

# After Brexit: Focus on the New Pharmaceutical Strategy for Europe

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**A**fter four and a half years of Brexit discussions and negotiations, the UK and the EU have managed to arrive at a trade agreement at the eleventh hour and avoid a hard Brexit. In the absence of an agreement, a hard Brexit would have been the default and would have had immediate and severe implications on (timely) access to medicines for patients. The deal

applies provisionally as of 1 January 2021, as it still must be ratified by, among others, the European Parliament. Notwithstanding, the trade agreement is welcomed by many stakeholders in the sector as it has lessened the uncertainty around the future relationship between the EU and the UK and has allowed for more clarity on future business operations.

Trade associations in the sector have called for continued regulatory alignment between the UK and the EU and while there is language on exploring continued (regulatory, I suggest) cooperation with EU institutions (i.e., the EMA) in the agreement, it is apparent that the UK regulator will pursue its own way. This is evidenced by their expedited reviews, and first worldwide approvals, of three different COVID-19 vaccines, the launch of the [Innovative Licensing and Access Pathway](#), and their search for [alternative partners beyond the EU for regulatory cooperation](#), to name but a few examples.

Along with forging this Brexit deal, the European Commission published its much-awaited [Pharmaceutical Strategy for Europe](#). This document spans a wide range of topics from antimicrobial resistance to reducing the impact of pharmaceuticals on the environment. While everything cannot be captured in this review, one notable initiative includes a proposal for an EU Health Emergency Response Authority (HERA). The COVID-19 pandemic has undoubtedly precipitated a desire for increased health emergency preparedness and augmented response planning. HERA will, among others, be responsible for identifying health threats, suggesting proper countermeasures, and addressing supply chain vulnerabilities (see more about the latter below).

Another rather significant proposal is to revise the legislation of medicines for children and rare diseases as outlined in an [Inception Impact Assessment \(IIA\)](#) on the subject. In IIA, the European Commission proposes to revise the legislation while dismissing non-legislative amendments, which is something industry would have preferred. Indeed, [a recent White Paper](#) proposes several non-legislative measures that would go a long way towards achieving the objectives outlined in IIA. Some of these proposals were already at hand and agreed on quite some time ago but were unfortunately delayed because of Brexit.

One of the objectives in IIA centers on unmet need. To this end, incentives are suggested to be (re)directed to areas of unmet need. Some novel rewards, such as transferrable vouchers, are also considered; reducing incentives, such as the six months Supplementary Protection Certificate, is proposed in areas not considered to be unmet needs. However, such topics are probably areas in which one should tread carefully. [A recent study](#) did lend evidence to the notion that incentives in the Orphan Drug Regulation were rather effective in promoting the development of new (paediatric orphan) drugs while the Paediatric Regulation, which is based on obligations, was not successful in delivering on one of its core objectives (i.e., more paediatric drugs).

Another objective in IIA focusses on access, which is to be facilitated by incentives contingent on market launch and the encouraged use of generic and biosimilar drugs. This is another area which requires careful consideration as there are many additional players with whom industry must negotiate above and beyond the regulators, such as HTA bodies, payers, local procurement bodies, and others, to make new drugs available to patients.

A third suggestion is to create a European Health Data Space. The EU pharmaceutical industry is seen as a strategic asset for public health, economic growth, jobs, trade, and science. Efficient access to (real-world) health data does provide a competitive edge, and interlinking health data across the EU is conducive to evidence generation supporting the development of (new) therapeutic entities. Accordingly, the Commission proposes to establish an interoperable European Health Data Space to improve exchange, access, and cross-border analysis of such data.

The European Commission also wants to address and improve regulatory efficiencies, including but not limited to bringing the “EU regulatory approval times onto par with those in other parts of the world.” This is an ambition that the industry has sought for quite some time and data show that [the EU regulatory system is significantly slower than its peers](#). The European Commission also wants to “develop and implement electronic product information,” the benefits of which cannot be underestimated and [a previous article](#) has discussed.

One final idea put forward is to introduce stronger obligations related to medicine supply and shortages. The European Commission thinks that shortages have been a concern in the EU for many years and that the situation worsened during the COVID-19 pandemic. To this end, they propose to “initiate and steer a structured dialogue with the actors in the pharmaceuticals manufacturing value chain.” This welcome suggestion fully aligns with industry’s desire to create a high-level forum to discuss this topic.