Department of Health & Social Care

Report on regulations made under sections 2(1), 10(1), 15(1) and 19(1) of the Medicines and Medical Devices Act 2021

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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 the existing regulations on human and veterinary medicines, as well as medical devices in the UK. The MMDA allows the UK to change the regulatory landscape for medicines and medical devices following our departure from the EU.

It is a statutory requirement for the Secretary of State for the Department of Health and Social Care (DHSC) to lay a report in Parliament every 2 years on all regulations made under the specified sections of the MMDA. The report needs to cover all regulations in force during the reporting period, which in this case was from 27 July 2021 to 27 July 2023. More detail can be found in the section 'Objectives of the report'.

Stakeholders were consulted over a 6-week period on how they felt the regulations were operating, as well as any suggestions for improvement. The responses received during our consultation varied in both volume and depth across the different regulations, with both positive and negative aspects being raised for almost all the regulations. The department's response to the feedback is also included in this report, which both addresses points raised and highlights where improvements have already been made.

A section outlining the aims of future regulations under the MMDA which are currently in progress, or which have been made outside of the current reporting period has also been included. These will be reported on during the second MMDA report, provided they are in force by the end of the next reporting period (28 July 2025).

Objectives of the report

Under part 5, section 46 of the MMDA, there is a reporting requirement on the operation of any regulations made under sections 2 (1), 10 (1), 15 (1) and 19 (1) that were in force during the time of the reporting period. The reporting period is defined as the period of 24 months beginning with the day the first set of regulations (made under these sections) come into force. This first reporting period was between 27 July 2021 and 27 July 2023.

This report must be laid by the Secretary of State in relation to regulations made either alone or jointly with the Northern Ireland Department of Health. Similarly, the Northern Ireland Department of Health is required to lay a similar report before the Northern Ireland Assembly relating to all regulations made under section 2 (1) or 10 (1) whether they were made jointly with the Secretary of State or alone.

This report will detail both stakeholder feedback and the department's response on how each of the regulations is working and suggestions for improvements stakeholders would like to see. This report will also give an overview of regulations currently in development which will be made using the powers of this act.

How the review was conducted

Questions asked

A standardised set of questions was presented to all stakeholders which provided the opportunity to share feedback on:

- any positive aspects of the regulations
- concerns
- suggestions on how to address those concerns
- any general feedback

All questions were presented as open-ended feedback boxes to allow full freedom of response.

Consulting stakeholders

The consultation period ran from 3 August 2023 to 15 September 2023. We engaged with a range of stakeholders, including:

- those involved with the policy design of these regulations
- representatives from across industry
- those who had been vocal in the initial consultations

We also sought feedback from the devolved administrations.

There was variation in the volume of respondents across the different regulations. The section 'Operation of regulations' below therefore reflects the length and depth of feedback received.

With thanks to those who responded to the request for feedback on the operation of these statutory instruments (SIs), the comments received are noted. Where appropriate, either DHSC or the Medicines and Healthcare products Regulatory Agency (MHRA) address the concerns and suggestions raised within the response.

Operation of regulations

This section provides an overview of, and feedback received for, all the regulations within the remit of this report. The regulations are discussed in the order in which they were made.

The Medical Devices (Coronavirus Test Device Approvals) (Amendment) Regulations 2021

Objectives of the regulations

These regulations made amendments to The Medical Devices Regulations 2002. The amendments require coronavirus test devices to be approved by the Secretary of State before being placed on market or put into service. They specify the application procedure for approval, and the performance requirements that such devices must meet for the purposes of approval. They also provide for exemptions from that procedure for public service use and provide that the Secretary of State must establish a register of approved coronavirus test devices.

An assessment of the impact of this instrument was published in February 2022. A copy of an iteration of the impact assessment is available on the Private coronavirus (COVID-19) testing validation consultation page.

Summary of feedback from consultees

Respondents highlighted a range of positive aspects of the regulations, and in general felt that the regulations work effectively. Feedback included that the regular update of the spreadsheet of COVID-19 test validation approved products works well, as it is clear to providers and the accreditation body whether or not applications for accreditation include approved devices. There was support for the intent of the regulations to require all antigen and molecular detection COVID-19 tests to undergo a mandatory validation process before entering the UK market, which was noted as especially important in circumstances where tests are used for private testing programmes.

