



Department
of Health &
Social Care

Medicines and Medical Devices Act 2021: 5 year report

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Department
of Health &
Social Care

Medicines and Medical Devices Act 2021: 5 year report

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Executive summary

The [Medicines and Medical Devices Act](#) (MMDA) became law in February 2021. The act provides the Secretary of State for Health and Social Care and the Department of Health in Northern Ireland with powers to amend existing regulations on human and veterinary medicines and medical devices in the UK, following the UK's departure from the EU.

It is a statutory requirement for the Secretary of State for the Department of Health and Social Care (DHSC) to publish a report on the operation of medicines and medical devices legislation after 5 years of the MMDA's passing. More detail can be found in the section 'Objectives of the report'.

This report is the result of work between DHSC, the Medicines and Healthcare products Regulatory Agency (MHRA), the Government Legal Department (GLD) and the Veterinary Medicines Directorate (VMD), an executive agency of the Department for Environment, Food and Rural Affairs (Defra).

The report draws on evidence gathered through:

- public stakeholder engagement
- internal assessments by policy and legal teams across DHSC, MHRA, GLD and VMD
- previous evaluations, including post-implementation reviews and parliamentary records
- debates at the time of the MMDA's passage

The review finds that the UK's regulatory frameworks for human medicines, veterinary medicines and medical devices, along with the relevant provisions of the MMDA, continue to operate effectively and maintain high levels of protection for patients, animals and the public. These frameworks have enabled meaningful policy development since 2021, including:

- wide-ranging updates to [The Veterinary Medicines Regulations 2013](#) (VMRs)
- the introduction of hub and spoke dispensing for human medicines under [The Human Medicines Regulations 2012](#) (HMRs)
- targeted amendments to [The Medical Devices Regulations 2002](#) (MDR 2002)

However, stakeholders report growing challenges in navigating the legislation due to cumulative amendments, increasing regulatory complexity and reliance on guidance to support interpretation. The review also identifies areas where procedural requirements within the MMDA can be disproportionately burdensome for minor or technical changes.

The report therefore recommends:

- targeted improvements to clarity, guidance and regulatory coherence
- more proportionate mechanisms for updating legislation
- consideration of future consolidation in the case of medical device

These recommendations aim to ensure the UK's regulatory frameworks remain agile and accessible while maintaining strong safeguards for public and animal health.

Objectives of the report

This report has been prepared in accordance with [section 46 of the MMDA](#), which places a statutory duty on the Secretary of State to lay before Parliament, at the end of the relevant period (5 years), a report on the operation of human and veterinary medicines and medical devices legislation. For all legislation in scope of the review, see annex A.

In particular, the act requires that this report must include an assessment on whether:

- some or all medicines and medical devices legislation should be consolidated or otherwise restructured
- provisions of human and veterinary medicines and medical devices legislation should be included in regulations or Acts of Parliament
- powers to make regulations should be modified or repealed

This requirement reflects Parliament's expectation that significant delegated powers should be subject to structured, post-legislative scrutiny.

In preparing the report, the Secretary of State must also consider any report made by a Parliamentary committee relating to the operation of medicines and medical devices legislation. For this review, consideration was given to relevant reports from:

- the House of Lords Delegated Powers and Regulatory Reform (DPRR) Committee and Constitution Committee in relation to the MMDA's procedural provisions
- the House of Lords Secondary Legislation Scrutiny Committee, as well as advice and publications from the government's independent Animal Sentience Committee (ASC) in relation to veterinary medicines legislation

The review covers the period from February 2021 to February 2026. Some regulations made during this period are excluded where they have not yet come into force or have not operated for long enough to allow a meaningful assessment. Legislation not in scope of the review can be found in annex B.

Summary of findings and recommendations

The review finds that the legislative frameworks for human medicines, veterinary medicines and medical devices, along with the relevant provisions of the MMDA, continue to safeguard public and animal health effectively. Across all regimes, stakeholders affirmed that the frameworks are fundamentally robust and fit for purpose.

However, 3 cross-cutting issues emerged consistently:

- complexity and fragmentation caused by cumulative amendments over time is leading to difficulty in navigating legislation
- heavy reliance on guidance, especially in fast-moving or technically complex areas, sometimes results in uncertainty about the legal status of requirements
- procedural rigidity under part 5 of the MMDA, particularly mandatory consultations and extensive use of the draft affirmative procedure, delays amendments to the legislation and may not be proportionate to the amendments

Regime-specific findings include:

- human medicines and pharmacy legislation operates effectively and is robust, but the HMRs can be difficult to navigate due to complexities arising from multiple amendments over time
- delegated powers for veterinary medicines operate well but the inability to revoke and replace the VMRs in full, and the absence of ambulatory references, limit clarity and flexibility
- medical device regulations are most in need of consolidation and structural reform due to outdated references, complexity and the cumulative effect of amendments

For a full list of recommendations, see the section 'Conclusion'.

In summary, this review recommends that the government:

1. Improve clarity and accessibility of legislation through consolidation where justified (particularly for medical devices), targeted improvements, and strengthened guidance.
2. Consider a more proportionate approach to consultation and parliamentary scrutiny of changes to regulations, to enhance regulatory agility without compromising oversight or safety.

3. Maintain awareness of, and where appropriate, harmonise with EU and international frameworks to support supply resilience, innovation and global trade.

Legislation relating to human medicines (under section 9 of the MMDA)

Pharmacy provisions

Overview

This section examines the operation of the legislative framework governing pharmacy services and the sale and supply of medicines, specifically sections 10, 15 and part 4 of the [Medicines Act 1968](#), and the relevant provisions of the HMRs.

The HMRs govern the licensing, manufacture, marketing, wholesale dealing and the sale and supply of medicines in the UK, whereas the Medicines Act 1968 governs pharmacy premises and processes. This is a complex and highly regulated area of the law.

Note that Section 131 of the Medicines Act 1968, which previously defined ‘wholesale dealing’, ‘retail sale’, and related expressions, was removed by the [Human Medicines \(Amendments Relating to Hub and Spoke Dispensing\) Regulations 2025](#). These definitions are now found solely in the HMRs, which ensures a single source of definition and is intended to provide greater clarity and reduce confusion going forward.

Overall, the pharmacy legislative framework continues to operate effectively and has supported important reforms such as the introduction of hub and spoke dispensing. However, cumulative amendments and cross-system interpretation challenges mean the framework can be difficult to navigate in practice. The recommendations from the below assessment therefore focus on improving clarity and supporting consistent interpretation. The assessment also includes reflections on the challenges using delegated powers under the MMDA which is considered under the ‘Part 5 of the Medicines and Medical Devices Act 2021’ section of the report.

Methodology

The assessment draws on internal DHSC subject matter expertise and evidence gathered through external stakeholder engagement. External evidence was collected through a joint MHRA and DHSC survey that was open between 21 July 2025 and 19 September 2025 and received 199 responses, 9 of which commented on pharmacy regulation and legislation. There were also 3 targeted workshop sessions that took place between 29 September 2025 and 6 October to allow stakeholders to raise any further issues directly. Respondents included healthcare professionals, qualified persons (QP) and representative trade organisations.

As the survey allowed respondents to provide feedback against pharmacy provisions as well as other regulations, it was not always possible to clearly discern which regulation a respondent’s score related to. To arrive at the conclusions below, the scores have been

considered alongside the qualitative feedback gathered through the survey and workshops, as well as the internal assessment of the regulations, to form a complete picture of how they are functioning.

Assessment of operation

DHSC believes the current legislative framework provides an effective and robust basis for regulating pharmacy services.

Since the MMDA came into force in 2021, the important development in this area has been the introduction of the Hub and Spoke Dispensing Regulations (2025). These regulations enable 2 pharmacies belonging to different legal entities to share responsibilities for dispensing medicines under hub and spoke arrangements, provided they meet defined minimum requirements. The introduction of the Hub and Spoke Regulations reflect policy intentions highlighted during the passage of the Medicines and Medical Devices bill in Parliament ([Hansard, 27 January 2021](#)), where ministers noted that the delegated powers would enable future changes to medicines legislation, including the expansion of hub and spoke dispensing beyond single legal entities. Introducing these regulations therefore represents a fulfilment of that original legislative intention. However, given that hub and spoke dispensing only came into force on 1 October 2025, it has not been possible to fully assess the functioning of them for this report.

