Community Pharmacy Scotland

Community Pharmacy Scotland response to: The Health and Sport Committee's call for evidence on the Impact of leaving the European Union on Health and Social Care in Scotland (January 2018)

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Who are Community Pharmacy Scotland (CPS) & what do they do?

Who we are

We are the organisation which represents community pharmacy contractor owners in almost every aspect of their working lives, and are the voice of these vital healthcare professionals as they deliver pharmaceutical care to the people of Scotland.

We are empowered to represent the owners of Scotland's 1256 community pharmacies and negotiate on their behalf with the Scottish Government. This covers all matters of terms of service and contractors' NHS service activity including remuneration and reimbursement for the provision of NHS pharmaceutical services.

What we do

We work with the Scottish Government on the development of new pharmaceutical care services and ensure that the framework exists to allow the owners of Scotland's community pharmacies to deliver these services.

The Scottish community pharmacy contract puts the care of the individual right at its centre and with its focus on pharmaceutical care and improving clinical outcomes, community pharmacy contractors and their employee pharmacists are playing an increasingly important role in maximising therapeutic outcomes and improving medicine safety. Community pharmacy is at the heart of every community and plays an important part in the drive to ensure that the health professions provide the services and care the people of Scotland require and deserve.

Community Pharmacy Scotland

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Background

Brexit is due to complete at 11pm UK time on Friday 29th March 2019.

Given the timescales and the stage of the current negotiations, the greatest risk is of the UK not being fully ready to have legislation returned, which could cause a significant number of issues. The single biggest mitigation against this for all related aspects from a Health & Sports Committee perspective is to have a two-year transitionary phase in place after the UK leaves the EU to allow all legislative and regulatory changes to be completed.

At present, there are 28 EU countries all working the same way, governed by the same regulations. When Brexit occurs, this is unlikely to be the case for all regulations. For private sector businesses, such as community pharmacy, if there are no guidelines for the businesses to work to, a patient safety risk will result.

The Government needs to mirror and replicate the EU structure.

If the above do not happen, negative safety, cost and supply issues are likely to occur.

At present in the UK, around 90% of medicines used are manufactured outside the UK, the split being 50/50 between the EU and India/China. The lack of tariffs between these groups and the UK post Brexit, could cause both safety and supply issues.

As a single example to illustrate the impact of Brexit on a very small subset of medical products:

1 million oncology diagnostic procedures are carried out each year in the UK using radio isotopes. 700,000 of these are completed with imported isotopes, with the remaining 300,000 UK produced isotopes being significantly more expensive than the EU Imports.

If appropriate legislation and agreements are not in place, the following are likely to result

• A lack of available EU Isotopes would impact on the diagnosis and treatment of disease.
• The isotope tests could be substituted with other tests, however there are not sufficient numbers of staff trained resulting in increased costs and decreased pace of treatment.
• Medical radioisotopes decay. If supply is delayed, then the decay reduces the number of treatments available by half for the same cost, which creates an increased cost and lower treatment levels.

• Isotope treatments are used to prevent surgery. A lack of these will result in increased surgery, which will lead to increased cost and longer waiting times.
• The UK is a net benefiter of research with 50% of the academic workforce being in the UK. In this specific example, if there is no agreement with the EU, UK patients will not be able to participate in EU trials, which means patients will miss out on the opportunity of potential life saving treatments and techniques if Isotopes are unavailable for research purposes.

PI, and other parallel trade could cease to exist without trade agreements in place - we currently depend on the free movement of goods to react to shortages in supply. This will not be possible without legislation in place.

In addition, PI trade saved the NHS am estimated 986.2 million Euros over the period 2004/09. While this is old data, it gives and idea of the potential size of the immediate increased costs

There is a risk to supply chains and patient access. Some manufacturers store vast quantities of stock in the EU which allows product to be moved easily when required, only entering the UK days before it reaches the patient. This cannot happen without a single market agreement, and will result in treatment delays.

Where products have different components made in different EU countries, there will be supply issues as they must cross borders multiple times before being assembled into the final product. Trade and customs differences could make the UK less attractive for manufacturers and cause issues EI-wide with medicines supply. For example, some inhaler components are exclusively manufactured in the UK, and if the cost or legality of using these were to be non-viable, there would be a break in production affecting patients and a loss of productivity for the UK.

It is difficult to envisage how these risks of increased cost and reduced availability could be mitigated without significant input to the health and social care budget. Risk analysis and management across the listed areas will all have an associated cost, which will not result in a significant saving for the UK upon Brexit.

