines Europe, have asked their company members to identify a **Single Point of Contact (SPOC)** in order to be in constant contact with EMA. **The SPOC concept comes on top of the currently available reporting processes** (MAHs remain bound by their existing obligations to monitor supply and supply disruption) **and goes beyond the simple reporting of shortages - it should also enable early information on any potential bottlenecks that might impact the availability/ supply/ delivery of medicines.** On 19 March EFPIA sent the list of SPOCs to EMA, requesting EMA to provide a single point of contact (name, role and e-mail address) to which the various companies can forward the relevant information on potential anticipated disruptions and related issues. EFPIA like other trade associations cannot act as a 'go between' due to antitrust concerns. EFPIA also requested that the confidentiality of the information be guaranteed. **The sharing of information between SPOCs and the Steering Group on Shortages should be followed by a clear dialogue with manufacturers on how best to address the situation.**

**We are extremely grateful that, after the discussions with the national authorities, the EMA has confirmed they will put the Single Point Of Contact (SPOC) system in place. We look forward to the quick implementation of the SPOC system and stand ready to provide any additional information or support as needed.**

## Continuity of manufacturing and supply is industry's priority n.1

In order to make sure that research-based pharmaceutical manufacturers continue to manufacture and distribute medicines to satisfy the needs of patients in Europe, we call upon the European Commission and Member States to work together and ensure that the following operational, regulatory, research continuity and strategic measures are implemented.

### Operational

- 1. National export bans** – due to the recent sequencing of unilateral Member State driven initiatives, we have seen a proliferation of full export bans for medicines and vaccines and/or medical equipment. While we understand the need for national governments to reassure their citizens, we imagine that the export bans were intended for preventing the parallel exportation of products/equipment already released for sale on the local market but not for finished or semi-finished goods **or PPE** manufactured locally and intended for distribution/sale in other Member States. **Export restrictions are encountered for PPE intended for shipment from an EU supplier to a non-EU manufacturing site for production of medicines for global markets including the EU. We call in the strongest possible way on the European Commission and Member States to work together and continue to allow the movement of medicines/vaccines and medical equipment (including PPE) from factories across Europe to where they are needed the most.**
- 2. Dedicated 'Green-lanes' for medicines/vaccines/medical and protective equipment at borders** – as several Member States have re-introduced controls at their national borders, there is an urgent need for the **creation of dedicated 'green-lanes' at border/customs controls where priority is given for trucks carrying medicines/vaccines/medical and**



**protective equipment for our sites. It is important for the continuity of manufacturing operations that this is extended to include components and starting materials.** We were grateful that the need for logistics routes to remain open was explicitly mentioned in the Commission's guidelines to Member States published on 16<sup>th</sup> March 2020. This being said, the guidelines remain to be implemented and enforced by Member States. **We still experience bottlenecks and delays e.g. when moving masks and protective equipment across the borders of Germany, France, to supply our sites in other countries (e.g. Italy, Spain or Switzerland – Please note that some companies have significant manufacturing capacity of critical products e.g. cancer treatment in Switzerland, which supply is directed to cover for Europe's demand).**

***Question: What are the measures in place for enforcement of the existing guidance? How can we report any events in the quickest and most effective possible way to the Commission and/or competent national authorities?***

3. **Manufacturing cadence** – manufacturing of medicines and vaccines needs to continue unencumbered. EFPIA member companies consider their employees as the best asset they have and take the utmost precautions to ensure that they can continue working in the safest possible conditions. In this respect, manufacturing of medicines is a highly controlled environment and companies need to ensure their workers carry the most appropriate Personal Protection Equipment (PPE). **We call upon Member States to ensure that pharmaceutical companies are listed on the priority list for distribution/supply of PPE at national level, and the prioritization of PPE for our sites is not hindered by, for example, government's measures to take control of the distribution or 'expropriation' of existing PPE supplies in the country.** This is crucial to ensure that our workers can continue their activity in a safe environment and avoid further manufacturing tensions due to contaminations and reduced workforce. This recommendation was well noted by Commissioner Breton on 13 March. **EFPIA would like to get more information on how this recommendation will be implemented and enforced at country level.** Furthermore, some authorities are requesting manufacturers to provide part of their stock of PPE to hospitals that are in urgent need.

