

# Chapter 8: Post-market Surveillance and Vigilance

## Section 48 - Post-market surveillance

### Background

- 48.1 Currently, under the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK medical devices regulations), once a medical device has been placed on the UK market, the manufacturer must continually monitor the performance of the medical device. This is called post-market surveillance.
- 48.2 Post-market surveillance requirements under the UK medical devices regulations could be made more stringent to help improve patient safety and strengthen the level of post-market surveillance activities conducted across all manufacturers placing medical devices on the Great Britain market.
- 48.3 The Regulations could set out clearer requirements for the manufacturer's post-market surveillance system and could require the manufacturer to summarise and report their post-market findings to the MHRA. Existing requirements are laid out in guidance, however improved regulation will help to achieve better harmonisation across manufacturers placing devices on the UK market. The objective of this would be to improve the ability of both the manufacturer and the MHRA to identify issues with a medical device and where necessary take appropriate action to safeguard public health.

### Possible Changes and Questions

- 48.4 The MHRA considers that the UK medical devices regulations could be amended to clarify and strengthen the requirement for manufacturers to implement a post-market surveillance system, in respect of all medical devices they have placed on the UK market. This could be based on the manufacturer's post-market surveillance plan, which collates and utilises information from:
- a. serious incident data (see section 49)
  - b. field safety corrective actions (FSCAs) (see section 49)
  - c. non-serious incident data, trend reporting (see section 50)
  - d. relevant literature e.g. scientific studies on the medical device or similar devices
  - e. data from registries
  - f. feedback and complaints from users and economic operators, and
  - g. information regarding similar medical devices
  - h. patient and public involvement.

We could require that the plan must outline how this information is to be collected and assessed.

**Q48.1 Do you think manufacturers should be required to implement a post-market surveillance system based on a post-market surveillance plan, which collates and utilises information from the range of sources listed in paragraph 48.4? ('Yes' / 'No' / 'Don't Know/No Opinion')**

48.5 The MHRA considers that the UK medical devices regulations could be amended to provide a detailed outline of what the post-market surveillance plan should address and what should be included. For example, we could require that the plan covers the methods used to collect, process, and assess data, the protocols in place to identify statistically significant increases in certain events, and the methods used to take corrective measures. This would help to encourage the use of more rigorous scientific methods to identify potential medical device safety issues.

**Q48.2 Do you think the UK medical devices regulations should provide a detailed outline of what the post-market surveillance plan should address, including the examples given in paragraph 48.5? ('Yes' / 'No' / 'Don't Know/No Opinion')**

**Q48.3 Please outline any other elements that a post-market surveillance plan should address.**

48.6 The UK medical devices regulations currently require manufacturers of general medical devices to carry out necessary post-market clinical follow-up (PMCF). PMCF involves a continuous process of collecting and analysing post-market clinical data from human use of a general medical device, over the device's expected lifetime. Manufacturers are required to use PMCF findings to update their clinical evaluation (see Chapter 7, Section 31).

48.7 The MHRA considers that the UK medical devices regulations could introduce similar requirements for manufacturers of IVDs. For example, IVD manufacturers could be required to carry out post-market performance follow-up (PMPF). We could require that this should be a continuous process to proactively collect and evaluate performance and relevant scientific data from the use of the IVD over its expected lifetime. IVD manufacturers could be required to use PMPF findings to update the performance evaluation of the device (see Chapter 7, Section 32).

**Q48.4 Do you think the UK medical devices regulations should require IVD manufacturers to carry out post-market performance follow-up (PMPF) and to use PMPF findings to update the IVD's performance evaluation? ('Yes' / 'No' / 'Don't Know/No Opinion')**

48.8 The MHRA considers that the UK medical devices regulations could require manufacturers to perform PMCF/PMPF pursuant to a PMCF/PMPF plan, unless the manufacturer has provided a justification that this is not applicable to the device in question. The UK medical devices regulations could detail what should be included in the PMCF/PMPF plan for example, the plan should specify the methods and

procedures to be applied for PMCF/PMPF such as evaluation of registers, gathering of user feedback etc.

