Biochemical Society
Charles Darwin House
12 Roger Street
London
WC1N 2JU

Medicines and Healthcare products Regulatory Agency
10 South Colonnade
Canary Wharf
London
E14 4PU

Dear Sir/Madam,

Re. Consultation on EU Exit no-deal contingency legislation for the regulation of medicines and medical devices

I am writing on behalf of the Biochemical Society in response to the current Medicines and Healthcare products Regulatory Agency (MHRA) inquiry on '*EU Exit no-deal contingency legislation for the regulation of medicines and medical devices*'.

The Biochemical Society represents over 7,000 molecular bioscientists, among whom the regulation of pharmaceuticals and medical devices is a significant issue to many. We welcome the MHRA's timely and pro-active consultation on this issue and are writing to highlight our concerns that in the event of a no-deal Brexit, the UK leaving the European Medicines Agency and the MHRA acting as a standalone regulator could have significant and damaging implications for public health, pharmacovigilance reporting, clinical trial authorisations, and patient access to new treatments in the UK.

We believe that the need for the UK to remain within the European Medicines Agency must be a top priority in the Brexit negotiations process, and subsequently in any agreement reached between the UK and the EU.

In the unavoidable event of a no-deal Brexit, the Society calls upon the MHRA to ensure any legislative and regulatory processes remain as closely aligned as possible to those currently employed by the European Medicines Agency and European Clinical Trials Regulation.

Countries that operate standalone national regulatory agencies have been shown to experience significant delays in accessing new treatments. For example, despite having a number of bilateral trade agreements with the EEA, patients in Switzerland access treatments 157 days later than those in the EU or US, while patients in Australia and Canada often receive treatments between 6 – 12 months later than patients in the EU. The Biochemical Society is concerned that as a standalone market and regulator, the UK may experience similar delays, which will be further exacerbated if our regulatory processes are not closely aligned with other major global regulators. Potential delays are likely to be far greater for those patients with rare and orphan diseases.

The Society is also concerned about potential loss of data sharing between the EEA and the UK if the UK is no longer a full participant of EMA databases. Data sharing is of particular importance to pharmacovigilance surveillance and reporting. Without the ability to participate fully in EMA databases, it will be much more difficult for the UK, with a significantly smaller patient population size and data set, to identify trends and safety problems for licensed drugs once they are on the market.

Once again this will be exacerbated for those patients with rare or orphan diseases. In the event of the UK leaving the EU without a deal, the MHRA should work closely with the EMA and other major global regulators to establish data sharing agreements, preferably full, bilateral participation, and access to pharmacovigilance and clinical trial databases for the benefit of patient safety and public health.

The Society also supports full alignment and harmonisation with the new European Clinical Trials Regulation following the transition period in the event of a no-deal Brexit, to allow the UK to participate fully in the provisions of the EU CTR and to access the EU portal and database. We are concerned that any partial alignment and regulatory divergence will result in the UK experiencing significant regulatory delays for clinical trial authorisation and an associated decrease in the UK's competitive position in the global market to the detriment of patient health, particularly in cases of small patient populations.

In summary, in the event of the UK leaving the EU without a deal, the Society believes it is essential for the MHRA to maintain close working relationships with the EMA and other major global regulators, in order to share best practice and ensure a streamlined, harmonised process for the regulation and licensing of new medicines and medical devices, and to work towards data sharing agreements for the benefit of public health.

We look forward to hearing the MHRA's response to the current consultation.

Yours faithfully,

Dr David Pye

Honorary Policy Officer of the Biochemical Society