Medicines & Healthcare products Regulatory Agency

Medicines and Medical Devices Act 2021 - Survey

About the survey

The Medicines and Healthcare products Regulatory Agency (MHRA), in collaboration with the Department of Health and Social Care (DHSC), is conducting a review of the UK's medicines and medical device regulatory framework, and we are seeking input from stakeholders across the sector, including patients and the public.

The review is a statutory obligation under the Medicines and Medical Devices Act 2021 and is being conducted in accordance with Part 6, Regulation 48 of the Act, which requires the government to assess the operation and impact of the legislation at least once every five years.

We would value your views and experiences on the regulations which are relevant to you or your organisation. Please provide us with unbiased responses and where possible, specific examples. The findings from the completed survey will inform the Review and a report to be published by the Secretary of State for Health and Social Care. All feedback will be anonymised in the final report.

The deadline for completing the questionnaire is **19th September 2025**. If you have any questions relating to this review and the completion of the survey, please email: Partnerships@mhra.gov.uk, with "*MMD Act Review*" in the subject line.

About the Review

The focus of the review is the legislation that govern the development, authorisation, supply, and oversight of medicines and medical devices in the UK.

These include:

- Human Medicines Regulations 2012 (HMRs): which set out the regime for the manufacture, authorisation, supply, and pharmacovigilance of medicines.
- Medical Devices Regulations 2002 (MDRs): which provide the regulatory framework for medical devices, including requirements for safety, performance, and conformity assessment.
- The Medicines for Human Use (Clinical Trials) Regulations 2004: which govern the conduct of clinical trials of medicinal products.
- Medicines and Medical Devices (Fees) Regulations: which outline the fees payable to the MHRA in relation to regulatory services.

The objectives of the legislation is to provide a clear framework and expectations for medicines and devices manufacturers and distributors, give the regulator oversight to ensure the requirements are met and action can be taken when they are not, to support supply to patients, and ensure the safety of those products. The UK medicines and medical devices regulations were originally derived from EU legislation which was transposed into UK law. Over time the regulations have been amended multiple times to reflect changes in scientific

practice, public health priorities, and regulatory standards. The Medicines and Medical Devices Act, passed in 2021, provides the primary powers that enable the UK to update and amend the legislation.

The purpose of this review is to evaluate whether the legislation is operating as intended now, if it continues to effectively protect public health, and avoids imposing unnecessary or excessive regulatory burdens. The review is also looking at the structure of the legislation and whether restructure or consolidation would make the regulations clearer or easier to implement.

Data Privacy

This Review complies with data protection legislation including the Data Protection Act 2018 (DPA) and the UK General Data Protection Regulation (UK GDPR). Personal data will be kept for no longer than necessary to fulfil our purpose in processing it. Any personal information will be anonymised. Information from this review, including personal information, may be disclosed in accordance with the access to information regimes. These are primarily the Freedom of Information Act 2000 (FOIA), the DPA, the UK GDPR and the Environmental Information Regulations 2004. The MHRA and DHSC will process your personal data in accordance with the DPA and UK GDPR and in most circumstances, this will mean that your personal data will not be disclosed to third parties. The lawful basis for processing personal data is article 6(1)(e) UK GDPR. Further information personal data is handled, including data subject rights, is available in the MHRA privacy notice, and DHSC privacy notice.

1 - About you

This section gathers background information about you or your organisation, including your role, sector, and geographical reach. It helps us understand the context of your feedback.

1. Which best applies to you:

- ○ I am responding as an individual
- ○ I am responding on behalf of an organisation

2. Are you?

- ○ a member of the public/patient
- ○ a patient representative organisation
- ○ a healthcare professional
- ○ a trade/professional association/organisation
- ○ Other (please specify)

3. Name of organisation (if applicable) (optional)

2 - Regulations Reviewed

Here, we ask which specific medicines and/or medical devices regulations you or your organisation have engaged with, to tailor your responses to relevant legislative areas.