Stakeholders welcomed the reassurance provided by the Coronavirus Test Device Approvals (CTDA) validation process on the efficacy of a number of test devices that were put into use and highlighted that having a coordinated standardised process improved the efficiency and speed with which these products could be introduced into service.

There were some concerns raised around the limited definition of a 'devolved public health body' and the impact this has for those who do not fit the definition and their ability to

procure tests under new contracts or produce their own tests. There was acknowledgement of a workaround, but concern remained on the ability to set up new procurement arrangements in the future.

Respondents raised a potential risk that administration of the regulations and supporting processes could delay or remove a device use in a case where other relevant supporting evidence is available to inform efficacy. This could be of particular importance where high throughput devices are being evaluated and removal leads to significant disruption or cessation of a SARS-CoV-2 diagnostic service. The approvals process for one particular assay was highlighted as appearing rigid in its application, and that it did not appear to wholly and transparently consider a wider body of evidence, including substantial independent external quality assurance data (generated outside the CTDA process itself) regarding the satisfactory performance of the assay.

Response to the feedback

Concerns were raised regarding the backdating of device validation which may have caused problems for providers, although it was acknowledged that this issue did not recur. DHSC can confirm that this practice has now ceased and that the MHRA, who has taken over CTDA desktop reviews from the UK Health Security Agency (UKHSA), will not backdate validations.

In addition, there were concerns raised about the limited flexibility within the regulations around the definition of a 'devolved public health body' and that not all bodies benefit from the exemptions these defined bodies can use. Regulations 39A and 34B were created to allow exemptions during the pandemic and continue to be used by some manufacturers. DHSC will consider the feedback received and the applicability of the regulations as we live with COVID-19. DHSC also acknowledges the request to explore an amendment to extend the definition of a 'devolved public body' and will consider the issue more closely with the devolved administrations to ensure the regulations operate effectively in all 4 nations.

With regard to the concerns raised around the risks to the approvals process and particularly the supporting evidence requirements, DHSC would like to note that MHRA has continued the protocol established by UKHSA of working with applicants to ensure all appropriate evidence is submitted for consideration and minimise the risks highlighted.

Respondents also asked for consideration of emergency or temporary approval of devices on balance of risk if delayed due to administrative processes that are shown to be of low-risk impact. Regulation 39A already provides this flexibility if required.

Finally, during the stakeholder consultation, DHSC received feedback relating to the regulatory framework for medical devices more generally that was not in relation to the

specifics of the SI in question. As those contributions fall outside the scope of the report, they will not be included in this response. However, they have been noted for future reference.

The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2022

Objectives of the regulations

These regulations amended the Human Medicines Regulations (HMRs) 2012 to provide greater flexibilities for the movement and supply of certain types of vaccines, in light of the COVID-19 pandemic. These regulations amended 5 provisions:

- regulations 3A and 19, which were extended to April 2024
- regulations 229, 233 and 235, which have been made permanent

Regulation 3A enables trained healthcare professionals or staff under the supervision of healthcare professions to conduct the final stage of assembly, preparation and labelling of COVID-19 vaccines without additional marketing authorisations or manufacturers' licences being required.

Regulation 19 allows COVID-19 and influenza vaccines to be moved between premises at the end of the supply chain, by providers operating under NHS arrangements and the medical services of His Majesty's Forces, that do not hold wholesale dealer licences.

Subject to various exceptions in part 12 of the 2012 Regulations, prescription only medicines may only be sold or supplied in accordance with a prescription of, or administered parenterally by, a healthcare professional who is classed as an appropriate practitioner. The 2012 Regulations already provide for either or both of these part 12 restrictions to be set aside by instruments known as patient group directions (PGDs).

Previously, PGDs issued under regulation 229 (exemption for supply by NHS bodies and local authorities) of the 2012 Regulations by a number of listed NHS bodies, or bodies exercising public health functions, could only set aside the first of these 2 restrictions - the limitation relating to prescriptions. Regulation 229 was amended in December 2020 to allow these PGDs also to set aside the second of these restrictions - the restriction relating to parenteral administration - until 1 April 2022. The ability to administer parenterally prescription only medicines supplied under a PGD made under regulation 229 is made permanent (regulation 5).