**Q48.5 Do you think the UK medical devices regulations should outline what should be included in the PMCF or PMPF plan, including the examples given in paragraph 48.8? ('Yes' / 'No' / 'Don't Know/No Opinion')**

**Q48.6 Please outline any other elements that a PMCF/PMPF plan should be required to address.**

**Q48.7 Do you think that manufacturers should be exempt from the requirement to perform PMCF/PMPF for a medical device or IVD pursuant to a PMCF/PMPF plan if such manufacturers provide sufficient justification? ('Yes' / 'No' / 'Don't Know/No Opinion')**

48.9 The MHRA considers that the UK medical devices regulations could be amended to outline how manufacturers should summarise and present the information from their post-market surveillance activities. It could include the requirement for:

- a. manufacturers of lower risk medical devices to summarise their findings in a 'post-market surveillance report' which would need to be updated when necessary and made available to the MHRA
- b. manufacturers of higher risk medical devices to summarise their findings in a 'periodic safety update report (PSUR)' which would also need to include information on the conclusions of the benefit-risk determination, findings of the PMCF/PMPF, the volume of sales of the medical device and information on the use of the medical device. This would need to be updated annually or bi-annually and submitted to the Approved Body involved in conformity assessment and the MHRA.

**Q48.8 Do you think the UK medical devices regulations should include requirements for manufacturers to summarise and present the information from their post-market surveillance activities in a post-market surveillance report or a periodic safety update report as they are described in paragraph 48.9? ('Yes' / 'No' / 'Don't Know/No Opinion')**

**Q48.9 If you have answered 'yes' to question 48.7, please outline which types or classes of medical devices should be subject to a post-market surveillance report and if there are any other elements which should be required for the post-market surveillance report.**

**Q48.10 If you answered have answered 'yes' to question 48.7, please outline which types or classes of medical devices should be subject to a periodic safety update report and if there are any other elements that should be required for a periodic safety update report.**

**Q48.11 If you answered have answered 'no' to question 48.7, please outline any alternative requirements for how the manufacturer should summarise and present post-market surveillance data.**

48.10 The MHRA considers that the UK medical devices regulations could include a requirement for manufacturers to upload post-market surveillance reports and periodic safety update reports to MHRA's device registration system with each registration renewal (see Chapter 4, Section 21 for further information on device registration). This could be made accessible to the public, subject to existing data protection legislation.

**Q48.12 Do you think manufacturers should upload post-market surveillance data to the MHRA devices register upon registration renewal? ('Yes' / 'No' / 'Don't Know/No Opinion')**

**Q48.13 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 48.1-48.12, including any impacts on you or other stakeholder groups.**

## Section 49 - Reporting of serious incidents and field safety corrective actions

### Background

49.1 Currently, under the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK medical devices regulations), manufacturers must submit vigilance reports to the MHRA when certain incidents occur in the UK involving their medical device - e.g. when a medical device may have caused life-threatening illness.

49.2 In these situations, the manufacturer will investigate the incident to establish the root cause of the incident and how this could be put right in order to reduce the risk to patients. They may also be required to undertake a field safety corrective action (FSCA) to correct the issue - e.g. by recalling the device from the market. Further information on this can be found in Section 47.

49.3 Most of the above requirements are provided for in guidance and they are not explicitly set out in the UK medical devices regulations. To help consolidate and clarify requirements around reporting of serious incidents and field safety corrective actions, the UK medical device regulations could be amended to include clearer requirements.

49.4 New reporting criteria and timescales could be introduced to ensure timely reporting to the MHRA of serious incidents and FSCAs relating to medical devices. The objective would be to ensure that problems concerning medical devices are brought to the MHRA's attention more promptly than under current requirements, allowing the MHRA to take appropriate corrective action where necessary - e.g. in cases where the manufacturer has not taken appropriate corrective action. The aim would be to more effectively safeguard public health.

## Possible Changes and Questions

49.5 The MHRA considers that the UK medical devices regulations could be amended to clarify that manufacturers should report to the MHRA:

- a. any serious incident, including those which are expected side effects (e.g. those listed in the instructions for use)
- b. any field safety corrective action (FSCA) (see Section 47), including any FSCA undertaken in a non-UK country in relation to a medical device which has also been made available on the Great Britain market.