Survey responses relating to the legislation covering pharmacy provisions and human medicines, demonstrate there are challenges for providers in understanding the legislation and determining which parts apply in different situations and clinical settings. Respondents did not identify any areas where the legislation was lacking or overly restrictive. Most issues related to how the legislation is implemented locally and operational challenges, such as on IT systems and how different parts of the health system coordinate with each other. DHSC officials consider these challenges to be more effectively addressed through system changes, clearer guidance and operational strategies rather than through legislative reform. This suggests that legislative restructuring is not required at this time.

Survey respondents from trade and professional associations and organisations rated the regulations as 7 out of 10 in how effectively they operate in practice (1 = not at all effective, 10 = extremely effective), with healthcare professionals rating the effectiveness lower at 5.6 out of 10.

Recommendation: pharmacy regulators and national and local professional leadership bodies should consider developing additional guidance to improve implementation and understanding of the legislation across relevant healthcare settings.

Structure, clarity and navigability of regulations

Stakeholders reported that the HMRs are complex and difficult to navigate, even though a fully consolidated version of the regulations is available on [legislation.gov.uk](https://www.legislation.gov.uk). On the question of how clear, well-structured and easy to navigate the legislation is, respondents from trade and professional organisations rated the regulations as 6.3 out of 10, with healthcare professionals rating them lower at 5 out of 10. Stakeholders noted that consolidation alone does not resolve the underlying complexity created by successive amendments. This feedback indicates that additional clarity, whether through improved guidance or clearer drafting, may be needed.

Further, one respondent identified a drafting inconsistency in regulation 235(3), which exempts regulation 214(1) but not 214(2). After review, DHSC and MHRA agree that this is an error and that regulation 214(2) should also be exempted. This technical amendment, that relates to the categories of person that may parenterally administer prescription-only medicines, has now been addressed as part of a separate HMRs package. No other overlapping or outdated provisions were identified.

Officials consider provisions within primary and secondary legislation to be appropriate. The Medicines Act 1968 remains the primary legislation governing pharmacy practice, while the HMRs serve as the principal secondary instrument regulating the licensing, manufacture, distribution and supply of medicines. This review does not recommend any changes to how pharmacy provision powers are allocated between primary and secondary legislation.

Recommendation: navigation of the legislation should be further supported by exploring opportunities to enhance the accessibility of the HMRs (such as clearer structuring, improved guidance, or signposting), acknowledging stakeholder feedback that consolidation alone has not resolved underlying complexity.

Use of MMDA delegated powers

Current delegated powers under the MMDA only allow for the HMRs to be amended or supplemented. As noted above, regulation-amending powers have been used recently in The Human Medicines (Amendments Relating to Hub and Spoke Dispensing etc.) 2025 (SI 2025/758), which came into force on 1 October 2025. This amendment enables 2 pharmacies belonging to different legal entities to share the responsibilities for dispensing medicines if they enter hub and spoke arrangements, subject to the minimum requirements specified in the regulations.

This is a major policy change, stipulating that the supply of medicines from the hub pharmacy to the spoke pharmacy under these arrangements is classed as a retail sale. This means that the hub pharmacy does not need to hold a wholesale dealing license.

During the introduction of this legislation officials noted that the draft affirmative process can be useful for complex policy and legal changes, such as this hub and spoke reform which included a 12-week consultation period. However in future the blanket inclusion of the draft affirmative procedure requirement could cause an unnecessary and excessive administrative burden for minor technical changes. DHSC and GLD officials believe that smaller technical changes could be made in a more agile fashion with either a reduced consultation period or an exemption to the consultation requirement.

These reflections are relevant to wider considerations under the section of this report, 'Part 5 of the Medicines and Medical Devices Act 2021', which examines consultation and parliamentary scrutiny requirements in more detail.

Summary of recommendations

The following recommendations are therefore made:

- pharmacy regulators and national and local professional leadership bodies should consider developing additional guidance to improve implementation and understanding of the legislation across relevant healthcare settings
- navigation of the legislation should be further supported by exploring opportunities to enhance the accessibility of the HMRs (such as, clearer structuring, improved guidance or signposting), acknowledging stakeholder feedback that consolidation alone has not resolved underlying complexity

The Human Medicines Regulations 2012 (SI 2012/1916)

Overview

This section assesses the HMRs and the relevant provisions in the MMDA that provide the powers to amend the legislative framework for human medicines.

The HMRs consolidated and rationalised medicines legislation into one set of regulations to aid the understanding and application of the law. It did so by repealing or revoking most of the Medicines Act 1968 and around 200 statutory instruments. The HMRs provide the regulatory framework for medicines on the UK market, including:

- the authorisation of medicinal products for human use
- the manufacture, importation, distribution, sale and supply of medicines
- labelling and advertising
- pharmacovigilance
- cross-border prescriptions

This legislative framework aims to ensure a high level of public health protection and the safety, quality and efficacy of authorised medicines.

The HMRs are subject to a post-implementation review every 2 years, with the latest review expected for publication in early 2026.

Overall stakeholders consider the HMRs largely robust and effective, but increasingly difficult to navigate due to complexities arising from cumulative amendments. Additionally, stakeholders reported navigating responsibilities under legislation from different parts of government added further complexity. For example, needing to consider MHRA/DHSC medicines packaging requirements alongside wider product and environmental legislation led by the Department for Business and Trade (DBT) and Defra. The recommendations from the assessment below therefore focus on improving guidance, alongside targeted improvements and simplification of legislation in specific areas. It also recommends keeping the need for more substantive consolidation and restructure under review.

Methodology

The assessment draws on internal MHRA and DHSC subject matter expertise and evidence gathered through external stakeholder engagement. External evidence was collected through a joint MHRA and DHSC survey that was open between 21 July 2025 and 19 September 2025 and received 199 responses, 93 of which commented on

the HMRs. There were also 3 targeted workshop sessions that took place between 29 September and 6 October 2025 to allow stakeholders to raise any further issues directly. Respondents included:

- patient groups
- healthcare professionals
- industry and trade associations
- academia
- charities

As the survey allowed respondents to provide feedback against the HMRs as well as other regulations, it was not always possible to clearly discern which regulation a respondent's score related to. In order to arrive at the conclusions below the scores have been considered alongside the qualitative feedback gathered through the survey and workshops, as well as the internal assessment of the regulations, to form a complete picture of how they are functioning.

In addition to stakeholder engagement specific to this review, evidence provided for the HMRs post-implementation review was also considered.

Assessment of operation

DHSC and MHRA believe the regulations are working effectively, but can be challenging to navigate - and in some areas may benefit from improvements.

Stakeholders reported that the HMRs are functioning relatively effectively in safeguarding public health and enabling access to safe and effective medicines for patients. The framework is considered robust and comparable to frameworks used by regulators in other jurisdictions.

However, stakeholders pointed to some areas of the legislation which they felt were imposing unnecessary regulatory burden, or where specific improvements would make them work better in practice. Survey respondents from industry and trade associations rated the regulations on average (mean) as 7 out of 10 (1 = not at all effective, 10 = extremely effective) and 6.4 out of 10 respectively in how effectively they operate in practice, with healthcare professionals rating the effectiveness lower at 5.5 out of 10.

Additionally, there was a general consensus that the current HMRs do not provide the appropriate level of flexibility to respond to new technologies, scientific advancements, changes in health care practice or public health issues. In some instances, this was the

reason given for a low rating of the regulations' effectiveness. This highlights the need for the regulatory framework to continue to evolve in the future in an agile fashion, to ensure effective regulation and safety of medicines as science and technology advance.

