Brexit, health care, and life sciences: plan for the worst

Negotiations continue between the UK and the EU27 for Brexit plans. Deal or no deal, leaders in health care, pharmaceutical, and life sciences are covering all bases. Becky McCall reports.

Following last week’s snubbing of the UK Government’s proposed Brexit plan by European Union (EU) leaders in Salzburg, anxiety continues to escalate around a potential no deal scenario. With just over 180 days until the UK exits the EU, several crisis scenarios are being played out to pre-empt possible food and medicine shortages, taking into account possible space constraints and security meltdowns. But healthcare, pharmaceutical, and life sciences leaders continue to express concern about what the future could hold—deal or no deal. “Hope for the best, but plan for the worst”, says Niall Dickson, co-chair of the Brexit Health Alliance, an organisation that aims to safeguard the interests of patients, health care, and research during negotiations around the UK’s exit. “The short-term question is getting over the end of March next year, but the bigger question is with the longer-term consequences, especially if there is no deal.” Uncertainty is writ large over how relations between the UK and EU will fare after March, 2019. But across pharma and the life sciences there is an overall sense of unity.

Mike Thompson is chief executive of the Association of the British Pharmaceutical Industry, which represents the interest of British pharma. He is encouraged by negotiations to date. “I have not heard one discordant voice from the life sciences ecosystem across Europe. The industry is unique as a sector in asking with one voice, representing both negotiating parties, saying that we want to stay working together.”

In preparation for no deal and the concerns around a potential medicines shortage, the UK Government has produced technical notes to guide the pharmaceutical industry, National Health Service (NHS) organisations, general practitioners, and pharmacies. Hugo Fry is the UK managing director of Sanofi, the French pharmaceutical company that started preparing for Brexit in March, 2017. “We are doing everything we can to mitigate this risk. For the NHS, patients, and pharmacies, it is business as usual as far as Sanofi medicines go. We will absorb the necessary financial pain on this one, which we are happy to do”, he says.

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The European Medicines Agency (EMA) has been actively monitoring how pharmaceutical companies are preparing for Brexit. According to EU law, the marketing authorisation holder, the qualified person for pharmacovigilance, the pharmacovigilance system master file, and certain manufacturing sites need to be based in the European Economic Area for a company to be able to market a medicine in the EU. This week, the EMA highlighted some potential supply issues relating to centrally authorised medicines (CAPs) in the EU. For 39 of these CAPs, the EMA has concerns that there could be supply shortages, because they still have an important step in the regulatory processes based in the UK. However, this number has decreased from earlier this year, when the EMA was concerned about 88 of these CAPs.

The UK Secretary of State for Health and Social Care Matt Hancock recommended that pharmaceutical companies stockpile an extra 6 weeks of drug supply to buffer any effect of no deal. His guidance also provides for a no-deal scenario, in which case the UK will continue to accept products that have been batch tested and released in accordance with EU rules. Hospitals, general practitioners, and pharmacies have been told not to stockpile additional drugs and devices or write longer-lasting prescriptions. Over-ordering is subject to investigation.

Currently, the EU is not reciprocating. “The EFPIA [European Federation of Pharmaceutical Industries and Associations] has highlighted to the European Commission that, in the event of a disorderly withdrawal, medicines currently exported from the UK to the EU27, would be subject to additional requirements”, explains EFPIA Director of Public Affairs, Elizabeth Kuiper. This could delay or prevent supply to patients—despite the efforts of our member companies. The EFPIA has called on the Commission to introduce some flexibility in this area, given the very specific challenges.

Certain products that cannot be stockpiled, such as some vaccines, present a greater challenge and might require airlifting, recommends the UK Government. Fry says airlifting is manageable, but stresses that a workable solution will need to be found in the short-term to mid term. “If under a no deal scenario, border delays carry on for months, then we might start
running into difficulties, in particular over flu vaccines. We ship around the end of August but might need to look at alternatives.”

With 45 million medication packs being exported from the UK to the EU monthly and 37 million shipping the other way, a deal of some sort is needed, he says. Dickson points out that other products—for example, insulin—are not made in the UK at all. Conversely, a prostate cancer drug is only made in the UK and supplies 80 countries, including all of Europe. “If the UK and the EU do not plan properly, both sides will suffer”, he stresses.

The organisation of the regulatory governing body is also a factor to take into account. At the moment, the UK Medicines and Healthcare products Regulatory Agency (MHRA) and the EMA work together. For the time being, the shared understanding is that, after Brexit, any existing marketing authorisations will be recognised by MHRA, but any new applications to EMA happening mid-Brexit will have to start the process again to ensure recognition by MHRA.

Going through a regulatory approval process is very lengthy and administratively heavy. “It may be that if [the UK] have to have [their] own separate regulatory system, then manufacturers will choose to launch [their product] in Europe and the USA...”

Monitoring is also likely to be affected. “Infectious disease control, for example, has one early warning system, one single database— it simply does not make sense to have two disconnected databases, for either party.” There is also one database for pharmacovigilance hosted by the EU, with British doctors providing 38% of alerts this past year. “Without these UK safety alerts, patients in Europe will be significantly disadvantaged.”

Pan-EU research projects are also central to any health-care and life sciences negotiations. Thompson points out that the UK is the third largest biopharmaceutical research cluster outside the USA and it is not in the EU’s interest to be disconnected from the UK base. “At a time when lots of money is being channelled into China, Europe could become a poor third [after the USA]. It really is not the time for Europe to further disaggregate.”

The EU Commission’s proposal for Horizon Europe, the foremost EU €100 billion research and innovation programme (2020–27), which will succeed Horizon 2020 and includes the UK, is currently under negotiation. Kuiper, representing the EU, agrees with Thompson. “Securing ongoing research collaboration between the UK and EU remains a priority for EFPIA. UK-EU scientific collaboration strengthens the EU’s global position in life sciences, attracting investment to the EU.”

In relation to Horizon Europe, Kuiper adds that “the framework of Horizon Europe contains some provision for third countries to participate in the scope of the programme”, which could, in theory, provide another route for the UK to work within this framework, although the UK would have to negotiate this.

Both Dickson and Thompson recognise the UK’s leadership in public health. Mark Weiss from the UK’s Faculty of Public Health, emphasises the effects of potential trade agreements on public health.

“The UK is a world leader in public health, and this can be converted into a competitive advantage as we develop our trade policy. In fact, our future trade agreements will have a far greater impact on the public’s health than the increased NHS funding of £20.5 billion”, he asserts.

“As we leave the EU, if we hope to develop a healthy economy based on the most productive and healthy workforce possible, it will be important for the public’s health to be core to trade negotiations.”

Of note, the government has committed to the EU public health duty known as do no harm after Brexit. “Recognising that threats to the public’s health do not respect borders, this commitment includes an unequivocal guarantee that our public health protections and standards will be the same or higher when we’ve left the EU”, explains Weiss.

Hardly a day passes without a new and often unexpected challenge with Brexit, but compared with other sectors, health and the life sciences seem to inspire more confidence overall.

However, Thompson acknowledges the challenges remain, and, with time running out, “whether the details of any specific sector will be understood by those doing a complex negotiation at 2AM is the bit that worries us all.”

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