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 to UK market

Contents

1. Executive summary

As the Medicines and Healthcare products Regulatory Agency (MHRA) develops a new international framework for recognition, it is proposed to amend the Human Medicines Regulations 2012, removing the powers granted under those Regulations for MHRA to rely on the decision of the European Commission (EC) to approve a medicine in the United Kingdom (UK) without any further consideration, through a procedure known as the European Commission Decision Reliance Procedure (ECDRP).

We are consulting on proposals to amend the Human Medicines Regulations 2012 to remove the power for the MHRA to rely on the decision of the European Commission when approving a medicine for the GB market.

The ECDRP will be replaced with a new international recognition framework, initial details of which can be found here.

While the new international recognition framework will replace the ECDRP, it is outside the scope of this consultation.

2. Introduction

2.1 Background

We are proposing to use powers under the Medicines and Medical Devices Act 2021 (MMDA) to amend the regulatory framework for approval of medicinal products.

Currently, Regulation 58(4C) of the Human Medicines Regulations 2012 grants the power to the MHRA to rely on the decision of the EC to approve a medicine in GB in order for the MHRA to authorise that medicine in GB without any further consideration, through a procedure known as the ECDRP. We are proposing to amend regulation 58, in order to remove that power.

At the time of UK leaving the European Union (EU), the ECDRP was put in place as a temporary measure, to avoid the risk that significant variance from EU licensing pathways or duplication of effort would lead to GB becoming a late-stage launch country.

Although regulation 58(4C) grants the power to the MHRA to rely on the decision of the EC to approve a medicine in GB, the intention was only to conduct an abbreviated assessment procedure, providing an alternate route for companies, or Marketing Authorisation Applicants, to obtain marketing authorisation. Further information of the process of applying for marketing authorisation via the ECDRP can be found here: European Commission (EC) Decision Reliance Procedure - GOV.UK (www.gov.uk). Below sets out the process where an application is made to MHRA following a positive decision from the EC.

Whilst the ECDRP provided market stability following UK's exit from the EU, we are now in a position to implement a more considered approach to our assessments and accept applications from a wider range of partners.
The ECDRP is one of four routes for products that make use of reliance procedure.
We will continue to operate the remaining routes beyond termination of the ECDRP:

- The ACCESS Consortium – this is a collaboration of regulatory authorities including Australia, Canada, Singapore, and Switzerland. We joined the group in October 2020. The ACCESS consortium is based on a true work sharing principle, to maximise international co-operation between partners, reduce duplication, and increase each Agency's capacity to ensure patients have timely access to high quality, safe and effective therapeutic products.

- Project Orbis, which provides a framework for concurrent reviews of oncology products among international partners. It aims to deliver faster patient access to innovative cancer treatments that cater to an unmet medical need and demonstrate notable results.

- The Mutual Recognition Decentralised Reliance Procedure (MRDCDRP), which allows us to take into account Marketing Authorisations approved in EU Member States (or Iceland, Liechtenstein, Norway) through decentralised and mutual recognition procedures to grant a Marketing Authorisation in the UK or GB.

We will also implement a new international approach to recognition to replace the ECDRP, increasing the number of routes available to innovators to access the UK market. Initial details of the new framework can be found here.

While the new international recognition framework will replace the ECDRP, it is outside the scope of this consultation.

While the ECDRP will be removed across the UK, medicines for the Northern Ireland market must currently follow the EU acquis as per the Northern Ireland Protocol. Changes being brought about as part of the Windsor Framework will enable the MHRA to issue a marketing authorisation for medicines for the whole UK market and ensure that medicines are available at the same time and on the same basis across the UK.

2.2 Policy objectives

The aim of this proposal is to remove a temporary procedure (the ECDRP). The ECDRP was introduced following UK's exit from the EU which allows us to rely on a decision to authorise a medicine taken by the EC without any further consideration, in order to authorise that medicine in GB. The purpose of this was to ensure patients continued to have timely access to safe medicines and medical innovations.

While the ECDRP allows the MHRA to grant a licence without any assessment of quality, safety and efficacy, relying on a decision of the EC, in practice the MHRA has found it needs to undertake limited assessment of scientific data in the majority of cases to be assured that there are no benefit risk or health issues due to incompatibility of the EC decision with the UK health system.

The ECDRP will be replaced with a new international recognition framework, initial details of which can be found here, and which will bring significant changes. It will allow for an abridged assessment of certain products by recognising approvals from trusted partner agencies worldwide, increasing opportunities for global collaboration and the number of routes for innovators to access the UK market. The new framework will also empower the MHRA as a sovereign regulator as we will be responsible for approving all 'recognition route' applications, ensuring compatibility with the UK health's system and alignment with our stringent standards of safety, quality and efficacy. These changes will pave the way for faster product approvals and thus will provide faster access to these products for UK patients.