Structure, clarity and navigability of the regulations

Stakeholders highlighted that the multiple amendments made to the HMRs over time have made them more complex to understand. Healthcare professionals on average rated the ease of navigating slightly lower at 5.4 out of 10 (1 = not at all easy to navigate, 10 = extremely easy to navigate) compared to industry at 6 out of 10, with patient groups and members of the public finding the regulations particularly hard to navigate 3 out of 10. This complexity can make implementation more difficult, and increase the risk of misinterpretation, especially where concepts lack definition or guidance is unclear. 72% of respondents suggested that significant or moderate changes should be made to the HMRs; 29% and 43% of respondents respectively.

There are some areas of the HMRs where survey respondents felt that updating and potentially streamlining parts of the regulations to reduce complexity or remove duplication would reduce burdens. For example:

- notifications relating to type IA variations (changes which have little or no impact on the quality, safety or efficacy of the product, such as administrative modifications)
- authorisation renewals
- artwork changes on packaging could be simplified

Open-text responses and wider stakeholder feedback, however, suggested that there is not a strong appetite for large-scale streamlining or consolidation of the HMRs, reflecting that although simplifying or streamlining in some areas may reduce regulatory burden, it could also present a risk. Respondents noted the importance of ensuring that any simplification or streamlining does not lead to a weakening of the regulations or have a negative impact on patient safety.

Industry stakeholders said that it can be challenging to navigate not only the HMRs (and other regulations covered by the MMDA) but also the wider legislative and regulatory landscape in order to fulfil their legal obligations. It was noted in particular that challenges arise where there is a need to comply with multiple pieces of legislation from across government (such as healthcare, trade or environmental considerations), and where these can appear to not be aligned or are difficult to understand. For example, needing to consider MHRA/DHSC medicines packaging requirements alongside wider product and environmental legislation led by DBT and Defra was cited as a challenge. Beyond ensuring guidance is clear, stakeholders called for increased and improved collaboration between relevant UK regulators.

Some stakeholders also noted that it can be challenging to understand the differences between EU and UK legislation, which can create a regulatory burden. Respondents noted that any restructuring or streamlining of the regulations could exacerbate this issue and have unintended consequences on patient safety.

Some stakeholders called for greater, and clearer, guidance to support industry and professionals in navigating and interpreting the HMRs. In addition, the HMRs require continuous updates to ensure they account for technological and scientific advancements, as well as continuing to support economic growth and innovation while protecting public health. Therefore, as the HMRs continue to be amended, which may add further complexity, simplification and consolidation will be kept under review.

Recommendation: improve guidance and explanatory materials to support industry and healthcare professionals in navigating the HMRs.

Recommendation: engage in more detailed discussions over the next year with stakeholders on which specific areas of the HMRs may benefit from updates, simplification and/or consolidation to increase clarity and reduce regulatory burden while minimising risk to patient safety.

The complexity of the regulatory system and of working across regulatory frameworks has been recognised in the [Regulatory Action Plan](#) (RAP). In March 2025 the government committed to cutting the administrative burden of regulation by 25% by the end of the Parliament, setting out a vision for doing so through the RAP. The RAP aims to:

- foster alignment on growth
- collaborate on cross-cutting policy issues
- share best practice
- drive cultural change within individual regulatory bodies
- eradicate duplication between regulators to support economic growth

Use of MMDA delegated powers

Current delegated powers under the MMDA only allow for the HMRs to be amended or supplemented. This limits future amendments including potential consolidation. It is also linked to the complexity highlighted by stakeholders as arising from cumulative amendments.

Recommendation: replace the MMDA power to “amend and supplement the law” with “making or replacing” regulations for medical devices and in vitro (IV) devices. This could

limit the complexity from cumulative amendments and create a more agile approach to regulation.

Current MMDA powers constrain the ability to incorporate external documents into the HMRs on an ambulatory basis. An ambulatory reference is a provision which cross-refers to the current version of external guidance, such as EU legislation or international technical standards. This limits flexibility and poses challenges for developing a more agile and responsive regulatory regime for which stakeholders voiced support.

Recommendation: Amend the MMDA to allow ambulatory references in human medicines regulations. This could improve regulatory agility and reduce administrative burden while maintaining consistency with international best practice.

The current processes set out in the MMDA to amend the HMRs include a requirement for public consultation and the draft affirmative procedure. This requires significant time and resource and is often not proportionate to the significance of the changes being proposed, for example, when making minor, technical changes or corrections. This can lead to delays in amending the HMRs to address emerging issues or make updates, meaning that emerging issues must be addressed through guidance while changes are being made. Industry and trade association stakeholders also raised concerns that delays in amending the HMRs could cause unintended divergence from EU regulations.

Further, the HMRs has been amended for non-medical prescribing - the extension of prescribing, administration and supply abilities to non-medical professionals. Given the public consultation and draft affirmative procedure requirements, non-medical professional groups raised concerns that the existing process to make such amendments is too slow and insufficiently reactive to changes or modernisations in clinical practice. Many healthcare professionals view this aspect of the HMRs as outdated, and that the slow pace of change limits innovation and improvements in healthcare.

These reflections are relevant to wider considerations under the section of this report 'Part 5 of the Medicines and Medical Devices Act 2021' (see 'procedural requirements'), which examines consultation and parliamentary scrutiny requirements in more detail.

Interactions with EU medicines regulations

The HMRs include several cross-references to EU legislation which were transposed into the regulations. Provisions within the HMRs were also amended to implement [The EU-UK Withdrawal Agreement](#) and then, the [Windsor Framework](#) (WF) agreement.

The WF arrangement for medicines addresses supply issues for Northern Ireland by bringing novel medicines under a UK-wide licensing regime operated by MHRA. The implementation of the WF means medicines in the UK are now separated into 2 categories. Category 1 covers medicines that previously fell within the mandatory or

optional scope of the EU's centralised procedure; they are generally innovative medicines, and new generic medicines are based on them. They are authorised by MHRA in accordance with UK law on a UK-wide basis. Category 2 medicines are all other medicines. These also have UK-wide licences but because EU law applies in Northern Ireland for these medicines, relevant EU law also applies to category 2 medicines.

As the EU updates its legislation in the future, the UK will review its regulations to ensure compliance with obligations under the WF. Stakeholders highlighted that it could be complex to comply with both EU and UK regulations. They stressed the importance of clear and accessible guidance that explains what any divergence from EU regulation would mean in practice, including through inclusion of clear examples and use cases, to reduce potential burdens that could arise.

There were also requests for more detailed guidance on how regulations for Category 1 and Category 2 medicines differ. Stakeholders pointed to [MHRA's Windsor Framework hub](#), which brings together information to help understand the main changes arising from the implementation of the WF, as a best practice example that could be followed in future.

Recommendation: monitor changes in EU human medicines regulations and ensure ongoing compliance with the WF, while also considering guidance to accompany future reforms and exploring ways to maximise ease of access.

Summary of recommendations

The following recommendations are therefore made:

- improve guidance and explanatory materials to support industry and healthcare professionals in navigating the HMRs
- engage in more detailed discussions over the next year with stakeholders on which specific areas of the HMRs may benefit from updates, simplification and/or consolidation to increase clarity and reduce regulatory burden while minimising risk to patient safety
- replace the MMDA power to “amend and supplement the law” with “making or replacing” regulations for human medicines. This could limit the complexity from cumulative amendments and create a more agile approach to regulation
- amend the MMDA to allow ambulatory references in human medicines regulations. This could improve regulatory agility and reduce administrative burden while maintaining consistency with international best practice

- monitor changes in EU human medicines regulations and ensure ongoing compliance with the WF, while also considering guidance to accompany future reforms and exploring ways to maximise ease of access

The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031)

The Medicines for Human Use (Clinical Trials) Regulations were not assessed as part of this review as the most recent amendments, [The Medicines for Human Use \(Clinical Trials\) \(Amendment\) Regulations 2025](#), are yet to come into force. They will come into force on 28 April 2026. The Medicines for Human Use (Clinical Trials) Regulation will be subject to a separate post implementation review in the future.

