Medicines & Healthcare products Regulatory Agency

The Medical Devices (Post-market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2024

Standardised format for periodic safety update report (PSUR)

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Introduction

This document is intended to guide manufacturers on what data to include within a periodic safety update report (PSUR). It is not mandatory to include sections which do not apply, and data may be displayed in an alternative form if appropriate. If a manufacturer decides that specific sections or datasets are not required, they should document the justification in the PSUR. The PSUR should be a stand-alone document that can be assessed independently from the supporting documentation.

Cover page

Include a cover page providing the relevant data to allow distinguishing between the various PSUR updates. As a minimum this should confirm:

- manufacturer details
- medical device(s) covered by the PSUR
- approved body name and organisation number
- PSUR reference number assigned by the manufacturer
- version number of the PSUR
- the data collection period covered by the PSUR
- table of contents

Executive summary

Add an executive summary providing a brief overview of the PSUR content, the main information related to benefits and risks and an overall conclusion regarding the acceptability of the benefit-risk profile.

It should include the following information:

- a brief description and status of any actions taken by the manufacturer based on the previous PSUR

- a brief description and status of any actions taken by the approved body as part of the review of the previous PSUR

- In case a change to the leading device gives rise to changes in the data collection period, provide a justification and a statement on whether the change affects the comparability of the results gained

- a clear statement declaring whether the benefit-risk profile has been impacted, either negatively or positively, based on the findings of the current PSUR (for example: “Based on the analysis of the collected data, the benefit-risk profile of the device(s) has not been (or has been) adversely impacted / remains unchanged”)

Description of the devices covered by the PSUR

This section should provide an overview of the devices covered by the PSUR, identifying any changes in terms of devices added or removed compared to the previous PSUR.

Include the following information for all devices covered:

- the information shall be broken down by the Basic UDI-DI(s), identifying any device changes within each Basic UDI-DI compared to the previous PSUR as this could impact comparability of results to the previous PSURs

- the device trade name(s) associated to the corresponding Basic UDI-DI(s) and the Global Medical Device Nomenclature (GMDN)

- device classification (risk class of device) in accordance with the applicable classification rules

- the intended purpose of the device(s) as per the instructions for use, any indications, contra-indications, and target populations

- first date of certification or declaration of conformity for the GB market (via either CE-mark or UKCA mark) and first date the device was put placed on the GB market/put into service if different

- status of the device(s): on the market (including whether subject to field safety corrective action) or no longer placed on the market

Device exposure information

a) Volume of sales

Provide data on the number of devices supplied in the UK, broken down by year, and totals since first available on the market. Present UK and worldwide (including UK) data, although data for other regions can also be included if desired. UK data may be separated into GB and Northern Ireland (NI) data. This should include relevant data for the various sizes, models and configurations of the device (see Table 1).

Data presented should be consistent throughout the PSUR to allow for comparison of data.

All tables in this guidance are intended to provide guidance to manufacturers and are only examples. It is up to the manufacturer to present the data in the most appropriate manner depending on the nature of the data and of the device.

Table 1 Volume of supplied product by region over time

Basic UDI-DI/device name or model					
Region	Number ($N_{1.2.3.4}$) of supplied devices				
	Total	Period T = Reporting Day+ preceding 12 months	Period T2 = T–12 months	Period T3 = T2-12 months	Period T4 = T3-12 months
UK*					
Worldwide, excluding UK					
Other eg EU/EEA (optional)					

*UK data can be broken down into GB and NI

b) Size and other characteristics of the population using the device

For devices where the sales numbers alone do not necessarily reflect the number of uses of the device, provide further information to illustrate the number (N) of people using the device within the UK and worldwide (see table 2). This includes estimates where relevant of the number of units implanted, the remaining active installed base or the device usage frequency. Explain the expected accuracy of this information with reference to any difficulties in obtaining this information where relevant.

Examples where this is the case include:

- a single piece of imaging equipment or a reusable medical device may have a lifetime of several years, and include multiple uses each day
- in the case of implants, multiple devices may be used in one patient, for example, several bone screws in one surgery.
- sales are not to end users (for example, to distributors) and therefore do not reflect device usage

Describe the characteristics of the different exposed patient group(s) where they have an impact on the performance of the device (see table 3). This should be compared to the expected usage where possible, identifying over- or underrepresented patient groups if clinically relevant. Consider the impact this may have on findings obtained previously and in the current PSUR.

