



Medicines & Healthcare products Regulatory Agency

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

Consultation Questions



1. 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.

2. 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

Please provide any further detail to your answer.

About you



Which best applies to you?

I am responding as an individual

I am responding on behalf of an organisation

For organisations



Name of organisation you are responding on behalf of

Type of organisation

Patient Representative Organisation

Manufacturer

Supplier

Healthcare Organisation

Other (Please Specify)

Number of organisations you represent (if applicable)

Please provide any other information relevant to the organisation

For individuals



Are you:

- A member of the public A patient A healthcare professional Other (please specify)

Where do you live, or if you represent an organisation, tell us the geographical area you cover? (Optional)

- England Northern Ireland Scotland Wales
- United Kingdom Other - please specify

Satisfaction survey - give feedback on participating

3. It was easy to participate in this opportunity

- Strongly disagree Disagree Neither agree or disagree Agree
- Strongly agree

4. The supporting information was understandable

- Strongly disagree Disagree Neither agree or disagree Agree
- Strongly agree

5. What could we do better?

Thank you for your time in completing this consultation.

If you have any further questions about this consultation, please get in touch by email at partnerships@mhra.gov.uk.