**Q49.1 Do you think the UK medical devices regulations should include requirements for manufacturers to report incidents and FSCAs to the MHRA including points (a) and (b) as above? ('Yes' / 'No' / 'Don't Know/No Opinion')**

49.6 The MHRA considers that under the UK medical devices regulations, a 'serious incident' could be defined as "any incident that directly or indirectly led, might have led or might lead to any of the following:

- a. the death of a patient, user or other person
- b. the permanent or temporary serious deterioration of a patient's, user's or other person's state of health
- c. a serious public health threat.

49.7 A 'serious deterioration' could be defined as:

- a. "life-threatening illness or injury,
- b. permanent impairment of a body structure or a body function,
- c. hospitalisation or prolongation of patient hospitalisation,
- d. medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function,
- e. chronic disease,
- f. foetal distress, foetal death or a congenital physical or mental impairment or birth defect;"

49.8 A 'serious public health threat' could be defined as: "An event which could result in an unexpected public health risk of death, serious illness or serious deterioration in the state of health affecting a significant population, and which may require prompt remedial action - **e.g. human immunodeficiency virus (HIV)** ."

**Q49.2 Do you agree with the proposed definitions for 'serious incident', 'serious deterioration' and 'serious public health threat'? ('Yes' / 'No' / 'Don't Know/No Opinion')**

**Q49.3 If you have answered 'no' to question 49.2, please outline what you would change about the proposed definitions?**

49.9 The MHRA considers that the UK medical devices regulations could be amended to require manufacturers to report any serious incident immediately after they have

established the causal relationship between that incident and their medical device or that such causal relationship is reasonably possible - and report this no later than the number of days set out below:

- a. 2 days after they become aware of the incident, in the event of a serious public health threat
- b. 10 days after they become aware of the incident, in the event of death or an unanticipated serious deterioration in a person's state of health
- c. 15 days after they become aware of any serious incident which is not covered under parts (a) or (b) above.

**Q49.4 Do you think the manufacturer should be required to report any serious incident in line with the time periods above? ('Yes' / 'No' / 'Don't Know/No Opinion')**

**Q49.5 If you have answered 'no' to question 49.4, please outline what the timeframe for reporting serious incidents should be, or any other changes you would make to the criteria set out in paragraph 49.9.**

49.10 The MHRA considers that the UK medical devices regulations could be amended to specify further procedures for manufacturers regarding reporting of serious incidents and FSCAs, including:

- a. the manufacturer can submit an initial report that is incomplete followed up by a complete report
- b. manufacturers must report any field safety corrective actions in advance of the field safety corrective action being undertaken, except in cases of urgency
- c. manufacturers can provide periodic summary reports instead of individual serious incident reports for serious incidents that occur with the same device or device type and for which the root cause has been identified or a field safety corrective action that has been implemented, or where the incidents are common and well documented, where agreed by the MHRA.

**Q49.6 Do you think the UK medical devices regulations should specify further procedures for manufacturers regarding the reporting of serious incidents and field safety corrective actions (FSCAs) including (but not limited to) the points made in paragraph 49.10 above? ('Yes' / 'No' / 'Don't Know/No Opinion')**

**Q49.7 Please outline any other requirements which should be introduced regarding reporting of serious incidents and field safety corrective actions should be.**

**Q49.8 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 49.1-49.7, including any impacts on you or other stakeholder groups.**

## Section 50 - Trend reporting

### Background

50.1 While the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK medical devices regulations) require manufacturers to report certain incidents to the MHRA, they do not require manufacturers to report other types of incident - such as an increase in expected undesirable side effects. For example, manufacturers are not required to report side effects that are listed on the information included with the medical device.

50.2 To strengthen the MHRA's ability to more effectively safeguard public health, we could introduce provisions in the Regulations to ensure that manufacturers report trends in all types of adverse incidents, whether serious or otherwise, to the MHRA. The objective would be to enhance the MHRA's ability to identify medical device issues and take appropriate corrective action where necessary - e.g. in cases where the manufacturer has not taken appropriate corrective action.

