Medicines (Gonadotrophin-Releasing Hormone Analogues) (Restrictions on Private Sales and Supplies) Order 2024

Lead department	Department of Health and Social Care
Summary of proposal	This legislation implements an indefinite ban on the sale and supply of puberty blockers to under-18s by private UK providers and prescribers in the EEA and Switzerland
Submission type	Impact Assessment – 29 November 2024
Legislation type	Secondary legislation
Implementation date	1 January 2025
RPC reference	RPC-DHSC-24022-IA (1)
Date of issue	10 February 2025

RPC opinion

Rating	RPC opinion
Fit for purpose	The assessment outlines a sufficient rationale, focussed on preventing unsafe prescribing to protect patient health, however, this could be improved with more evidence to indicate the scale of the issue. The IA considers a suitable shortlist of three options, based on recommendations from independent reviews. The SaMBA provided is sufficient. The assessment includes a reasonable qualitative justification for the preferred way forward, drawing on evidence from the Commission on Human Medicines (CHM) and the Cass Review[1]. The regulatory scorecard could be improved by providing a quantified indication of the burden faced by businesses and a consideration of the potential trade impacts.

[1] Final Report – Cass Review

RPC summary

Category	Quality	RPC comments
Rationale	**Green**	The assessment outlines the problem under consideration and the argument for intervention, which is focussed on the need to prevent unsafe prescribing practices to protect patient health and wellbeing. This could be improved by including more evidence to indicate the scale of the issue.
Identification of options (including SaMBA)	**Green**	The IA considers three shortlisted options, based on recommendations from independent reviews. This assessment could be improved by providing greater detail on why other potential options were not considered. The SaMBA provided is sufficient.
Justification for preferred way forward	**Green**	The assessment includes a qualitative justification for the preferred way forward. This justification is sufficient, drawing on evidence from CHM and the Cass Review.
Regulatory Scorecard	**Satisfactory**	The scorecard provides a brief summary of expected impacts on businesses and households, including estimation of an NPV figure. This could be improved by providing a quantified indication of the scale of the burden faced by businesses and a consideration of the potential trade impacts.
Monitoring and evaluation	**Good**	The assessment includes a good M&E plan, with a clear timeframe, objectives and set of potential data sources. This could be improved by considering how the policy could be evaluated after the relatively short PIR period.

Summary of proposal

Gonadotropin-Releasing Hormone agonists for pubertal suppression (commonly known as puberty blockers) are prescribed to children presenting with gender dysphoria (meaning there is a mismatch between their assigned gender at birth and their own sense of gender identity). The NHS has stopped the routine prescription of puberty blocker treatments to under-18s and routes patients to specialised services, and so any prescribing occurs 'off-label', typically issued by private providers in the UK or from providers in the European Economic Area (EEA) or Switzerland. This was previously subject to temporary bans.

After an evidence review, including a consultation, the Commission on Human Medicines (CHM) has advised that "the current prescribing and care pathway for GnRH agonists for gender dysphoria/incongruence presents an unacceptable safety risk for children and young people under 18 years without significant additional safeguards". As a result, CHM recommended that the temporary restrictions on puberty blockers from EEA/Switzerland prescribers is extended indefinitely, with the restrictions on UK private providers due to be reviewed in April 2027.

The IA assesses the following options:

- Allow the temporary ban to expire
- Continue with the temporary restrictions for a further short period
- Implement an indefinite ban

The Government opted to implement an indefinite ban, subject to the recommended review.

Rationale

Problem under consideration

The IA sets out the problem under consideration as current prescribing practices being unsafe, leading to risks to patient health and wellbeing. This has been supported using evidence from CHM and the Cass Review, which argues that there is insufficient evidence to support the routine use of puberty blockers for gender dysphoria in children, meaning that current prescribing practices pose an unacceptable safety risk. In addition to this, the review raised the potential risk of prescribing from overseas providers, as they are subject to less stringent regulation than those in the UK.

To help demonstrate the scale of the problem, the assessment could be improved by including evidence from DHSC on the number of patients that are currently prescribed puberty blockers. There is a discussion of the potential number of patients affected in the assessment's consideration of the Net Present Social Value, however the Department could effectively use this as part of its problem under consideration.

