Academy of Medical Royal Colleges

Regulation of Medicines as the UK leaves the EU

Academy and the British Pharmacological Society Statement

06 July 2017

The Academy of Medical Royal Colleges and the British Pharmacological Society welcome the letter from the Secretaries of State for Heath and Industry to the Financial Times on 4 July, titled 'The UK wants to continue to work with the EU on medicines' (copied below).

We have been clear that that the future of medicines regulation is one of the key issues that has to be addressed in terms of healthcare as part of the Brexit negotiations and this letter provides considerable reassurance in the current period of uncertainty.

We agree with Mr. Hunt and Mr. Clark that these negotiations should be guided by: ensuring patients in the UK and the EU continue to have access to the most effective and innovative medicines; protecting patient safety through the strongest regulatory framework, and; sustaining close working relationships with our European partners.

This public statement, coupled with the commitment to set up a UK regulatory system that protects the best interests of patients and supports the life science industry, should the desired relationship with the EU not be achieved, is welcome.

Professor Alan Boyd, President of the Faculty of Pharmaceutical Medicine, who has led the Academy's work on this issue said,

'As the Government has recognised it is essential that the issues of regulation of medicines and devices are properly resolved for the safety and benefit of patients.

We would urge the Government to closely involve professional bodies representing clinicians and the industry itself as discussions progress and seek their input and expert advice to enable the best outcome to be achieved for patients and the industry in the UK.'

Academy of Medical Royal Colleges

Copy of the letter from Jeremy Hunt and Greg Clark to the Financial Times

Sir,

We want to provide assurance over the UK government's plans for the regulation of medicines as we leave the EU. The UK is fully committed to continuing the close working relationship with our European partners. Our aim is to ensure that patients in the UK and across the EU continue to be able to access the best and most innovative medicines and be assured that their safety is protected through the strongest regulatory framework and sharing of data. As Theresa May, the UK prime minister, has stated, we want deep, broad and dynamic co-operation and in this context, the UK would like to find a way to continue to collaborate with the EU, in the interests of public health and safety.

We have three principles which will help us rise to the challenge of developing a new regulatory system post Brexit: patients should not be disadvantaged; innovators should be able to get their products into the UK market as quickly and simply as possible; and we continue to play a leading role promoting public health.

First, we must continue to place patient safety at the heart of regulation. There are numerous examples of how the UK/EU partnership has had a positive impact on the lives of patients, for example in tackling rare diseases, close collaboration has led to over 130 new licensed products.

Second, we must provide certainty and long-term stability. Our focus is on supporting initiatives across Europe that will be vital to developing the next generation of products — big data, genomics and ever greater support for medical research and scientific collaborations.

Third, as part of our modern Industrial Strategy we will build on the UK's legacy as a leader in medical innovation — from Edward Jenner developing the world's first vaccine in rural Gloucestershire in the 1790s to unleashing the potential of new cell and gene therapies today. The Medicines and Healthcare Products Regulatory Agency (MHRA) wants to work with all types of innovators, ensuring new medicines can reach patients quickly. Drug development is a global business — and we will look to continue to work closely with the European Medicines Agency, and our international partners.

Whatever the outcome of Brexit negotiations, we are clear that should we not achieve our desired relationship with the EU, we will set up a regulatory system that protects the best interests of patients and supports the UK life science industry to go from strength to strength. We will seek to process licences as quickly as possible, certainly no more slowly than at present. Our fee pricing will be competitive with current levels. However, our door will always be open to a deep and special relationship with the EU which remains the best way to promote improved patient outcomes both in Europe and globally.

Jeremy Hunt UK secretary of state for health

Greg Clark UK secretary of state for business