### Possible Changes and Questions

50.3 The MHRA considers that the UK medical devices regulations could be amended to require manufacturers to report:

- a. for general medical devices and IVDs - any statistically significant increase in the frequency or severity of incidents that could have a significant impact on the benefit-risk analysis
- b. for IVDs - any significant increase in expected erroneous results established in comparison to the stated performance of the IVD or respective assays.

**Q50.1 Do you think the manufacturer should be required to report any statistically significant increase in the frequency or severity of incidents/erroneous results as set out in paragraph 50.3 above? ('Yes' / 'No' / 'Don't Know/No Opinion')**

**Q50.2 Please provide your reasoning (including any available relevant evidence) to support your answers to question 50.1, including any impacts on you or other stakeholder groups.**

## Section 51 - Analysis of serious incidents and field safety corrective actions

### Background

51.1 Currently, when a problem with a medical device is identified, the manufacturer will investigate the issue and may undertake a field safety corrective action (FSCA) to correct the issue - e.g. the manufacturer may recall the device from the market. A

field safety notice (FSN) is the method used by the manufacturer to tell their customers what the problem is, the risks involved and what actions the customer needs to take. This advice could range from: "stop using the medical device and return it to the manufacturer" to "please read and keep these new instructions on how to use your device safely".

51.2 The UK medical devices regulations could set out an obligation for manufacturers to submit field safety notices (FSNs). This is currently provided for in MHRA guidance however, to help ensure better consistency across industry, the Regulations could also set out the procedure by which FSNs should be submitted to and be reviewed by the MHRA. Setting this out in the UK medical devices regulations would give manufacturers greater clarity about their obligations and better enable the MHRA to ensure that appropriate measures are taken when an issue is identified with a medical device which could adversely affect the health and safety of medical device users and/or the public.

### **Possible Changes and Questions**

51.3 The MHRA considers that the UK medical devices regulations could be amended to include minimum requirements for the content of the field safety notice (FSN) to ensure all FSNs are drawn up to the same standard and that they contain all the information that the MHRA considers important. The UK medical devices regulations could set out the requirement for manufacturers to issue FSNs as part of their Field Safety Corrective Actions and to submit the draft content of the FSN to the MHRA for review where necessary, except in cases of urgency. The Regulations could require that the field safety notice includes the medical device nomenclature (see Chapter 4, Section 18) and relevant UDIs (see Chapter 4, Section 19).

**Q51.1 Do you think manufacturers should be required to issue field safety notices (FSNs) as part of their field safety corrective actions and to submit the content of the FSN to the MHRA for comment, except in cases of emergency? ('Yes' / 'No' / 'Don't Know/No Opinion')**

**Q51.2 Do you think the UK medical devices regulations should set out the minimum requirements for the content of field safety notices issued by manufacturers? ('Yes' / 'No' / 'Don't Know/No Opinion')**

51.4 The MHRA considers that the UK medical devices regulations could be amended to require the MHRA to notify the manufacturer or, where relevant, their UK Responsible Person of new risks it has identified through active monitoring of data to identify trends, patterns and signals in cases where these risks have already been subject to public disclosure.

**Q51.3 Do you think the MHRA should be required to notify the manufacturer or their UK Responsible Person of new risks it has identified through active monitoring of data in cases where these risks**

**have already been subject to public disclosure? ('Yes' / 'No' / 'Don't Know/No Opinion')**

51.5 There is currently no requirement for manufacturers, in their investigations of medical devices, to consult with patients and members of the public who have lived experience with the devices.

**Q51.4 If we were to mandate patient and public involvement and engagement in the medical device regulations, as part of manufacturers' vigilance obligations, what form should this take?**

**Q51.5 At what stages would you expect manufacturers to engage patients and the public? Multiple Choice:**

- a. periodically once their medical device is on the market
- b. only when they or the MHRA becomes aware of a safety issue with the device
- c. other – please specify?

**Q51.6 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 51.1-51.5, including any impacts on you or other stakeholder groups.**