

The Human Medicines Regulations 2012

Lead department	Department of Health and Social Care
Summary of proposal	A post-implementation review of The Human Medicines Regulations 2012, assessing effectiveness across four themes: pharmacovigilance; cross-border prescriptions; wholesale distribution and sale and supply; and the Falsified Medicines Directive, covering changes and implementation experience since the 2017 review.
Submission type	Post-implementation review (PIR) 23 January 2026
Implementation date	14 August 2012
Department recommendation	Keep
RPC reference	RPC-DHSC-26126-PIR(1)
Opinion type	Formal
Date of issue	24 February 2026

RPC opinion

Rating¹	RPC opinion
Fit for purpose	The PIR provides proportionate evidence to support the Department's recommendation to keep the Regulations. Qualitative evidence and contextual analysis after EU exit and the Windsor Framework demonstrate that core objectives—patient safety, secure supply chains, and appropriate cross-border dispensing—continue to be met. For the next statutory cycle, the Department should consider returning to an open consultation, as used in 2017, to broaden participation and improve coverage.

¹ The RPC opinion rating is based only on whether the evidence in the PIR is sufficiently robust, as set out in the [Better Regulation Framework](#), to support the departmental recommendation. RPC ratings are fit for purpose or not fit for purpose.

RPC summary

Category	Quality ²	RPC comments
Recommendation	Green	Evidence is proportionate to a statutory PIR of low impact. The review sets out objectives, reports stakeholder signals across the four themes, and explains policy changes post-EU exit/Windsor Framework. The Department should clarify ownership and cadence for planned guidance updates (e.g., Wholesale Dealer's Licence exemptions; cross-border e-signatures) to improve assurance on milestones and accountability.
Monitoring and implementation	Satisfactory	Implementation evidence shows functioning pharmacovigilance processes, secure wholesale controls and workable dispensing arrangements. The PIR explains adaptations since 2017, EU exit and COVID. The Department should consider returning to an open consultation, as used in 2017, to broaden participation and improve coverage.
Evaluation	Satisfactory	The PIR discusses objectives, unintended effects, and justifies a qualitative approach. It acknowledges sample limitations, and policy changes. The Department should monitor SMB experience through targeted engagement.

The 2012 regulations include a requirement for the Secretary of State to review them from time to time and to set out in a published report — a post-implementation review — the conclusions of the review carried out. The first report was required to be published before the end of the period of five years, beginning with the day on which the regulations came into force (14 August 2012), and for subsequent reports to be published at intervals not exceeding five years. A report was published in 2017, but not since. It appears, therefore, that publication of the present PIR is later than the

² The RPC quality ratings are used to indicate the quality and robustness of the evidence used to support different analytical areas. The definitions of the RPC quality ratings can be accessed [here](#).

commitment in the legislation, and we recommend the Department undertakes the next periodic review within the five-year deadline.

Summary of proposal

The Department's review examines whether The Human Medicines Regulations 2012 remain effective following significant legal and operational changes since 2017. The regulations consolidate medicines legislation governing authorisation, manufacture, importation, distribution, sale and supply, labelling, advertising and pharmacovigilance, with the overarching aim of protecting public health while ensuring safe, high-quality, efficacious medicines reach patients. To preserve clarity, the PIR groups provisions into four themes—pharmacovigilance, cross-border prescriptions, wholesale distribution and sale and supply, and the Falsified Medicines Directive (FMD)—and describes how each has operated across the review period. The review sets out the comparability with the 2017 approach.

Since 2017, EU exit and the Windsor Framework have materially altered the regulatory context in which the regulations operate. The PIR explains the introduction of UK-wide licensing, the categorisation of products into Category 1 and Category 2, and the disapplication of EU safety-feature verification in Northern Ireland from 1 January 2025. It records pandemic-related amendments and targeted legislative updates to specific provisions, including changes affecting active substances and distribution practice. These developments are presented as contextual changes that affect implementation conditions. The review is attentive to the continued role of applicable EU law for Category 2 products, ensuring conclusions remain precise about territorial scope and timing.

The evidence base combines a targeted questionnaire sent to 70 organisations (11 responses) with subject-matter expertise from MHRA and DHSC, complemented by relevant impact assessments and guidance. Maintaining methodological continuity with 2017 allows like-for-like interpretation while recognising that the present sample is narrower than the earlier open consultation. Findings are, therefore, triangulated across respondent themes and official sources, and are reported with caveats about attribution limits. Where possible, the PIR distinguishes between operational frictions amenable to guidance and process fixes, and areas that may merit consultation or legislative adjustment.

Overall, the PIR concludes that the objectives remain valid, the measures broadly work as intended, and limited, proportionate refinements to guidance and implementation could reduce burden further without compromising safety or supply resilience.

Recommendation

The Department recommends keeping the regulations. The PIR evidences this with several sources: most respondents judge pharmacovigilance effective for patient safety; pharmacies report continuity of care from cross-border dispensing; wholesale controls support supply-chain integrity; and remaining FMD provisions deter infiltration while Windsor arrangements simplify NI processes. The qualitative approach appears justified by low estimated business impacts and statutory scope, and by referencing prior IAs and Regulatory Triage Assessments.

Stakeholder and market evidence indicates that cross-border rules aid patient access, particularly for pre- and post-treatment courses and for movement across the island of Ireland, while some online-prescribing models create validation risks. Pharmacovigilance obligations are generally workable, with targeted simplifications addressing legacy burdens for Traditional Herbal Registration holders. Wholesale licensing promotes consistent standards, though pharmacies perceive administrative load and ambiguity around exemptions.

