Medicines & Healthcare products Regulatory Agency

MHRA

Health and Sport Committee
The Scottish Parliament
Edinburgh
EH99 1SP

04 March 2020

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Further information for questions raised by the Health and Sport Committee

Dear Lewis Macdonald,

Thank you for the opportunity to attend and give evidence during the session on supply and demand for medicines on 21 January 2020. You asked that I write to the Committee with further information on the following points and I have consulted colleagues in the relevant parts of the Agency on the following points:

1. **The practical implications of the UK no longer leading in scientific assessments and work within the European Medicines Agency**

   As described during the session, outside the EMA, the MHRA is taking the necessary steps to maintain world class approach to the licensing and regulation of certain classes of medicines, to support both the best possible access to drugs, and the domestic life sciences industry. The existing regulatory approaches remain in place during the Withdrawal Period to the end of 2020. The MHRA will continue to provide a national market entry route for companies to introduce products to the UK market. As negotiations begin with the EU and other partners across the globe we will continue to the explore the opportunities for co-operation to ensure that the UK remains at the forefront of global regulation, through appropriate vehicles (e.g. mutual recognition agreements).

2. **The standard of evidence presented to the MHRA and whether the licensing regime can be better used to incentivise drug manufacturers to develop drugs which are clinically effective**

   All decisions on approval of medicines, wherever these are taken, are based on satisfactory demonstration by the applicant of the safety, quality and efficacy of new medicines. In the UK, the decisions are informed by independent advice from the Commission on Human Medicines. The MHRA does not plan to change the evidence standards for approval of new medicines and will use existing flexibilities, such as conditional approval and incentives for rare diseases to ensure that unmet clinical needs can be met by licensing of new products. MHRA will also explore opportunities for use of real-world data in support of regulatory decision making, particularly in market-entry decisions.

3. **The role of the MHRA in assessing the outcomes from a clinical and cost effectiveness perspective if the claimed outcomes of a drug are different to the actual patient outcomes following use**

   As discussed during the session, the remit of MHRA is evaluation of the safety, quality and efficacy of new medicines. The benefit/risk profile is kept under review following approval of the medicine and MHRA will act on emerging new data to include further information for prescribers and patients in product literature and amend the claims that can be made by manufacturers or to suspend or revoke the marketing authorisation, as necessary.

I hope that you find these answers helpful. Please let me know if you require any more information.

Jonathan Mogford
Director of Policy