GB MIR and FSCA schema implementation guide

A step-by-step guide on implementing GB schemas for submission of MIR and FSCAs.

The following user guide provides details on how to implement GB schema changes.

Version 1
May 2025

Contents

Introduction

This document will guide users through the changes being made to reporting manufacturer incident reports (MIR) and field safety corrective action reports (FSCAs) to the MHRA following implementation of the Medical Devices (Post-market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2024.

Section 1: Background

Serious incidents involving medical devices which occur in the UK and meet vigilance reporting criteria must be reported to the MHRA by the manufacturer or their UK Responsible Person via the Manufacturer's Online Reporting Environment (MORE) portal. FSCAs affecting devices in the UK and trends in incidents should also be reported using this portal.

The data standards used to report are updated for reports relating to Great Britain (GB) due to the new set of regulations - The Medical Devices (Post-market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2024 which amends the UK Medical Devices Regulations (UK MDR) 2002 by inserting a new Part 4A on post-market surveillance (PMS) requirements for medical devices, including in vitro diagnostic (IVD) devices and active implantable medical devices which apply within GB.

Further information on the post-market surveillance requirements can be found here: The Medical Devices (Post-market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2024: guidance on implementation - GOV.UK.

MORE services

You should continue to refer to the following supporting documents for use of MORE:

- MORE Registrations - user reference guide
- MORE Submissions - user reference guide

These documents will be updated in line with the new requirements.

In the MORE portal, registered users will be able to make submissions via manual data entry via the web forms within MORE portal, XML report upload, or via Application Programming Interfaces (API). The MORE web forms that are available include:

- Manufacturer Incident Report (MIR)
- Field Safety Corrective Actions (FSCAs)

- Trend Reports
- Periodic Summary Reports (PSRs)
- Serious Adverse Events (SAEs)

This document outlines changes to MIR and FSCA schemas. Trend reports, PSRs and SAEs have no changes.

Section 2: Summary of changes to MIR and FSCA

The below table shows a high-level summary of the changes made from MIR 7.2.1 and FSCA 2.8 to support the new GB schemas.

Update	Impacts to xsds	
	MIR (all versions)	FSCA (all versions)
xsd Name changes	Yes	Yes
Schema text change from EU to GB	Yes	No
Removal of 'EUDAMED Number of NCA'	Yes	No
Removal of 'Reference number assigned by EUDAMED for this incident'	Yes	No
Removal of 'FSCA EUDAMED reference numbers'	Yes	No
Enable collection of UK Responsible Person contact details	Yes	Yes
Restrict nomenclature to allow GMDN only	Yes	Yes
Addition of 'UK Approved Body (UKAB) ID number(s)'	Yes	Yes
Addition of 'UK Approved Body (UKAB) certificate number(s) of device'	Yes	Yes
Mandating of IMDRF Annex codes A, B, C, D, E, F, G	Yes	No
Addition of 'UDI Issuing entity'	Yes	Yes
Addition of 'UDI DI'	No	Yes

Addition of 'UDI PI'	No	Yes
Addition of 'Basic UDI-DI'	No	Yes
Addition of 'Unit of use UDI-DI'	No	Yes
Addition of IMDRF Annex A, B, C, D, E, F, G	No	Yes
Addition of field to ask 'If you think the FSCA is unique and a suitable IMDRF term is missing, briefly explain:' for IMDRF Annex A, B, C, D, E, F, G	No	Yes
Addition of 'The number of devices placed on the market or put into service in Great Britain'	No	Yes
Addition of 'The estimated number of users affected in Great Britain'	No	Yes
Restrict 'Notified body ID number' type to numbers only	No	Yes
Addition of 'Notified body certificate number'	No	Yes

To aid comparison to the existing MIR 7.2.1 schema, the MIR help text has been annotated with the changes to the fields. Any changes between EU MIR 7.2.1 and the GB schema are on the tab named '7.2 Help text GB'. Please note that some elements within the xsd will be changed which are not part of the existing help text. Each change to the MIR xsd is provided below.

Please note the PDF is not supported as a submission route and has not been since the current MORE portal was launched in 2022. Submissions must be via MORE, and you can send reports via API, post or webform.

