Medicines & Healthcare products Regulatory Agency

Health Institution Exemption – Stakeholder survey: Call for Evidence Analysis Summaries

Published November 2025

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Introduction

In line with our roadmap deliverable, the Medicines and Healthcare products Regulatory Agency (MHRA) are looking to refine the current policy and guidance on the Health Institution Exemption (HIE) in Great Britain (GB) to align with the government's missions, including the 10-Year Health plan for England, and the Life Sciences Sector Plan.

We want to ensure the HIE policy position will continue to support access to safe, effective devices for patients and that we minimise any supply disruption. To successfully deliver a policy that delivers on this, we need a good understanding of how the HIE is currently used across GB, to what effect, and any challenges in its implementation.

To build this understanding, health sector engagement is important. The MHRA has limited visibility over devices that are manufactured and used within health institutions - there is no requirement in the UK Medical Devices Regulations 2002 (MDR 2002) for these devices to be registered with the MHRA.

We also appreciate the difficulties many health institutions face in navigating the current HIE guidance. Under existing regulations, there is an explicit exemption for *in vitro* diagnostic (IVD) devices that are manufactured and used within the same health institution, with further clarification provided in the IVD-specific guidance. However, the position is less clear for general medical devices (GMDs). The MHRA guidance provides that the exemption extends to GMDs, but there is no explicit regulatory provision equivalent to that for IVDs.

Therefore, NHS Trusts and Boards are developing, manufacturing, and using devices based on guidance that needs to be updated. The MHRA are working on a longer-term HIE policy, which will be informed by engagement with clinicians, scientists, engineers, physicists, patients, and the public. Future regulatory changes beyond the upcoming guidance that will be introduced as part of the longer-term HIE policy development will be preceded by the appropriate statutory public consultation.

Methods

To help build this knowledge and understanding, a public questionnaire was launched in August 2025 to gather information on why and how the HIE is currently being used in practice across GB, and to what effect. The survey comprised of six sections designed to gather insights into the following:

- **Motivations:** why, and to what perceived impacts, are health institutions using the HIE?

- **Conditions of use:** under what conditions are health institutions using the HIE currently, including QMS approaches, to help us understand the level of assurance of these devices being undertaken in the market already.

- **Extent of use:** what is the nature and level of devices the HIE is being used for.

Results

The MHRA received 137 responses to the survey between August and September of 2025, 91% of these indicated that they were located in GB. The analysis below contains information from all respondents.

Thematic observations

- **Widespread but varied use of the HIE.** Just over half of respondents indicated that they use the HIE, primarily to meet unmet clinical needs and when no suitable commercial alternatives exist. However, usage varies significantly across organisations, with many citing confusion over key definitions and the scope of the HIE.

- **Strong internal governance but limited external oversight.** Most respondents follow robust internal processes, including QMS adoption and with technical documentation about the device. However, post-market surveillance and external incident reporting (e.g. to MHRA) are low, indicating a potential gap to consider when reviewing regulatory requirements for using the HIE.

- **Guidance is known but it is not clear**. While awareness of the HIE guidance is high, only a third of users find it clear. Many respondents called for more detailed, practical, and device-specific guidance.

- **Limited device transfer and off-site use.** Most devices are manufactured and used within the same premises. Transfers to other entities or use in patients' homes are rare, but where they occur, they raise compliance concerns and highlight the need for clearer rules. Many respondents called for the scope of the HIE to be expanded to better align with current care practices.

- **Use of the HIE for clinical investigations appears to be low however it may be increasing.** A minority of respondents indicated they have active HIE clinical investigations (CIs) on-going (approximately 15 active CIs), though this number may be higher as many respondents were unsure. There is an indication that use of the HIE for CIs has been increasing over the past 5 years. Unfortunately, there is limited

information on the types of devices used in HIE studies, or the circumstances when the HIE may be used during a clinical investigation.

Survey results by section

Section 1: About your organisation

The survey received 137 responses, with 66% of respondents operating in the public healthcare services sector and 76% based in England. Respondents indicated their organisation delivers services across GB, with coverage in England (83%), Scotland (29%), and Wales (27%). This survey featured multi-select questions allowing respondents to choose multiple answers. Accordingly, some response percentages may exceed 100%. Notably, 60% of respondents indicated they did not represent a health institution as defined in the survey, highlighting potential variation in how organisations interpret or align with the HIE framework and definitions.