4. Please tick the specific regulation(/s) you or your organisation have reviewed, worked with, or are relevant to you.

- [ ] Human Medicines Regulations 2012 (HMRs)
- [ ] Medicines (Fees) Regulations
- [ ] Medical Devices Regulations 2002
- [ ] Medical Devices (Fees) Regulations
- [ ] The Medicines for Human Use (Clinical Trials) Regulations 2004
- [ ] Sections 10, 15 and 131, and Part 4 of the Medicines Act 1968 (relating to Pharmacies
- [ ] N/A

3 - Operation of the Regulations

This section seeks your views on how effectively the regulations are operating in practice, including their impact on public health, the areas that work well, and any challenges, burdens, or ambiguities you have experienced.

5. How well do you think the current legislation protects public health? (Please select the option that best reflects your view.)

- ○ a. Very effectively – the legislation provides strong and appropriate public health protections
- ○ b. Effectively – the legislation generally works well to protect public health, with minor gaps
- ○ c. Somewhat effectively – there are noticeable gaps or areas for improvement
- ○ d. Ineffectively – the legislation does not adequately protect public health
- ○ e. Not sure / No opinion

6. Please briefly explain your answer and, where possible provide examples to support your view. (optional)

7. In your experience on, a scale of 1 to 10, how effectively do the regulations work in practice? This refers to the clarity, enforceability, consistency, and practical impact of the regulations in achieving their intended outcomes (1 = Not at all effective, 10 = Extremely effective)

Select

8. Please briefly explain your answer and, where possible provide examples to support your view. (optional)

9. Have you encountered any issues, blockers, or areas of ambiguity when using the regulations?

- ◯ Yes
- ◯ No
- ◯ Unsure

10. Please provide examples of the issues, blockers, or areas of ambiguity you have encountered (optional)

11. Are there any particular areas of the regulation which you consider impose unnecessary or excessive regulatory burdens?

- ◯ Yes
- ◯ No
- ◯ Unsure

12. Please provide examples of the areas which you consider impose unnecessary or excessive regulatory burdens (optional)

13. How do UK regulations compare with those of other regulators or international comparators (e.g., EU, FDA)? (optional)

4 - Structure of the Legislation

This section seeks your views on the clarity, structure, and navigability of the legislation, including any overlapping or outdated provisions, and the current balance between flexibility and oversight, the division between legislation and guidance.

14. On a scale of 1 to 10, how clear, well-structured, and easy to navigate do you find the legislation? (1 = Not at all clear or easy to navigate, 10 = Extremely clear, well-structured, and easy to navigate)

Select

15. Are there any overlapping, duplicative, or outdated provisions?

- Yes
- No
- Unsure

16. Please briefly explain your answer and, where possible provide examples to support your view. (optional)

17. Do the regulations provide the appropriate balance of flexibility to respond to new technologies or emerging public health issues, and robust regulatory oversight?

- a. Strongly agree
- b. Agree
- c. Neither agree nor disagree
- d. Disagree
- e. Strongly disagree

18. Do you think the current balance between what is set out in legislation versus what is provided in supporting guidance is appropriate?

- a. Yes – the current balance is appropriate
- b. No – too much is in legislation that should be in guidance
- c. No – too much is in guidance that should be in legislation
- d. Unsure

19. Please briefly explain your answer and, where possible provide examples to support your view. (optional)

5 - Streamlining

This section explores views on whether the legislation should be streamlined to reduce complexity, duplication, and administrative burden. Streamlining may involve simplifying language, removing outdated or redundant provisions, and making changes to the structure of the legislative framework. It also considers whether the potential benefits of such changes would outweigh the possible disruption and adjustment required during the transition period.

20. What is your view on the extent to which the legislation should be streamlined? (Please select the option that best reflects your view.)