***Question: Several companies have compiled some indicative figures on required PPE for their manufacturing sites. How can the Commission ensure that companies will have priority access to PPE in the coming weeks in case of transfer of equipment to hospitals? How can the Commission facilitate a common approach with national authorities, to ensure that both EU and national emergency centers which are involved in the procurement and distribution of equipment and masks do take due account of the need to prioritize equipment for manufacturing sites?***

**Vaccines** manufacturers are facing unexpected issues such as the **need to find alternative providers of raw materials and reagents.** Some providers are not able to maintain their normal operations as they are not considered critical businesses by authorities in their country. This may not have an immediate impact on the availability of vaccines but could create a future health problem due to the long leads to manufacture vaccines.

4. **Free movement of key/critical employees** – we are concerned that **the proliferation of measures to automatically quarantine any citizen coming from any Member State upon**



entering a particular Member State will lead to significant disruptions of operations (both manufacturing and transportation, in the case of truck drivers). **Examples we see today are:**

- a. The situation between Slovenia and Croatia, with a high risk that critical workers from Croatia are quarantined when they commute back from Slovenia;
- b. Restriction of movement of cross-border commuters who are essential employees or maintenance support staff for manufacturing sites (e.g. France - Germany);
- c. Reports of restriction of movement or quarantine of drivers: specifically, Poland has imposed an obligation at their border which increases the border delay up to 30 hours.

A possible mitigation activity would be for the **Single Point of Contact** to identify those workers and for them to receive a special permit from EU Commission/EMA to be able to cross borders. **We also urge Member States to consider other measures that can facilitate continuation of manufacturing of supply, including priority access to education for the children of health workers where schools are still operational.**

5. **National stockpiling requirements** – an increasing number of countries are requesting stockpiles. While we understand the reasons for that, this is seriously disrupting supply in this critical moment preventing other countries from getting access to the medicines and vaccines they need. **We ask the European Commission to urgently provide formal guidance to EU Member States to stop countries from stockpiling.** Companies should not be forced to support any request to stockpile additional volumes within a specific country to ensure they can continue to supply against normal demand, helping to ensure continuity of supply across Europe and the globe. Where we see a real increase in demand for some products we will do our best to supply, but this will be difficult to manage if we need to supply to meet the demand coming from unilateral national stockpile initiatives. **We would expect the EU Executive Steering Group on Shortages caused by major events to provide the Commission with a set of concrete recommendations** and the Commission to clearly act upon those countries introducing unilateral stockpiling requirements that put at risk the overall supply of critical COVID-19 medicines in Europe.
6. **Demand planning/forecasting** – manufacturing capacity and cadence are normally scaled up to ensure that they meet the needs of patients in normal circumstances. In order for EFPIA members to better plan their manufacturing capacity and make sure that all possible measures have been taken to assure continuity, **we urgently call upon the European Commission/Member States/European Center for Disease Control to regularly share with us their most pessimistic predictions for the number of COVID-19 infections as well as any relevant type of sub-analysis (per age group, expected severity, per country etc.). Furthermore, any other predictions for the number of other patients whose treatment will be disrupted due to the prioritization within hospitals are welcome. This information is crucially needed by manufacturers so that they can adequately forecast demand and make the necessary planning both in terms of EU wide manufacturing capacity but also detailed distribution arrangements to supply those medicines to the right regions at the right time.**
7. **Stock level data sharing** – European trade associations are precluded from collecting detailed information about stock, manufacturing capacity, potential shortages, sales etc from their members due to anti-trust measures. **We call on the European Commission and**



**EMA to open direct lines of communications with EFPIA member companies in order to provide these detailed company-specific data and assessments.** EFPIA together with AESGP, Medicines for Europe and Vaccines Europe, have asked their company members to identify a **Single Point of Contact (SPOC)** in order to be in constant contact with EMA. **The SPOC concept comes on top of the currently available reporting processes** (MAHs remain bound by their existing obligations to monitor supply and supply disruption) **and goes beyond the simple reporting of shortages - it should also enable early information on any potential bottlenecks that might impact the availability/ supply/ delivery of medicines.** On 19 March EFPIA sent the list of SPOCs to EMA, requesting EMA to provide a single point of contact (name, role and e-mail address) to which the various companies can forward the relevant information on potential anticipated disruptions and related issues. EFPIA like other trade associations cannot act as a 'go between' due to antitrust concerns. EFPIA also requested that the confidentiality of the information be guaranteed. **The sharing of information between SPOCs and the Steering Group on Shortages should be followed by a clear dialogue with manufacturers on how best to address the situation.**