Also, subject to various exceptions in part 12 of the 2012 Regulations, prescription only medicines and pharmacy medicines must be sold or supplied, by or under the supervision of a pharmacist, on premises that are a registered pharmacy. Regulation 6 amends regulation 233 (exemption for supply etc under a PGD by person conducting a retail pharmacy business) to permanently provide that PGDs that permit persons lawfully conducting a retail pharmacy business to set aside these restrictions, can include the sale, supply or administration of a medicinal product used for vaccination or immunisation against coronavirus or influenza (subject to the other conditions in regulation 233 also being made out).

Another route to exceptions from the core part 12 restrictions are a series of exceptions set out in schedule 17, which are targeted at various practical situations and occupational health schemes. In addition to doctors and nurses who may administer prescription only medicines as part of occupational health schemes, regulation 7 amends regulation 235 (exemption for sale, supply or administration by certain persons) to make permanent the other specified categories of registered healthcare professionals to administer coronavirus and influenza immunisations as part of the occupational health schemes of local authorities and specified NHS bodies.

Summary of feedback from consultees

Respondents highlighted positive aspects of the regulations including the more flexible ways of working created by the changes to PGDs and the national protocol, and the exemption from a wholesale dealer's licence to facilitate rapid movement of the vaccine to where it was most needed.

There were no concerns raised in the feedback received, neither were there any suggestions for improvement.

General feedback was that the regulations have worked well and provided the ability to meet operational requirements both at scale and locally. Praise has been received for introducing these regulations in a way that both provides efficiencies and has taken operational deployment into consideration.

Response to the feedback

We are pleased with the stakeholder feedback received during the collation of this report. Taking into account this feedback, and the public consultation held in August 2023, we will be extending these regulations in the new year. Our response to the public consultation on supporting the delivery of COVID-19 and influenza vaccination is available on GOV.UK.

The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022

Objectives of the regulations

These regulations amend the HMRs 2012 which govern the arrangements across the UK for the licensing, manufacture, wholesale dealing and sale or supply of medicines for human use, and The Medicines for Human Use (Clinical Trials) Regulations 2004 which govern the conduct of clinical trials of medicinal products for human use. The amendments make provision for the establishment and operation of the statutory version of the early access to medicines scheme (EAMS) - there has previously been a non-statutory version of the scheme. EAMS has the purpose of giving patients with life threatening or seriously debilitating conditions early access to medicinal products that are either not authorised or not authorised for that particular condition.

Putting EAMS on a legislative footing provides legal clarity which benefits industry, patients and healthcare professionals, to support patient access to innovative therapies in advance of licensing decisions.

Summary of feedback from consultees

Respondents were generally very positive about EAMS and considered that providing the legal clarity was a welcomed move. It was not felt by any respondents that introducing a statutory basis for EAMS has had any adverse effect on the application process or operation of the scheme itself.

Respondents found that the timelines stated on the MHRA website for application processing did not match up to what has been experienced, which makes planning and delivery of these schemes more difficult. There were concerns around the cost of the scheme as this may be prohibitive for smaller companies, as well as the regulatory burden of the application process, in comparison to early access schemes in other markets.

Respondents asked whether the definition of 'unmet clinical need' also took into account availability of licensed medication to patients through the NHS, and not only whether treatments had a marketing authorisation.

Finally, several responders noted that the guidance available on EAMS needed updating to provide further clarity - for example, on timescales, data collection requirements, pharmacovigilance and the decision process. Such guidance updates would also make the scheme more attractive and easier to navigate.

Response to the feedback

MHRA was pleased to note that the introduction of the statutory scheme for EAMS was welcomed by stakeholders and that the scheme itself is regarded very positively.

MHRA acknowledges that applicants have experienced extended timescales in accessing services including EAMS, and has made significant progress in restoring performance to be within customer expectations of timeframes in core areas of the agency.

Stakeholders raised questions around EAMS submission requirements. To support potential applicants with the EAMS submission process, MHRA offers opportunities to discuss the data requirements and optimum timing for an EAMS submission at various stages in the process - for example, at a scientific or regulatory advice meeting or EAMS pre-submission meeting.