There are also a number of sectors where the UK relies on EU labour, not least in health, social care and the medicines industry. These will be discussed more fully below, but it in summary any move to restrict free movement of the labour force or which would make the UK less attractive to work in will have serious consequences for the health of the Scottish people.

Below, we have discussed the specific topics on which the Health and Sport committee have requested comment on. Some have been omitted where we do not have the necessary expertise to pass comment, or the topic has not been obviously relevant to our practice.

1. Data Protection

We do not anticipate that there will be any major risks to health and social care in Scotland as a result of Brexit with regards to Data protection, providing that the GDPR is transposed into domestic law or signed up to via some other mechanism. The ICO has been lobbying for data protection reform for most of the last decade and the GDPR will deliver the changes needed for the era of big data and automated decision-making. It will give the public confidence that their data is secure and give businesses and governments alike comfort in controlling and processing data within clearly defined parameters and across borders into countries which abide by the same rules. The extensive preparatory work which has been undertaken in all sectors would go to waste if the UK were to diverge from common EU standards, and businesses would struggle to comply with two sets of data protection law. Most will share data with other EU member states in order to perform necessary processing of their gathered data.

This may be done directly or as a result of their third-party contractors' practices. It is already challenging to ensure legal compliance with data protection law across an increasingly complex landscape, and it would become more difficult again should the UK choose to have different arrangements. The UK could also become viewed as either a "risky" country with which to send/receive data, or one which has overly burdensome requirements for doing so. This may have an impact on the attractiveness of the UK's offering in future trade agreements.

From a community pharmacy perspective, our greatest concern is that patient information can flow between healthcare professionals where appropriate and necessary for healthcare purposes. The GDPR does allow for this under set conditions, and there have been advances towards this goal in each of the home nations – notably, Scotland lags behind the rest of the UK at present. The biggest threat that Brexit could pose is that GDPR is not adopted and the replacement data protection law somehow restricted health information flow. Not having the right information to hand at the right time can have a negative impact on patient care.

With regards to common frameworks, data protection is a reserved matter and as such there would be no concern with it being dealt with as a UK-wide Brexit consideration.

2. Reciprocal Healthcare

The biggest risk that the Scottish Health and Social care system faces in this respect is that there is no transitional period or that current EHIC arrangements are not adopted into domestic law in time for March 2019. This would leave Scottish citizens (both with and without existing healthcare conditions) vulnerable when travelling in EEA member states. Where private insurance did not cover an incurred medical cost, the NHS may end up meeting costs which would be uncontrolled.

This risk could be mitigated by having a transitional period wherein either the relevant legislation is transposed or new, similar arrangements are made (preferably the former).

We believe that, given Health is almost entirely a devolved matter, it is inappropriate that reciprocal healthcare is dealt with using a common framework following Brexit. It is difficult to comment without speculating, but whilst any arrangement would likely mirror Westminster's initially, the devolved nations must have the freedom to pursue relationships with individual countries independent of one another.

3. Funding

The Brexit Campaign highlighted that the UK provides £350m per week to the EU. There were some suggestions that this could be spent in the NHS. When these calculations were made, there was no account taken of the funding which the UK receives back from the EU, which is ~£175m per week. If the remaining £175 could go solely to the NHS, this would go some way to supporting the costs for the implementation of Brexit Legislation for Health and Social Care.

It is of note that recent figures for the Financial Times advise that the value of Britain's output has fallen to around 0.9% lower than was possible if the country had voted to stay in the EU. This equate to almost £350m per week.

The uncertainty of Brexit affects business making long term decisions. This is likely to be harmful to health in Scotland due to lower incomes, poor quality work opportunities and unemployment. The impact of any changes in employment rights are unclear, and may have an effect on health, particularly for agency and part-time workers.

Where the economic performance is reduced, a reduced income for government follows. This could impact on public services, including the NHS.

4. Mutual Recognition of professional qualifications

This has already been widely debated, with a consultation on the EU MRPQ directive having been concluded and published in October 2016. The responses to this consultation highlighted that there is broad concern from healthcare regulators in the UK that current EU legislation prevents robust checks on clinical knowledge and language skills being performed for those applying to practice in the UK. It follows that bringing this legislation fully under UK control would allow for the bar to be set high for professionals seeking to work in Britain.

The main potential risk is that requirements are set too high without proper stakeholder consultation, which would stem the flow of healthcare professionals into the country at a time when there are serious recruitment and retention issues.

