# COVID-19 AND THE LIFE SCIENCES SECTOR



An article discussing the impact of the 2019 novel coronavirus disease (COVID-19) on the life sciences sector.

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The life sciences sector has been at the centre of efforts to respond to the COVID-19 pandemic. The sector has invested considerable resources into research and development (R&D) focused on COVID-19 diagnostics, potential treatments for COVID-19 patients and vaccines that could provide the public at large with immunity against COVID-19 infection. In parallel with R&D efforts, the sector has also been seeking to ensure undisrupted supplies of medicines and medical equipment, both for COVID-19 and other diseases, and the continued development of medicines for other unmet medical needs.

This article reviews some of the areas most impacted by COVID-19, namely, R&D, clinical trials, supply chains, regulatory compliance and intellectual property (IP). It also considers the steps taken by the industry and public bodies to minimise disruption to regular business activities and to promote the development and supply of medicines and medical equipment for use against COVID-19. Industry has turned its attention to finding ways to mitigate and resolve the pandemic, resulting in the short-term neglect of some other priorities. However, the flexibility and agility of the response across the sector is likely to result in medium and longer-term changes to ways of working which could benefit the sector as a whole, even if it also results in some challenges, particularly in the IP sphere.

## RESEARCH AND DEVELOPMENT

COVID-19 is at the heart of current R&D efforts, with the R&D response spanning a wide range of areas including vaccines, antigen and antibody testing, therapeutic medicines and respiratory devices. The R&D efforts in relation to therapeutics have focused on both novel medicines and the repurposing of existing medicines. Much of this R&D activity is in the form of collaborations, across both the private and public sector. Such collaborations allow stakeholders to share risk and bring the possibility of achieving quicker results.

It is clear from these collaborations, and a study relating to the search for a COVID-19 vaccine by the Coalition for Epidemic Preparedness Innovations, that many of the developers are small, or inexperienced in large-scale pharmaceutical development and manufacturing (*CEPI: CEPI publishes analysis of COVID-19 vaccine development landscape (9 April 2020)*). This increases the importance of collaboration across the industry, with large multinationals able to support smaller players in speeding up research processes and scaling up manufacture and distribution. Significant international co-operation will also be needed between governments, public health bodies and regulators to ensure that successful innovations can be brought to the global market both safely and quickly.

Examples of partnerships between the public and private sectors include the UK government's funding to support clinical trials investigating COVID-19 vaccines run by Imperial College London and by the University of Oxford.

The latter has entered into an agreement with AstraZeneca in relation to the large-scale manufacturing and distribution of the vaccine.

No longer at the top of the agenda, R&D outside COVID-19 has been significantly affected. Resources have been diverted to the front line in response to COVID-19. In addition, it has been, and continues to be, difficult for R&D sites to operate as normal within government social-distancing guidelines, leading some companies to announce temporary R&D shutdowns. In the long-term, these issues are likely to lead to delays in product launches and pipeline gaps. Pharma companies may look to transactions involving products in late-stage development to help fill any gaps in their in-house pipelines.

## CLINICAL TRIALS OF VACCINES AND MEDICINES

Across Europe, EU bodies and certain national authorities have released COVID-19-related guidance for clinical trials of vaccines for and medicines used in the treatment of COVID-19 and for clinical trials of other indications. However, given the national regulation of clinical trials, the guidance is not fully harmonised across the EU. The guidelines cover a broad range of topics but a notable theme throughout is the increased pragmatism taken by regulators. Most regulators have suggested a more centralised approach to monitoring activities and there has been a promotion of the use of technology and "virtual" methods where possible.

The industry has moved quickly to initiate clinical trials for COVID-19, but the pandemic has had a significant impact on trials in other indications that were ongoing (or planned) at the time of the outbreak. Perhaps unsurprisingly, there are reports of a material decrease in the number of new patients entering clinical trials for studies that are actively recruiting. This decrease is likely linked to guidance from a number of regulators on exercising caution in the recruitment for new trials.

Site closures and concerns about supply chain disruptions mean that alternative approaches to supply of medication and to monitoring of the trials (compliance, conduct, safety, quality and so on) are needed. The trials that are likely to progress most successfully in these times are the more innovative: the "tech-trials", where as much as possible is carried out virtually. It remains to be seen what the long-term impact of the global lockdowns will be for supply chains and the availability of active product ingredients, and its subsequent effect on whether trials can continue.

