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Regulations Post-Brexit Impact on Pharma & LifeSciences

Q & A

24/08/2021

Now that the Brexit transition is over and we can look back, what was the cost to the pharma industry as a result of Brexit and the difficulties with the supply of safe and compliant medicines?

Brexit has cost the industry a lot in terms of hours and money. Resources that could have been spent on innovation and strengthening compliance and cooperation across the block; were instead diverted to Brexit planning and risk mitigation. Supply of medicines has not been disrupted as a result of the combined effort and cooperation between the MHRA, EMA and competent authorities in other EU member states.

So, what did those authorities do in those instances…

Companies supplying medicines into or from the UK were encouraged to act early.
- For those supplying from manufacturing or importation sites in Britain, arrangements were made to remain in compliance with the new EU rules, such as moving Batch control testing and providing for EU27 or Northern Ireland QP's and QPPV's.
- For sites supplying into Britain from the EU, the MHRA acted quickly to define their requirements and industry either adjusted their supply chain or obtained new WDA authorisations with the required Responsible Person for Import or RPi to allow them to continue to import medicines into Britain from the EU.

What would you say have been some of the most difficult challenges in getting ready for the Brexit transition?

There have been significant difficulties and, as Consultants, we have witnessed first-hand the challenges experienced by Industry for example, managing the new UK import checks for companies with their primary presence in the EU, that wished to continue limited supply into the UK.

Not all existing 3PL partners had the capacity to manage the new import checks; particularly for their smaller clients. This resulted in some of these smaller EU based companies having to either relinquish

the ownership of their stock to established wholesalers and hence control over sales and promotion, or alternatively having to obtain a WDA in their own name including an associated RP and RPi.

And what about difficulties for UK manufacturers?

And in the other direction the changes to free trade arrangements meant that British manufacturers could no longer access EU markets and sell their medicines freely across the EU trade block. The lack of a comprehensive Mutual Recognition Agreement has resulted in these companies been classified as third country importers, necessitating the set up new EU marketing authorisations and retesting and of their products by QPs located in the EEA.

How have companies been approaching the requirements around the Northern Ireland Protocol, and how can pharma companies practically manage FMD requirements from January 2022?

The EU and UK recently issued a joint declaration to provide industry an additional 12 months beyond the withdrawal period to make the arrangements for EU compliant pack supply to NI. Therefore, serialised packs can still be supplied across the UK up to the end of this year; however, this extension to the flexibility of the transition period ends on the 01st of Jan 2022. After this date, supply to NI will require manufacturers in Great Britain to separate GB and NI Stock Keeping Units (SKU's), have access to Securemed, the UK-NI Medicine Verification System (or NMVS), in order to serialise product for supply into Northern Ireland.

Securemed became the UK-NI NMVS from 1st January 2021 and all Marketing Authorisation Holders with valid MAs for Northern Ireland can continue uploading data to Securemed via the EU Hub as normal.

So, are we going to get more guidance or clarification from EMA/UK?

Discussions are ongoing between the European Commission and UK Government and further guidance will undoubtedly be issued. However, the industry must work on the assumption that only fully EU compliant packs can be supplied in NI from the 1st of Jan 2022.

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Will this be a challenge for the Pharma industry?

Ensuring that packs supplied to NI are compliant will be a challenge as packaged medicines for this territory will need to follow both EU and UK regulations. Up to now, the expectation has been that the packs supplied to NI would be subjected to import, batch control testing and QP certification in NI or the EEA. Also, it will be obligatory for the packs to bear the EU marketing authorisation information, carry the unique identifiers required by the delegated regulation and also detail both the EU and UK processes on reporting potentially adverse drug reactions or falsification in the patient information leaflet (PIL). Pharma companies have major deadlines looming at the end of this year and have been preparing for these deadlines even though the final outcome is not yet clear.

The EU require Marketing Authorisation Holders covering Northern Ireland to be based in the EU or Northern Ireland; whereas the MHRA's position remains that the Marketing Authorisation Holder can be located in the UK or EU.

Is there a resolution to this situation?

Yes, this is under discussion, but it is not yet resolved. Directive 2001/83/EC requires that the MAH is located within the EEA. This was modified via the NI protocol to exclude the UK apart from the specific situation of medicines authorised by the UK in respect of Northern Ireland, where an MAH in NI could be established. Therefore, the EU position up to now has been that PLNI authorisations can only be held by EEA or Northern Ireland based entities and not by entities established in GB. And therein lies the difference of opinion.

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How are the MHRA and EU commission looking to address the difficulties experienced by industry and achieve a common ground?

This has been addressed in a more recent "non-Paper" issued on the 26th Jul 2021 by the EU Commission to propose solutions and collate feedback from Pharma companies on the potential solutions.

The "non-Paper" proposes an alternative solution for companies wishing to supply to Northern Ireland. Rather than having to move the MAH to NI/EEA and to establish separate import, batch control testing and QP certification in NI or the EEA, it would be possible to locate these activities in GB by exception providing certain conditions are met.

…so, what are those conditions?

This would be conditional on certain requirements around NI supply being met such as:

- Full EU alignment on implementation of the falsified medicines directive
- Continued compliance to EU standards around quality, safety, and efficacy.
- The NI products would be restricted from sale anywhere else in the EU
- There would need to be a public database of all drugs distributed to NI in this way
- Finally, the MHRA would have to inspect facilities to EU standards and access would also be required for EU Competent authorities to carry out inspections to verify compliance of the PLNI MAs with EU GMP.

There are, of course, political issues to consider and it remains to be seen how this is received by the industry, the MHRA and the UK political establishment.

So, having that all sorted, is that the end of the legislative changes as a result of Brexit for medicines suppliers or are there still other deadlines for the industry?

Yes, there are still other deadlines.

In addition to sorting out all the revised requirements around NI supply, there is still a lot to do for many companies. While existing central authorisations were grandfathered over to GB authorisations, there are still deadlines in the coming years. Baseline sequences and revised artwork for the grandfathered GB authorisations will be required to be submitted and the transition to supply in these revised packs completed.

It's also important to note that in subsequent years, it is likely that there will be perpetual rounds of negotiation as every new EU requirement or new proposed directive will require assessment before implementation with respect to the UK and, in particular, Northern Ireland.

Do you see any long-term difficulties for the regulation of medicines in the UK after Brexit?

In future, as many companies outside Europe assess and prioritise markets, the UK may not be automatically included based on the need to set up partnerships or separate WDA or MIA authorisations and to have multiple SKUs for supply into GB and NI. The requirement for separate marketing authorisations could mean that smaller companies might not give precedence to to obtaining UK approval over the larger EEA market. If the UK diverges from US and EU guidance and the regulatory burden becomes significant, the UK risks not having the same level of access to new medications.

So, is this actually the case?

This does not appear to be the case at the moment and, in fact, the UK is instead streamlining their guidance and regulations. This is evidenced by the (Innovative Licensing and Access Pathway) ILAP, a new pathway to reduce the time to market for innovative medicines and also the EC Decision Reliance Procedure (ECDRP) a Fastrack mechanism for obtaining GB licences for existing CAP authorisations.