

# Cover letter template for notification of "withdrawn products" by marketing authorisation holders

( < FROM MAH ON HEADED PAPER > )

<Date>

*Name of regulatory authority,  
Address*

## **RE: Notification of "withdrawn product"**

Dear <Name> ,

Please find herewith enclosed our notification for a

- Centrally authorised medicinal product in accordance with Article 13 and 14b of Regulation 1027/2012
- Nationally Authorised medicinal product in accordance with Article 23a and 123 of Directive 2012/26/EC

<Product Name(s)> , <INN(s)> , <MAH> , <EVCODE>

To take the following action(s):

- Cease the marketing of a medicinal product (permanently or temporarily)
- 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

I declare that the reason(s) for such action(s) are:

- Based on the grounds provided in Articles 116 and 117 of Directive 2001/83/EC;
- Not based on the grounds provided in Articles 116 and 117 of Directive 2001/83/EC.

I herewith confirm that together with this cover letter an Excel spread sheet (template EMA/445787/2013) entitled <MAH file name> is submitted containing all the required information related to the medicinal product(s) concerned.

Yours sincerely,

<Signature of authorised contact person>  
<MAH>

cc:

<PTL for centrally authorised medicinal product>  
<Rapporteur>  
<Co-Rapporteur>  
Encl(s) <Number> Excel file