The Medicines (Products for Human Use) (Fees) Regulations 2016 (SI 2016/190)

Overview

[The Medicines \(Products for Human Use\) \(Fees\) Regulations 2016](#) make provision for the fees payable to the MHRA in relation to the regulatory functions it carries out under the HMRs and 2004 Regulations.

The MHRA also charges fees in relation to the regulation of medical devices and blood products for transfusion which are set out in [The Medical Devices \(Northern Ireland Protocol\) Regulations 2021](#) and [The Blood Safety and Quality Regulations 2005](#).

Overall, stakeholders consider the regulation to be operating effectively. However, there are challenges arising from the interaction of primary legislation. The recommendations from the below assessment therefore focus on seeking legislative coherence to simplify the process of updating fees regulations.

Methodology

The assessment draws on internal MHRA and DHSC subject matter expertise and evidence gathered through external stakeholder engagement. External evidence was collected through a joint MHRA and DHSC survey that was open between 21 July 2025 and 19 September 2025 and received 199 responses, 40 of which commented on The Medicines (Products for Human Use) (Fees) Regulations 2016. There were also 3 targeted workshop sessions that took place between 29 September and 6 October 2025 to allow stakeholders to raise any further issues directly. Stakeholder groups represented were:

- patient groups
- healthcare professionals
- industry representatives
- trade associations
- academia
- charities

As the survey allowed respondents to provide feedback against The Medicines (Products for Human Use) (Fees) Regulations as well as other regulations, it was not always possible to clearly discern which regulation a respondent's score related to. In order to arrive at the conclusions below, the scores have been considered alongside the qualitative

feedback gathered through the survey and workshops, as well as the internal assessment of the regulations, to form a complete picture of how they are functioning.

Assessment of operation

DHSC and MHRA believe the regulations are operating effectively but would benefit from a simplified amendment process. The regulation sets out the fees payable and the legal basis upon which to charge them. Stakeholder feedback suggested they are operating effectively in this regard. However, there are challenges arising from the impact of the consultation requirements in section 45 of the MMDA.

While The Medicines (Products for Human Use) (Fees) Regulations are amended using powers under the MMDA, fees charged under The Medical Devices (Northern Ireland Protocol) Regulations 2021, and The Blood Safety and Quality Regulations 2005, are amended using powers in the [European Union \(Withdrawal\) Act 2018](#) (EUWA). These 2 pieces of primary legislation place different procedural requirements on MHRA when it exercises powers under them to amend its fees. The assessment found that better alignment of the powers in the 2 acts may promote legislative coherence and offer opportunities to further simplify the amendment process.

Recommendation: consider legislative amendments to the MMDA that promote legislative coherence with the EUWA to simplify the process for updating medicines fees regulations.

These reflections are relevant to wider considerations under the part 5 of the MMDA (procedural provisions) section of this report, which examines consultation and parliamentary scrutiny requirements in more detail.

Summary of recommendations

The following recommendation is therefore made:

- to consider legislative amendments to the MMDA that promote legislative coherence with the EUWA to simplify the process for updating medicines fees regulations

The Veterinary Medicines Regulations 2013 (SI 2013/2033)

Overview

This section assesses the VMRs and the relevant provisions in parts 3 and 5 of the MMDA that provide the powers to amend the regulatory framework for veterinary medicines.

The VMRs set out the regulatory regime governing the manufacture, importation, wholesale distribution, marketing, supply, administration and advertising of veterinary medicines in Great Britain (GB). They provide the legal requirements for:

- marketing authorisations
- manufacturing and wholesale dealing authorisations
- controls on active substances
- labelling and packaging standards
- notification and reporting duties

The regulations also specify who may supply and administer veterinary medicines, the conditions of supply and the rules governing internet retailing and advertising.

The MMDA supplements this framework by conferring powers on the Secretary of State to amend or update the VMRs, establish and revise fee structures for regulatory services delivered by the VMD, and provide for enforcement mechanisms including the appointment of inspectors and the creation of offences. These powers enable the regime to be updated to reflect changes in scientific practice, regulatory standards and market developments.

While the EU regulations on veterinary medicinal products ([Regulation \(EU\) 2019/6](#)) and medicated feed ([Regulation \(EU\) 2019/4](#)) no longer apply in GB, they remain relevant comparators given their continuing influence on industry practices and data requirements across Europe.

This section of the report also considers 2 parliamentary committee reports that reviewed recent changes to the VMRs.

Overall, the veterinary medicines framework continues to operate effectively and has supported substantial policy reform since 2021. However, internal and stakeholder feedback highlighted limitations in flexibility, including the inability to revoke and replace

the VMRs in full and the absence of powers to make ambulatory references, which affect clarity and adaptability. The recommendations from the below assessment therefore focus on targeted improvements to enhance clarity while continuing to maintain high standards of animal health and welfare.

Methodology

The assessment draws on internal VMD subject matter expertise and evidence gathered through external stakeholder engagement. External evidence was obtained through a 4-week call for evidence launched on 1 September 2025 by VMD, supplemented by direct feedback from relevant professional and industry bodies. A total of 79 responses were received. Respondents included veterinary surgeons and nurses, suitably qualified persons, manufacturers, wholesale distributors, farmers and other keepers of animals, feed business operators, pet owners and industry associations.

Assessment of operation

Since 2021, the MMDA powers have been used to make changes to the VMRs, and VMD believes the current framework is operating effectively.

In May 2024, the government made a significant range of updates to the VMRs, to reflect changes and technical advances in the veterinary medicines industry, including the supply chain, as well as to future-proof the regulatory regime. The changes also aim to encourage the development of new and innovative products and reduce the development and spread of antimicrobial resistance (AMR). These changes include:

- updates to definitions, strengthened inspector powers and tightened advertising rules for veterinary medicines
- alignment of UK marketing authorisation processes with recent EU reforms to reduce regulatory burden while maintaining consistency between GB and Northern Ireland, alongside UK specific measures such as revised data protection periods to support innovation
- minor improvements to manufacturing authorisation procedures, complemented by new registration requirements for active substance production and distribution to enhance oversight
- refinements to prescribing and supply practices with online retailers being required to register, and regulatory burdens on veterinarians and other qualified professionals being reduced to improve access to medicines
- clarifications to the prescribing cascade with updated withdrawal periods to protect food safety while avoiding unnecessary treatment barriers

- strengthened medicated feed requirements in line with EU standards, including measures to reduce antibiotic use
- requirements on companies marketing exempted medicines for small pets to register and submit annual reports
- tightened requirements for antibiotic veterinary medicines with new restrictions on prophylactic antibiotic use in groups of animals to combat antimicrobial resistance
- revised fees for marketing and manufacturing authorisations and the introduction of additional fees for certain inspections and the provision of scientific advice

Structure, clarity and navigability of the regulations

Stakeholders are content with the structure of the VMRs. VMD and GLD officials do not consider the MMDA in need of restructuring or consolidation for veterinary medicines. The existing provisions for veterinary medicines are all still required and no areas were identified where streamlining would improve effectiveness.

The current balance of provisions between primary and secondary legislation is considered appropriate. The delegated powers within the MMDA cover all the essential areas of veterinary medicines legislation and policy. The secondary legislation for veterinary medicines sets out all the technical requirements and detail for the manufacture, import, sale, supply and use of veterinary medicines.

The VMRs serve as a comprehensive and accessible ‘one-stop shop’ for all technical and operational requirements, and stakeholders value this clarity. Moving technical provisions into primary legislation may risk creating unnecessary complexity.

Recommendation: maintain the current placement of technical provisions within secondary legislation to avoid unnecessary fragmentation as the VMRs function effectively as a comprehensive and accessible single instrument.

Use of MMDA delegated powers

The delegated powers granted by the MMDA allow for the existing legislative regime to be amended or supplemented, meaning they can only build on the existing VMRs. The current powers restrict the ability to revoke or replace existing legislation in its entirety.