Comments were also received in relation to burdens, including costs, for smaller companies and the ability to charge for treatments. Where MHRA provides a direct service for medicines regulatory work, such as EAMS, a fee is charged for cost recovery. The principles for how the agency charges fees are set by HM Treasury in Managing public money. The basic principle is “the standard approach is to set charges to recover full costs”. Charging for, and potential funding of, treatment is beyond the remit of MHRA.

Stakeholders raised the issue of whether the definition of availability took into account commissioning and access to patients and clinicians via the NHS. If a medicine meets a high unmet medical need and is likely to offer a major advantage over other methods actually used in the UK, this would meet eligibility criteria for EAMS. This MHRA position on major advantage has been consistent throughout the existence of EAMS and is outlined in the EAMS guidance. The legislative provisions therefore include this same requirement to "demonstrate that the medicinal product offers a major advantage over methods of preventing, diagnosing or treating the condition already in use in the United Kingdom". There is flexibility within this definition, since a major advantage could be improved efficacy, or similar efficacy but better overall tolerability, compared to methods already in use.

Additionally, stakeholders highlighted the need for EAMS to be transparent, and decisions would benefit from patient representation. MHRA agrees and takes action to ensure that EAMS decisions are well made and understood. As part of the EAMS process, the independent Commission on Human Medicines (CHM) and their expert advisory groups (EAGs) are consulted for advice at least once during all EAMS scientific opinion procedures. Independent advisory committees include lay members in addition to experts. MHRA is committed to ensuring there is patient input into decision-making on scientific assessments. Summary minutes of meetings are published as soon as possible after each meeting, giving information about these decisions. Positive scientific opinions are

published along with a public assessment report that explains in lay language how the medicine works, is used and was studied, the benefits and risks, the reasons for giving the positive scientific opinion, and the measures in place to monitor and manage risks. Commercially sensitive information is not included in the summary minutes, and negative opinions are not published as this could discourage future EAMS applications.

The EAMS webpage and guidance is in the process of being updated and is currently expected to be published early 2024. The updated material will include further details and information on the following points raised by stakeholders:

- collection of real-world data within EAMS
- the reporting of individual case safety reports
- further clarity on the meaning of 'major advantage'
- a link to the latest treatment protocols

The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023

Objectives of the regulations

These regulations make amendments to legislation setting out the fees charged by MHRA in relation to the regulation of medical devices and blood components for transfusion. They update a range of fees in line with the increased costs of providing these regulatory services, ensuring that MHRA recovers the cost of its regulatory activity in accordance with HM Treasury’s 'Managing public money' principles.

Summary of feedback from the consultees

There was no feedback received for this particular regulation.

The Medicines (Products for Human Use) (Fees) (Amendment) Regulations 2023

Objectives of the regulations

These regulations make amendments to The Medicines (Products for Human Use) (Fees) Regulations 2016. They make provision for the fees payable in relation to authorisations, licences, certificates and registrations in respect of medicinal products for human use,

including those under the HMRs 2012 and The Medicines for Human Use (Clinical Trials) Regulations 2004.

The fee amounts specified in these regulations represent an increase in the existing fees of 10% or more. They were set following a consultation by MHRA on proposed changes to their statutory fees. The consultation response published by MHRA on 31 January 2023 provides details of the proposals, a summary of the consultation responses and the government's response.

Summary of feedback from consultees

The amendments to fees were generally accepted by stakeholders who recognised the need to ensure cost recovery for MHRA's regulatory activities, and that this was important for ensuring a consistent level of service.

The general feedback from respondents was that the increased fees came with an expectation that there would be improvement in service levels and would enable MHRA to have resources and infrastructure to deliver on their core regulatory responsibilities. Respondents highlighted that the fee changes were positioned as necessary to maintain service levels, but reported concern that in many areas the increase in fees was not currently reflected in performance.

Respondents suggested that greater transparency on how the increase in fees are being used to facilitate improvements within MHRA would be welcomed.

Respondents would also appreciate visibility on the associated fee structures of upcoming procedures and frameworks being implemented in the near future, such as implementation of the Windsor Framework and the International Recognition Procedure.

Response to the feedback

Generally, whenever MHRA provides a direct service for medicines, medical devices or blood components for transfusion regulatory work, a fee is charged to recover the costs. The principles for how the agency charges fees are set by HM Treasury in Managing public money.

