Royal College of Nursing

BREXIT: RCN PRIORITY
EU regulations on professionals and medicines

What are the issues?

Laws from the European Union (EU) have had a huge impact on the UK health and care services and the patients who use them.

EU regulations contribute to the following in the UK:

- standards of training for nursing staff and mutual recognition of health professional qualifications
- development and approval of medicines
- clinical trials participation and regulation
- licensing of medical devices which includes contact lenses, x-ray machines, pacemakers and hip replacements
- licensing of in-vitro medical devices, for example pregnancy tests and blood sugar monitoring systems for people with diabetes.

The education and training of registered nurses in the UK must currently conform to standards set out by the EU. This is contained in a law called the Mutual Recognition of Professional Qualifications (MRPQ) Directive[1]. It is the responsibility of the Nursing and Midwifery Council (NMC) to enforce these standards, which include checking that an applicant has completed the agreed number of training hours in clinical placements[2].

What does this mean?

As well as raising the standards of nursing education, the MRPQ Directive has enabled the UK to recruit nurses and doctors from Europe to fill our own workforce shortages. The Directive also includes language checks on EU nurses and a duty on all EU member states to inform one another about suspended or banned professionals, both of which are important and positive developments for patient safety[3].

If the UK decides to move away from these jointly developed standards, the UK may lose important safeguards, lose access to alert mechanisms, and miss out on crucial exchanges between professional regulators. This may add implications to the UK's ability to recruit and retain nursing staff who are EU nationals.

The RCN calls on the UK Government to align regulatory requirements with the EU and create a level playing field between the remaining member states, the UK and the wider international sphere. This will be especially beneficial for developing a coherent UK workforce strategy.

There is a possibility that the UK will find it more difficult to access medicines and medical devices if we choose to create new frameworks which are different from EU regulations. This may cause delays in new drugs being made available for patients, for example, in the case of cancer drugs, we could see delays of 12 to 24 months for UK patients[4].

Making any changes to the EU regulatory framework for clinical trials would also significantly increase the burden on UK researchers and pharmaceutical companies. They would need to seek separate permissions for trials in both the UK and the EU and would need to provide different datasets to both UK and EU regulators[5]. This could make the UK a less attractive place to conduct clinical trials, with knock-on effects for access to new medicines and offers to participate in trials for patients.

Brexit Scorecard

The RCN has rated progress on the RCN's five priorities by RED, AMBER and GREEN.

Red indicates that there has been no firm commitment made by the UK Government on this issue and how to resolve it.

1 EU Directive 2005/36/EC Annex V.2 (5.2.1)

2 NMC, *Standards for pre-registration nursing education*. Available at: https://www.nmc.org.uk/globalassets/sitedocuments/standards/nmc-standards-for-pre-registration-nursing-education.pdf. March 2010.

3 NHS Employers, *Mobility of health professionals across Europe*. Available at: http://www.nhsemployers.org/your-workforce/recruit/employer-led-recruitment/international-recruitment/mobility-of-health-professionals-across-europe. June 2016.

4 Ross Hawkins, *Cancer drugs may be delayed after Brexit, say experts*. Available at: http://www.bbc.co.uk/news/health-38922366 February 2010.

5 British Medical Association, *Brexit briefing: Medical research*. Available at: https://www.bma.org.uk/collective-voice/influence/europe/brexit/bma-brexit-briefings/medical-research January 2018.

Amber indicates some UK Government commitment or statement but no agreement on practical application with the EU.

Green indicates a firm commitment from the UK Government and the EU including on practical implementation.

RED WARNING

It is unclear how Brexit will affect any of these important areas. Depending on the final agreement on the relationship between the EU and the UK, there is a danger for regulations and standards of nursing education, and access to medicines to be affected with negative consequences for staff and patients.

What needs to happen?

Any changes to existing arrangements within the MRPQ Directive must be evidence-based and considered carefully. A thorough review should be undertaken to find an approach that places a greater emphasis on increasing our workforce in the UK whilst recognising nursing as a global profession. The UK benefits hugely from European recruitment of nurses and our services must continue to be able to recruit from across the continent, at least in the short term.

The UK Government must ensure continued close collaboration between the UK and the EU on medicines regulation. Ensuring timely access to medicine is critical for all patients in the UK. To achieve this, the UK Government is likely to require a formal agreement with the EU to continue to support and participate in relevant assessments, with a commitment that the UK will maintain and enhance these standards in the future. There are non-EU countries like Switzerland, which have made arrangements to work closely with the European Medicines Agency on a bi-lateral basis[6].

The UK Government should agree mutual recognition of the CE mark between the UK and the EU. The CE mark indicates compliance with EU health and safety standards and allows for free movement of products. This is important for ensuring that patients have timely access to medical devices. A number of non-EU countries, for example Australia, New Zealand and Switzerland, already have bi-lateral arrangements with the EU on this issue.

Similarly, the UK Government should also ensure close collaboration with EU partners on clinical trials. This should be done through replicating the EU Clinical Trials Regulation and agreeing that the UK takes part in pan-European clinical trials.

How can you help?

Lobby your local MP on this issue, to ensure continued collaboration on recognition of qualifications, medicines and access to clinical trials. This is the most effective way of holding the UK Government to account. You can contact the RCN to receive one of our 'How to lobby' toolkits, and you can speak to your country/regional office for support. You can find details of who your local MP is here: http://www.parliament.uk/get-involved/contact-your-mp/

As the RCN we are:

Collaborating with organisations across health and care to ensure that the health regulatory dimension of leaving the EU is understood and prioritised by the UK Government.

Working constructively with the UK Government and Parliament, the Welsh Government and National Assembly for Wales, the Scottish Government and Parliament and stakeholders in Northern Ireland to campaign for the MRPQ to be retained, and for UK patients to continue to benefit from clinical trials.

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6 European Medicines Agency press release, *EU and Swiss regulators sign confidentiality agreement*. Available at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2015/07/news_detail_002374.jsp&mid=WC0b01ac058004d5c1 July 2015