Argument for intervention

The IA sets out the need for government intervention with the claim that as the current temporary ban was set to expire, further action was required to address the potential risks with inappropriate prescribing. Therefore, the Government decided that an indefinite ban was necessary to address the concerns raised by CHM on a long-term basis. The IA supports this argument by discussing some of the potential harms that could be caused by a failure to intervene, such as the return of prescribing through routes that do not have adequate evidence confirming their safety and efficacy. The Department claims that this would carry both long- and short-term consequences, as supported by the Cass Review. Allowing prescribing from outside of the UK to occur would also limit the ability of the Government to collect monitoring data which would limit further research and learning.

The assessment could also be improved by drawing evidence from the Cass Review in its argument for intervention to help better demonstrate specifically the potential harms of a failure to intervene.

Objectives and theory of change

The IA states that the Government's policy objectives are to ban inappropriate prescribing, ensure continuity of care and appropriate support to all patients and any ongoing prescribing being performed within a research protocol. The Department linked these overall objectives to a set of intended outcomes from the intervention. The Department does well to assess each of the objectives against the SMART criteria, however, it acknowledges that measurement of outcomes will be challenging. Given the requirement to review the policy in 2027, the assessment would be improved by the inclusion of more measurable objectives that could be used in the review. The Department also does well to set out its theory of change in a logic model (Figure 3 in the IA), showing the process of moving from the initial problem to the policy.

Identification of options (inc. SaMBA)

The IA does not include a set of longlisted options, instead it focusses on the shortlist of three potential options: allowing the temporary ban to expire, continuing with the temporary restrictions for a short period and implementing an indefinite ban.

The IA justifies this by the work that was done previously to develop policies to address the identified risks, including an IA published in May 2024 and updated in August 2024, drawing on the 2024 consultation, CHM review and the subsequent recommendations. The IA usefully set out details on the various reviews and papers that have contributed to this evidence base, however the assessment could be improved by the inclusion of greater detail on how this has specifically influenced the policy development process to produce the three options and a discussion of the quality of existing research, helping to set out why other options were not viable.

The assessment does briefly discuss a couple of other potential options: a 'do minimum' option and a 'more aggressive' option. A potential do minimum was not assessed in detail as the Government considered an indefinite ban as the minimum

intervention required to achieve the policy objectives, however the IA would be improved with further discussion of these potential minor interventions, with a justification for why these would not meet the objectives. The more aggressive option was also rejected, as banning a wider list of medicines would go against the clinical advice received by the Government.

Consideration of alternative options to regulation

The Department has not considered any alternative options to regulation. This is acceptable given the context based on the CHM recommendations and the Cass Review focusses on a move from a temporary ban to an indefinite one removes the possibility of alternative options. Despite this, the assessment should include a justification that covers why consideration of alternatives to regulation has not been possible in these circumstances.

Small and Micro Business Assessment

The assessment includes an adequate SaMBA. The Government decided not to exempt small and micro businesses (in this case pharmacies) from the measures, as unsafe practices cannot be allowed in some businesses rather than others. In addition, the Department estimates that the impact on business will be negligible, and so the impact on small and micro businesses will be minimal even without an exemption. This justification is sufficient.

The SaMBA could be improved by discussing potential mitigations targeted towards small and micro businesses on areas such as compliance. The assessment could also be improved by considering the potential impact on medium sized businesses.

Justification for preferred way forward

Appraisal of the shortlisted options

The Department assessed three shortlisted options qualitatively, with allowing the ban to expire treated as the ‘business as usual’ baseline scenario. This is focussed on comparing the business-as-usual scenario and the preferred option, as the temporary and indefinite bans have a similar impact, with the key difference being only the level of long-term clarity provided to patients and prescribers. The IA also includes a table setting out the qualitative differences between the baseline and preferred option as part of the summary of analysis and evidence. The assessment concludes that an indefinite ban of puberty blockers is the Government’s preferred way forward.