Stakeholder feedback indicated that users of the VMRs find the current amend-and-supplement model difficult to navigate. The recent update to the VMRs contained over 250 changes, and the inability to revoke or replace legislation has caused confusion for stakeholders. Respondents noted that being required to add to, rather than revoke and replace, the existing regulations has resulted in a framework in which cumulative amendments create uncertainty for stakeholders.

Recommendation: replace the MMDA power to “amend and supplement the law” with “making or replacing” regulations for veterinary medicines. This could limit the complexity from cumulative amendments.

Additionally, part 3 of the MMDA does not confer the power to make ambulatory references in secondary legislation. An ambulatory reference is a provision which cross-refers to the current version of external guidance, such as EU legislation or international technical standards. This power would ensure the latest versions of guidance could be referenced directly. This restriction complicates the drafting of regulations and balancing legislative requirements with flexible regulation, as references in the legislation can quickly become outdated and require amendments to remain accurate.

The recent updates to the VMRs also included some changes that mirrored the following 2 EU regulations:

- veterinary medicinal products ([Regulation \(EU\) 2019/6](#))
- medicated feed ([Regulation \(EU\) 2019/4](#))

The VMRs were updated to ensure that the technical data that must be submitted with the application for a marketing authorisation, including the packaging and labelling, would be consistent with EU rules.

Officials noted that these updates reflect the reality that the veterinary pharmaceutical industry is set up to cover the region of Europe as a whole, which includes the UK. Maintaining broadly consistent data requirements enables companies to submit similar dossiers across regulatory jurisdictions, thereby reducing administrative burdens and supporting the continued availability of veterinary medicines in the UK.

Some details in the 2 EU regulations are set out in tertiary legislation and guidelines. Since the MMDA does not provide powers to make ambulatory references, the VMRs cannot directly reference these evolving regulations. The requirements are periodically updated; therefore, the VMRs need to be regularly amended to reflect these changes which can be disproportionately burdensome.

Recommendation: amend the MMDA to allow ambulatory references in the VMRs. This could improve regulatory agility and reduce administrative burden while maintaining consistency with international best practice.

Parliamentary committee reports

Two committees reviewed the recent changes to the VMRs:

- Secondary Legislation Scrutiny Committee

- Animal Sentience Committee (ASC)

The Secondary Legislation Scrutiny Committee

The Secondary Legislation Scrutiny Committee reported the amendment to the VMRs as an instrument of interest in the [18th Report of Session 2023 to 2024](#). The committee asked for clarity on several points:

any impact of the changes to the cost of medicines

the potential for divergence between GB and Northern Ireland as a result of the updates to the GB VMRs

In the report, VMD responded on the impact of the changes on the cost of medicines, that veterinary medicine is a private service, and prices vary across the sector due to differing overheads. The government does not track individual product costs, and pricing is not regulated by law; the costs of veterinary medicines are determined by market forces, not legislation.

In the report, VMD responded on the risk of divergence between GB and Northern Ireland, that the changes to the GB VMRs largely mirror EU requirements. This alignment is necessary because, under the WF, Northern Ireland continues to follow certain EU rules for veterinary medicines. This allows for shared packaging and labelling across GB and Northern Ireland, supporting UK-wide marketing of veterinary medicines. Some of the British-specific changes diverge slightly from legislation applying in Northern Ireland but would not disrupt supply to Northern Ireland. These changes include streamlined processes for businesses and support for innovation in veterinary medicine. The government confirmed that they are committed to ensuring uninterrupted supply of veterinary medicines to Northern Ireland, including through continued engagement with EU counterparts and through clear guidance.

Animal Sentience Committee

The Animal Sentience Committee (ASC) assessed recent revisions to the VMRs to consider any potential unintended impacts on animal welfare in their independent [Assessment of Veterinary Medicines Regulations \(2013\) revisions report](#) in 2024. They focused on areas where regulatory changes might reduce welfare standards despite broader goals of sustainability, food safety and 'One Health'.

The ASC reviewed the draft regulations, consulted stakeholders in veterinary, farming and animal health sectors, and raised queries with the VMD. The VMD provided clarifications and indicated planned amendments in response to ASC's concerns. The main concerns identified by the ASC were:

- the prescribing cascade, with the ASC highlighting that the provision discouraging cascade use (off-label prescribing) may undermine farm assurance schemes that require pain relief for procedures like calf castration, potentially harming welfare
- advertising of veterinary medicines, with the ASC supporting limiting advertising of prescription-only medicines to lay audiences but urged clearer guidance for suitably qualified persons to ensure access to appropriate alternatives and support professional development

The ASC concluded that they were satisfied that animal welfare has been adequately considered. The ASC stated that the 2 highlighted areas above (cascade use and advertising) could be mitigated through stakeholder engagement and clear implementation guidance. Following the ASC's recommendations, VMD updated its cascade and advertising guidance in 2024 and communicated these changes to all inspected retailers and suppliers of veterinary medicines.

Recommendation: improve guidance and explanatory materials to support industry and professionals in navigating the VMRs.

Summary of recommendations

The following recommendations are therefore made:

- maintain the current placement of technical provisions within secondary legislation to avoid unnecessary fragmentation as the VMRs function effectively as a comprehensive and accessible single instrument
- replace the MMDA power to “amend and supplement the law” with “making or replacing” regulations for veterinary medicines. This could limit the complexity from cumulative amendments
- amend the MMDA to allow ambulatory references in the VMRs. This could improve regulatory agility and reduce administrative burden while maintaining consistency with international best practice
- improve guidance and explanatory materials to support industry and professionals in navigating the VMRs

The Medical Devices Regulations 2002 (SI 2002/618)

Overview

This section assesses [The Medical Devices Regulations 2002 \(MDR 2002\)](#) and the relevant powers in the MMDA that allow the government to amend the domestic regulatory framework for medical devices.

The MDR 2002 provides the regulatory framework for medical devices including IV diagnostic devices in GB. The MDR 2002 incorporated 3 EU directives for medical devices into UK law:

- for medical devices, [Directive 93/42](#)
- for active implantable medical devices (AIMD), [Directive 90/385](#)
- for IV diagnostic devices, [Directive 98/79](#)

Since the introduction of the MMDA, which empowered the government to amend the MDR 2002, MHRA has made several amendments to the regulations. These changes reflect MHRA's role as the sovereign regulator for GB and, under the WF, MHRA's designated role as the competent authority for EU medical devices regulations and IV diagnostic medical devices regulations in Northern Ireland. It aims to ensure a functional domestic regulatory framework to safeguard public health, ensure the safety of medical devices, support the availability of medical devices, and position the UK as a favourable location for research, development, manufacturing and supply of medical devices.

Overall, while the MDR 2002 continues to safeguard patient safety, stakeholders report that the regulations are lengthy and complex to navigate. The recommendations from the below assessment therefore focus on the strong stakeholder support for consolidation and streamlining, improved guidance and addressing complexity.

Methodology

The assessment draws on MHRA and DHSC internal subject matter expertise and evidence gathered through external stakeholder engagement. Evidence was collected through the joint MHRA and DHSC stakeholder survey that was open between 21 July 2025 and 19 September 2025 and received 199 responses, 71 of which commented on the MDR 2002. There was also a programme of accompanying workshops, providing both quantitative and qualitative insights. Respondents included healthcare professionals, industry representatives, trade associations, academic bodies, charities and patient groups.

As the survey allowed respondents to provide feedback against the MDR 2002 as well as other regulations, it was not always possible to clearly discern which regulation a respondent's score related to. In order to arrive at the conclusions below, the scores have been considered alongside the qualitative feedback gathered through the survey and workshops, as well as the internal assessment of the regulations, to form a complete picture of how they are functioning.

Assessment of operation

DHSC and MHRA believe the regulations are working effectively but can be challenging to navigate, and in some areas may benefit from improvements.

The primary aim of the MDR 2002 is to set a regulatory standard to ensure the safety and performance of medical devices in protecting public health. A total of 43% of stakeholders who responded to the survey, who answered the question "How well do you think the current legislation protects public health?", found legislation to be "somewhat effective" or "effective" in safeguarding public health. Stakeholders were asked to rate how clear, well-structured and easy to navigate the legislation is, and rated it a mean average of 5 out of 10 (1 = not at all effective, 10 = extremely effective).

