Putting patients at the forefront of Brexit decisions

As formal ratification of the Withdrawal Agreement and the Political Declaration is delayed in the UK, the European healthcare sector highlights the importance of putting the safety of patients and public health at the forefront of the debate.

A disorderly exit from the EU by the UK has very real and tangible consequences for patients in both the EU and the UK. From the healthcare sector's perspective, the transition period afforded by the withdrawal agreement and political declaration is critical as it provides some time for healthcare partners to continue to adapt to new regulatory requirements, manufacturing and supply issues including customs arrangements to ensure an uninterrupted supply of medical technologies to patients.

The scale of the task should not be underestimated;

- around 45 million packs of medicines leave the UK destined for patients in Europe every month with 37 million packs heading the opposite way. In total that is around 1 billion packs of medicine crossing the border between the UK and the EU each year;
- In large scale trauma incidents, such as recent terrorist attacks in both the Europe Union and UK, Hospital and even local Distribution Centre stock piling of specialist Emergency Trauma Packs can suddenly run low owed to unforeseen demand. These products are not routinely stock piled to a large enough scale for an unexpected major event owed to efficiency and shelf-life reasons. However, owed to the scale of free movement of goods between the UK and EU, emergency trauma packs can be flown in – at a moment's notice – from any other distribution centre in Europe.

Given the uncertainty around the process of voting on the withdrawal deal and the terms of the UK's future relationship with the EU, the healthcare sector has invested heavily in ensuring that stakeholders are prepared for every eventuality.

As part of those contingencies, a series of immediate actions must be taken in order to protect patients and public health in the event of a no-deal scenario, including:

- The introduction of measures that will continue to recognise UK based testing at least until it can be transferred to the EU.
- A mutual recognition agreement for all CE marked medical technologies granted by a UK based notified body (for EU) or granted by an EU continent based notified body (for UK).

- The introduction of measures to enable the continued UK participation in key data sharing platforms that protect public health and medicines and medical technologies safety in Europe.
- Discussions between relevant authorities and the sector to co-ordinate contingency plans such as putting fast track lanes or priority routes for medicines and medical technologies into ports and airports.
- Medicines and medical technologies, including clinical trial materials, should be temporarily exempted from any new customs and borders checks.
- Enable paperwork and regulatory checks to be completed away from the physical border.

- The European Air Safety Authority (EASA) should recognise certificates issued in the UK to ensure that planes can continue to fly.
- Exploring the possibility of , for a defined period, also exempting active pharmaceutical ingredients (API) and raw materials for medicines from border checks to ensure manufacturing of medicines continues with limited disruption.

To prevent patients being impacted, the members of the Brexit HealthCare Alliance underline the importance of the UK's orderly exit from the EU. Whatever the outcome of the UK parliament vote it is vital that immediate and intense focus is given to healthcare issues including the regulation and supply of medicines and medical technologies in the post-Brexit relationship.

The Alliance members believe that an explicit commitment to securing long-term, extensive cooperation in the field of health is in the best interests of patients and public health. In addition to the above, this includes agreements in vital areas we have been calling for since the start of the negotiations; the establishment of a common framework for collaboration in health research and knowledge exchange between the EU27 and the UK, clinical trial legislation, European Reference Networks, and cross border healthcare and reciprocal healthcare arrangements including movement of professionals, and a collective efforts from both sides to ensure a high level of public health.

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