The IA uses its Figure 2 to draw contrasts between the health risks to patients when the temporary ban is allowed to expire, showing how all patients using prescriptions from the EEA and Switzerland would be worse off, and new patients receiving prescriptions through NHS primary care and private UK providers also facing increases in health risks. This helpfully demonstrates the conclusions of the research conducted into the different options. Given this measure makes a temporary regulation into a permanent set of requirements, the assessment of impacts correctly

summarises these impacts relative to a do-nothing counterfactual in which the temporary ban expires, rather than against that of the status quo.

The IA does not monetise any of the potential impacts of the preferred option, however it does set out a qualitative summary of the social and business impacts. This includes an attempt to provide an indication of how many patients may be affected, using DHSC data to show there were around 500 10–17-year-olds receiving puberty blockers on the NHS between September 2023 and August 2024, and 6,033 patients on the NHS Children and Young Peoples Gender Services waiting list in July 2024. The assessment estimates that the number of patients presenting with gender dysphoria is significantly lower than 6,033, however the Department is unable to demonstrate this as there is no data available on the number of patients prescribed puberty blockers from private providers in the UK or EEA.

The Department appraisal of its preferred option could be improved by considering the cost of increased access to UK-regulated GPs and mental health services, as the Department has proposed that these services will form part of the mitigation against the risks of increased mental and physical problems as result of a ban.

Selection of the preferred option

Overall, the qualitative options appraisal of the measures is appropriate to justify the selection of the preferred option. The IA has discussed the potential impacts from each of the options, setting out how they perform against the Government's policy objectives and why this has led to the selection of the preferred option, using evidence from the Cass Review, CHM and others.

Regulatory Scorecard

Part A

The Department uses the scorecard to set out how it considers the policy to have a positive impact on total welfare, driven by a positive impact on households. This is caused by a health gain for patients through safer prescribing, monitoring and support, and improved research. The assessment includes a brief summary of the possible business impact, with pharmacies facing the reduced obligation of having to check the validity of EEA and Swiss prescribers, balanced with the burden of ensuring compliance with the new regulation. The Department states therefore that the overall effect is negligible, however the assessment could be improved by illustrating this with an indication of the scale of pharmacies affected or a rough monetisation of the familiarisation and compliance costs they may face.

The IA could also be improved by considering potential risks that may affect the benefits being realised, such as the potential for private online sales of puberty blockers without a prescription. The assessment also could also consider the possible indirect impacts on civil society organisation's such as charities that assist patients with gender dysphoria.

The assessment could have discussed the 'neutral' rating of distributional impacts in greater detail, given the policy specifically affects a group of patients with protected characteristics that are likely to be significantly impacted.

Part B

The IA includes a very brief explanation of the potential impacts on the business environment and international considerations. This includes the potential for an administrative benefit for some businesses which currently find processing overseas prescriptions burdensome; however, this policy would affect only a very small proportion of total overseas prescription sales. The scorecard also mentions the possible impact on overseas businesses; however, the IA could be improved by commenting more specifically on the potential effects of the policy on trade, given the Government have banned the importing of this set of medicines to the UK.

The IA could have discussed how the risks of overseas prescribing are dealt with in other medial circumstances with other drugs given the IA's emphasis of the risk of less stringent regulation in other countries.

Monitoring and evaluation

The IA includes a satisfactory plan for monitoring and evaluation. The Department has set out how it plans to conduct a post-implementation review (PIR) by 1st October 2027. This is based on a formal requirement within the legislation. This is a relatively short time after implementation and has been justified by the Department as it can enable quick remedial action if aspects of the new system are sub-optimal.

The M&E plan sets out the intended objectives of the monitoring process and what it sets out to deliver, as well as metrics and potential data sources that could be used to support this. The Department does well to set out clearly the PIR date, however the IA could provide more detail on a longer-term monitoring and evaluation strategy beyond the two-and-a-half-years period after implementation, in the case of the legislation remaining in place following the initial PIR. The assessment would also be improved with discussion about any research and clinical trials which could provide a basis for deciding whether continuing with a ban is appropriate or not.

The Department states that it will assess potential unintended consequences as part of the review, however the assessment could be improved by including a discussion of these potential risks and unintended consequences, as well as the possible effect of external factors on the intervention.

Regulatory Policy Committee

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