A balance must be struck between raising the basic standards of competence for entry onto this country's professional lists and making the UK an attractive and achievable destination for those wishing to emigrate from their home country.

As the regulation of healthcare professionals is a reserved matter, the use of a common framework approach would be of no consequence.

5. New medicines and clinical trials

The UK is a net benefiter of research.

It is widely perceived that Scotland punches above its weight under the current system, attracting more research funding per head of population than other countries. For instance: the £356.3 million of research funding Scotland received from the RCs in 2011/12 represented 13.1% of total UK funding; as a comparator Scotland's population represents 8.4% of the UK population the €351 million funding from FP7 in 2007-12 represented 9.3% of total FP7 funds awarded to the UK. Research commissioned by the Scottish Government shows that Scotland has a very high citation rate and has an increasing number of EU and international collaborations.

If there is no agreement with the EU, UK patients will not be able to participate in EU trials, which means patients will miss out on the opportunity of potential lifesaving treatments.

The European Medicines Agency is unique in the world, co-ordinating and supporting interactions between over fifty national competent bodies, including the UK MHRA.

It not only pools the expertise, resources and IT from these countries but has regulatory powers along with the European Commission to ensure that medicines are safe, effective and of a high quality throughout all EU member states. Losing the MHRA's membership in the EMA network could lead to some medicines having to be re-authorised, without the pooled resources and information available to EU member states.

The UK would also lose the benefit of pharmaceutical companies using the EMA's decentralised or mutual recognition procedures which can speed up new medicines availability significantly. All new medicines would have to go through the entirely separate authorisation procedure in the UK which would ultimately lead to delays in innovative treatments being available for Scottish patients, or indeed to companies choosing not to enter the UK market as a result of the additional "barriers" put in place.

6. Procurement

In this section, we will consider both private and public procurement.

With regards to private procurement, the community pharmacy network in Scotland (and indeed the rest of the UK) has decades of experience in effectively purchasing medicines for NHS use – indeed, a significant proportion of our members' funding is modelled to incentivise efficient procurement as this contributes to driving medicines prices down. The full effects of Brexit on private procurement of medicines cannot be predicted, but we would expect to see an increased difficulty in accessing medicines and almost certainly price increases across the piste – around 90% of the medicines used in the UK are not made here, with 50% being made in other EU member states.

Factors such as customs agreements, loss of free movement of staff and product, medicines regulation, currency and taxation fluctuations and also public procurement behaviours will all have an effect on the availability and price of medicines. We are currently experiencing unprecedented medicines shortages which are placing a real strain on the community pharmacy network. Any further pressures may well result in businesses becoming non-viable which will have a dramatic effect on patient care and access to not only medicines but also the essential frontline healthcare services which are increasingly provided by our members. We cannot ignore the impending Falsified Medicines Directive (FMD) either – this is an important piece of pan-European legislation which will allow member states to detect where counterfeit medicines enter their system using a shared repository of information about each and every pack of medicine released for human use within the EEA. As we understand, the intention is for the UK to carry on with the considerable work already completed and remain a part of this initiative, abiding by its requirements. However, progress has stalled in the UK and the likelihood of all parties being ready by the go-live date of February 2019 is slim. This may lead to a reassessment of whether to have a UK-specific FMD arrangement or none at all, which would have negative implications for the supply chain. We would see supply delays as medicines and raw ingredients crossed borders if we did not mirror exactly the EU FMD, and if there were no similar initiative in place Britain could become an attractive repository for any counterfeiters, putting patients in Scotland at risk.

Public procurement is again a complex area which affects our network in a number of ways. Although technically devolved, the process and rules for public procurement of products or services over a set threshold value are set by EU regulation.

Scotland therefore has little policy freedom to deviate from pan-European arrangements. This is not necessarily a negative, however, as the EU legislation creates a truly level playing field and clear instruction for businesses in all member states, and opens up many more options for local government and public authorities when going through tender processes. It also drives improvement of industry, as feedback on rejected tender applications must be given if requested.

The concern that Brexit will bring is that a deviation from EU procurement rules could unfairly advantage or disadvantage a given business, and may make the UK a less attractive place to apply for contracts – this would even be the case for each of the home nations if a common framework agreement is not pursued. Public procurement of medicines and medical equipment is absolutely crucial in ensuring that taxpayer's money is utilised as effectively as possible. However, public procurement of medicines is on the increase, and we are concerned that when linked with the upcoming single national formulary in Scotland, this may lead to disinvestment from the pharmaceutical industry as has happened in New Zealand. Any deviation from EU procurement law which would allow more aggressive bargaining by public bodies could accelerate any decisions such as this and would have many unintended consequences including employment and R&D loss.

