Regulation of medicines, biotechnology devices and healthcare products

On 20 November 2017 the European Medicines Agency (EMA) announced their intention to relocate from London to Amsterdam due to the UK’s decision to leave the European Union. It is nearly 12-months to the day since this announcement, and, other than the movement of a major regulatory headquarters, the UK is no closer to knowing what impact Brexit is likely to have on the regulation of medicines and healthcare products in the UK.

So what happens if the UK and EU fail to come to an agreement and the UK leaves the EU without a deal? How will our medicines be regulated and who will regulate them?

The second question was answered in part by the UK Government in its collection of guidance technical papers published in August 2018 entitled ‘How to prepare for a no-deal Brexit’. These papers propose that the Medicines and Healthcare Products Regulatory Agency (MHRA), currently an executive agency of the UK Department of Health and Social Care, would become a stand-alone regulator, making decisions and carrying out functions that are currently undertaken at an EU level. This would include decisions on marketing authorization, pharmacovigilance reporting and paediatric investigation plans. Following this announcement, the MHRA has also issued a consultation on the proposed changes required for legislation and regulatory processes in the event of a no-deal Brexit.

While it is good news that both the Government and the MHRA are preparing for a no-deal Brexit, there are many who hope that the negotiations will go favourably and the UK can remain part of the EMA. The remit of the EMA extends beyond just the marketing authorization of novel medicines and biotechnology devices. It has removed multiple barriers and rationalised costs for new treatments entering the market. With a centralised process and a market of over 500 million, European patients are often some of the first in the world to access new treatments - sometimes months and years before patients in other parts of the world.

It is no surprise then that a number of the big pharmaceutical companies, including AstraZeneca and Eisai, publically petitioned the UK Government to commit to a centralised process for drug regulation and to remain within the EMA. Submitting applications to marketing authorization bodies is already a lengthy and expensive process and it is no wonder that pharma would prefer to go through a single regulator. A centralised process is not just advantageous for the manufacturer. Patients across the EU also benefit as having multiple regulatory bodies across Europe, all within the same regulatory framework, means that the workload is shared, and medicines are therefore approved more quickly, with patients having faster access to new and life-saving treatments. There are concerns that an independent UK, with a market of only 65 million, will not be able to negotiate the same pricing deals and the NHS may end up paying more for treatments that are available at a much cheaper cost in the EU. While the EMA is by no means perfect, Members of Parliament also see the sense in a centralised marketing authorization process, with a vote in June this year showing a majority voting in favour of the UK remaining in the EMA.

Despite this show of support, whether or not the UK remains part of the EMA is dependent on the outcomes of the Brexit negotiation process and, at the time of writing, the respective parties are yet to come to a deal.

So what happens if the UK and EU fail to come to an agreement and the UK leaves the EU without a deal? How will our medicines be regulated and who will regulate them?

The second question was answered in part by the UK Government in its collection of guidance technical papers published in August 2018 entitled ‘How to prepare for a no-deal Brexit’. These papers propose that the Medicines and Healthcare Products Regulatory Agency (MHRA), currently an executive agency of the UK Department of Health and Social Care, would become a stand-alone regulator, making decisions and carrying out functions that are currently undertaken at an EU level. This would include decisions on marketing authorization, pharmacovigilance reporting and paediatric investigation plans. Following this announcement, the MHRA has also issued a consultation on the proposed changes required for legislation and regulatory processes in the event of a no-deal Brexit.

While it is good news that both the Government and the MHRA are preparing for a no-deal Brexit, there are many who hope that the negotiations will go favourably and the UK can remain part of the EMA. The remit of the EMA extends beyond just the marketing authorization of human medicines; they monitor pharmacovigilance, administer the granting of orphan drug status and regulate veterinary products and devices. A centralised authorization process is positive for industry, positive for patients and positive for global health. A UK departure from the EMA will only be to our detriment for the foreseeable future.

If you wish to get involved in the Policy Spotlight or join the Policy Network, please email biopol@biochemistry.org.