From Saturday 1 April 2023, new fees were introduced for a range of MHRA services. A review of the agency's statutory fees, conducted in 2022, identified numerous activities that were no longer fully recovering costs, and that new services had been introduced for which new statutory fees were required. The changes followed a public consultation conducted between August and November 2022 which heard the views of patients, public and industry.

Going forward, MHRA plans to update its fees on a more regular basis to ensure the fees remain financially sustainable and to help provide the service levels that customers expect. The agency will also continue to consult and engage with industry and stakeholders on fee proposals to ensure transparency.

Significant progress has been made in restoring performance to be within customer expectations of timeframes in core areas of the agency. However, MHRA acknowledges that further work is needed on improving service delivery. Going forward, MHRA will be building on the performance data that they publish to increase transparency and provide a more comprehensive overview of performance of the agency's core activities.

The Medical Devices (Amendment) (Great Britain) Regulations 2023

Objectives of the regulations

The Medical Devices (Amendment) (Great Britain) Regulations 2023 make amendments to The Medical Devices Regulations 2002. The purpose of the amendments was to extend the periods for which certain medical devices that comply with EU legislation can be placed on the market in Great Britain (GB).

Summary of feedback from consultees

Respondents highlighted a range of positive aspects to the regulations including UK self-determination and lessons learnt by the UK from difficulties arising from the new EU regulations. It was noted that the amendments provided more time for approved bodies and commercial manufacturers to prepare for the future medical device regulatory changes and reduce disruption to medical device supplies for the UK in health and social care. Improvements in the information published on the MHRA website were also praised.

Lastly, the ongoing acceptance of CE certification (CE marking indicates that a product has been assessed by the manufacturer and deemed to meet EU safety, health and environmental protection requirements) in line with requirements in the EU has been raised as helpful to manufacturers. Respondents noted that the longer transition periods and recognition of CE marking within GB may support GB manufacturers in maintaining current CE certificates and the continued supply of their devices to Northern Ireland in the short to medium term.

There were also a number of concerns raised. Many respondents felt that the delay in laying these amendments reduced their overall impact, resulting in a significant and detrimental effect on business and reputation in the EU. Respondents also felt that the changing implementation timescales, coupled with other related government

announcements regarding continued use of CE marking has meant that significant investment in people, processes and systems places their investments at high risk as more clients now opt not to progress, or to delay, their UKCA (UK Conformity Assessed) marking. It was also felt that it is was not clear as to why the extension of the time period of acceptance of EU marking was so long, in the absence of clarity on the wider medical devices' regulatory framework.

During the consultation, there were several comments received in regard to communication and the guidance available. Respondents felt that there was insufficient communication between MHRA and UK approved bodies and industry about these changes, either formally or through guidance documents. It was also felt that there was a lack of understanding by manufacturers and within industry on what the requirements to achieve UKCA marking actually were. It was suggested that much of this could be improved with better guidance, but also that a more coordinated approach to UKCA and CE marking across UK government departments would avoid inconsistency and reduce confusion for sectors.

With regards to timings, it was raised that in-vitro diagnostics (IVDs) are a clear concern as manufacturers placing devices onto the GB market using EU directive certification are only valid until 2025 under EU legislation. Therefore, there is a 'cliff edge' then for these devices, especially if they have not moved over to the IVD regulations (IVDR). New legislation needs to be in place sooner rather than later so manufacturers can plan accordingly.

It was also noted that the transition timelines, which have been defined as allowing recognition of CE marking until 2028 or 2030 depending on certification of the device, allow for plenty of time for manufacturers to implement changes. However, these also have the shorter-term effect of reducing the immediate urgency of compliance to the UK Medical Devices Regulations by reducing the immediate pressure on approved bodies' capacity and manufacturer resources, but also means the majority will continue to rely on CE marking and not progress to UKCA marking, making it completely deprioritised. There is also the potential risk that the deadline cliff edge to move to UKCA marking may be moved further down the line, causing uncertainty. It was suggested within the feedback received that a review of preparedness for the end of the transitional arrangements should be planned and that this should be undertaken well in advance of the existing dates for the transitional period to give fair warning to business and to avoid them incurring additional costs.