MIR xsd changes

The changes are made to the following MIR xsds:

- Initial
- Combined initial and final
- Follow-up
- Final (reportable incident)
- Final (non-reportable incident)

A detailed summary of each change is provided below.

1. xsd name changes

Summary of change	EU MIR schema 7.2.1	GB schema 7.2.1	Comments
xsd name change	incident-Initial-v7.2.1.xsd	incident-InitialGB-v7.2.1.xsd	
	incident-InitialFinal-v7.2.1.xsd	incident-InitialFinalGB-7.2.1.xsd	
	incident-Followup-v7.2.1.xsd	incident-FollowupGB-v7.2.1.xsd	
	incident-FinalRep-v7.2.1	incident-FinalRepGB-v7.2.1	
	incident-FinalNonRep-v7.2.1	incident-FinalNonRepGB-v7.2.1	

2. Text change to the schema description

Impacted schema	EU MIR schema 7.2.1	GB schema 7.2.1	Comments
incident-InitialGB-v7.2.1.xsd	Schema for INITIAL reports about Incidents for EU vigilance exchange.	Schema for INITIAL reports about Incidents for GB vigilance exchange.	
incident-InitialFinalGB-v7.2.1.xsd	Schema for COMBINED INITIAL AND FINAL reports about Incidents for EU vigilance exchange.	Schema for COMBINED INITIAL AND FINAL reports about Incidents for GB vigilance exchange.	
incident-FollowupGB-v7.2.1.xsd	Schema for FOLLOW-UP reports about Incidents for EU vigilance exchange.	Schema for FOLLOW-UP reports about Incidents for GB vigilance exchange.	

incident-FinalRepGB-v7.2.1	Schema for FINAL REPORTABLE reports about Incidents for EU vigilance exchange.	Schema for FINAL REPORTABLE reports about Incidents for GB vigilance exchange.	
incident-FinalNonRepGB-v7.2.	Schema for FINAL NOT REPORTABLE reports about Incidents for EU vigilance exchange.	Schema for FINAL NOT REPORTABLE reports about Incidents for GB vigilance exchange.	

3. Removal of 'EUDAMED Number of NCA'

Impacted schema	EU MIR schema 7.2.1	GB schema 7.2.1	Comments
All five MIR schemas	Field exists for 'EUDAMED Number of NCA'	'EUDAMED Number of NCA' field removed	

4. Removal of 'Reference number assigned by EUDAMED for this incident'

Impacted schema	EU MIR schema 7.2.1	GB schema 7.2.1	Comments
All five MIR schemas	Field exists for 'Reference number assigned by EUDAMED for this incident'	'Reference number assigned by EUDAMED for this incident' field removed	

5. Removal of 'FSCA EUDAMED reference numbers'

Impacted schema	EU MIR schema 7.2.1	GB schema 7.2.1	Comments
All five MIR schemas	Field exists for 'FSCA EUDAMED reference numbers'	'FSCA EUDAMED reference numbers' field removed	

6. Enable collection of UK Responsible Person contact details

Impacted schema	EU MIR schema 7.2.1	GB schema 7.2.1	Comments
All five MIR schemas	Allowed values: -Manufacturer -Authorised Representative -Other, please specify	Allowed values: -Manufacturer -Authorised Representative -Other, please specify -UKRP	

7. Restrict nomenclature to allow GMDN only

Impacted schema	EU MIR schema 7.2.1	GB schema 7.2.1	Comments
All five MIR schemas	Medical terminology – allowed values: -EMDN -GMDN -UMDNS(ECRI) -GIVD/EDMS -Other, please specify	Medical terminology – allowed values: -GMDN	

8. Addition of 'UK Approved Body (UKAB) ID number(s)'

Impacted schema	EU MIR schema 7.2.1	GB schema 7.2.1	Comments
All five MIR schemas	No field for 'UK Approved Body (UKAB) ID number(s)'	New field for 'UK Approved Body (UKAB) ID number(s)'	

9. Addition of 'UK Approved Body (UKAB) certificate number(s) of device'

Impacted schema	EU MIR schema 7.2.1	GB schema 7.2.1	Comments
All five MIR schemas	No field for 'UK Approved Body (UKAB) certificate number(s) of device'	New field for 'UK Approved Body (UKAB) certificate number(s) of device'	

