

Impact of Brexit on Medicines Supply.

Not surprisingly there are a great number of unknowns around the impact on supply of medicines from leaving the European Union. The Department of Health has commissioned Ernst & Young (EY) to explore the potential impact of the UK's withdrawal from the EU and to understand how suppliers are preparing for the change with the aim of identifying any specific actions that need to be taken to ensure a smooth transition. The study covers medicines, radioisotopes; vaccines and public health countermeasures and will focus on the period immediately before and after the UK's withdrawal from the EU, rather than longer-term arrangements.

Impact may be seen in the following areas.

Regulation: The UK has maintained a strong regulatory authority in the MHRA and they issue licenses for 80% of medicinal products available in the UK. However this relies heavily on the work of the European Medicines Agency. As has been highlighted in the media the central office for this will move from London to Amsterdam. The Government are seeking associate membership of the EMA post Brexit but it is not clear if this will be accepted. If it is not accepted then companies may be required to fulfil additional regulatory requirements for the UK which may in turn reduce the attractiveness of using the UK as an early launch site for medicines.

Supply Issues: There are approximately 15,000 medicines licensed for use in the UK; many of which have complex international supply chains. Approximately 75% come from or via the EU. Changes to EU/UK regulatory requirements, border clearance processes, tariffs and foreign exchange regulations and all have the potential to impact on the medicines supply chain. The impact is uncertain but there may be increased issues with medicines shortages or breaks in the supply chain. There is also a risk of an impact on price (e.g. exchange rate fluctuations, increased costs to companies e.g. from duplication in regulatory arrangements will be passed on, in primary care, risk of losing the benefit of lower cost parallel imports of branded medicines etc).

From a community pharmacy perspective there may be an impact on their business as a result of loss of parallel imports. The exchange rate has previously influenced this but it could impact on the sustainability of some community pharmacies. This is however also unclear.

Workforce: While we do have EU citizens employed within NHS Scotland and NHS GGC it is not a main source of pharmacy workforce. There are two Universities in Scotland that deliver a pharmacy degree and several that deliver the NC in pharmaceutical Care for Pharmacy Technicians. We would not expect Brexit to have a large impact on available pharmacy workforce.

Planning

We would expect National Services Scotland/National Procurement to be the leader on advice and response for NHS Scotland in this area as they are the experts in procurement. This would be a key area for a once for Scotland approach in terms of advice and response bearing in mind there is a huge degree of uncertainty and differing views on the impact of Brexit.