There were some concerns raised around MHRA's ability to police the self-declaration from manufacturers that their products meet the requirements set out in EU 2023/607 when their EU directive certificates' expiry dates have passed. It was suggested that there be a request for manufacturers to submit a letter issued by the EU notified body, which confirms that the requirements of EU 2023/607 are met.

Finally, it was highlighted that a full impact assessment was not carried out in advance of The Medical Devices (Amendment) (Great Britain) Regulations 2023, and therefore one should be conducted for the ending of the transitional period.

Response to the feedback

Firstly, we would like to thank those who responded to the request for feedback on the operation of these regulations. The comments received have been noted.

With regards to the comments about timing, we acknowledge this. The government does endeavour to lay all legislation in a timely manner and give sufficient notice of all legislative changes. It is not always possible to give as much notice of changes as would be optimum, due to parliamentary time constraints. The transition periods set out in these regulations are for CE marked medical devices. This was to give certainty to industry and other stakeholder groups about longer term supply stability of these products to the GB market during the period of wider regulatory changes. The transition provisions are in place to enable a smooth transition to the future medical device regulatory framework. The longer-term aim is to reduce the UK's reliance on CE marked medical devices, introducing broader supply chains that draw from UKCA marked medical devices and those that will come onto the market via an international recognition route. We are confident that approved bodies will play a significant role in the future medical devices regulatory regime, including their role in post-market surveillance.

We would also like to thank respondents for the constructive feedback provided around communications from MHRA and the department to stakeholders. Good communication between MHRA and stakeholders is vital and MHRA has refined its engagement and communication strategy in recent months, since this SI was laid. MHRA will continue this engagement with the approved bodies and other stakeholders.

MHRA has published information on GOV.UK (Implementation of medical devices future regime) on the changes these regulations made to The Medical Devices Regulations 2002, recognising that some manufacturers may require support to understand their impact. We recognise there was some initial confusion with the information on this page and this has been amended to improve clarity. In addition to the guidance already published, further information will be made available about the planned changes to The Medical Devices Regulations 2002 in due course. Changes will be supported by guidance and the MHRA and DHSC will work closely with stakeholder groups to help them understand the impact of these changes.

The approach to recognition of the CE marking for manufactured goods sectors is discussed regularly across responsible departments. It is understood that it is not always appropriate or possible to treat all manufactured goods sectors in the same way and, as high-risk goods, medical devices require additional oversight beyond some other sectors.

However, it is acknowledged that communication of these differences can be improved and DHSC is working closely with the Department for Business and Trade on this.

The potential risks of the approach taken to introduce the transition periods for CE marked devices are understood. When the upcoming wider regulatory changes are published in 2024, manufacturers will have a clear picture of the requirements under the new regulatory system and will be able to determine their most suitable regulatory route to market. Approved bodies will understand their requirements under each route so they can tailor their services. Sufficient time will be given for industry to transition to the updated regulations to mitigate the impact of any cliff edge as much as possible.

MHRA is preparing for the end of the transitional arrangements. This includes monitoring industry readiness for the future regulatory regime and the development of an international recognition framework for medical devices with approval from trusted regulators to support supply chains.

In addition, alongside the SIs that are planned to introduce the legislative changes to the medical devices regulatory framework, MHRA is also considering industry readiness more broadly. This will include guidance on the implementation of the new regulations. DHSC and MHRA will continue to engage with all stakeholders as that work develops. The situation is being closely monitored and DHSC and MHRA will take action as needed to support continued supply of safe medical devices of all types for UK patients.

We would also like to address the concerns around MHRA's ability to police the self-declaration from manufacturers that their products meet the requirements set out in EU 2023/607. Under the terms of the extension of CE certificates granted in Regulation (EU) 2023/607, written confirmation of the formal extension is not required. However, MHRA requests that manufacturers provide a written declaration that key conditions for extension of the certificate (under EU Medical Device Regulation Article 120) have been met. MHRA will monitor compliance with these devices in the same way they monitor any other medical device registered for sale in the UK. It is the responsibility of the manufacturer or its UK responsible person to ensure their CE certificate is valid.

During our stakeholder consultation, we also received feedback relating to the regulatory framework for medical devices more generally that was not in relation to the specifics of the regulations in question. As these fall outside the scope of this report, these were not included within this response. However, we do acknowledge these comments and will note them for future reference.