10. Mandating of IMDRF Annex codes

Impacted schema	EU MIR schema 7.2.1	GB schema 7.2.1	Comments
All five MIR schemas	Annex A – minimum of one IMDRF code required	No change to Annex A – minimum of one IMDRF code required	If appropriate IMDRF code cannot be found then the following advice is given: Annex A: If a specific term can not be classified please select code A27
All five MIR schemas	IMDRF Annex B - optional	IMDRF Annex B – minimum of one IMDRF code must be included	Annex B: If a specific term can not be classified please select code B21 or B22 as appropriate
All five MIR schemas	IMDRF Annex C - optional	IMDRF Annex C – minimum of one IMDRF code must be included	Annex C: If a specific term can not be classified please select code C22

All five MIR schemas	IMDRF Annex D - optional	IMDRF Annex D – minimum of one IMDRF code must be included	Annex D: If a specific term can not be classified please select code D15, D16 or D17 as appropriate
All five MIR schemas	IMDRF Annex E - optional	IMDRF Annex E – minimum of one IMDRF code must be included	Annex E: If a specific term can not be classified please select code E2401, E2402 or E2403 as appropriate
All five MIR schemas	IMDRF Annex F - optional	IMDRF Annex F – minimum of one IMDRF code must be included	Annex F: If a specific term can not be classified please select code F24 or F28 as appropriate
All five MIR schemas	IMDRF Annex G- optional	IMDRF Annex G – minimum of one IMDRF code must be included	Annex G: If a specific term can not be classified please select code G07001 or G07002 as appropriate

11. Addition of 'UDI Issuing entity'

Impacted schema	EU FSCA schema 2.8	GB FSCA schema 2.8	Comments
All five MIR schemas	No field for ‘'UDI Issuing entity'	New field for ‘'UDI Issuing entity' Allowed values:	

		- GS1 - IFA - HIBCC - ICCBBA	

FSCA xsd changes

The following changes are made to FSCA xsds. Where the change differs per schema the changes are provided per schema. Where the change is identical in the different schemas this is shown.

- Initial
- Follow up
- Final

12. xsd name changes

Impacted schema	EU FSCA schema 2.8	GB FSCA schema 2.8	Comments
xsd name changes	FSCA_InitialEU_v2.8.xsd	FSCA_InitialGB_v2.8.xsd	
	FSCA_FollowupEU_v2.8.xsd	FSCA_FollowupGB_v2.8.xsd	
	FSCA_FinalEU_v2.8.xsd	FSCA_FinalGB_v2.8.xsd	

13. Enable collection of UK Responsible Person contact details

Impacted schema	EU FSCA schema 2.8	GB FSCA schema 2.8	Comments
All three FSCA schemas	Allowed values: -Manufacturer -Authorised Representative	Allowed values: -Manufacturer -Authorised Representative	

	-Other, please specify	-Other, please specify -UKRP	

14. Restrict nomenclature to allow GMDN only

Impacted schema	EU FSCA schema 2.8	GB FSCA schema 2.8	Comments
All three FSCA schemas	Medical terminology – allowed values: -EMDN -GMDN -UMDNS(ECRI) -GIVD/EDMS -Other, please specify	Medical terminology – allowed values: -GMDN	

15. Addition of 'UK Approved Body (UKAB) ID number(s)'

Impacted schema	EU FSCA schema 2.8	GB FSCA schema 2.8	Comments
All three FSCA schemas	No field for 'UK Approved Body (UKAB) ID number(s)'	New field for 'UK Approved Body (UKAB) ID number(s)'	

16. Addition of 'UK Approved Body (UKAB) certificate number(s) of device'

Impacted schema	EU FSCA schema 2.8	GB FSCA schema 2.8	Comments
All three FSCA schemas	No field for ‘UK Approved Body (UKAB) certificate number(s) of device'	New field for ‘UK Approved Body (UKAB) certificate number(s) of device'	

17. Addition of 'UDI Issuing entity'

Impacted schema	EU FSCA schema 2.8	GB FSCA schema 2.8	Comments
All three FSCA schemas	No field for ‘‘UDI Issuing entity'	New field for ‘‘UDI Issuing entity' Allowed values: - GS1 - IFA - HIBCC - ICCBBA	

