Key Takeaways from the PDA Brexit Opportunities & Challenges in the Pharmaceutical Industry

This event was a pioneering collaboration between PDA UK & Ireland to bring their mutual interest in this hot topic and how it impacts and presents new possibilities for the pharmaceutical industries in both Ireland and Great Britain & Northern Ireland.

Siegfried Schmitt, Chairperson of PDA UK, acted as Master of Ceremonies on the day. The event allowed participants to hear from specially selected speakers and pose pertinent questions to the panel of experts.

The complexity of Brexit is enormous. Throughout the day it was noted that Brexit has often been underestimated. The unforeseen consequences it has in general and in particular on the pharmaceutical industry. Areas of compliance, regulatory, fiscal, logistics and patient access to clinical trial medicines have all been disrupted and have required change in the post-Brexit world.

Language has become very nuanced. The interpretation and application of the rules can be sometimes inconsistent and is almost constantly changing.

Northern Ireland Protocol

Charley Maxwell, Orion Consulting, spoke about the pressing need for the Northern Ireland Assembly to vote on extending the current arrangements until there is an agreement on the Northern Ireland protocol. For some NI Pharma producers the unfettered access to the EU market is considered a positive advantage and means that there is no requirement for a "permanent cost duplication. There was potential for misalignment between the EU and UK markets in terms of serialization, however this was resolved by way of the small markets derogation to ensure continuity of patient supply. Trusted trader and green channel solution could be some of the ways to accommodate NI protocol political concerns. In its current form the NI Protocol bill would mean that derogations would be made permanent & would apply to veterinary medicine. Distributors could continue to supply NI with "GB" packs as long as they were only intended to be for NI i.e. non-serialised, tested in GB and with a UK Marketing Authorisation.

QP & Batch Release

This topic was covered in detail by Ann McGee of MIAS Pharma. Batch certification and release have to be handled by 3rd party outsourced companies to ensure compliance with EU regulation for UK pharma goods. This causes disruption to the supply chain and could result in delays for vital medicines to patients – particularly in clinical trial scenarios where delivery time of medicines to patients is crucial. Batch disposition must be carried out in EU/EEA countries so UK companies have to make arrangements to transfer MAs to EU/EAA based companies. This impacts export and import controls. If not managed correctly this can lead to customs delays.

Regulatory Update

Graham Donaldson of Pharmalex gave an in depth overview of regulatory challenges post Brexit. All existing Centrally Authorised (CAP) MAs were converted into UK MAs effective in Great Britain (only) and issued with a new MA number on 1 January 2021, in a process known as 'grandfathering'. All existing Centrally Authorised (CAP) MAs were converted into UK MAs

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The MHRA has had to devise new licencing procedures in particular for non digitised products. There are options for UK companies for MAs for UK only, GB & NI and for EU only. European Commission (EC) Decision Reliance Procedure – ECDRP is actively encouraged by the MHRA for variations, to reduce workload, and speed up approval process. This also reduces divergence between the CAP MA and GB MA.

Ireland Industry Perspective

Pat Ivory IBEC highlighted their lobbying of the House of Lords sub-committee on the NI Protocol to maintain the gains of the Good Friday Agreement and for trade between Ireland & UK particularly where complex supply chains are in operation. The EU have preserved the supply of medicinal products in Northern Ireland. For three years, it allows UK medicinal products to be sold in Ireland, Malta and Cyprus with no requirement for authorisation holders to be established in the EU. Strong emphasis on building up trust in between UK, Ireland and EU to resolve outstanding issues. For example on labelling recommendation for a common CE marking system rather than dual labelling to reduce duplication of costs.

Expert Panel

The Q&A session was facilitated by using Slido which allowed the attendees to pose questions anonymously and vote on polls. The interaction quickly transformed into live questions from the floor with detailed responses from the panel. The overall feedback from participants was extremely positive both in the subject matter covered and what they personally learned and could apply in their day to day roles. There was a general agreement in the room that more QPs are required and investment in training for a steady supply of this key role needs to be high on the pharmaceutical sector’s agenda.

Legal Perspectives

Trevor Dempsey of BDO outlined the customs regulations and Incoterms, invoice and transport documentation and registrations required post-Brexit for importation. There are significant challenges to time and cost implications due to the new processes. This can impact on previous SLA agreements which may not have been foreseen. These need to be updated and agreed between parties. Bridget Clinton of Arthur Cox gave a potted history of Ireland UK relations from the Normans right through to present day. She highlighted that all contracts now need to be Brexit-proofed. Areas of concern and focus should be Change control management, Management of regulatory change, Price adjustment mechanisms, Rights and consequences of termination, MAC clauses and Force majeure.

Industry Perspective

Mark Jackson from Merck Life Science UK gave a birds-eye view of how Merck implemented a specialist global team to deal with Brexit and its consequences. The old adage of prepare for the worst and hope for the best was adhered to with a detailed review of all potential scenarios and how they could affect their operations using a risk assessment approach. Merck prepared for a no-deal Brexit. Some of the actions they took included – increasing inventory levels in UK

& Ireland, reviewing and amending transport modes, expanded in house customs expertise to support increased complexity and volume, Hypercare team set up to look after customers with key communication initiatives and ensuring delivery of product, loss of EU workers has resulted in higher labour costs due to previous reliance on foreign workers. New Products are now typically licenced for GB and Ireland/Northern Ireland. Some key global partners were not as prepared as Merck had been led to believe, however the impact of this was mitigated by the high level of Merck preparedness.

Overall the event was a great success with many participants requesting a follow up event once the NI protocol political situation is resolved. As with all PDA events there was ample opportunity to mix, network and get to visit the exhibitors during the breaks. Special thanks to all our sponsors for making the day possible.

In summary, while Brexit is here to stay, its full implications and opportunities for the Pharma industry are evolving and fluid. We might wonder had King of Leinster Dermot MacMurrough not arranged the marriage of his daughter Aoife to Strongbow in 1170 in return for military assistance, how history and the present day negotiations on Brexit may have unfolded differently?