Finally, it was raised that, as a full impact assessment was not carried out in advance of these regulations being laid, one should be conducted for the end of the transition period. A full impact assessment was not required for these regulations, as it is only required when costs associated with the change reach £5 million. Should a full impact assessment

be required for any future changes to The Medical Devices Regulations 2002, one will be completed and published.

Plans for future regulations

The following regulations are in progress and the current intention is to lay them under the powers within the MMDA during the next reporting period. This list is accurate up to the date of publishing (29 February 2024).

Original pack dispensing and whole pack dispensing of medicine containing valproate

The Human Medicines (Amendment Relating to Original Pack Dispensing) (England and Wales and Scotland) Regulations 2023 were made in September 2023, outside of this reporting period, and as such they will be included in the next report. These regulations provide pharmacists flexibility to dispense up to 10% more or less than the prescription to allow medicines to be dispensed in their original packs. This is an important commitment in the Community Pharmacy Contractual Framework 5-year deal (CPCF - 2019 to 2024) and also linked to the Primary care recovery plan (published in May 2023). The regulations also ensure the supply of medicines containing valproate are always in original packaging. This is a commitment following the Cumberlege report on safety of medicines and medical devices. Due to the patient safety considerations involved, these regulations needed to be made as quickly as possible, so they were laid as GB-only in September 2023. Separate legislation will need to be approved in Northern Ireland when the Assembly has reformed.

Amendments to revoke (and later replace) the automatic recognition pathway for medicines licensed by the European Medicines Agency (EMA)

The European Commission Decision Reliance Procedure (ECDRP) allows MHRA to grant a licence without any assessment of quality, safety and efficacy, relying on a decision of the European Commission (EC). This facilitates the approval of a GB-only Marketing Authorisation (GBMA) for products approved by the EC. This was introduced as a temporary measure lasting 2 years from 1 January 2021. In July 2022 this period was extended until 31 December 2023, when MHRA replaced the ECDRP with the new International Recognition Procedure, using existing powers in regulation 58(4A) of the HMRs. These regulations will remove the power contained in regulation 58(4C) of the HMRs, which enables the ECDRP.

Point of care (POC) medicines regulatory framework

MHRA is introducing a new tailored framework for the regulation of products manufactured at the point where a patient receives care (POC). This will mean that new medicines with short shelf lives and highly personalised medicines can more easily be made in or near the POC and provided to patients. Medicines will also be manufactured in relocatable units under the new framework, where it is necessary to do so for reasons related to deployment. It is also a commitment under the Life sciences industrial strategy to provide world-leading support for innovation.

The Human Medicines (Amendments relating to Hub and Spoke Dispensing etc.) Regulations: hub and spoke dispensing (pharmacy efficiencies)

This SI will deliver policy to help the pharmacy sector to secure efficiencies required under the CPCF 2019 to 2024 by amending medicines legislation so as to remove the restrictions which prevent hub and spoke dispensing arrangements from being carried out between pharmacies owned by different legal entities.

Hub and spoke dispensing occurs when different stages of the dispensing process takes place at different registered pharmacy sites. For example, a 'hub' pharmacy will carry out its actions which make up dispensing of the medicines that have been ordered at a 'spoke' pharmacy, which can then be supplied to the patient from the spoke or direct to the patient from the hub.

The policy proposals go beyond simply removing the barrier that currently limits hub and spoke arrangements to pharmacies within the same legal entity as they also include elements to ensure the safe and effective implementation of the policy, ensure accountability and provide transparency for patients.

The SI also allows dispensing doctors (usually GPs in rural areas who provide pharmaceutical services) to act as a spoke for the purposes of these proposals. The SI may be laid as GB-only if the Northern Ireland Assembly has not reformed by the time that we come to make the relevant legislation. If the SI is laid as GB-only, separate legislation will need to be approved when the NI Assembly has reformed in order to implement these policy proposals in Northern Ireland.

Dental hygienists and therapists’ supply: amendments to expand who can supply and administer medicines

This SI will enable dental hygienists and dental therapists to supply and administer medicines using exemptions to ensure patients receive the best care in the right place, without unnecessary delays or hand-offs.