While the new international recognition framework will replace the ECDRP, it is outside the scope of this consultation.

3. The proposal

We are proposing to amend the Human Medicines Regulations 2012 to remove the power in regulation 58(4C) for the MHRA to rely on the decision of the EC to approve a medicine for the GB market.

The power to rely on a decision of the EC, known as the ECDRP, is a temporary measure that was put in place for a period of 3 years from 1 January 2021 in order to provide market stability following EU Exit. This measure is scheduled to end on 31 December this year.
In place of this power, we will implement a new international framework for recognition, initial details of which can be found here. While the new international recognition framework will replace the ECDRP, it is outside the scope of this consultation.

Question

"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 GB 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/Unsure - Please provide any further detail to your answer]

Annex A – Legal basis and assessment of the matters set out in section 2 of the Medicines and Medical Devices Act 2021

The Medicines and Medical Devices Act 2021 (the Act) received Royal Assent on 11 February 2021. We propose to make the legislative changes under consultation in this document using powers in Part 2 of the Act, which provides powers to make regulations about human medicines.

This consultation is conducted in line with the consultation requirement in section 45(1) of the Act.

Section 2 of the Act states that public health must be the overarching objective of the appropriate authority when making regulations. Section 2 requires that when assessing whether regulations would contribute to the objective of 'safeguarding public health', the appropriate authority must have regard to three factors:

1. The safety of human medicines
2. The availability of human medicines
3. The likelihood of the relevant part of the United Kingdom (UK) being seen as a favourable place which to –
    a. Carry out research relating to human medicines
    b. Conduct clinical trials, or
    c. Manufacture or supply human medicines

As set out in section 2(4) of the Act, where regulations under subsection (1) may have an impact on the safety of human medicines, the appropriate authority may make the regulations only if the authority considers that the benefits of doing so outweigh the risks. The MHRA have given due consideration to these factors in our proposals.

While the European Commission Decision Reliance Procedure (ECDRP) allows the Medicines and Healthcare products Regulatory Agency (MHRA) to grant a licence without any assessment of quality, safety and efficacy, relying on a decision of the European Commission (EC), in practice the MHRA has found it needs to undertake limited assessment of scientific data in the majority of cases to be assured that there are no benefit risk or health issues due to incompatibility of the EC decision with the UK health system.

ECDRP has enabled the MHRA to offer an abbreviated assessment procedure of up to 67 days for products that have already gone through the European Union (EU) procedures, avoiding duplication and costs for manufacturers, and making the most efficient use of the MHRA resource. This has prevented delays to access new treatments by UK patients. It also means medicines licensed by the EC for Northern Ireland (NI) have a prompt Great Britain licensing route reducing potential disparities in access created by the NI Protocol.

In addition to the European Reliance route, the MHRA has also been able to approve products through UK only National Applications, the Access consortium (working with Australia, Canada, Singapore and Switzerland) and through the US Food and Drug Administration's Project Orbis in advance of a European Medicines Agency's decision demonstrating that alternative routes to market other than ECDRP are viable and attractive to industry.

The safety of human medicines is a priority of our new international recognition framework. The new international framework will also:

- increase the availability of human medicines by increasing the number of routes available to overseas innovators to access the UK market;
- keep the UK an attractive market for developers and manufacturers of medical products who have, or plan to obtain, approvals from other global regulators.

The new framework is outside the scope of this consultation.

Annex B – Consultation questions and how to respond

How to respond

The Government invites responses on the specific questions raised. The questions can be found through the document and are also listed in full in below.

This consultation will close on 27 September 2023. Please respond through our online consultation survey.

Responses to this consultation will be carefully considered and reviewed and will feed into decisions that are made when considering the drafting of secondary legislation and finalising any proposals. As this consultation is being carried out jointly with the Department of Health in Northern Ireland, consultation responses may be shared.

Consultation questions

Question 1

The power to rely on a decision of the European Commission, known as the European Commission Decision Reliance Procedure (ECDRP), is a temporary measure that was put in place to provide market stability following EU Exit.

Question

"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 GB 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/Unsure - Please provide any further detail to your answer]

Question 2

In considering amendments to the Human Medicines Regulations 2012, Ministers must comply with the Public Sector Equality Duty (PSED). PSED requires that public bodies have due regard to the need to:

- eliminate discrimination
- advance equality of opportunity
- foster good relations between different people when carrying out their activities

In Northern Ireland (NI), new policies must be screened under Section 75 of the Northern Ireland Act 1998, which places a statutory duty on public authorities, to mainstream equality in all its functions, so that equality of opportunity and good relations are central to policy making and service delivery. In addition, new or revised policies must be rural proofed in

line with the Rural Needs Act (NI) 2016 which requires public authorities to have due regard to rural needs.