Attribution is handled cautiously. The PIR recognises confounders from EU exit, pandemic-era changes and the Windsor Framework, avoiding over-claiming causal effects. It explains why a qualitative design remains proportionate for low-impact measures and how agency intelligence supplements limited survey coverage. Counter-arguments, such as claims that supply issues arise more from quality assurance than falsification, are acknowledged alongside safeguards and options for targeted consultation on safety-features.

The evidence is proportionate under the BRF for a 'Keep' recommendation. The review demonstrates that objectives remain appropriate and could not be achieved with significantly less regulation without risking safety or supply security, while proposing proportionate guidance updates. The Department should track impacts of the 2025 General Pharmaceutical Council (GPhC) online-pharmacy safeguards, and planned guidance revisions, with named owners and dates, to support transparent implementation.

Monitoring and implementation

Proportionate

Implementation and monitoring arrangements appear proportionate to the regulations' risk and estimated business impacts. Pharmacovigilance reporting continues to support timely safety action, with Windsor Framework changes clarifying Category 1 post-authorisation conditions. Wholesale licensing and dispensing exemptions are implemented through established MHRA/DHSC guidance. The PIR explains why quantitative estimates would be disproportionate, relying instead on targeted stakeholder evidence and agency intelligence. The Department should publish indicative milestones for guidance updates on WDL exemptions and cross-border electronic signatures, to demonstrate predictable delivery.

Range of evidence

The PIR draws on a targeted questionnaire (11 returns across professional bodies, trade associations and parallel importers), MHRA and DHSC expert input, prior IAs/RTAs and published guidance. Coverage spans pharmacovigilance, cross-border prescriptions, wholesale distribution and FMD. While the response rate is modest, the sources are complementary and aligned to low-impact statutory review requirements. To strengthen balance, the Department should plan to capture patient-group perspectives and devolved administrations' implementation feedback in the next cycle, and log how GPhC's 2025 safeguards and Windsor changes will be monitored using data.

Gaps in evidence justified

The PIR transparently explains limits from sample size, timing and feasibility, noting that full cost-benefit analysis would require new surveys, disproportionate to risk. It addresses confounding from EU exit and pandemic responses, and clarifies where Windsor Framework changes remove previous constraints. Inference rests on converging qualitative signals and expert judgement consistent with RPC guidance for low-impact measures. The Department should set a light-touch plan to systematise ongoing evidence collection—naming datasets and frequency. With a response rate of 16%, breadth should be increased next cycle via, for example, an open consultation to mirror 2017.

Evaluation

Policy objectives considered

The PIR restates objectives across the four themes and tests them against post-2017 operational realities. Pharmacovigilance aims to ensure timely safety action through proportionate reporting and post-authorisation tools; cross-border provisions prioritise continuity of care subject to professional and territorial safeguards; wholesale provisions secure the supply chain while allowing practical exemptions; and FMD-related measures deter infiltration absent EU safety-features. The objectives remain appropriate given UK-wide licensing and Windsor Framework adjustments.

Unintended effects

The review identifies burdens on pharmacies from wholesale licensing processes, operational frictions in verifying cross-border prescriptions and e-signatures, and compliance costs in the specials sector under active-substance controls. It records perceptions that some burdens may exacerbate supply issues and acknowledges risks from online prescribing models based outside the UK. These effects are weighed against safety and access benefits, with mitigations via guidance updates, GPhC safeguards and potential consultation on a UK-tailored safety-features regime. The PIR should log measurable follow-ups for each risk to support proportionate, time-bound mitigation.

Original assumptions

The PIR notes assumptions from earlier IAs and the 2017 review: low expected demand for cross-border dispensing, qualitative proportionality for low-impact measures, and the role of wholesale licensing in supply-chain assurance. Evidence remains consistent with those priors while recognising context shifts from EU exit and pandemic measures. Where assumptions drive burden (e.g., WDL thresholds and exemptions), the Department should test whether guidance clarifications, or digital verification tools, deliver the anticipated balance between safety and administrative simplicity, without unintended displacement effects.

Whilst the PIR records previous EANDCBs, it should assess their accuracy, covering familiarisation hours for pharmacies and wholesalers, recurring record-keeping/verification tasks, and system changes linked to wholesale licensing and safety-features. The Department should include an original assumptions versus outcomes section, recording whether outcomes were lower, similar or higher, provide a reason, and the action undertaken. This creates a baseline for the next review, and improves the credibility of assessments.

SMBs

Impacts on small and micro businesses are acknowledged in pharmacy settings and specialist manufacturers. The PIR records administrative load from WDL processes and active-substance compliance in the specials sector. Exemptions for collection and delivery improve access, but require clear controls to avoid uneven burdens. Proportionate mitigation includes clarifying eligibility thresholds and documentation, and exploring lightweight digital tools for cross-border verification. The Department should monitor SMB experience through targeted engagement.

Intervention required

Retaining the regulations is reasonably stated as the appropriate intervention to protect patients and ensure supply-chain integrity. The review explains why less regulation would risk undermining pharmacovigilance capability and wholesale assurance, while more onerous regimes (e.g., blanket verification) are unnecessary post-Windsor. Limited, targeted changes—chiefly guidance clarifications and consultation on safety-features—represent proportionate next steps.

Improvements or alternative options considered

Alternative options raised by stakeholders include removing the WDL requirement for pharmacies, expanding exemptions, or introducing upstream track-and-trace. The PIR assesses trade-offs and favours guidance refinement over deregulatory change, maintaining equitable licensing coverage to protect the supply chain. It notes MHRA portal improvements and the scope to consult on tamper-evident devices.

Future impacts considered

The review anticipates ongoing evolution under UK-wide licensing, further professional scope changes and digital prescription flows. It recognises that online-prescribing safeguards and guidance updates may shift burdens across actors.

Regulatory Policy Committee

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