Pharmacy technicians and PGDs: amendments to the HMRs 2012 so that pharmacy technicians can supply and administer medicines under PGDs

This SI will enable registered pharmacy technicians to supply and administer medicines using PGDs. This aims to support ambitions within the NHS Long Term Plan and CPCF to maximise the use of skill mix in pharmacy teams. This will allow a greater range of patient facing services to be offered in community pharmacy and allow pharmacy technicians to be further utilised as part of multi-professional teams across all healthcare settings.

Regulations 3, 19 and 247A: protocol amendments to use expanded workforce outside of a pandemic

Regulation 247A is the mechanism that allows the expansion of the workforce who are legally and safely able to administer a COVID-19 or influenza vaccine under an approved protocol, to ensure that the UK has the available workforce to administer vaccines at the pace required during a pandemic. This SI will amend the HMRs to expand this workforce outside of a pandemic. For regulations 3 and 19, see 'The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2022' section above.

Diagnostic radiographers and operating department practitioners: amendments to the HMRs to expand who can supply and administer medicines

This SI provides for independent prescribing by diagnostic radiographers and the use of PGDs by operating department practitioners to ensure patients receive the best care in the right place, without unnecessary delays or hand-offs.

Naloxone: amendments to expand access to this life-saving drug

The primary purpose of the SI is to amend the rules in the HMRs regarding the settings permitted to supply and distribute naloxone, a drug which reverses the effects of an opioid overdose, for patients to take and use (if required) at home without a prescription. Currently, only drug treatment services can supply take-home naloxone to individuals without a prescription. However, many services do carry it to be able to administer in an emergency, which is already permitted under the HMRs. This legislation would seek to expand the number of professionals and services that can supply take-home naloxone.

Clinical trials regulatory framework reform

This SI will deliver MHRA's reform of UK clinical trials regulation as a key post-Brexit opportunity to reform life sciences regulation.

Technical amendments to the HMRs (PHE amendments)

This SI will amend references within the HMRs to Public Health England (PHE) which has now been dissolved. Those references to PHE will be amended to either UKHSA or DHSC to reflect which organisation has inherited the respective functions that were previously held by PHE. The definition for PHE within the HMRs will be removed and a definition for UKHSA inserted. The SI will also amend references to the Regional Health and Social Care Board (HCSB) in Northern Ireland, which has also been dissolved, to reflect that these functions have now migrated to the Department of Health in Northern Ireland.

Medical devices framework

A series of statutory instruments will establish a new regulatory framework for medical devices in GB, which will improve patient safety, account for advances in science and technology and support greater access to innovative devices.

This includes:

- transitional arrangements (SI 1): this SI was laid within the first reporting period and is covered in 'The Medical Devices (Amendment) (Great Britain) Regulations 2023' section above

- post-market surveillance (SI 2): an SI to introduce strengthened post-market surveillance requirements. This SI has now completed the notification period required

by the World Trade Organization. MHRA intends to lay this SI in spring 2024, for coming into force in winter 2024

- future regime core framework (SI 3.1): this SI prioritises elements of the future regime with the capacity to have the most rapid impact on patient safety and will improve access to innovative devices through the introduction of a framework for international recognition. This is a substantial, multi-chapter SI. MHRA plans to begin to share draft legal text with stakeholders in early 2024. The aim is for this SI to come into force in 2025

- future regime enhanced regulations (SI 3.2): MHRA will continue to work with stakeholders across industry, healthcare and academia to introduce further proportionate changes to The Medical Devices Regulations 2002 in a subsequent SI following targeted stakeholder engagement and potentially a further public consultation

Amendments to The Veterinary Medicines Regulations 2013

This SI will update The Veterinary Medicines Regulations 2013 in respect of GB, to modernise rules on how veterinary medicines should be marketed, manufactured, supplied and used.

This reflects developments and technical advances, reduces regulatory burdens to support the industry, and will more closely align regulatory frameworks between GB and Northern Ireland.

The amendments will also introduce measures to help reduce the risk of development and spread of antimicrobial resistance, in line with government commitments.

Annex: questions asked to stakeholders

What aspects of the regulations are working well? Please list any positive aspects of the regulations here.

Do you have any concerns on how the regulations are working?

Do you have any suggestions on how the regulations could be changed to address any concerns raised above?

Please share any general feedback, that hasn't been captured above, on how the regulations are operating.

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