

**Consultation on amendments to the Human Medicines Regulations 2012 relating to the removal of the European Commission Decision Reliance Procedure route to UK market**

**Royal Pharmaceutical Society Response**

**The MHRA proposes to amend the Human Medicines Regulations 2012 to remove the power contained in regulation 58(4C), which allows the MHRA to rely on the decision of the European Commission to approve a medicine for the Great Britain market. This will end the temporary procedure known as the ECDRP on the scheduled date of 31 December 2023. Do you support this proposal?**

* Yes
* No
* No opinion

**Please provide any further detail to your answer.**

Rationale: The other regulatory alliances with for example the Access Consortium and Project Orbis, will allow MHRA to collaborate with other trusted regulatory authorities such as FDA, TGA, Swiss Medic and HSA to facilitate access to medicines for the UK market in a more timely manner. It is widely known that the EMA centrally authorised product route is considerably slower than many other regulators. So it would be assumed that collaboration with other Health Authorities would provide quicker access to products on the UK market, of course subject to the NICE assessment. Timely access to medicines for pharmacies is essential to ensure patients don’t experience unnecessary delays when accessing medicines for their care.

**Do you think the proposals could impact people differently with reference to their protected characteristics covered by the Public Sector Equality Duty set out in section 149 of the Equality Act 2010 or by section 75 of the Northern Ireland Act 1998? If so, please provide details below.**

* Yes
* No
* No opinion