BHTA Response to Consultation

MHRA – Pre market medical devices regulation – stakeholder impact survey

Submitted via online consultation response form on 19-Jun-26 (https://www.gov.uk/government/calls-for-evidence/pre-market-medical-devices-regulation-stakeholder-impact-survey); auto-generated Response ID: **NOT PROVIDED [see below end of document]**

This Word document mirrors the questions & responses in the online form:

- **Questions = Bold Text**
- BHTA Answers = Regular Text

1 Which of the following best describes you or the organisation you work for? If more than one option applies, please select the one that is most relevant. If you wish to reflect multiple roles, please complete separate entries for the survey.

Other

2 Do you believe that the 2026 Regulations will encourage innovation?

"Innovation in healthcare is the process of introducing new ideas, methods, technologies, products, or services aimed at improving healthcare delivery, patient outcomes, and overall efficiency within the healthcare providers (e.g. NHS). It includes the creation and implementation of concepts, ideas, technologies, processes, and services that benefit clinical outcomes and enhance patient experiences."

Unsure

3 Please explain your answer to the previous question: 'do you believe that the 2026 Regulations will encourage innovation?'

For companies, new, added expenses in MHRA's reformulated [and likely-to-further-change] fee infrastructure will average in the 10s-of-thousands, and for some it will be in the 100s-of-thousands. Taken together, these costs will add millions to the cost of doing business in the UK – and will have deleterious effects on: UK med tech innovation, inward investment to the UK, and UK plc. Moreover, it is not the case that only larger companies with large numbers of GMDN registrations will be affected. There are many UK SMEs with high numbers of GMDN registrations for which these proposed fees will represent a significant proportion of turnover. *(For more detail, please see BHTA's response to 2024 MHRA Fees Consultation, Q11.)*

In general, the regulations are fit for purpose, however most problems our members have experienced are as a result of the MHRA overseeing those regulations. Again, after a difficult period in the last 3 years, we welcome MHRA's increased clarity of late. Our members remain concerned, however, that MHRA is resourced appropriately enough to carry out its responsibilities as a regulator

under the new UK medical device regulations. It is essential that MHRA staff have the right familiarity with the medical device landscape, UK regulations, and timelines considered reasonable by business for appropriate operation. Businesses need predictability, appropriate advance notice, and clear regulatory pathways in order to invest confidently. This is especially important for innovation – although no less crucial for business-as-usual operation. *(For more detail, please see BHTA's response to 2025 MHRA Medicines and Medical Devices Act 2021 Survey, Q8.)*

MHRA's performance has affected both routine operations and progress in innovation. While there has been some improvement, focusing on resolving specific issues and allocating resources accordingly has led to delays in other areas, which have taken considerable time to recover. The service delivered should demonstrate both quality and cost-effectiveness, and MHRA staff should be supported through enhanced training and additional resources to strengthen their skills and expertise. We strongly support MHRA's recent renewed openness to engagement with industry, and to proactive collaboration; this is essential to creating regulation and – perhaps even more importantly – guidance on the regulation that will work in the real world. Close collaboration with industry, as well as interaction with patients, are vital if MHRA is to remain an effective regulator, while safeguarding innovation and access, which are crucial to the UK remaining a leader in medical devices. *(For more detail, please see BHTA's response to 2025 MHRA Medicines and Medical Devices Act 2021 Survey, Q10.)*

The existence of separate legislation for medical devices in Great Britain and Northern Ireland creates an unnecessary burden. Differing requirements and duplicated regulatory submissions add complexity, raise compliance costs, and discourage innovation. This regulatory split can delay the availability of new devices in one or both regions, without delivering any clear improvements in safety or quality. *(For more detail, please see BHTA's response to 2025 MHRA Medicines and Medical Devices Act 2021 Survey, Q12.)*

Post-Brexit, the UK is viewed as a region of additional complexity and another "box to tick" alongside EU/CE-mark regulation if a company wants to operate across both the EU and UK. The current approach to international recognition is inadequate – although we acknowledge that MHRA's forward-looking IR plans mean help is on the way. To re-establish the UK's position as a competitive and leading market, MHRA must enhance its strategy for global collaboration and data sharing in the medical device sector. Closer alignment with trusted international regulators would help eliminate duplication, speed up access to innovative products, and make the UK a more appealing destination for global manufacturers. This is especially critical in light of the growing regulatory divergence following Brexit. *(For more detail, please see BHTA's response to 2025 MHRA Medicines and Medical Devices Act 2021 Survey, Q13.)*

4 Do you think that the 2026 Regulations will result in increased and broader access to innovative devices?

Unsure

5 As a result of these regulations being implemented, do you think the proportion of adverse medical device incidents across Great Britain will increase, decrease or stay the same?