8. **Increased demand for some product categories and threats of unilateral decisions by Member States** – For some categories of products (e.g. HIV, pneumococcal vaccines) that can be used in the treatment of COVID-19 some companies are currently facing an evolving unstable situation, with significant increased demand from all countries for some of their HIV products (stockpiling), the need to guarantee needs for HIV patients, the threat of seizure of pharmaceutical supplies or stocks in several countries via emergency power, etc. **Vaccine manufacturers observe an increased demand for some vaccines for respiratory diseases, e.g., pneumococcal, pertussis and influenza vaccines and manufacturers are currently reviewing whether current production capabilities can be increased. The increase in demand for pneumococcal vaccines over the last few weeks in certain markets, manufacturers are experiencing intermittent backorders. This increase has just occurred, so manufacturers are evaluating the pattern of demand to determine the duration of the stockout and have adjusted production schedules to replenish as soon as possible.**
9. **Supply chain disruptions that could be caused due to lack of action on the side of the local authorities to better manage the 'panic' purchase of prescription medicines at the pharmacy level** - A growing number of companies' affiliates have received requests from local authorities as well as distributors to resupply much more than usual supply levels triggered by an increased demand from the pharmacies. Although a few patient organisations in Europe are actively advising patients against 'panic' stockpiling (*including in Denmark and Poland*), some have given no advice, and in other markets online patient communities (*which often have cross border impact*) are advising patients to resupply up to 3 times the normal amount of medication. Although it is utterly understandable for authorities and/or patient organizations to recommend to high-risk patient categories to refill their prescriptions for a longer period of time in order to avoid them travelling unnecessarily, such a demand shock is problematic for supply chains. We would like to reassure patients, healthcare professionals and national authorities that manufacturers are able to continuously meet normal prescriptions today and in the immediate future. There should be zero change in the level of confidence that patients have in the pharmaceutical distribution ecosystem. Against this backdrop, and to avoid supply chain disruptions across



Europe, we recommend that the European Commission provide guidance to Member States to:

- **Recommend healthcare professionals and pharmacists to continue to supply normal prescriptions levels to patients across Europe.**
- **Consider alternative measures already today, to re-supply patients in due time in case of exceptional circumstances (allow for family members or volunteers to fill out the prescription, allow home delivery services etc.).**
- **Level the flow of products across pharmacy and distributor levels on essential drugs, to ensure that products are readily available in the markets and can be supplied in case of urgency/stock-out.**

**A recent example of very effective national legislation to address this is from Finland.** If the European Commission would recommend similar measures to all Member States this would address the situation before shortages become a reality.

In short, in Finland:

- Pharmacies are obligated to ensure adequate amount of medicines is available but need to avoid ordering unnecessary big amount of medicines from wholesalers even if medicines demand can temporarily increase.
- Pharmacies need to make sure that medicines are used and dispensed appropriately according to terms of Marketing Authorisation and delivery. Pharmacies need to dispense prescription medicines at most the amount responding 3 months use.

**10. Guidance required from ECDC on routine vaccination in Europe** - we see an increasing number of countries adapting their implementation National Immunisation Programmes (NIP). We understand authorities are carefully balancing social distancing in out-patient clinics and managing the current burden COVID-19 imposes on the healthcare systems with protecting population against important diseases through national immunization programs (NIP). It is important though to ensure that the public health situation does not worsen due to insufficient protection against important vaccine preventable diseases. Especially if this lockdown situation continues, we recommend the ECDC issue a guidance to secure the continuation of the NIP. This should be accompanied with very concrete practical advice on the actual implementation (no waiting time for parents with newborns, maximal hygiene conditions, special dedicated clinics). Examples:

- Poland - the recommendation aims to limit the gathering and contact of children and parents in outpatient clinics. (Poland maintains only vaccinations at birth (HB, Tuberculosis) and post exposure vaccination (Td, T, Rabies));
- Dutch decision to postpone group vaccinations (Spring campaigns) until after summer-holidays: MMR (9 yo), dTaP (9yo), HPV - girls (13yo) – For MenACWY (14yo) group sessions are cancelled but vaccinations will have to be given;
- The Austrian authorities recommend to vaccinate only if the risk-benefit assessment is positive.

