Medicines & Healthcare products Regulatory Agency

MHRA communication following the updated to the European Commission Implementing Regulation 520/2012

This communication is to instruct UK Marketing Authorisation Holders on compliance with pharmacovigilance requirements, ahead of the EU's forthcoming amendment to the Commission Implementing Regulation (CIR) on 12 February 2025.

Background

The European Commission (EC) have updated the Commission Implementing Regulation (CIR) 520/2012 via amending CIR 2025/1466, published on 22 July 2025. The CIR will come into effect on 12 February 2026, apart from Article 1, points (7) and (9) which came into effect on 12 August 2025.

Following implementation of the Windsor Framework arrangements for medicines on 1 January 2025, UK authorised medicinal products are classified into one of two technical categories (Category 1 and Category 2). All UK authorised products are subject to the requirements set out in the Human Medicines Regulations (HMR) 2012.

The requirements for pharmacovigilance are set out in Part 11 for all UK authorised medicinal products. Category 1 products are further subject to regulations stipulated within HMR Schedule 12A and Category 2 products subject to regulations stipulated within the CIR 5020/2012, with the requirements presently aligned between Schedule 12A and CIR 520/2012.

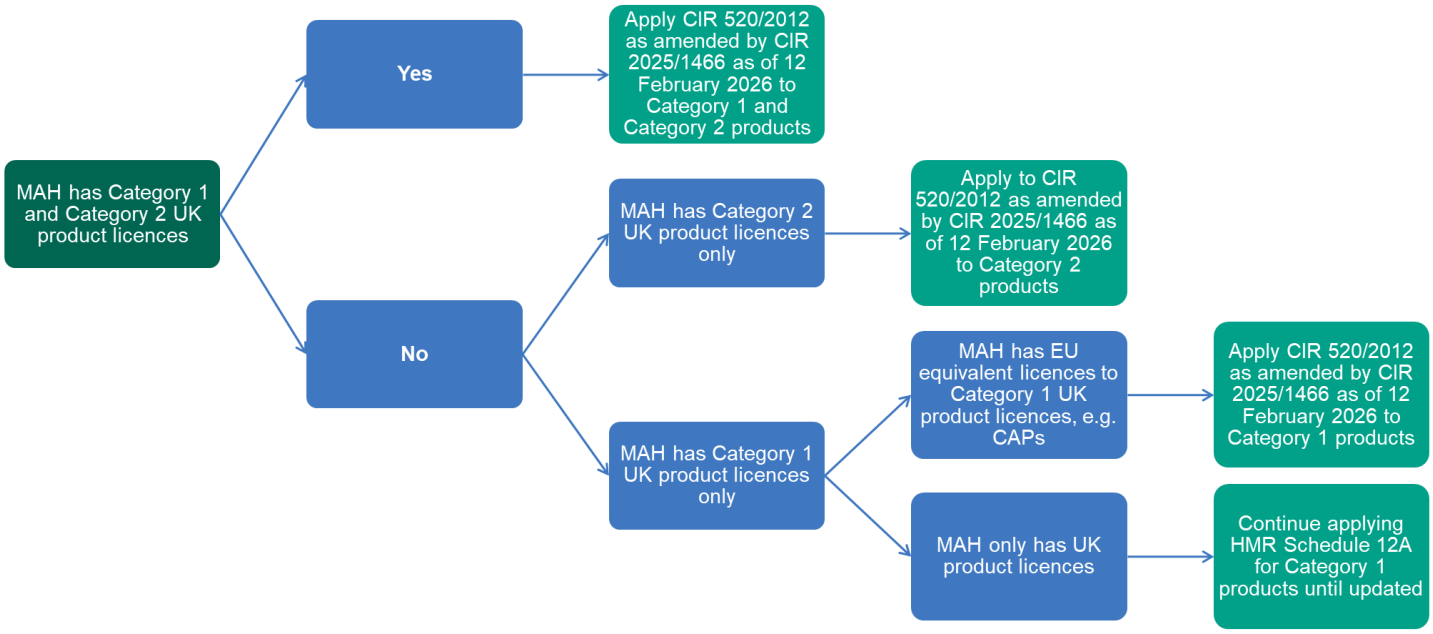
Current status

From 12 February 2026, when the amended CIR 520/2012 comes into effect, HMR Schedule 12A and CIR 520/2012 will no longer be aligned, meaning the legal text for specific requirements for UK authorised Category 1 and Category 2 products will be different regarding the conduct of pharmacovigilance. Category 2 products will be subject to the revised CIR; whilst Category 1 products are subject to the non-aligned Schedule 12A.

To mitigate any undue burden on UK marketing authorisation holders (MAH) resulting from different pharmacovigilance requirements, the following approach will be taken (also refer to Figure 1):

- Where an MAH has both Category 1 and Category 2 products within their product portfolio, they should follow the regulations set out within the CIR 520/2012 as amended for both Category 1 and Category 2 products.
- Where an MAH has Category 1 products only in the UK, they should continue to follow the existing HMR Schedule 12A, unless they have equivalent licenses within the EU in which case the amended CIR should be adhered to.

Figure 1 – Application of CIR 520/2012 as amended vs HMR 2012 Schedule 12A to UK authorised products



In due course the MHRA will consider appropriate updates to HMR 2012 Schedule 12A to reflect the updates made to the CIR 5/20/2012. In the meantime, if there are any further questions please contact:

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