Unsure

6 What percentage change in the proportion of adverse medical device incidents across Great Britain do you expect due to the 2026 Regulations? (E.g. -10% (i.e. reduction) or +10% (i.e. increase). If you are unsure, please enter a range. (optional)

BHTA considers it very, very difficult to predict how changes to the proportion of GB adverse medical device incidents might or might not be attributed to the 2026 Regulations. It is difficult to track the historical trend of GB adverse medical device incidents full-stop, since – so far as we are aware – MHRA has produced directly comparable data for only 2 years (and even these data do not appear defined in such a way as allow confidence that one is comparing apples to apples):

- **2024/25**: c. 56,000 medical device incidents assessed (p. 3, https://assets.publishing.service.gov.uk/media/687dfe6d5f0f5104b9806be9/MHRA_Impact_Report_24_25.pdf)
- **2023/24**: 31,364 adverse incident reports for medical devices for medicines and medical devices (p. 30, https://assets.publishing.service.gov.uk/media/66a8ed880808eaf43b50d9df/MHRA_Annual_Report_2024_low_res.pdf)

If these two years' figures are directly comparable – and it is unclear whether they are – that is a 79% increase in adverse incidents over one single year. We would suggest:

- Historical data are mined, if possible, to produce as many directly comparable year-on-year figures as possible;
- Analysis of this should be published to provide an accurate historical baseline for at least 10 years, preferably 20 years;
- This baseline should be used as a starting point for analysis of the possible effects of the 2026 Regulations;
- MHRA should publish any methodology they have used, or propose to use, to evaluate different drivers of adverse event data.

MHRA is likely to have access to better opinions on statistical modelling than BHTA, but we would suggest:

- This effort would involve the participation of at least MHRA, DHSC, NICE, and the NHS.
- Year-on-year fluctuations of between +10% and -10% should be regarded as within the margin of error when attempting to attribute what percentage might be due to the 2026 Regulations.

7 Do you think that the 2026 Regulations will result in increased confidence in the NHS and medical devices?

Unsure

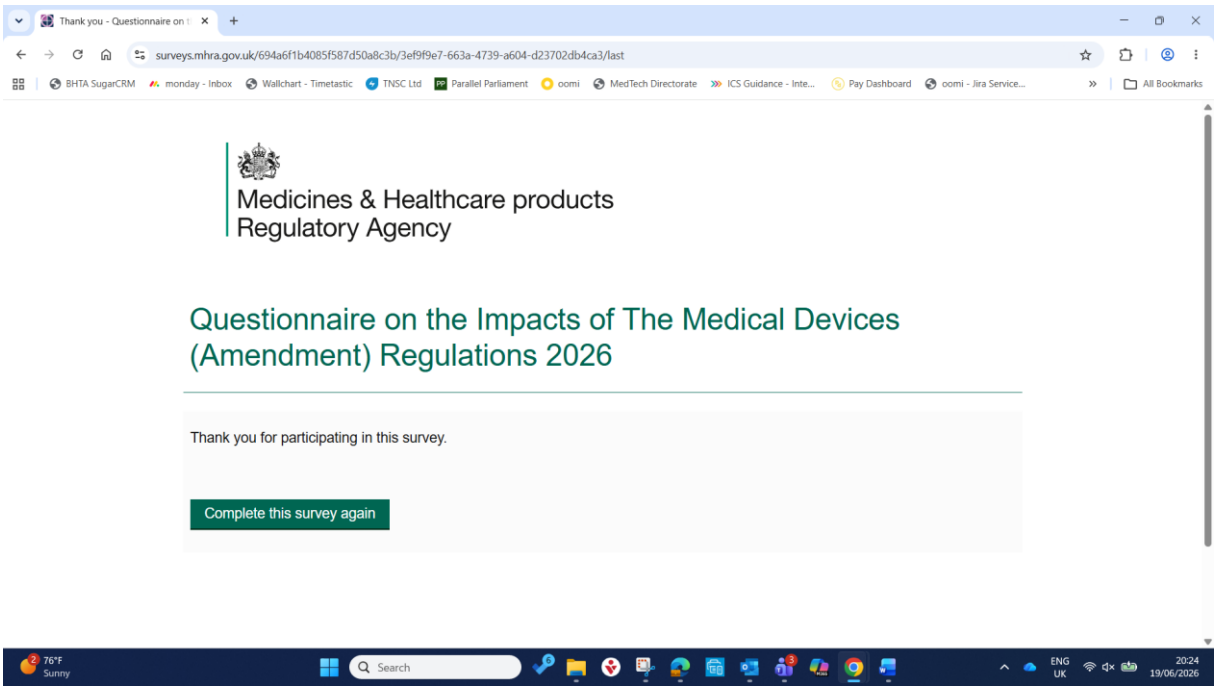
8 Have you reported incidents related to medical devices using the Yellow Card scheme?

Yes

9 Have you ever been part of a recall?

No

Online response system did not provide formal confirmation of receipt of response; screenshot of screen immediately after pressing "Submit" is below:


Thank you - Questionnaire on t
surveys.mhra.gov.uk/694a6f1b4085f587d50a8c3b/3ef9f9e7-663a-4739-a604-d23702db4ca3/last
BHTA SugarCRM
monday - Inbox
Wallchart - Timetastic
TNSC Ltd
Parallel Parliament
oomi
MedTech Directorate
ICS Guidance - Inte...
Pay Dashboard
oomi - Jira Service...
All Bookmarks
Medicines & Healthcare products Regulatory Agency
Questionnaire on the Impacts of The Medical Devices (Amendment) Regulations 2026
Thank you for participating in this survey.
Complete this survey again
76°F
Sunny
Search
ENG
UK
20:24
19/06/2026