The main trends are the following:

- Countries recommend to **postpone non-mandatory vaccination** appointments
- Countries recommend to continue the mandatory vaccination **in the first year of life**
- Countries that highly recommend the uptake of **pneumococcal vaccination** for high-risk individuals / vulnerable groups and seniors



- 11. Secure manufacturing and supply of influenza vaccination season 2020/2021 and other vaccines against respiratory pathogens** – influenza vaccines must be manufactured, delivered and administered within a defined period each year to ensure at-risk groups are vaccinated before the influenza season starts. Like all influenza vaccine manufacturers, global supply for season 2020/21 vaccines depends on the uninterrupted operation of manufacturing and distribution networks from now through to the end of September. Disruption at any point can have a compounding effect on delivery timelines. Therefore, **we ask the Commission and National Competent authorities to maintain their efforts to secure green lanes and access to key airports to ensure unrestricted, timely cross-border movement of semi-finished and finished products.**

#### Research continuity

1. **Clinical trials continuity** - COVID-19 is materially impacting global medicines development programmes (clinical trials, regulatory approval delays, inspections, etc.). In the case of clinical trials, challenges have been experienced due to quarantines, site closures, travel limitations, disruptions in supply chain for investigational and ancillary products and infection of trial investigators and patients. All of these challenges may lead to discontinuities in the protocol management and data integrity of trials, which threatens to devalue the considerable investment by patients, investigators, healthcare organisations and sponsors.
2. **Maintaining clinical research in Europe requires clear guidance and flexibility under these challenging circumstances.** Even where infection hasn't directly intervened, quarantine, social distancing and broader COVID-19 concerns may prevent patients from being able to reach the trial site. Organisations managing and sponsoring clinical trials are also experiencing a higher proportion of staff working from home during this period. Monitoring, data collection, investigational products supply and lab and imaging work may be affected. This is leading to reports of protocol and standard operating procedure deviations due to missed visits, or changes in processes. Flexible approaches (e.g. remote monitoring, homecare visits, direct shipment of drug) that maintain the standards of GCP but with managed alternatives to ensure trial integrity and patient benefit are urgently needed.

**Conduct of vaccine clinical trials** – vaccine manufacturers have put on-hold or are adapting the design of ongoing trials impacted by COVID-19 measures. In order to ensure the continuum of development plans, we need **EMA/HMA to allow a rapid restart of studies put on hold after the crisis, as well as expedited review of amendments of impacted trials.** In addition, timelines for evaluation of new Clinical Trials Applications (CTAs) should follow the normal timelines as much as possible.

3. The oversight of clinical trials is done at national level which may result in a patchwork of solutions - a **pan-European approach (consolidated guidance, good practice sharing, points to consider) may mitigate and slow down the disruption of clinical research. International alignment** on these measures beyond Europe would also ensure that this exceptional situation is consistently addressed in the global programme of clinical research, for the reliance of all patients and healthcare systems around the world.



4. We welcome the CHMP's statement of March 16, which sets out some important principles for clinical research under consideration. However, **we call on the European Commission, EMA and the Heads of Medicines Agencies to meet with clinical research sponsors and CROs as soon as possible to discuss arrangements to support ongoing clinical trials in Europe that are being affected.**
5. We take note that the EMA has released **on 20 March 2020** as specific Guidance on the Management of Clinical Trials during the COVID-19 (Coronavirus) pandemic ([https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/guidanceclinicaltrials\\_covid19\\_en.pdf](https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/guidanceclinicaltrials_covid19_en.pdf)). **Our regulatory experts are currently analyzing the Guidance and will finalize their observations by 29 March. We regret that the Guidance leaves a wide spectrum to Member States to act as they wish instead of endorsing a more unified and harmonized approach. We will revert with any additional information during the call on 27 March after we have taken stock of the contents of the guidance.**