18. Addition of 'UDI DI’

Impacted schema	EU FSCA schema 2.8	GB FSCA schema 2.8	Comments
All three FSCA schemas	No field for ‘UDI DI'	New field for ‘‘UDI DI’	

19. Addition of 'UDI PI’

Impacted schema	EU FSCA schema 2.8	GB FSCA schema 2.8	Comments
All three FSCA schemas	No field for ‘UDI PI'	New field for ‘‘UDI PI’	

20. Addition of 'Basic UDI-DI’

Impacted schema	EU FSCA schema 2.8	GB FSCA schema 2.8	Comments
All three FSCA schemas	No field for ‘Basic UDI DI'	New field for ‘'Basic UDI DI’	

21. Addition of 'Unit of use UDI-DI’

Impacted schema	EU FSCA schema 2.8	GB FSCA schema 2.8	Comments
All three FSCA schemas	No field for ‘Unit of use UDI-DI'	New field for ‘'Unit of use UDI-DI’	

22. Addition of IMDRF Annex A, B, C, D, E, F, G

Impacted schema	EU FSCA schema 2.8	GB FSCA schema 2.8	Comments
All three FSCA schemas	No field to collect IMDRF Annex A	Addition of field to collect IMDRF Annex A. Addition of field to ask ‘If you think the FSCA is unique and a suitable IMDRF term is missing, briefly explain:’ Minimum of one IMDRF code required.	If appropriate IMDRF code cannot be found then the following advice is given: Annex A: If a specific term can not be classified please select code A27

All three FSCA schemas	No field to collect IMDRF Annex B	Addition of field to collect IMDRF Annex B. Addition of field to ask 'If you think the FSCA is unique and a suitable IMDRF term is missing, briefly explain:' Minimum of one IMDRF code required.	Annex B: If a specific term can not be classified please select code B21 or B22 as appropriate
All three FSCA schemas	No field to collect IMDRF Annex C	Addition of field to collect IMDRF Annex C. Addition of field to ask 'If you think the FSCA is unique and a suitable IMDRF term is missing, briefly explain:' Minimum of one IMDRF code required.	Annex C: If a specific term can not be classified please select code C22
All three FSCA schemas	No field to collect IMDRF Annex D	Addition of field to collect IMDRF Annex D. Addition of field to ask 'If you think the FSCA is unique and a suitable IMDRF term is missing, briefly explain:' Minimum of one IMDRF code required.	Annex D: If a specific term can not be classified please select code D15, D16 or D17 as appropriate
All three FSCA schemas	No field to collect IMDRF Annex E	Addition of field to collect IMDRF Annex E. Addition of field to ask 'If you think the hazard is unique and a suitable IMDRF Code is missing, briefly explain:' Minimum of one IMDRF code required.	Annex E: If a specific term can not be classified please select code E2401, E2402 or E2403 as appropriate
All three FSCA schemas	No field to collect IMDRF Annex F	Addition of field to collect IMDRF Annex F. Addition of field to ask 'If you think the hazard is unique and	Annex F: If a specific term can not be classified please select

		a suitable IMDRF Code is missing, briefly explain:' Minimum of one IMDRF code required.	code F24 or F28 as appropriate
All three FSCA schemas	No field to collect IMDRF Annex G	Addition of field to collect IMDRF Annex G. Addition of field to ask 'If you think the component is unique and a suitable IMDRF term is missing, briefly explain:' Minimum of one IMDRF code required.	Annex G: If a specific term can not be classified please select code G07001 or G07002 as appropriate

23. Addition of 'The number of devices placed on the market or put into service in Great Britain'

Impacted schema	EU FSCA schema 2.8	GB FSCA schema 2.8	Comments
All three FSCA schemas	No field for 'The number of devices placed on the market or put into service in Great Britain'	New field for 'The number of devices placed on the market or put into service in Great Britain'	

24. Addition of 'The estimated number of users affected in Great Britain'

Impacted schema	EU FSCA schema 2.8	GB FSCA schema 2.8	Comments
All three FSCA schemas	No field for 'The estimated number of users affected in Great Britain'	New field for 'The estimated number of users affected in Great Britain'	

25. Update type for field 'Notified body ID number'

Impacted schema	EU FSCA schema 2.8	GB FSCA schema 2.8	Comments
All three FSCA schemas	Notified body ID number allows 50 characters including text	Notified body ID number will only allow numbers	Aligning FSCA with MIR standard