Qualitatively, a majority of stakeholders reported in open text-responses and during targeted workshops that they had experienced issues, blockers or areas of ambiguity when using the regulations.

Structure, clarity and navigability of the regulations

Many stakeholders stated in open-text responses that the MDR 2002 are difficult to navigate due to their length and complexity, having been amended several times since they came into force in June 2002. They also attributed these challenges to the fact that the regulations are rooted in pre-EU exit European Economic Area (EEA) legislation. This is resulting in the continued inclusion of references to repealed EU legislative instruments.

For the question, "What is your view on the extent to which the legislation should be streamlined?", 67% of stakeholders who answered expressed support for either moderate or significant changes to restructure and simplify the legislation (36% and 31% respectively). They noted that streamlining would have "very positive" or "somewhat positive" impacts on them or their organisation. Open-text responses were also strongly in favour of consolidating and streamlining, and this was further reinforced during workshops with industry and trade association representatives. Stakeholders highlighted, however, that it is important that any streamlining or consolidating does not inadvertently lead to a weakening of the regulations or any impacts on patient safety.

Recommendation: consider legislative options to consolidate and streamline the regulations to address concerns about the complexity of the regulation, while mitigating risk to patient safety and public health.

Of the stakeholders who responded to the survey, 43% - primarily representing trade associations - felt that the current balance between legislation and supporting guidance was not appropriate. Some believed that too much detail was embedded in legislation and should instead be covered in guidance, while a similar proportion felt the opposite - that guidance should be more firmly embedded in legislation. A significant proportion of stakeholders were unsure whether the current balance was correct. Some stakeholders noted in particular that the regulations are heavily supplemented by MHRA guidance in fast moving areas where legislation has not kept pace with emerging technologies. There was also strong support from stakeholders for guidance to be transparent, version-controlled, and for greater clarity as to its legal status.

Recommendation: improve guidance and explanatory materials to support industry and healthcare professionals in navigating the MDR 2002.

Impact of divergence with regulations in other jurisdictions

The impact of divergence with regulations in other jurisdictions was raised by stakeholders. Stakeholders noted there is a need for harmonisation with other jurisdictions' regulations, both to support the availability of IV devices on the British and Northern Ireland markets, and to ensure that devices developed in the UK are fit for export to international markets.

The upcoming consultation on proposals to indefinitely recognise CE marked medical devices, was welcomed by stakeholders, who noted that it would support the favourability of the UK as a place in which to manufacture and supply medical devices.

Recommendation: consider an appropriate level of global harmonisation, in order to reduce regulatory burden, increase innovation, and enhance UK competitiveness. This approach will ensure clarity in regulation where dual frameworks apply across the UK.

Use of MMDA delegated powers

Current delegated powers under the MMDA only allow for the MDR 2002 to be amended or supplemented. This limits future amendments including potential consolidation. It is also linked to the complexity highlighted by stakeholders as arising from cumulative amendments.

Current MMDA powers also constrain the ability to incorporate external documents into the MDR 2002 on an ambulatory basis. This limits flexibility and poses challenges for

developing the more agile and responsive regulatory regime for which stakeholders voiced support.

Recommendation: replace the MMDA power to “amend and supplement the law” with “making or replacing” regulations for medical devices and IV devices. This could limit the complexity from cumulative amendments and create a more agile approach to regulation.

The current process set out in the MMDA to amend the MDR 2002 include a requirement for public consultation and the draft affirmative procedure. This requires significant time and resource and is often not proportionate to the significance of the changes being proposed, for example, when making minor technical changes or corrections. This can lead to delays in amending the MDR 2002 to address emerging issues or make updates, meaning that such changes must be addressed through guidance in the interim. Industry and trade association stakeholders raised concerns that delays in amending the MDR 2002 could cause unintended divergence from EU regulations.

These reflections are relevant to wider considerations under the section of this report ‘part 5 of the MMDA (procedural provisions)’, which examines consultation and parliamentary scrutiny requirements in more detail.

Interactions between medicines and medical devices regulations

Stakeholders raised that there is a high level of complexity in navigating the HMRs and MDR 2002 alongside each other. They noted this is becoming more common given the increasing prevalence of devices used to administer medicinal products, which include a medicine in the medical device or where the medicine acts as ancillary to the medical device. To ensure effective operation of the regulations in practice, both sets of regulations need to be complementary while avoiding duplication of requirements. Clear guidance is needed to help with navigating the interface of the 2 sets of regulation.

Recommendation: as part of any future consolidation or streamlining of the MDR 2002, take forward specific amendments to improve alignment with the HMRs.

Summary of recommendations

The following recommendations are therefore made:

- consider legislative options to consolidate and streamline the regulations to address concerns about the complexity of the regulation, while mitigating risk to patient safety and public health
- improve guidance and explanatory materials to support industry and healthcare professionals in navigating the MDR 2002

- consider an appropriate level of global harmonisation, in order to reduce regulatory burden, increase innovation and enhance UK competitiveness. This approach will ensure clarity in regulation where dual frameworks apply across the UK
- replace the MMDA power to “amend and supplement the law” with “making or replacing” regulations for medical devices and IV devices. This could limit the complexity from cumulative amendments and create a more agile approach to regulation
- as part of any future consolidation or streamlining of the MDR 2002, take forward specific amendments to improve alignment with the HMRs

Part 5 of the Medicines and Medical Devices Act 2021

Overview

This section assesses the 5 provisions in part 5 of the MMDA which sets out the framework for how regulations under parts 2 to 4 are to be made and scrutinised by Parliament.

During passage of the Bill, the DPRR Committee and the Constitution Committee both raised concerns about the breadth of delegated powers included, the former in their [19th report](#), and the latter in their [10th report](#). In the [government's response to the DPRR Committee](#), a number of provisions were introduced to strengthen parliamentary oversight and transparency:

- strengthen consultation requirements: a statutory duty to conduct public consultation before making regulations under parts 2 to 4, extended at the Lords Committee stage to require that consultation documents include a summary of the government's initial assessment of the proposed changes. This should include how the overarching objective of safeguarding health (for medicines and medical devices), welfare or the environment (for veterinary medicines) has been considered
- a new reporting duty: a biennial obligation to consult on, prepare and lay before Parliament reports on the operation of regulations made under sections 2, 10 and 15, summarising stakeholder concerns, the government's responses, and any forward plans for further regulation
- expanded use of the draft affirmative procedure: in line with the DPRR Committee recommendations, regulations on labelling, packaging, advertising and prescribing in relation to human medicines, and on supply, labelling, packaging, and advertising in relation to veterinary medicines, are now subject to the draft affirmative procedure rather than the negative
- introduction of the made affirmative procedure for emergencies: amendments at the Lords Committee stage provided that urgent regulations responding to risks of serious harm to health could be made using the made affirmative procedure, balancing flexibility with parliamentary oversight

As such, part 5 of the MMDA includes the following 5 provisions intended to create a robust governance structure and ensure appropriate scrutiny of delegated powers:

- [consequential and incidental provisions in section 43](#)

- [devolved competence in section 44](#)
- [consultation requirements in section 45](#)
- [reporting requirements in section 46](#)
- [procedural requirements in section 47](#)

Overall, part 5 was designed to provide safeguards and ensure robust scrutiny of delegated powers to legislate on human and veterinary medicines and medical devices. In practice, however, sections 45 and 47 have introduced rigidity and inefficiency. DHSC, MHRA, GLD and VMD officials reported that mandatory consultation for all SIs and the blanket use of the affirmative procedure have significantly slowed down technical updates. The recommendations from the below assessment therefore focus on improving proportionality in processes and requirements for making regulation and parliamentary scrutiny.

Methodology

The assessment of part 5 draws on internal evidence from policy and legal teams across DHSC, MHRA, GLD and VMD. These teams provided case studies and feedback on their experiences of legislating under the MMDA, particularly in relation to consultation requirements, reporting cycles and parliamentary procedure.