We appreciate the guidance issued last Friday by EMA, the GCP Inspectors Working Group, the Clinical Trials Facilitation and Coordination (CTFG, HMA), the Clinical Trials Expert Group (CTEG) and the European Commission (EC). The flexibilities indicated will support the continuation of clinical research in these challenging times, as far as possible. However, **we still need National Competent Authorities (NCAs) to also align and apply these flexibilities to the trials in their jurisdictions, and we would ask the EU authorities to proactively engage with all NCAs to achieve this in practice.**

Because of pressures on healthcare systems, companies are still halting trial recruitment and trial beginnings in many cases. Practical changes are being explored to address clinical design requirements (e.g. endpoint measurement) where in-person clinical visits are not possible. The impact of these collective changes has the potential to weigh down the European clinical research environment for many months to come, and we are seeking solutions with the EU and Member State authorities that are efficient (e.g. limited requirement for substantial modifications) and effective (e.g. preserving data integrity).

We are looking forward to engaging with the Biostatistics Working Party and the EU and HMA authorities on the forthcoming guidance addressing data integrity to manage the extensive impacts on the clinical research currently underway in Europe. The concerns we have put forward are echoed in a recent BIO/BioCentury survey on the impact of COVID-19 on clinical trials globally. The survey highlights that Europe remains the region of highest concern for initiating clinical trials and of high concern (together with the US) for active trials. This reflects both our considerable investment in Europe for clinical research as well as the circumstances we are facing.

## Regulatory

1. **Remote audits/Self-certification** – in order to ensure the continued operation of manufacturing facilities, EFPIA members are currently limiting access to facilities (including for own employees) only to essential workers. **Given the exceptional circumstances, we call upon EMA and national regulatory agencies to consider the possibility of a 30-day delay in the currently scheduled regulatory audits, or accept a process of remote audits or allow for company self-certifications.**



2. **Packaging and labelling flexibility** – fulfilling demand for medicines/vaccines/medical equipment also depends on the ability of manufacturers to easily move stock, in large volumes, from one Member State to another. **We call upon the EMA and regulatory authorities to waive certain packaging and labeling requirements for their national markets in order for manufacturers to be able to shift existing stocks to where the patient need is highest.**
3. **Companies are being requested by some market regulators to prioritize the manufacture and supply of domestic pack variants over export for products that have been identified as medically critical.** While we fully understand their approach, there is a risk that this leads to an imbalance for other European markets. It is important to continue to take a ‘one Europe’ approach despite the difficult situation and allow companies to balance their own order fulfilment in order to ensure supply can reach patients in other countries. On the other hand, in the same spirit, we need support from authorities to avoid that the supply that is sent to address the needs of some markets ends in other markets.
4. **Clarification of regulatory submission prioritization** – At least one EFPIA company has received the information from the French Regulatory Agency (ANSM) that variations, which are not directly related to Covid-19 or useful to avoid any shortage, should be delayed for the time being. As the EU regulatory procedures are largely shared between EU regulatory agencies (eg. CP, MRP/DCP, work sharing), **EFPIA asks EMA/HMA to clarify if there are common prioritization rules to be followed by industry and what are these rules.** This will allow manufacturers to plan their activities accordingly.

#### World-wide/Strategic

1. **Export bans (India)** – the same export restrictions which affect manufacturing and distribution within the European Union are enacted worldwide as well, especially by India. **We call upon the European Commission to address this topic at the highest diplomatic level.**

We welcome the increasing contacts between Commissioner Kyriakides and her Indian counterpart on the coronavirus situation. **We hope this communication channel will help us to address the restrictions in place in the India market, which are becoming critical particularly for APIs. These export permits allowing companies to import APIs from India have not yet been approved by the Indian Government and we need European authorities to ensure this situation is addressed as soon as possible.** Furthermore, in addition to the export restrictions, the situation is now aggravated by the restrictions of mobility of Indian workers. We urge the Commission to get support from Indian authorities to secure letters allowing manufacturing employees and suppliers to go to work. It is important to ensure labour but also transportation and customer officials are available to allow free flow of trade.