26. Addition of ‘Notified body certificate number’

Impacted schema	EU FSCA schema 2.8	GB FSCA schema 2.8	Comments
All three FSCA schemas	No field for ‘Notified body certificate number’	New field for ‘Notified body certificate number’	

Implementation Steps

Please use the resources available [to be released soon] to update your systems and processes in line with the GB xsd schemas to ensure compliance with the PMS requirements. Submissions under PMS legislation for GB should be reported using the GB schemas, and xml submissions should include the correct schema within the xml header. Reports for Northern Ireland can continue to be submitted in line with EU requirements.

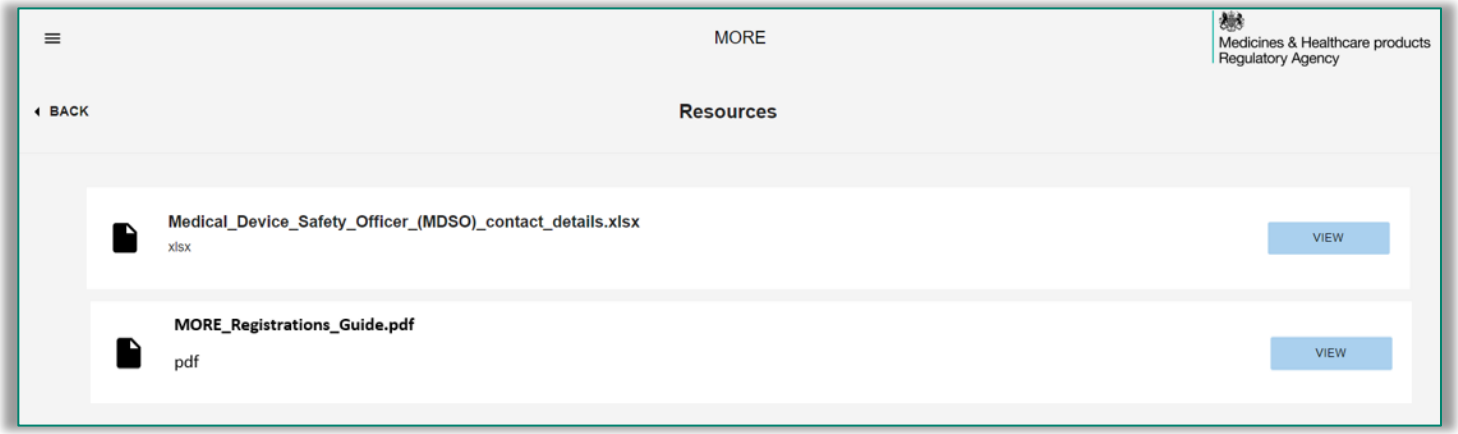
If you need to provide a new submission to a previously submitted MIR or FSCA, you should update the schema in line with the new requirements, and it will be linked on the MHRA system as usual. Explicitly, it is acceptable to have a first submission using EU schema, and a second submission using GB schema.

During the transition period you can submit using the EU schema or new GB schemas. After the end of the transition period, you must use the GB schema to fulfil your reporting requirements under the PMS legislation.

Resources

Additional documentation to support the implementation of the GB schema will be provided within the resources tile and will include an overview of the changes made, an updated MORE submissions guidance document, a bridging document for MIR helptext, updated xsds and example xmls.

You will also be able to access these resources within MORE via the ‘Resources’ tile on the dashboard or left-hand side burger menu.



Glossary

Acronym	
API	Application Programming Interfaces
FSCA	Field Safety Corrective Action
IVD	In Vitro Diagnostic
UK MDR	UK Medical Devices Regulations
MHRA	Medicines and Healthcare Products Regulatory Agency
MIR	Manufacturer Incident Report
MORE	Manufacturer's Online Reporting Environment
PMS	Post-Market Surveillance
PSR	Periodic Summary Report
SAE	Serious Adverse Event
UKRP	UK Responsible Person

Help and Contact Details

Support will be available via aic@mhra.gov.uk. Please use the heading “PMS implementation information request:Entity Name”.

Revision History

This table sets out the revision history.

Version No.	Effective date	Change
1.0	05/2025	First version