These characteristics should include patient demographic aspects, for example, usage setting (healthcare establishments, A&E, home use) patient age, gender, comorbidities, ethnicity. Take into account any limitations arising from General Data Protection Regulations - individual patients should not be either directly or indirectly identifiable from the data included in the PSUR.

Table 2 Estimated size of the population using the device over time

	Estimated size ($N_{1.2.3.4}$) of the population using the device			
Region	Period T = Reporting Day+ preceding 12 months	Period T2 = T- 12 months	Period T3 = T2-12 months	Period T4 = T3-12 months
UK*				
Worldwide, excluding UK				

Other eg EU/EEA (optional)				

*UK data can be broken down into GB and NI

Table 3 Characteristics of the population using the device over time

	Estimated size ($N_{1.2.3.4}$) of the population with characteristic X using the device			
Region	Period T = Reporting Day+ preceding 12 months	Period T2 = T-12 months	Period T3 = T2-12 months	Period T4 = T3-12 months
UK*				
Worldwide, excluding UK				
Other eg EU/EEA (optional)				

*UK data can be broken down into GB and NI

Repeat table 3 for all relevant characteristics.

Device performance information

a) Vigilance data

Vigilance data consists of information concerning serious (that is, reportable) incidents, field safety corrective actions (FSCAs) and trend reports. The data could be presented in tables, figures and/or in text format, to provide an accurate summary and appraisal for the reported data collection period and to compare with the same types of data from the previous PSURs.

Present the data by the device (Basic UDI-DI), or device group/family level. When justified, the data can be presented for combinations of devices, for example, a device and its accessory.

i. Information on serious incidents

The aim is to present the serious incidents and their impact on the overall device safety. This section should characterise the data from at least 3 different perspectives:

- the device problems

- the root cause
- the health effects on the person(s) affected

In addition to the data, provide a summary text regarding any new types of serious incidents which have occurred since the last report.

Report data regarding serious incidents using the IMDRF Adverse Event Terminology (AET) when available.

The MHRA considers usages of the Level 2 terms/codes sufficient to enable the grouping of the serious incidents.

Report both the codes and the terms.

When applicable, report both absolute figures and rate of the serious incidents and split the data by region. As a minimum the regions should include separate data for the UK and worldwide (including UK), but additional regions may also be included.

Examples of the data presentation include:

- the most frequent medical device problems by the IMDRF Adverse Event Terminology (AET) Annex A – Medical device problem, by year to year (see Table 4)

- the most common investigation findings as part of the completed 'cause investigation' of the serious incidents by the IMDRF Adverse Event Terminology (AET) Annex C – Investigation findings (see Table 5)

- the most serious consequence for the patient/user by the IMDRF Adverse Event Terminology (AET) Annex D – health effects/health impact (see table 6), split by the most relevant investigation conclusion terms/codes which are related to the detected health impacts

Table 4 Total number (N) and rate (%) of the serious incidents by IMDRF AET Annex A – Medical device problem by time and region over time**

Basic UDI-DI/device name or model									
		Number N and % of incidents							
IMDRF Adverse Event – Medical Device problem (Annex A) code and term	Region	Period T = Reporting Day + preceding 12 month		Period T2 = T – 12 months		Period T3 = T2 -12 months		Period T4 = T3 - 12 months	
		N	%	N	%	N	%	N	%
	UK*								

	Worldwide, excluding UK								
	UK*								
	Worldwide, excluding UK								

*UK data can be broken down into GB and NI

** The denominator is compatible to the number of devices in table 1 or based on manufacturer's reasoning e.g., reusable instruments

Table 5 Total number (N) and rate (%) of the serious incidents by IMDRF AET Annex C – Cause investigation-investigation Findings by time and region over time**

Basic UDI-DI/device name or model									
		Number N and % of incidents							
IMDRF Adverse Event – investigation findings (Annex C) code and term	Region	Period T = Reporting Day + preceding 12 months		Period T2 = T – 12 months		Period T3 = T2-12 months		Period T4 = T3-12 months	
		N	%	N	%	N	%	N	%
	UK*								
	World wide, excluding UK								
	UK*								
	World wide, excluding UK								