We propose to **use the system of SPOCs** to immediately obtain exact information from companies to obtain an overview of those registered/authorized medicinal products/raw materials (both for human and veterinary use) that could be potentially impacted by these



measures. This could be done immediately at EU level and shared with national authorities – as opposed to companies responding to individual MS requests (on 26 March, Belgium launched such a data collection exercise).

2. **Proactive approach with the US** - More importantly we should learn from recent experience and the Commission should pro-actively reach out to the US administration where several companies have major manufacturing sites located in the US supplying the entire world market. We call upon the Commission to proactively set up a sustained dialogue with the US administration in order to avoid any unilateral US decision that could negatively impact the supply of medicines to Europe.

For the research-based industry, the ability to maintain manufacturing and supply chain operations without any hinderance with the US is perhaps more important than the same with China or India. For example, in the Boeing/Airbus case, one of the sectors put forwards for retaliatory tariffs are APIs. We urge both side, at this time, to refrain from further hindering trade in APIs as 26% of all APIs necessary in Europe come from the US.

3. **Air freight of critical medicines** – another emerging issue is the reduction in air traffic leading to less capacity to move medicines and materials around Europe and beyond. Pharmaceutical manufacturers rely on capacity in passenger flights to ship medicines and ingredients rapidly and securely. With the spread of the COVID-19 outbreak, we have seen a dramatic reduction in passenger flights that normally carry these pharmaceutical goods. We cannot find viable alternatives that allow manufacturers to continue the much-needed flow of goods required to maintain production of medicines for patients. Addressing this issue requires coordination between the European Commission, Governments, air carriers, logistics operators and industry to ensure that we can continue to produce and ship medicines to where they are needed. The reduction of air freight should not be considered only from the angle of Asia (India and China are major sources of manufacturing) but also from the angle of USA where several companies have major manufacturing sites supplying the entire world market. We call upon the Commission to proactively set up a sustained dialogue with the US administration in order to avoid any unilateral US decision that could negatively impact the supply of medicines to Europe.



## **Appendix 1**

### **Ongoing R&D programmes (up to 26 March 2020)**

#### **Treatment developments**

- [AbbVie](#) announced it is partnering with global authorities to determine the effectiveness of HIV drugs in treating COVID-19. AbbVie is supporting clinical studies and basic research with lopinavir/ritonavir, working closely with European health authorities and the U.S. Food and Drug Administration (FDA), Centers for Disease Control and Prevention, National Institutes of Health and the Biomedical Advanced Research and Development Authority to coordinate these efforts.
- [AstraZeneca's](#) Research and Development (R&D) teams have also been working expeditiously to identify monoclonal antibodies to progress towards clinical trial evaluation as a treatment to prevent COVID-19. More than 50 virology, immunology, respiratory, and protein engineering experts across research, clinical, regulatory, and manufacturing are placing the highest priority on developing a treatment to minimise the global impact of the disease.
- [Eli Lilly](#) and AbCellera (Canadian biotech firm) have entered into an agreement to codevelop antibody products for the treatment and prevention of COVID-19. The collaboration will leverage AbCellera's rapid pandemic response platform, developed under the DARPA Pandemic Prevention Platform (P3) Program, and Lilly's global capabilities for rapid development, manufacturing and distribution of therapeutic antibodies.
- [EFPIA is working with the Innovative Medicines Initiative \(IMI\)](#) on potential actions to support collaborative research programs in order to fast-track the development of therapeutics.
- [Gilead](#) has initiated two Phase 3 clinical trials of remdesivir in countries with high prevalence of COVID-19. The company is also supporting two Phase 3 trials in China and a global Phase 2 trial led by the U.S. National Institute of Allergy and Infectious Diseases. Gilead donated drug and provided scientific input for these studies. Gilead has provided remdesivir to physicians for compassionate use to treat several hundred severely ill patients with confirmed COVID-19, and has accelerated manufacturing of remdesivir at risk, in anticipation of potential future supply needs.
- [GSK](#) is entering into the new collaborative research effort, the COVID-19 Therapeutics Accelerator. The aim of the Accelerator is to bring pharmaceutical companies and expert academic institutions into coordinated research programs, with the aim of bringing the most promising molecules forward that could be used to treat cases of COVID-19. GSK will contribute by making available compounds from its libraries for screening for activity against COVID-19. In addition, GSK is evaluating its marketed pharmaceutical products and medicines in development to determine if any could be used beyond their current indications in response to the pandemic. Further, GSK is evaluating options to make available specialised laboratory space to help in research and testing of COVID-19.
- [Johnson & Johnson](#), in partnership with the Rega Institute for Medical Research, University of Leuven (Belgium), are working to identify existing or new compounds with antiviral activity against COVID-19 that could contribute to providing immediate relief to the current outbreak.



