

Withdrawal letter template

(< FROM MAH ON HEADED PAPER >)

Date: <dd month yyyy>

Executive Director
Medicines Control Agency (MCA)
Off Bertil Harding Highway
Kotu East, Kanifing Municipality,
P.O. Box 3162, Serekunda
The Gambia

Dear Sir/Madam,

Subject: Withdrawal of <Product Name>, (INN), strength(s), pharmaceutical form(s) – MCA Registration No (if applicable)

For the withdrawal of initial marketing authorisation application

I would like to inform you that, at this point of time, <MAH's name> has taken the decision to withdraw the application for Marketing Authorisation of <Product Name>, (INN), strength(s), pharmaceutical form(s)>, which was intended to be used for <applied for MAH's proposed indication>.

OR

For the withdrawal of variation application linked to an extension of indication for a medicine already authorised I would like to inform you that, at this point of time, <MAH name> has taken the decision to withdraw the application for <a new indication> <a change to the marketing authorisation> for <name of the product>, <to add <a <strength><pharmaceutical form>,> in the <treatment of /prophylaxis against/diagnosis of> <disease>.

This withdrawal is based on the following reasons

<Please state the reasons for the withdrawal. The following is included as possible examples, amongst others>:

<identification of major manufacturing issues>

<identification of major pre-clinical issue>

<identification of major clinical issues>

<identification of major GxP issues>

<the NMRA considers that the data provided do not allow the committee to conclude on a positive benefit risk balance>

<Company's marketing strategy>

Other: <please elaborate>

<Please provide any further detailed comment as appropriate>

<Provide information on the consequences of the withdrawal on ongoing clinical trials and compassionate use programme>

<Provide additional information on any future plan for development of the product>

Annex 1 - Guideline for Withdrawal, Suspension, Revocation or Cancellation of Marketing Authorisation of Medicines

We reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

I agree for this letter to be published on the MCA website.

Yours sincerely,
<Signature from the MAH>