MAH intends to take action to withdraw* a product from the market

Centralised Authorisation Procedure

What is the marketing authorisation procedure?

National Authorisation Procedure (incl. MRP, DCP)

Where is the action to take place?

EU

Third Country

Is action based on grounds set out in Art. 116 and 117 of DIR 2001/83/EC?

YES

NO

Notify EMA no less than 2 months before the interruption in the placing on the market of the product (unless exceptional circumstances)

Notify EMA forthwith

END

Is action based on grounds set out in Art. 116 and 117 of DIR 2001/83/EC?

YES

NO

Notify concerned Member States and EMA

END

Is action based on grounds set out in Art. 116 and 117 of DIR 2001/83/EC?

YES

Notify concerned Member States no less than 2 months before the interruption in the placing on the market of the product (unless exceptional circumstances)

Notify EMA forthehwith

END

Is action based on grounds set out in Art. 116 and 117 of DIR 2001/83/EC?

YES

NO

END

Actions to withdraw *:
- cease temporarily or permanently the marketing of the product;
- suspend the marketing of a medicinal product;
- withdraw a medicinal product from the market;
- request the withdrawal of a marketing authorisation;
- not to apply for the renewal of a marketing authorisation.