- [Merck](#): As part of the global effort to investigate potential therapeutics for COVID-19 and Merck's support of independent research, Merck recently donated a supply of interferon beta-1a (Rebif®) to the French Institut National de la Santé et de la Recherche Médicale (INSERM) following a request for use in a clinical trial. The trial is sponsored by INSERM and its launch has been announced by the French Health authorities on March 11.
- [Novartis](#) announced that it has entered new collaborative research efforts such as the COVID-19 Therapeutics Accelerator, coordinated by the Bill & Melinda Gates Foundation, Wellcome, and Mastercard, as well as a COVID-19 directed partnership organized by the Innovative Medicines Initiative. Novartis is contributing by making available several compounds from its libraries that are considered suitable for in vitro antiviral testing. In addition, the company is rapidly evaluating other existing products to see if any could be utilized beyond their approved indications in response to the pandemic.
- [Pfizer](#) announced that it completed a preliminary assessment of certain antiviral compounds that were previously in development and that inhibited the replication of coronaviruses similar to the one causing COVID-19 in cultured cells. Pfizer is engaging with a third party to screen these compounds under an accelerated timeline and expects to have the results back by the end of March.
- [Pfizer](#) also outlined a detailed 5-point action plan to battle COVID-19. The plan includes a commitment to sharing its clinical development and regulatory expertise to support other smaller biotech companies that are screening compounds or existing therapies for activity against the virus causing COVID-19.
- [Regeneron Pharmaceuticals](#) announced an expanded agreement with the U.S. Department of Health and Human Services (HHS) to develop new treatments combating the novel coronavirus
- [Regeneron Pharmaceuticals and Sanofi SA](#) started a clinical program evaluating Kevzara, originally a drug to treat arthritis, in patients hospitalized with severe COVID-19. Kevzara is a fully-human monoclonal antibody that inhibits the interleukin-6 (IL-6) pathway by binding and blocking the IL-6 receptor. IL-6 may play a role in driving the overactive inflammatory response in the lungs of patients who are severely or critically ill with COVID-19 infection.
- [Roche's](#) Actemra was approved by China on March 5 to treat Covid-19 patients with lung complications. Roche has donated nearly \$2m-worth of Actemra to China to help the country manage the COVID-19 outbreak". Actemra has been on the European market since 2010 for treatment of several kinds of arthritis.
- [Roche](#) announced that they are working with the Food & Drug Administration (FDA) to initiate a Phase III clinical trial to evaluate the safety and efficacy of Actemra in hospitalised adult patients with severe COVID-19 pneumonia. This is the first global study of Actemra in this setting and is expected to begin enrolling as soon as possible in early April with a target of approximately 330 patients globally, including the US.
- [Takeda](#) announced that it is initiating the development of a drug to treat people infected with the novel coronavirus. The experimental drug would be derived from the blood of coronavirus patients who have recovered from the respiratory disease. In parallel, Takeda is also exploring whether currently marketed and pipeline products may be an effective treatment option for infected patients.

Source: <https://www.ifpma.org/subtopics/novel-coronavirus-covid-19-industrys-rd-efforts/>

#### Diagnostics :



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- [Roche](#) announced that the FDA issued an Emergency Use Authorization for its diagnostic kit cobas® SARS-CoV-2 Test, advancing coronavirus testing to meet urgent medical needs. Roche is committed to delivering as many tests as possible and is going to the limits of production capacity.
- [Takeda](#) is partnering with public entities and other pharmaceutical companies through the Innovative Medicines Initiative (IMI) in Europe to leverage collective expertise in the hope of developing diagnostics for COVID-19 as well as inhibitors to help prevent future outbreaks.