## SUPPLY CHAINS

Robust supply chains are the backbone of the world economy and crucial to the life sciences sector. Disruptions affecting suppliers, which control the worldwide supply of components of the pharmaceutical and medical device industry, can have a huge impact on the life sciences industry.

Demand shocks (sudden changes in the demand for goods given the same supply) and trade restrictions are extremely disruptive to supply chains. The COVID-19 pandemic has triggered both phenomena at an unprecedented level. It has become vital for pharmaceutical and medical device companies to be able to handle the sudden surge in demand for medicines and equipment. They have to keep up with demand, despite suppliers' factories shutting down production, reduced factory working hours, a reduced workforce and delivery delays. Meanwhile, some of their products are playing an increasingly important role in lifting lockdown measures. For example, in some EU countries, there are requirements for citizens to wear personal protective equipment (PPE) such as masks in public locations.

In an attempt to ensure the continued availability of medicines during the pandemic, regulators and governments have been taking steps to maintain supplies and to enable swift changes in manufacturing processes and supply chains. For example, the EU has been seeking to take a co-ordinated approach to avoid medicines shortages and supply disruptions across the EU, with the European Medicines Agency (EMA) co-ordinating member states' efforts to prevent and mitigate possible disruptions. This has involved establishing an EU Executive Steering Group on Shortages of Medicines Caused by Major Events and a system for monitoring ongoing or anticipated shortages of medicines used for treating COVID-19. In addition, the European Commission has published:

## EXPORT BANS

Demand shock has led national governments and the EU Commission to implement export bans in order to protect the local supply of PPE in their countries or within the EU. Member states, including Germany and France, initially introduced bans on exporting PPE to other EU member states and non-EU countries. The bans were only lifted after the EU put an export authorisation scheme in place on 14 March 2020, requiring an export authorisation before PPE could be exported outside of the EU (Implementing Regulation (EU) 2020/402; see *Legal update: COVID-19: European Commission Implementing Regulation requiring export authorisation of medical personal protective equipment published in Official Journal*). This Regulation entered into force on 15 March 2020 for a six-week period, after which it was superseded by Implementing Regulation (EU) 2020/568. The latter was valid until 26 May 2020 and was narrower in scope than its predecessor, as it covered fewer products and allowed the export to more destination countries without an export permit (see *Legal update: COVID-19: Commission Implementing Regulation (EU) 2020/568 requiring export authorisation of medical personal protective equipment published in Official Journal*). As Implementing Regulation (EU) 2020/568 has not been renewed, there are no longer any EU law restrictions on the export of PPE. Supplies within the customs territory of the EU were not restricted by either of the Regulations.

Experts have warned about the negative consequences of export bans, stressing that pharmaceutical and medical device supply chains need to work across borders. Export bans might lead to retaliatory measures from other regions that could affect the availability of medicines for European patients. Through restrictions, countries and regions risk isolating themselves and their citizens from the global supply network.

- Guidelines on the optimal and rational supply of medicines to avoid shortages during the COVID-19 outbreak (OJ 2020 C 116 I/01) (see *Legal update, COVID-19: European Commission guidelines on supply of medicines to avoid shortages during outbreak*).

- A Q&A regarding regulatory expectations during the COVID-19 pandemic, which details various regulatory measures including exceptional change management processes for changes in the supply chain and manufacturing of medicines for the treatment of COVID-19 medicines (see *Legal update, COVID-19: EMA issues guidance on regulatory flexibilities for marketing authorisation holders (EU)*).

Despite these measures at the EU-level, national governments continue to impose restrictions on the supply of medicines. For example, the UK government imposed restrictions on the parallel exportation and hoarding of 196 medicines as of 23 April 2020.

## REGULATORY COMPLIANCE

Regulators have demonstrated agility and responsiveness in the face of the COVID-19 pandemic.

The EMA moved quickly to permit all of its committees to sit virtually and announced that it would conduct a rolling review of the evidence supporting a marketing authorisation for a new indication for remdesivir in COVID-19. The EMA will consider the evidence submitted in each module of the application as and when it is submitted rather than waiting until the entire evidence package is complete. It seems likely that the EMA will reach a conclusion on the remdesivir application very shortly, which would represent an unprecedented two-month assessment time for any medicinal product in the EU.

The EMA has also announced measures for acceleration of development support and evaluation procedures for COVID-19 treatments and vaccines, including:

- Rapid and free scientific advice, reduced to 20 days compared to the regular 40/70 day time frame.

- Rolling reviews; each cycle normally requiring a two week review period.
- Maximum active review time for marketing authorisations reduced to 150 days from 210 days.
- Rapid provision of CHMP opinions on compassionate use.