*UK data can be broken down into GB and NI

** The denominator is compatible to the number of devices in table 1

Table 6 IMDRF AET Annex F – Health effects-health impact code of the serious incidents by IMDRF AET Annex D – Investigation conclusion in last 4 years

Basic UDI-DI/device name or model

IMDRF Adverse Event – Health Impact (Annex F) code and term	Region	Number of Serious Incidents	Investigation Conclusion code +term$_1$ %	Investigation Conclusion code +term$_2$ %	Investigation Conclusion code +term$_3$ %	Investigation Conclusion code +term$_4$ %
	UK*					
	Worldwide, excluding UK					
	UK*					
	Worldwide, excluding UK					

*UK data can be broken down into GB and NI

ii. Information from trend reporting

Provide a summary of the trends which have been reported for the period of the PSUR and compare with the information from the previous PSURs. This includes trends which could have a significant adverse impact on the risk analysis, not only those giving rise to a risk of a serious injury. The summary should include the following information:

- device model/trade name(s) affected/scope
- manufacturer's reference number
- date trend identified
- date reported to MHRA if applicable
- a brief description of the nature of trend including pre-determined thresholds against which the trend was measured
- status of the trend investigation at the time of the PSUR, including whether it led to any corrective or preventive actions (include FSCA reference number where applicable).

iii. Information from field safety corrective actions (FSCA)

Provide a summary of the FSCAs reported to the MHRA for the period of the PSUR and confirm any links to prior FSCAs listed in previous PSURs. The summary should include the following information:

- device model/trade name(s) affected/within scope
- manufacturer's reference number
- date of the final FSN
- a brief description of the reason for action
- regions impacted/within scope
- date reported to MHRA if applicable
- status of the FSCA at the time of the PSUR, including target date for completion

An example of the data presentation is in table 7 below.

Table 7 FSCA initiated in current reporting period and open FSCAs

Device models within scope	Manufacturer Reference Number	Date of Final FSN	Description and rationale for action taken	Regions within scope	Date reported to MHRA (if applicable)	Status of the FSCA*

* completed/ongoing/target for completion, as applicable to the region at the time the data collection time ended

b) Proactive data analysis from defined populations

Present information and data sets generated from any proactive PMS activities designed to systematically analyse data on device performance in a defined population in this section. This should include but is not limited to any PMCF or PMPF studies which have been undertaken.

The manufacturer should refer to the main findings and conclusions of the PMCF activity documented in the PMCF evaluation report. Data presented should be linked to the PMS plan and the PMCF plans.

(i) Manufacturer sponsored PMCF studies or registries

This section should include a summary of the findings generated from the analysis of data from specific PMCF studies or registries sponsored by the manufacturer. If PMPF studies are undertaken by the manufacturers of IVD devices in advance of provisions being introduced in GB legislation, these should be included here.

(ii) Independent clinical studies, or registries/databases

Provide the following information for each study/registry reviewed:

- the name or registry reference
- the type of registry (prospective or retrospective data collection)
- the findings in comparison to the devices with same intended use and justify any identified differences
- information about any new risks identified from this data set

(iii) Information from review of scientific/specialist literature

Identify any new scientific publications with conclusions impacting understanding of the safety or performance of the device. For detailed information about literature searches conducted and results generated, the manufacturer may refer to the technical documentation.

c) Data from other sources including incidents not considered serious

(i) Feedback and complaints

Every manufacturer should have a system in place for gathering and analysing feedback and complaints. Sources should include users, distributors, importers patients and the public (including social media). The most common complaints should be presented in this section of the PSUR with the following considerations:

- identification of data source
- grouping of complaints by the IMDRF Adverse Event Terminology (AET) - Annex A – Medical device problem (including the term and code) or internal event codes including term
- occurrence rate with specified timeframe
- justification for inclusion of these groups of complaints and exclusion of those not presented
- information whether the presented complaints have led to initiation of preventive and / or corrective actions (CAPA)

(ii) Information about user experience in relation to safety and performance, including through patient and public engagement

Manufacturers must proactively seek feedback from different user groups, including healthcare professionals and patients where relevant and appropriate.

The manufacturer should consider the most suitable and achievable ways to capture this information and the necessary frequency of this activity, facilitating feedback in the least burdensome way for users, dependent upon the type of device and its circumstances of use (for example, over the counter devices, devices used at home and/or by vulnerable populations).

