BREXIT Updated Impact Statement

It's less than a year until the UK leaves the EU. Every day passing leaves less time to deal with the (potential) impact and for pharma companies worldwide which supply the EU, its MRA partners and / or UK to be able to legally continue to supply patients in the those territories with medicines. What steps are definitely needed will probably not become clear until some time in the Transition Period which currently planned to end 31 Dec 2020. At present UK Govt continues to "assure" that all will be well, but the EU seems to have a different take on the matter. Main issues are:-

- QP certification processes
- Siting / re-siting of finished product testing labs
  Analytical transfers
- Licence amendments to reflect the above in both UK and EU
- New licence approvals

The UK says businesses should not have to adapt twice to new rules and regulations - suggesting it agrees on a largely "status quo" arrangement. During the Transition Phase free movement of people, goods and money can continue, and that UK will still be subject to European Court of Justice rulings. The Brexit Secretary also wants a UK "right to object" to new EU laws with which it doesn't agree. The UK also wants to be able to strike trade deals with other countries.

The EU has already taken some contingency measures including:-

- **Redistribution of UK's portfolio of centrally authorised products**

The EU27 Member States and the European Medicines Agency (EMA) have completed the reallocation of the medicines for which the UK MHRA and VMD are currently rapporteur or co-rapporteur appointed by the scientific committees to coordinate the evaluation of a medicine. Over 370 centrally authorised products have been transferred to new rapporteurs and co-rapporteurs from the EU27 Member States, plus Iceland and Norway, The new (co)-rapporteurships were to be communicated to the relevant marketing authorisation holders before the end of April 2018.

- **EMA survey of pharma companies on their preparedness for Brexit**

EMA has surveyed marketing authorisation holders of centrally authorised medicines that are located in the UK, or who have quality control, batch release, and/or import manufacturing sites or a qualified person for pharmacovigilance (QPPV) or pharmacovigilance system master file (PSMF) in the UK, on their plans to submit transfers, notifications or variations to their marketing authorisations in the context of the UK withdrawal from the EU. The purpose is to identify those companies where there is a need for concerted action to address medicines supply concerns due to Brexit in order to protect human and animal health and secondly, to help the EMA and the European Commission plan resources in the areas where these submissions will be processed. Information from the survey will also be used to inform next steps in Brexit preparedness for EMA, the European Commission and the European medicines regulatory network.

- **EMA relocation**

EMA found it necessary to make a hurried move from its offices in London to an EU member State City. Amsterdam was finally chosen and EMA says the move from London must be complete by March 31 2019. This move appears to take no account of a Transition Period / Implementation phase and necessitates an initial move into temporary accommodation in Amsterdam whilst construction of new EMEA office is underway.

Joint position

Both EMA and MHRA wish to avoid disruption to medicines supply within their respective territories

Pharma companies

The promise of a 21 month Transition period in which they will need to interpret / understand and then implement required changes may not seem enough for them to change / delay their current Brexit preparations. Instead they may feel the need to proceed with their contingency plans without further delay and prepare for a worst case scenario. Some may reduce their contingency plans to the bare minimum, but it would not be sensible to stop contingency planning altogether.

(note AZ has indicated that it is to spend £21.2million on new facilities in Sweden to ensure that it can continue to sell drugs across the EU post Brexit. It considers this a waste that could be better spent on developing drugs. [source Daily Telegraph Feb 4 2019]

No one knows

- Most of the essential practical detail of how medicines manufacture and supply will be affected
- Whether, despite EU & UK medicines and their regulatory practices / GMP being aligned and confirmed so by inspection, it will be possible to form an early MRA between EU and UK and thereby ensure uninterrupted supply and patient safety in both territories.
- Whether common sense will prevail

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