Section 2: Scope of the health institution exemption (HIE) use (who, what, where)

Just over half of respondents (51%) confirmed they use the HIE and of those, 77% confirmed their devices are manufactured and used within their premises or immediate vicinity, without the intent to transfer. For respondents who do not use the HIE, the main reasons included the availability of commercial alternatives (23%), lack of awareness of the HIE prior to the survey (22%), and lack of clarity on the scope of use (22%). Additional reasons cited included using other regulatory routes such as UKCA marking or custom-made devices pathway or finding the HIE not applicable to their work.

Software as a medical device (including AI as a medical device) and general medical devices (excluding software and implantable devices) were the most common device types manufactured under the HIE, at 54% and 52% respectively. Respondents also indicated that the vast majority of requests for device manufacture come from within the organisation (97%). The volumes of devices manufactured under the HIE per year were varied, with 45% producing less than 20 devices annually in total. Two-thirds (66%) of respondents confirmed they produce multiple types of devices, typically between 2 - 10 types, and 75% said they produce similar volumes for each device type. Most respondents (86%) indicated do not believe they manufacture devices on an “industrial scale”.

Only a small proportion of respondents (4%) indicated that some devices manufactured under the HIE are used outside their health institution’s premises or immediate vicinity without full compliance to MDR 2002. These devices, which are typically used in patients’ homes, were reported by just five respondents, with 2 out of the 5 of those estimating usage volumes between 501 - 1000 devices per year. While this highlights isolated instances of extended use of the HIE, the low response rate suggests strong overall adherence to MDR 2002 restrictions on use of the HIE.

Regarding device transfers to other entities, 76% of respondents confirmed they do not manufacture devices with the intent to transfer. Among the minority who do, most reported low volumes - 50% said fewer than 20 devices are transferred on average annually. These transfers typically occur between health institutions and are often driven by specialist R&D laboratories or service arrangements with other hospitals. This reflects a limited but purposeful extension of the HIE use in collaborative clinical or research contexts.

Section 3: How the HIE is used in practice

The majority of respondents (90%) reported adopting a Quality Management System (QMS) when manufacturing devices under the HIE, with 76% holding a formal certification in ISO 15189, ISO 13485, or ISO 9001 standards. Many also maintain comprehensive documentation for their devices, including technical documentation (94%), incident reports (94%), approvals for use records (65%) and change management records (82%).

Respondents indicated that, before manufacturing devices under the HIE, they do consider commercial alternatives available on the market (79%). However, the level of ongoing market surveillance conducted (e.g. after the devices have been manufactured and/or used) is significantly reduced (only 36% confirmed yes).

When asked about voluntary compliance with MDR 2002 requirements, encouragingly many respondents indicated they already meet several key requirements, such as meeting relevant essential requirements (74%), meeting relevant standards or common specifications (73%), or producing a technical file for medical devices (69%) - demonstrating a strong commitment to ensuring device safety. Despite this proactive approach, voluntary post-market surveillance and incident reporting to the MHRA was low for devices produced under the HIE at only 36%. Respondents also reported diverse approaches to device oversight for devices manufactured under the HIE, with no single method being adopted. This gap highlights the need for clearer guidance and more consistent practices to ensure continued safety for devices manufactured under the HIE.

Section 4: Reasons for using the HIE in practice

Most respondents indicated they use the HIE to meet unmet clinical needs (90%) and because no commercial alternative exists (91%), or the commercial alternative is not suitable to meet the clinical needs (64%). There was strong agreement that the HIE is vital for patient access to innovative, tailored medical devices – especially for complex cases with unique patient needs. Respondents also indicated that, whilst commercial factors and faster access to medical devices are benefits of the HIE, there is a need for clearer, risk-proportionate regulations that safeguard patients without limiting innovation.

Over half of the respondents (51%) indicated that they have experienced barriers to or issues with their preferred use of the HIE. When asked to expand on the reasons why, respondents noted the main barriers stem from vague guidance, ambiguity in definitions and operational constraints. This lack of clarity on the HIE requirements often leads to difficulty with applying the HIE consistently – particularly when coupled with cost, expertise and resource constraints. Concerns were also raised on how the current HIE policy fits with the recent rapid advancements in health technology, particularly for software devices. Many respondents raised concerns on how the inability to transfer devices outside of the "immediate vicinity" could lead to duplication of effort and resources and fragmented delivery of care.

Section 5: HIE – Medical device safety and performance

Most respondents (86%) reported having systems or processes in place to monitor the safety and performance of medical devices manufactured under the HIE, though the specific monitoring activities varied across respondents. Positively, 73% said they had not encountered or been notified of any safety or quality issues, with the few examples provided relating to third-party materials and reagents or minor usability concerns. In addition, 84% of respondents indicated they had not experienced any other (non-safety or quality) issues with devices manufactured under the HIE, suggesting a generally positive safety and performance profile.