For further information and advice on undertaking patient and public engagement, see Medical devices: post-market surveillance - GOV.UK.

(iii) Real-world data sources

This section should include any other data from any real-world sources not listed above. Provide a list of the data sources and findings with specific reference to safety and performance of the device.

Examples include:

- electronic health records
- digital health-monitoring devices
- data from the UK's Clinical Practice Research Datalink (CRPD)
- data on the number of times an app has been downloaded

- usability experiences of patients and other users of devices
- proactive surveys to interact with users of the device

Comparison with available information on similar devices

Compare safety and performance data generated from these activities to other similar devices with the same intended purpose.

This should include comparison with information where publicly available on similar medical devices made by other manufacturers inside and outside GB, (for example, results of a PMCF study made publicly available in the manufacturer's summary of safety and clinical performance (SSCP), Cochrane Library or other libraries). The type and location of this information should be provided.

When possible, evaluate a comparison of the devices with the same intended purpose with any possible differences in safety and performance reported.

Where there are known differences in the usage of similar devices in GB to the rest of the world, this should be taken into account and data provided to an appropriate level of granularity.

Preventive and corrective action

Provide a list of all preventive and/or corrective actions (CAPA) taken to address a risk or non-conformity compromising the performance or safety of the device. The manufacturer can exclude CAPAs associated with any FSCAs listed above in section 'a) iii' but should make it clear that they have done so. Provide the following information for each CAPA:

- the device model/trade names(s) affected/within scope
- manufacturer's reference number
- initiation date
- CAPA description/type of action
- the root cause (internal codes with the explanation, IMDRF terms/codes or free text)
- status of the action (closed/ongoing/target date for completion)
- effectiveness of the CAPA

An example of the data presentation is in table 8.

Table 8 CAPA initiated in current reporting period and open CAPA

Basic UDI-DI/device name or model							
Initiation Date	Manufacturer Reference Number	Device models within scope	CAPA description	Root Cause *	Status of the CAPA	Effectiveness of the CAPA if closed**	Target date for completion if ongoing

* internal codes with the explanation, IMDRF codes or free text

** If CAPA is still open then this is not applicable, if CAPA is closed comment on whether it is resolved, not resolved or comment if additional CAPA has been opened.

Findings and conclusions

The manufacturer should provide an updated conclusion on the benefits and risks of the device from evaluation of the PSUR data. If there has been a negative impact on the overall benefit-risk determination, the manufacturer should outline all actions planned or already undertaken to mitigate this risk.

In the case of system or procedure packs, the focus should be on analysing PMS information relating to the safety and performance of the combined use of the devices in the pack.

a) Validity of the data

The manufacturer should identify any limitations in the data or its evaluation if these have had a significant impact on the strength of conclusions that can be drawn.

Examples of the types of limitations include:

- reduced sales or usage of the device
- known bias from feedback obtained or enrolment into a PMCF study
- limitations in the boundaries of a dataset used to validate a diagnostic test (for example, pathogen variants outside the boundaries of the dataset used to validate a lateral flow test can be excluded)

b) Overall conclusions from data analysis

The manufacturer should outline any new or emerging clinical risks, common occurrences of poor performance, or when claimed benefits have not been achieved within the current reporting period.

For any new or emerging risks, the manufacturer should provide information on the seriousness and full potential clinical impact of the risk associated with specific patient groups, device models, accessories used, geographical regions, duration of risk.

In concluding the acceptability of significant risks, the manufacturer should confirm within the documented risk analysis whether the nature and prevalence of the risk/incident is within justified thresholds derived from state of the art, against which the manufacturer is monitoring. State of the art should be determined through comparison to the benefit-risk profile associated with alternative devices with the same or similar intended purpose, and with other available treatment options.

The manufacturer should also describe any new clinically meaningful benefits that have been identified from evaluation of the data.

The manufacturer should present evidence-based conclusions to determine whether the benefit-risk profile of the device has changed and make a declaration as to whether there has been an adverse impact on the benefit-risk profile of the device.

c) Actions taken to address conclusions

The manufacturer should describe actions to address any negative impact on the overall benefit-risk determination of the devices. This includes action to reduce as far as possible newly identified or emerging risks and occurrences of poor performance.

The manufacturer should provide a timetable for the completion of any actions which are planned (cross referenced to any listed CAPA/FSCA) and an assessment of the effectiveness for those already completed.