Hurry Up and Wait: Brexit from a Regulatory Point of View – Part 2

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

By Lynn Hansen, Director of Clinical and Regulatory Affairs, Pharmatech Associates

In Brexit Part 1, I expressed my Brexit thoughts as Theresa May was providing a tearful resignation and now the United Kingdom has the return of an energetic Boris Johnson, one of the primary proponents of Brexit and new Prime Minister (PM), who has brought back Brexit supporters to his cabinet, ousting the cabinet Theresa May had in place.

For this new stage, I would like to provide a more positive side to this adventure instead of the dread and gloom of the negative side of Brexit. As the PM stated in his first address to the House of Commons, "Brexit will take place on the 31st of October, for the purpose of uniting and reenergizing our great United Kingdom. Making the UK the greatest place on earth."

Deal or No Deal

The primary positive for the life sciences community is that there are contingency plans, in the form of numerous government guidance/instructions developed for "a Brexit deal" or "no Brexit deal." A regulatory professional in the UK can find and follow Brexit guidance for business in the number of guidances provided. So far, most of the documents I have reviewed carry the following statement: "Leaving the EU with a deal remains the government's top priority. This has not changed. However, a responsible government must plan for every eventuality, including a no deal scenario. We are continuing with our no deal planning to ensure we are fully prepared."

Another positive is the implementation period for the life science sector. The UK and EU agreed the terms of an implementation period will be honored to the end of December 2020. This informative document will guide the Life Sciences community through the period before, during, and after Brexit for their company's regulatory status.

It's important to note that 2020 is a very full year of regulations for the UK/EU sectors, new Clinical Trials Regulation (CTR), EU Medical Devices Regulation (MDR) will fully apply from May 2020, and new EU Regulations

MHRA and ICH

Another positive will be when the UK's Medicines and Healthcare Regulatory Agency (MHRA) becomes the UK regulatory authority once again, it may end up obtaining their own seat on International Council on Harmonization (ICH). The MHRA, as the UK's representative, currently participates in the ICH as part of the EU's delegation, and sits on many of the ICH's expert working groups, allowing it to influence international standards. MHRA often is more progressive and open-minded than other European Agencies and may help advance changes faster.

Professor Boyd from the Academy of Medical Royal Colleges has stated: "It will be very important that the UK gets a seat at that table because that is what controls medicines regulation on a global basis. Again, it is something that has not been talked of very much, but it is a very important group and is an example of our international influence."

Since the beginning of the EU Life Science community, the MHRA has created and provided high standards that have been incorporated into the EU guidelines and regulations. Compliance with these guidelines and regulations will continue in the EU and in the UK due to these becoming national laws.

After Brexit, the UK can apply for Observer status at the ICH and then for full membership, as a Regulatory Member, after two years. Big pharma also has a concern that the UK's absence from the EU decision-making will shift the regulatory sectors towards a more precautionary environment. A more precautionary environment can be the beginnings of a less supportive side to innovation.

Living and Working Post-Brexit

I asked some Life Sciences professionals what they consider a positive aspect of Brexit and, although change is hard for anyone to handle, they all confirmed that the UK will continue to provide the highest standards for protecting all patients, while at the same time continue to research into more options in more areas to benefit mankind.

My own team of Life Science professional includes a couple of UK Qualified Persons (QP), and a regulator within global big pharma. In the UK, a QP must be an experienced professional with an in-depth critical understanding of pharmaceutical manufacture and distribution. It is a legal requirement for every manufacturer of pharmaceutical products to have a QP. A QP is on the front line for the certification and release of every batch of each product; the QP is essential to the safe control of medicines. UK QPs will be in the same level of demand. However, their role will be "weakened" exporting into the EU, and the current shortage of QPs will be worsened by the amount of certification now needed from imports from the EU.