

Annex IV

Conditions for lifting the suspension of the marketing authorisations

Conditions for lifting the suspension of the marketing authorisation(s)

For the suspensions of intravenous gadodiamide, gadopentetic acid, and gadoversetamide containing medicinal products to be lifted, the Marketing Authorisation Holder(s) shall provide evidence

- for clinically important benefits that are currently not established in an identified population or indication and which outweigh the risks related to the product.
- or that the product (potentially modified or not) does not undergo significant dechelation and does not lead to retention of gadolinium in tissues.