European and External Relations Committee

The EU referendum and its implications for Scotland

Written submission from Margaret Beveridge

I currently work as a Business Developer in the Pharmaceutical Industry - specifically with Contract Service Organisations (CSOs), providing services to Pharmaceutical Companies. CSOs provide services such as contract manufacturing of pharmaceuticals (for both clinical trials and commercial products), packaging and labelling, analytical services, etc. Scotland has a rich supply of world class CSOs – from fairly large companies with Regional Facilities in Scotland such as Aptuit, Hologic and Source BioScience to smaller, purely Scottish companies – e.g Symbiosis and The Antibodies Company.

All of these facilities and their suppliers (of lab equipment, reagents, etc) will be seriously affected by Brexit and some may have to re-locate to the EU to remain in business.

The reason for this is that the EU created a unique position in the global Pharmaceutical world – that of EU Qualified Person (QP). All pharmaceuticals arriving in the EU from USA, Asia, RoW must be released for human use by a person holding the position of EU QP. Following this release, the supplies are free to move to any EU country, with no further release or analytical requirements. To take one example:- supplies of a new pharmaceutical that have been manufactured in the USA for use in a clinical trial with multiple clinical sites throughout the EU. Currently these can be sent to the UK for release and the supplies are then free to move to any of the clinical sites in the EU, with no further release or re-analysis required. Post Brexit, if a US company sends its clinical supplies to the UK, the UK QP release will not be accepted by EU QPs (as currently happens with Switzerland) and the supplies will require further release and analysis when they are sent to the EU. Using a UK CSO means they must also employ a EU CSO – so why will they not go straight to the EU CSO and exclude the UK?

The company for which I currently work is located in Liverpool (Geryon Pharma), but following Brexit we intend to re-locate, to remain in the EU. If Scotland manages to retain EU membership, the company will re-locate to Scotland. If not, we will re-locate our warehouses to Ireland.

I believe many other CSOs will also be looking to re-locate or downsize their UK offices, to continue to be attractive to the global pharmaceutical market.

It is also a danger that the UK will be excluded from many clinical trials – meaning patients will not have access to new drugs until approved. Companies currently apply for a pan-European licence for many clinical trials – if they have to apply separately to the MHRA in the UK, many may not consider it worthwhile.

I'm lucky that I work from home and will be able to continue work for my company post Brexit, but it will involve more travel. I believe there is a unique opportunity for Scotland to capitalise on Brexit by becoming the preferred EU centre for CSOs, many of which are currently located in the rest of the UK, but only if we can retain EU membership.