We do not consider that our proposals risk impacting people differently with reference to their protected characteristics or where they live in NI. We welcome any further views on this point.

Question

"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/Unsure - Please provide any further detail to your answer]

Data Protection and Privacy Information

1. Introduction

You can read the MHRA Privacy Notice to find out in general terms the types of personal data we process and why; as well as information about your rights and how to raise concerns.

This privacy notice sets out the approach to this consultation that the MHRA will take to handle information appropriately and to comply with information legislation.

This privacy notice covers documents gathered and created during this consultation and anything in which information of any description is recorded, whether in paper or electronic form.

2. Legal requirements for information management and privacy

The consultation complies with data protection legislation including the Data Protection Act 2018 and the UK General Data Protection Regulation (UK GDPR).

We rely on UK GDPR Article 6(1)(e) as our legal basis for processing your personal data. This allows us to process personal data when this is necessary for the performance of our public tasks in our capacity as a regulator.

Information provided to the MHRA may include some special category personal data. Our lawful basis for processing such information is set out in UK GDPR Article 9(2)(i) and the Data Protection Act Schedule 1, Part 1(3). Both relate to situations where the processing is necessary for reasons of public interest in the area of public health.

3. Lawful basis and purpose of processing personal information

The consultation may collect and use personal information for the purpose of gathering views to inform our approach to removing the ECDRP route to UK market for medicines.

Individuals whose personal information is held by the MHRA for purposes of the consultation have given their consent to use their information for the purpose of the consultation. In the case of personal information, the purpose is to read and analyse the information provided to improve understanding of the key considerations raised by individuals and organisations for our work to remove the ECDRP route to UK market for medicines.

The information may also be used to help explore issues and direct further areas of research.

4. Security and confidentiality

Only members of the MHRA working on the removal of the ECDRP route to UK market for medicines will have access to the information. These would include the following: the policy team, the Consultation Coordinator, and the team analysing the consultation responses. Authorised personnel from SurveyOptic Ltd (the online survey platform) will also have access to personal information. Those who do are aware of their obligations and responsibilities when handling personal and confidential information. They are subject to employment, contractual and other professional obligations regarding confidential and official information, both during the review and afterwards.

All personal and confidential information is stored securely to prevent loss or inappropriate access.

5. Sharing information

The MHRA will hold the personal information you provide in this consultation and use it for the purpose of informing the approach to removing the ECDRP route to UK market for medicines.

Due to the fact this is a joint consultation with and the Department of Health in Northern Ireland, responses to this may be shared with policy officials in Northern Ireland. All data shared with Northern Ireland will be anonymised. We don’t intend to share your personal data with any other third party other than our data processors, SurveyOptic Ltd (the online survey platform), who act only upon our instructions. We will handle any specific requests from a third party for us to share your personal data with them in accordance with data protection law. We will not sell your personal data.

Information published in response to this consultation, including personal information, may be published or disclosed in accordance with the access to information regimes. These are primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 2018 (DPA), the UK General Data Protection Regulation 2016 (GDPR) and the Environmental Information Regulations 2004.

If you wish the information you provide to be treated as confidential, please contact us at partnerships@mhra.gov.uk. It would be helpful if you could explain to us why you regard the information you have provided as confidential. Any information not published, including personal information, may still be subject to disclosure in accordance with the Freedom of Information Act. If we receive a request for disclosure of such unpublished information, we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. We will not take a standard confidentiality statement included in an email message as a specific request for non-disclosure.

The MHRA will process your personal data in accordance with the DPA and UK GDPR and in the majority of circumstances this will mean that your personal data will not be disclosed to third parties. However, the information you send us may need to be published in a summary of responses to this consultation.

6. Retention and destruction of documents

We will retain the responses to this consultation until our work on the removing the ECDRP route to UK market for medicines is complete.

Following the consultation, a response to the consultation will be published outlining its findings and recommendations. It is anticipated that the final response will not include any personal data. The contributions will be retained for a period of 2 years after the final consultation response has been published.

7. Rights

You have several rights which are outlined in the MHRA Privacy Notice: https://www.gov.uk/government/publications/mhra-privacy-notice. For greater detail on when they apply please refer to the Information Commissioner's website If you wish to exercise any of your rights, or have any questions or concerns, please contact our Data Protection Officer at dataprotection@mhra.gov.uk.

Produced by the Medicines and Healthcare products Regulatory Agency. www.gov.uk/mhra