- a. No changes are needed – the legislation is already clear and appropriately structured
- b. Minor changes – some small areas could benefit from clarification or simplification
- c. Moderate changes – there are several areas that could be improved through streamlining
- d. Significant changes – the legislation would benefit from a major simplification and restructuring
- e. Unsure / No opinion

21. What impact, if any, would streamlining the legislation have on you or your organisation?

- a. Very positive impact
- b. Somewhat positive impact
- c. No impact
- d. Somewhat negative impact
- e. Very negative impact

22. In your opinion, would the benefits of streamlining the legislation outweigh any potential downsides?

- Yes
- No
- Unsure

23. Please briefly explain your answer and, where possible provide examples to support your view. (optional)

6 - New Regulations Made Under the Medicines and Medical Devices Act (MMDA)

This section gathers feedback on the implementation and effectiveness of recent statutory instruments introduced under the MMD Act, and asks whether they are meeting their intended goals.

Since the MMD Act was passed, a number of new regulations have been made using the powers granted by the Act:

- The Medical Devices (Coronavirus Test Device Approvals) (Amendment) Regulations 2021
- The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022; made changes to introduce an early access scheme into law where early access to medicines before they have a marketing authorisation is given to patients with life threatening or seriously debilitating conditions.
- The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2022
- The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023 and The Medicines (Products for Human Use) (Fees) (Amendment) Regulations 2023; made changes to update the fees charged by the MHRA to ensure the regulator recovers the cost of its regulatory activity.
- The Medical Devices (Amendment) (Great Britain) Regulations 2023; made changes to extend the periods for which certain medical devices that comply with EU legislation can be placed on the market in Great Britain.
- Human Medicines (Amendment Relating to Original Pack Dispensing) (England and Wales and Scotland) Regulations 2023; made changes to allow pharmacists the flexibility to dispense up to 10% more or less than the prescribed quantity for medicines, if it allows for dispensing in the original pack.
- The Human Medicines (Amendments relating to Registered Dental Hygienists, Registered Dental Therapists and Registered Pharmacy Technicians) Regulations 2024 ; made changes to expand the scope of practice for dental hygienists, dental therapists, and pharmacy technicians to allow the supply of POMs in specific situations without a prescription.
- Human Medicines (Amendments Relating to Naloxone and Transfers of Functions) Regulations 2024

Additional regulations* have been introduced more recently since the Act was passed; however, those legislative changes are not yet in force or have been in force for less than six months, and their operation and impact cannot yet be meaningfully assessed.

**The Human Medicines (Amendment) (Modular Manufacture and Point of Care) Regulations 2024, The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025, The Medical Devices (Post-market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2024, The Medicines (Products for Human Use) (Fees) (Amendment) Regulations 2025, The Human Medicines (Amendments Relating to Hub and Spoke Dispensing etc.) Regulations 2025*

24. Have you had experience of interacting with the new regulations listed above?

- ○ Yes
- ○ No
- ○ Unsure

Please select which new regulations you have interacted with? (optional)

- ☐ The Medical Devices (Coronavirus Test Device Approvals) (Amendment) Regulations 2021
- ☐ The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022;
- ☐ The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2022
- ☐ The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023
- ☐ The Medical Devices (Amendment) (Great Britain) Regulations 2023
- ☐ Human Medicines (Amendment Relating to Original Pack Dispensing) (England and Wales and Scotland) Regulations 2023
- ☐ The Human Medicines (Amendments relating to Registered Dental Hygienists, Registered Dental Therapists and Registered Pharmacy Technicians) Regulations 2024
- ☐ Human Medicines (Amendments Relating to Naloxone and Transfers of Functions) Regulations 2024
- ☐ The Medicines (Products for Human Use) (Fees) (Amendment) Regulations 2023

25. How well do you think the new regulations are operating? (optional)

- ○ a. Very effectively
- ○ b. Effectively
- ○ c. Somewhat effectively
- ○ d. Ineffectively
- ○ e. Not sure / No opinion

26. Have you encountered any issues or concerns in their implementation? (optional)