Hurry Up and Wait: Brexit from a Regulatory Point of View

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You Brexit, You Buy It – Europe and the New Regulatory – Part 1 of 2

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With Brexit looming, questions and concerns hover like a grey cloud over the UK pharmaceutical industry. Industry insiders and colleagues in London found that the confusion surrounding what comes next was offset by a constant and wearying news update on Brexit. The resignation of Prime Minister Theresa May on Friday, May 24, 2019 did not bring any more sunshine to the situation. Regulators have to find a way forward to proceed to an understanding of how to deal with the changes, and revolving dates.

Up to now, the best resource for any questions and answers related to the UK's withdrawal from the European Union is the latest revision (04), published on February 01, 2019 that covers medicinal products for human and veterinary use within the framework of the centralized authorization procedure, established by the European Medicines Agency (EMA). https://www.ema.europa.eu/en/documents/other/questions-answers-related-united-kingdoms-withdrawal-european-union-regard-medicinal-products-human_en.pdf

Separation Anxiety: Brexit

With the primary Brexit date having been set for March 29, 2019, a large number of companies have by now prepared for the transfer of their marketing authorization to a holder established in the EU. But if your company has not yet performed this task then I would recommend the transfers be completed sooner rather than later. Since the original exit date for Brexit has passed and an extension has been granted to October 31, 2019 , it is recommended to have your marketing authorizations transferred as soon as your company has decided where in the EU it will reside.

What is a Regulator to Do?

As soon as a company determines the country the marketing authorizations (MA) will be transferred to, there are a number of procedures and steps to take. Transition of MA, batch testing, manufacturing and batch release processes, referral procedures and submission of safety information originating in the UK per the regulations provided by the EMA and the European Commission. Additional facilities could also be set up in new EU country, which will entail additional costs.

The MHRA regulates medicines, medical devices and blood components for transfusion in the UK. MHRA is an executive agency, sponsored by the Department of Health and Social Care.

As dates are in flux will continue to be modified, I highly recommend that as a regulator you keep an eye on the Brexit-related guidance for companies.

The EMA document relating to the UK withdrawal provides the most current information, via a series of guidances, for any regulator handling the transfer of marketing authorizations, manufacturing and batch release processes, referral procedures, and submission of safety information originating in the UK. Also included in this series of documents is information on the issuing of EMA certifications. EMA was not printing these certificates from February 25 – March 14, 2019 due to the relocation of the Agency to the Netherlands.

Check Box

About the only item marked complete in the Brexit Regulatory environment has been the closing of the EU main office in the UK and the opening of the new EU Regulatory Affairs office in the Netherlands. In November 2017, the European Council voted from a list of 19 cities on where to move the EMA headquarters and Amsterdam won. Not all the 900 staff members of the EMA relocated, but as of March 4, 2019, the official address of the Agency is that of its permanent building in Amsterdam Zuidas.

European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

From 11 March 2019, all EMA face-to-face meetings take place at EMA's temporary premises in Amsterdam, the Spark building, until EMA moves into its permanent facilities. The address below is for attending EMA meetings:

European Medicines Agency
Orlyplein 24
1043 DP Amsterdam
The Netherlands

Slowing to a Standstill, Grinding to a Halt

Although the initial hope for the MHRA to maintain the close relationship with EMA during the transition timeframe has all but vanished, the EMA has reallocated MHRA's marketing authorizations to other existing EU

No company should sit and wait for the final date, now set for October 31, 2019, to begin the transition process. I recommend that the process begin now. With so many procedures and changes that will need to be made to the various MA, the reviews will take time because the new country may not be as knowledgeable as the UK has been. This can become a lengthy process and it may hinder the supply chain of products to clinical trials and patients.

New Facilities and Higher Costs

In May 2019 the EMA and the European Commission informed UK companies of the need to set up facilities within mainland Europe if they wished to continue importing medicines into the EU after Brexit. A "batch control" site within a member state would have to be established to confirm the drug had been manufactured in accordance with EU requirements, as well as "pharmacovigilance" teams to monitor the safety of medicines. Some companies have moved forward and have set up additional facilities for specific requirements, and others still seem to be pondering the need to move forward. The cost associated with having duplicate facilities during the transition is an additional expense that will eventually be passed onto the patient populations.

Understanding Changes

The EEA and the European Commission have created guidances that will assist any regulator in the process and requirements for the transfer of MAs to a EU country. The regulator needs to be monitoring the documents regularly, to keep abreast of the agency's updated guidances.

Brexit for the pharmaceutical industry is a disappointment because of all the knowledge that has been developed over the years being shifted away from the UK. The question is how well will the industry survive after all is said and done. The UK will now be a third country and they will have to rebuild. Some fragments of the industry may become stronger, such as the Biotech sector. The MHRA will have to collaborate with Europe, and may find a way to stimulate innovation in drug development stemming from the UK as well.

Regulators keep guiding the management of the transition for the pharmaceutical, medical device, biotech, and veterinary companies so that the supply chain of valuable products for many patient populations can be maintained. Over the next few months there will be additional updates to the current timelines and expectations that can be evaluated. New companies and new direction for existing companies may rise out of the conceivable chaos. In part II of this column, we will give an update on the changes as additional information becomes available.

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