As part 5 concerns internal legislative processes rather than operational regulatory frameworks, external stakeholder engagement was not undertaken for this part of the review.

Section 43: consequential and incidental provisions - assessment of operation

Section 43 allows regulations under the act to make consequential, supplementary, incidental, transitional or saving provisions. This is a standard drafting tool to ensure regulations operate coherently and can accommodate necessary follow-on changes.

No operational difficulties or negative feedback have been reported. Section 43 functions as intended, providing flexibility without raising practical concerns.

Recommendation: retain section 43 in its current form. No amendment required.

Section 44: devolved competence - assessment of operation

Section 44 includes clarification that Northern Ireland departments may not make provisions under the act beyond their devolved competence. This reflects the constitutional framework of the Northern Ireland Act 1998 and ensures that the MMDA's powers are applied consistently across the UK.

No issues have been raised in practice. The provision has ensured the limits of devolved competence. Section 44 continues to provide necessary constitutional safeguards. It has not been identified as a constraint or source of delay.

Recommendation: retain section 44 in its current form. No amendment required.

Section 45: consultation requirements - assessment of operation

Section 45 requires the relevant authority to conduct a public consultation before making regulations under parts 1 to 4 of the MMDA. The provision allows for urgent regulations to bypass this requirement, such as in the disapplication of provisions relating to human medicines or medical devices where there is a risk of serious harm to health.

DHSC and MHRA officials drafting legislation under the act reported that the mandatory duty to consult on all statutory instruments, regardless of scope or impact, created significant delays. It was noted that consultation is required under the act, even for non-controversial, minor, technical amendments, or a machinery of government change where no other legislative outcomes are realistic.

One case study cited highlighted challenges to amending references in the HMRs to reflect the dissolution of Public Health England (PHE) and the Health and Social Care Board (HSCB) in Northern Ireland. PHE's functions were transferred to the UK Health Security Agency (UKHSA), DHSC and NHS England, while HSCB's functions moved to the Department of Health in Northern Ireland. Made under [The Human Medicines \(Amendments Relating to Naloxone and Transfers of Functions\) Regulations 2024](#) amendment to the HMRs, the amendment updated the names of these organisations in the regulation. However, despite being technical in nature and non-controversial, government had to launch a consultation under section 45 provisions. Fewer than 5 responses were received in total and there were no challenges. The changes took a year to be laid due to these disproportionate consultation requirements.

Another case study cited was in regard to MHRA fees. MHRA fees uplift process has a fixed timetable and changes must come into force at the start of the financial year. Delays to the start date can result in lost income as MHRA cannot charge the new correct fee until that date. Despite running their usual process on time, their 2025 fees uplift faced delays due to consultation and processes to respond.

Removing the need for consultation in the MMDA in cases where MHRA is only increasing existing fees in line with their fixed timetable to ensure cost-recovery, would reduce this risk of delay and loss of income. Where the fee increase is only to ensure cost-recovery, there are no policy options to meaningfully consult on and scrutiny is already provided by HM Treasury and Parliament. By comparison, no consultation is required when MHRA updates its medical devices fees under the Medical Devices (Northern Ireland Protocol) Regulations 2021, or its blood components for transfusion fees under

The Blood Safety and Quality Regulations 2005 as they are amended using powers under the EUWA. MHRA's view is therefore that removing the consultation requirement in instances where fee uplifts are made purely for cost-recovery purposes would reduce administrative burden and financial risk, while maintaining appropriate oversight.

Evidence suggests that the current duty to consult is overly rigid and undermines the ability to make timely and proportionate regulatory changes. While the requirement was intended to strengthen accountability, in practice it has introduced disproportionate delays, particularly for technical or low-impact amendments. Technical or low-impact amendments could be added to the list of exemptions in subsection (4). Alternatively, a formal tiered consultation model could be implemented to expressly permit short consultation periods and targeted consultation groups in certain, listed, circumstances.

Recommendation: amend section 45 to allow for shorter consultation periods and consultation requirement exemptions in cases of technical or low-impact amendments, while maintaining appropriate oversight.

Section 46: reporting - assessment of operation

Section 46 includes a reporting requirement where the relevant authority must publish reports every 2 years on the operation of regulations under parts 1 to 4. This reporting requirement is not time-limited and must be fulfilled every 24 months. It must include every statutory instrument in force made using the delegated powers, including those previously reported on. The [first 2-year report](#) provides an overview of all regulations made and in force under sections 2 (1), 10 (1), 15 (1) and 19 (1) of the MMDA in force during the reporting period of 27 July 2021 to 27 July 2023. The second 2-year report covering the reporting period of 27 July 2023 to 27 July 2025 is expected to be published in 2026.

The reporting duty provides an important parliamentary scrutiny capability, providing parliament with detailed visibility of existing regulation, future regulatory plans, and operation from the perspective of relevant officials and affected stakeholders.

However, operational evidence suggests that biennial reporting is overly resource-intensive, particularly as the number of SIs increase. The first report required extensive cross-government engagement and legal clearance. With the number of amendments expected to rise steadily, the workload will increase exponentially for each subsequent report.

This creates a recurring administrative burden that diverts resources away from substantive regulatory work and risks creating stakeholder engagement fatigue, as the same groups are repeatedly asked to contribute to consultations, regulatory development, SI post implementation reviews and biennial reporting. DHSC officials reported duplication with existing transparency mechanisms and question whether the biennial cycle remains proportionate.

While transparency remains crucial, given that implementation timelines for new amendments can run from 6 to 11 months or longer, an extended reporting period, for example from 2 to 5 years, could reduce the administrative load on regulators while also allowing more meaningful post-implementation evidence to emerge.

Recommendation: review section 46 with a view to streamlining reporting obligations to ensure reporting remains proportionate, appropriate and effective.

Section 47: procedure - assessment of operation

Section 47 includes the parliamentary procedures required to implement SIs under parts 1 to 4. In practice, most instruments default to the draft affirmative procedure, meaning they require approval by both Houses of Parliament (and, where applicable, the Northern Ireland Assembly) once laid, before being made into law. Urgent instruments can use the made affirmative procedure, which allows them to come into force more expeditiously than the draft affirmative procedure, requiring approval by both Houses of Parliament after being signed into law. Only a small number of provisions use the negative procedure where either House can revoke the legislation within 40 parliamentary days after the instrument is laid.

During the passage of the bill, parliament emphasised that the scope of the powers required additional safeguards and more robust scrutiny mechanisms, given the limited constraints in the bill as introduced ([Hansard, 19 October 2020](#)). In response to these concerns, the government amended the bill to extend the use of the affirmative procedure.

However, operational experience now suggests that proportionality is lacking. All regulations under parts 1 to 4 default to the draft affirmative procedure, unless they fall within narrow exceptions. While this provides strong oversight and was justified during passage as a safeguard against broad powers, internal feedback suggests that its uniform application is disproportionate for minor, technical or administrative changes and consumes Parliamentary time inappropriately.

Further, feedback from officials in the Northern Ireland Department of Health highlighted the need for a mechanism to enable legislation to progress jointly when the Northern Ireland Assembly is not sitting for an extended period. For example, between April 2022 and January 2024, the absence of the Assembly meant Northern Ireland could not advance necessary amendments.

As highlighted in previous sections of this report, officials and stakeholders noted as part of the HMRs and MDR 2002 assessments that parliamentary procedure requirements limit regulatory agility. They take significant time and resource that is often not proportionate to the significance of the changes being proposed. This can lead to delays in amending regulations to address emerging issues or make updates, meaning that such changes must be addressed through guidance in the interim. This slow pace of change may also

limit innovation and improvements in healthcare and make regulation insufficiently reactive to changes or modernisations. Delays in amendments could also cause unintended divergence from EU regulations.

Section 47 does provide for the use of the made affirmative procedure in emergency cases under section 7 of the MMDA. This mechanism has functioned as intended.

Recommendation: conduct a legal review of the original draft bill, which included different parliamentary procedures for certain powers, in the context of current operational experience, to identify which powers could revert to that model.

