

Annex III

Conditions for lifting the suspension of the marketing authorisations

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For the suspension of products containing paracetamol, modified and prolonged to be lifted, the competent authorities shall ensure that the below conditions have been completed by the marketing authorisation holders.

The marketing authorisation holders shall provide evidence in support of proportionate, feasible and effective measures to prevent the risk of overdose and minimise the risk of hepatic injury following intentional or accidental overdoses with modified release paracetamol containing products.