Source: <https://www.ifpma.org/subtopics/novel-coronavirus-covid-19-industrys-rd-efforts/>

### Vaccines Europe - List of projects for the development of a coronavirus vaccine (16 March)

- **CureVac** is developing a mRNA based prophylactic vaccine against SARS-CoV-2, funded by CEPI and in collaboration with CEPI. Curevac is preparing a clinical study that expects to start in early summer in Germany and Belgium. Curevac is in contact for scientific advice on this vaccine development with EMA, PEI (Germany) and with FAMHP (Belgium).
- **GSK** is supporting vaccine development by providing access to its pandemic vaccine adjuvant platform to selected institutions and companies with promising vaccine candidates. In doing this we are contributing to a coordinated effort, focusing on the most promising approaches to enable development of strong candidate vaccines for COVID-19. Access to our adjuvant technology is being provided through CEPI, the Coalition for Epidemic Preparedness Innovations or directly, in bilateral agreements. So far, we have announced two collaborations one with the University of Queensland and the second with Clover, a Chinese company and other collaborations are under discussion. In the pandemic flu setting, our adjuvant system has been shown to be antigen-sparing, i.e. less of the antigen is needed per dose to protect an individual than would be needed in a vaccine without the adjuvant included. If this is shown to be the case with our adjuvant system for COVID-19 vaccines, we would be able to protect more people, as less antigen would be needed per person, a crucial advantage in the case of a pandemic where high numbers of doses are needed for broad protection and manufacturing capacity is limited.
- **Johnson & Johnson** has mobilised resources in response to the outbreak to develop a preventive vaccine candidate against this coronavirus, leveraging Janssen's AdVac® and PER.C6® technology, that provide the ability to rapidly upscale production of the optimal vaccine candidate. These are the same technologies that are used in the development and manufacturing of Janssen's investigational Ebola vaccine and are also used to construct the Company's Zika, RSV and HIV vaccine candidates. In addition, Johnson & Johnson is collaborating with regulators, healthcare organizations, institutions and communities worldwide to help ensure our research platforms, existing science and outbreak expertise can be maximized to stem this public health threat. Johnson & Johnson's efforts to expedite development and production of a vaccine are enhanced by the existing COVID-19 vaccine collaborations between Janssen and the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response (ASPR) at the U.S. Department of Health & Human Services. On March 13, 2020, a new collaboration was announced with the Beth Israel Deaconess Medical Center (BIDMC) to support the development of a preventive vaccine candidate for COVID-19. The parties



have commenced preclinical testing of multiple vaccine prospects, with the aim to identify by the end of the month a COVID-19 vaccine candidate for clinical trials.

- **MSD** have deep expertise in vaccines and infectious diseases. As a science-driven company that aims to address some of the world's biggest health care challenges they are carefully monitoring the situation. As an initial step, based on the information available at this time, MSD has established a team of scientists to assess internally available vaccine assets for potential to impact the COVID-19 and related viruses.
- **Pfizer** is working to advance their own potential antiviral therapies and is engaged with BioNTech on a potential mRNA coronavirus vaccine.
- **Novavax** Advances Development of Novel COVID-19 Vaccine. Vaccine candidate derived from coronavirus spike (S) protein. Matrix-M™ adjuvant expected to boost immune responses. Phase 1 clinical trial planned for late spring
- **Sanofi** announced in February 2020 a collaboration with the Biomedical Advanced Research and Development Authority (BARDA), part of the U.S. Department of Health and Human Services, to advance a novel COVID-19 vaccine candidate. Work is underway to leverage previous development of a SARS vaccine candidate using Sanofi's recombinant DNA technology. COVID-19 belongs to the same family of coronaviruses as SARS. Research materials can be produced relatively quickly for clinical testing because we have a licensed influenza vaccine based on this platform. Further, this technology has the advantage of being highly scalable, allowing Sanofi to potentially rapidly produce large quantities of the coronavirus antigen. Sanofi is also coordinating with the Coalition for Epidemic Preparedness Innovations (CEPI) and sharing its vaccine R&D experience and expertise to advance vaccine solution.
- **Seqirus** is providing scientific and technical expertise and its well-established MF59 adjuvant technology to the University of Queensland in Australia to help fast-track the development of their CEPI-funded n-COV19 vaccine candidate using novel molecular-clamp technology.