Recommendation: amend section 47 to permit wider use of the made affirmative or negative procedure for specified technical or administrative changes and retain the draft affirmative procedure for substantive policy changes to preserve appropriate oversight.

Summary of recommendations

The following recommendations are therefore made:

- retain section 43 in its current form. No amendment required
- retain section 44 in its current form. No amendment required
- amend section 45 to allow for shorter consultation periods and consultation requirement exemptions in cases of technical or low-impact amendments, while maintaining appropriate oversight
- review section 46 with a view to streamlining reporting obligations to ensure reporting remains proportionate, appropriate and effective.
- conduct a legal review of the original draft bill, which included different parliamentary procedures for certain powers, in the context of current operational experience, to identify which powers could revert to that model
- amend section 47 to permit wider use of the made affirmative or negative procedure for specified technical or administrative changes and retain the draft affirmative procedure for substantive policy changes to preserve appropriate oversight

Conclusion

The Medicines and Medical Devices Act 2021 5-Year Report demonstrates that the UK's legislative frameworks for human medicines, veterinary medicines and medical devices continue to operate effectively, maintaining high standards of safety and public and animal health. The act has enabled significant policy development and regulatory adaptation since its enactment, supporting the UK's position as a leader in health innovation and regulatory science.

However, in the course of the review, regulatory complexity and inaccessibility, regulatory agility and disproportionate legislative requirements, and the need to be able to adapt to international change all emerged as cross-cutting challenges to be addressed.

Firstly, while the frameworks are fundamentally robust, cumulative amendments and reliance on guidance have increased complexity, making regulations harder to navigate for healthcare professionals, industry and the public. There is a need for improved clarity, consolidation where justified, and strengthened guidance to support consistent interpretation.

Secondly, certain procedural requirements under the MMDA can be disproportionate for minor or technical changes, leading to delays in implementing necessary updates and a slow pace of change in the face of innovation. A more proportionate approach to consultation and parliamentary scrutiny would enhance regulatory agility without compromising oversight.

Thirdly, maintaining awareness of EU and international frameworks and remaining committed to appropriate global harmonisation remains important to support supply resilience, innovation and global trade.

Throughout this review, extensive engagement with stakeholders - including patients, healthcare professionals, industry, regulators and the public - has provided valuable insights into the strengths and challenges of the current frameworks. The collaborative efforts of teams across DHSC, MHRA, VMD and the GLD have been essential to delivering this report and its recommendations.

Summary of recommendations

The review makes the following recommendations, grouped by regulatory area.

Human medicines and pharmacy

The reviews recommendations are:

- pharmacy regulators and national and local professional leadership bodies should consider developing additional guidance to improve implementation and understanding of the legislation across relevant healthcare settings
- navigation of the legislation should be further supported by exploring opportunities to enhance the accessibility of the HMRs (such as clearer structuring, improved guidance or signposting), acknowledging stakeholder feedback that consolidation alone has not resolved underlying complexity
- continue to update and provide clear guidance to support the implementation of regulatory changes
- engage in more detailed discussions over the next year with stakeholders on which specific areas of the HMRs may benefit from updates, simplification and/or consolidation to increase clarity and reduce regulatory burden while minimising risk to patient safety
- replace the MMDA power to “amend and supplement the law” with “making or replacing” regulations for human medicines. This could limit the complexity from cumulative amendments and create a more agile approach to regulation
- amend the MMDA to allow ambulatory references in human medicines regulations. This could improve regulatory agility and reduce administrative burden while maintaining consistency with international best practice
- continue to monitor changes in EU human medicines regulations, ensure ongoing compliance with the WF and keep guidance up to date
- consider legislative amendments to the MMDA that promote legislative coherence with the EUWA to simplify the process for updating medicines fees regulations

Veterinary medicines

The review’s recommendations are:

- maintain the current placement of technical provisions within secondary legislation to avoid unnecessary fragmentation as the VMRs function effectively as a comprehensive and accessible single instrument
- replace the MMDA power to “amend and supplement the law” with “making or replacing” regulations for veterinary medicines. This could limit the complexity from cumulative amendments

- amend the MMDA to allow ambulatory references in veterinary medicines regulations. This could improve regulatory agility and reduce administrative burden while maintaining consistency with international best practice
- continue to update and provide clear guidance to support the implementation of regulatory changes

Medical devices

The review's recommendations are:

- consider options to consolidate and streamline the regulations to address concerns about the complexity of the regulation, while mitigating risk to patient safety and public health
- continue to update and provide clear guidance to support the implementation of regulatory changes
- consider an appropriate level of global harmonisation, in order to reduce regulatory burden, increase innovation and enhance UK competitiveness. This approach will ensure clarity in regulation where dual frameworks apply across the UK
- replace the MMDA power to “amend and supplement the law” with “making or replacing” regulations for medical devices and IV devices. This could limit the complexity from cumulative amendments and create a more agile approach to regulation
- as part of any future consolidation or streamlining of the MDR 2002, take forward specific amendments to improve alignment with the HMRs

Part 5 of the MMDA (procedural provisions)

The review's recommendations are:

- retain section 43 in its current form. No amendment required
- retain section 44 in its current form. No amendment required
- amend section 45 to allow for shorter consultation periods and consultation requirement exemptions in cases of technical or low-impact amendments, while maintaining appropriate oversight
- review section 46 with a view to streamlining reporting obligations to ensure reporting remains proportionate, appropriate and effective

- conduct a legal review of the original draft bill, which included different parliamentary procedures for certain powers, in the context of current operational experience, to identify which powers could revert to that model
- amend section 47 to permit wider use of the made affirmative or negative procedure for specified technical or administrative changes and retain the draft affirmative procedure for substantive policy changes to preserve appropriate oversight

DHSC extends its gratitude to all stakeholders who contributed to this review. Their engagement and expertise have been invaluable in shaping the recommendations and ensuring that the UK's regulatory frameworks for medicines and medical devices remain effective, agile and responsive to future challenges.

The government is committed to taking forward these recommendations, working collaboratively with all partners to ensure that the regulatory environment continues to protect safety and public and animal health.

Annex A: legislation in scope of the review

For the purposes of this report, “medicines and medical devices legislation” is defined by the MMDA as comprising:

- the law relating to human medicines within the meaning of section 9 of the MMDA. Section 9 defines “law relating to human medicines to mean” sections 10, 15 and 131, and part 4 of the Medicines Act 1968:
 - section 10 of the Medicines Act 1968 is concerned with exempting pharmacists - registered pharmacies, a hospital, a care home or a health centre - from the requirements to hold a manufacturers licence or to have marketing authorisation to supply medicines
 - section 15 of that act is concerned with varying the terms of those exemptions
 - part 4 is concerned with the governance of pharmacies in the UK
 - section 131 is concerned with defining terms used in the above legislation
- The Human Medicines Regulations 2012 (SI 2012/1916)
- The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031)
- The Medicines (Products for Human Use) (Fees) Regulations 2016 (SI 2016/190)
- The Veterinary Medicines Regulations 2013 (SI 2013/2033)
- The Medical Devices Regulations 2002 (SI 2002/618)
- parts 2 to 5 of the MMDA:
 - part 2 is concerned with the regulation of human medicines, including disclosure of information on the medicines, and the disclosure of information under international agreements
 - part 3 is concerned with the regulation of veterinary medicines, including the disclosure of information under international agreements
 - part 4 is concerned with the regulation of medical devices
 - part 5 is concerned with the procedures for making secondary legislation within the scope of parts one to 4, including consultation and reporting requirements
- regulations made under those parts

Annex B: legislation not assessed

The following legislation has not been assessed:

- [The Medicines for Human Use \(Clinical Trials\) \(Amendment\) Regulations 2025](#)
- [The Human Medicines \(Amendments Relating to Hub and Spoke Dispensing etc.\) Regulations 2025](#)
- [The Human Medicines \(Amendment\) \(Modular Manufacture and Point of Care\) Regulations 2024](#)

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