7. Public Health

The EU, through the Lisbon Treaty, has introduced policies to promote public health, including standards for medicines.

At present, there are 28 EU countries all working the same way, governed by the same regulations. When Brexit occurs, this is unlikely to be the case for all regulations.

For private sector businesses, such as community pharmacy, if there are no guidelines for the businesses to work to, a patient safety risk will result.

The Community Pharmacy contract in Scotland provides excellent public health services in Smoking Cessation, Sexual Health and the treatment of minor ailments, all of which have improved the health of the nation. Further work is planned on alcohol and weight management interventions, which will require investment to deliver the patient outcomes to improve further the health of the Scottish Nation.

The European Centre for Disease Control provides a pan-EU surveillance and alert role to ensure all countries are aware of emerging threats and hazards. It is essential that the UK remains a part of this process, or the health of the public will be placed at risk.

Where health related powers return to Westminster from the EU, Scotland needs to ensure that these are devolved as opposed to following a common framework, as our public health services are already at a more advanced stage than other home nations and development would suffer if it was necessary to pursue UK legislative change to allow further innovation.

8. Research and Life Sciences

The UK is a net benefiter of research with 50% of the academic workforce being in the UK. If there is no agreement with the EU, UK patients will not be able to participate in EU trials, which means patients will miss out on the opportunity of potential life saving

9. Tobacco

Scotland has delivered public health through tackling tobacco: plain packaging, advertising bans and tackling cross-border smuggling have all reduced the burden of smoking-related disease across Scotland. These initiatives have been influenced and part-funded by EU policies and expert recommendations, meaning that our impressive progress in this area may not have been as successful nor as rapid as it has been. Our national aim of being tobacco-free by 2034 may be put at risk as a result of Brexit.

E-cigarettes are widely used in Scotland, and their short and long term effects are still a relative unknown. This is particularly the case as the devices available vary considerably. This variation has been reduced recently thanks to an EU directive which imposed a minimum set of standards for devices and made illegal devices not conforming to these. This has protected the people of Scotland and would not have been as easy to implement as a single country due to the overseas manufacturing of these products. It has also allowed Scotland to move forward with investigating the possibility of using these devices as a quitting aid in the fight against tobacco, which again would have been impossible without this EU standardisation.

10. Workforce

Second to (and closely connected to) issues with procurement, this is where some of the bigger risks for the health and social care system in Scotland lie. Approximately 3% (12,000) of the total health and social care sector workforce is comprised of EU nationals. This is not an insignificant number of people, and represents a varied and valued skill base which could potentially be lost should Scotland be a less attractive work destination post-Brexit.

However, we must consider more than the initially obvious direct impact on patient care as a result of losing EU national workers from within the sector. Medicines accessibility is already a concern in the UK, with more ongoing shortages and adjusted prices for medicines than have ever been recorded. The manufacturing, wholesaling and parallel importing sectors are just three parts of a highly complex medicines supply chain, and they risk to lose labour resource from all levels of their operations. These positions can range from unskilled distribution roles to highly specialised individuals such as research and development scientists and company directors. Losing a tranche of resource in these areas could destabilise the supply chain further, and almost certainly increase costs for these businesses and thus the NHS.

One specific example to illustrate the impact that this could have on patients is the current shortage of those able to fill the role of Qualified Person (QP). Each manufacturer and Importer must have a QP who is certified to an EU specification before batches of medication can be released for clinical trial or to the public. UK organisations are already having to reach out to other member states to fulfil these positions, and Brexit may make this more difficult again on two fronts. Firstly, Scotland may become less attractive or feasible a country to move to for these highly trained and essential individuals. Secondly, the UK may choose not to adopt the EU approach or specification for a QP, which would result in all current QPs having to retrain (3-4 years) and risk affecting reducing the safety of medicines reaching the public. Certainly, the speed at which medicines are released for use in the UK will be drastically reduced unless arrangements for the workforce are very similar to the status quo.

In short, there are a number of clear risks to patients in altering the free movement of workers who contribute to our health and social care system, but it is our opinion that there are also an unknown number of unintended consequences which will have negative effects for the Scottish public and the NHS. Beyond the opportunity to raise entry requirements for professionals, it is challenging to see any potential benefits of Brexit on this workforce in the face of such challenges.