Incident reporting is well-established internally, with 87% of respondents confirming they use incident reporting systems/platforms like Datix or report to designated sections of their organisation. However, external reporting to national systems remains limited - only 24% use the MHRA Yellow Card scheme, and even fewer report via the MORE platform (19%). Some respondents noted alternative reporting routes, such as through the Incident Reporting and Investigation Centre (IRIC), internal meetings, or direct communication with manufacturers. These findings highlight the need for clearer, more consistent reporting pathways to ensure robust oversight and learning for devices manufactured under the HIE.

Section 6: HIE – Current guidance and information

Awareness and use of the current HIE guidance is relatively high, with 74% of all respondents indicating they are familiar with it and 60% actively using it. When considering only respondents who use the HIE, these figures rise to 96% and 86% respectively. However, only 33% of HIE users expressed that they find the current guidance clear, prompting some to rely on alternative sources, most notably the IPEM guidance, used by 77% of those respondents who use the HIE and are seeking additional support.

Respondents highlighted several areas where the HIE guidance needs improvement. Key themes included the need for software-specific examples, clearer definitions of terms like

“health institution” and “legal entity,” and practical case studies to illustrate application - especially for universities and collaborative partnerships. There were repeated calls for more detailed content outlining best practices, scope of use (e.g. transfer of devices, community care, cross-trust referrals), and clarity around clinical investigations. Many also requested tailored guidance for specific device types and clinical functions such as assistive technology, bioinformatics/software, genomics and rehabilitation.

Section 7: HIE use in clinical investigations

Several respondents with ongoing Clinical Investigations (CIs) under the HIE would appear relatively low with 89 (65%) of respondents indicating they have no CIs currently being undertaken under the HIE and only 15 (11%) indicating they have active CIs under the HIE. These numbers differ slightly when considering only respondents who indicated they use the HIE, to 41 (60%) and 13 (19%) respectively. However, there appears to be some confusion between testing being completed, presumably with IVDs or medical devices being used under the HIE, and Clinical Investigations of a medical device to which the question refers. When considering further responses attached to this question, the number of respondents with active HIE CIs is approximately 8. Though it is possible for this number to be higher as 32 (24%) respondents indicated they do not know if they have CIs under the HIE with this proportion staying fairly consistent when only considering those who use the HIE, at 14 (21%). Furthermore, it is difficult to ascertain the total number of Clinical Investigations ongoing under the HIE as the responses to the survey vary greatly (ranging from 1 – 10,000) and it is not clear for each response if they are correctly referring to clinical investigations. This confusion highlights a need for clearer guidance specific to Clinical Investigations under the HIE.

34 respondents (71%) indicated that they do not know if clinical investigations under the HIE involve particular types of devices, or particular circumstances with only 8 (17%) and 6 (13%) of respondents indicating yes and no respectively. This trend continues when considering respondents who use the HIE, with 17 (61%) not knowing if CIs under the HIE involve particular devices or circumstances with 6 (21%) indicating yes and 5 (18%) indicating no. Within the further detail provided on the “Yes” responses we can see there are varying use cases for HIE CIs such as patient specific 3D surgical guides and new tracheostomies, though this further detail is limited in quantity. Additionally, it may be that some of these active clinical investigations may qualify as performance evaluations for IVDs instead of Clinical Investigations of medical devices based on some of the responses e.g. measurements of analytes, testing of analytes in patient bodily fluids etc. which again indicates a need for clearer guidance in this area.

The response to the final question indicates that the use of the HIE in Clinical Investigations (in the view of respondents) has increased in the past 5 years, though only when considering those who responded with a definitive increase or decrease. 33% (16 responses) suggested

there is an increase, and when considering those who use the HIE this climbs to 39% (11 responses). Only 6% (3 responses) indicated they felt use of HIE clinical investigations has decreased in the last 5 years and this jumps very slightly to 7% (2 responses) when considering those who use the HIE. More respondents indicated that they do not know if the use of the HIE has changed in the past 5 years (50% falling slightly to 42% when considering those who use the HIE) either by selecting do not know or through a free text response that indicated the same.

Conclusion

The feedback gathered provides valuable insights into how the HIE is currently being applied in practice and the breadth of its use. Respondents identified key areas for improvements, providing a clear, evidence-backed basis to inform future guidance updates and broader policy development on the HIE. Notably, many of the key themes raised in the survey also align with informal feedback gathered from previous stakeholder engagement and site visits, reinforcing a consistent and clear direction for future work.