(See *Legal update, COVID-19: EMA's expedited support and assessment procedures (EU)*.)

The EU-level Q&A regarding regulatory expectations during the COVID-19 pandemic (see *Supply chains*) also draws attention to regulatory flexibilities available to the developers of non-COVID-19-related medicines so as to reduce regulatory burdens during this time including:

- Zero-day mutual recognition procedures.
- Justified postponement of renewal applications.
- Automatic exemption from sunset clause requirements on request.

The medical devices industry, providing COVID-19 testing kits, ventilators and PPE, has been at the forefront of the pandemic. The European Commission has issued guidance to assist member states in providing derogations from EU regulatory requirements and permitting non-CE marked devices to be placed on their markets (see *Legal update, COVID-19: European Commission publishes Guidance document on medical devices, active implantable medical devices and in vitro diagnostic medical devices*). An example of a national government's approach to medical device regulation is the UK, which has been issuing its own specifications and requirements for the testing and approval of medical devices irrespective of CE marking.

In the US, the FDA has issued a number of emergency use authorisations for COVID-19-related products, including antigen and antibody testing kits, PPE, respiratory support equipment and medicines. This included the issuance of an emergency use authorisation for remdesivir for use in treating COVID-19 on 20 May 2020, following the announcement of initial positive clinical trial results by the National Institutes of Health.

## INTELLECTUAL PROPERTY

Despite some disruption to IP offices and courts hearing IP disputes, given the fundamental role of effective IP protection life sciences companies are broadly continuing to implement their IP strategy as usual, at least for activities outside of COVID-19. However, the life sciences landscape and traditional R&D model has temporarily changed in the light of the global concerted effort to address COVID-19. Currently, proprietary knowhow, libraries and clinical data are being shared on an unprecedented scale with the aim to develop diagnostics, therapeutics and vaccines. This framework of sharing and co-operation may also extend to manufacturing abilities in the event a diagnostic, therapeutic or vaccine is developed.

Companies are more likely to accept greater than usual IP risk now to facilitate a rapid response to COVID-19, but this may lead to more disputes in the medium to long-term.

Many companies are repurposing existing products for application against COVID-19. This is likely to lead to an increase in secondary patent applications, in particular for second medical use patents. In parallel, companies will need to consider how to enable the deployment of existing IP against COVID-19 without damaging the existing markets for their products that provide companies with the income necessary to invest in continued R&D.

In the long-term, the increase in collaborations within the life sciences industry, with other sectors and the public sector may foster a blueprint for a new pharmaceutical research model. This, in turn, is likely to lead to an increase in the IP issues associated with complex collaborations.

In addition, life sciences companies are facing calls from non-governmental organisations and some governments to waive their IP rights concerning COVID-19 products on a voluntary basis or otherwise be obliged to do so. The life sciences sector has responded by engaging in efforts to ensure that IP rights will not constitute a barrier to the availability of medicines for COVID-19, including by increasing internal manufacturing capacities and collaborating with third-party manufacturers. There has always been close scrutiny of pharmaceutical companies and the monopolistic nature of patents, which some see as contradictory to public interest. Yet the value of patents has never been more apparent than it is now. Patent incentives have established a strong technological foundation from which many inventions have been repurposed to respond as quickly as possible to COVID-19. Furthermore, patents have fostered innovation by permitting patentees to recover R&D costs, thereby providing an incentive for companies to invest in new lines of research, including research that may lead to new COVID-19 diagnostics, therapeutics and vaccines.

## LIFE SCIENCES AND COVID-19: FUTURE DEVELOPMENTS

The life sciences industry and other stakeholders have reacted with considerable agility and flexibility in responding to the COVID-19 pandemic and in ensuring that the supply of existing medicines and equipment continues with as little disruption as possible.

Given the evolving nature of the pandemic and the continuing search for effective treatments and vaccines, further industrial efforts, funding and adaptations to regulatory procedures are regularly being announced. As we are still at a relatively early stage of the pandemic, there remain many unanswered questions, including the extent to which the response to the pandemic will lead to lasting changes in the funding and R&D models for the life sciences industry, as well as to the regulatory framework for medicines and medical devices. There will certainly be many lessons learned for future health crises, as well as for the development and supply of medicines and medical devices outside of public health emergencies. However, it will likely be some time before it will be possible to assess properly the impact of disruption to the development of medicines and medical equipment outside of COVID-19 use.


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