

**DECLARATION FORM FOR SUBMISSION OF DDPS  
(Detailed Description of the Pharmacovigilance System)  
ALREADY APPROVED BY MEMBER STATES DURING A PREVIOUS MR/DC/CENTRALISED  
PROCEDURE.  
TO BE COMPLETED BY THE APPLICANT.  
[NOTE: DDPS MUST STILL BE SUBMITTED IN ANNEX 5.20 TO THE APPLICATION FORM]**

**1. CURRENT PROCEDURE NUMBER:**

**2. NAME OF THE APPLICANT:**

**3. PRODUCT NAME IN RMS OF CURRENT PROCEDURE:**

**4. DDPS (VERSION AND DATE) TO WHICH THIS DECLARATION RELATES:**

**5. PREVIOUS MR/DC/EU PROCEDURE NUMBER(S) AND DATES FOR WHICH THIS VERSION OF THE DDPS HAS PREVIOUSLY BEEN ASSESSED:**

**6. MEMBER STATES INCLUDED IN THE PROCEDURE(S) WHEN THE DDPS WAS PREVIOUSLY ASSESSED DURING A MR/DC PROCEDURE:**

**7. HAVE ALL ISSUES RAISED AT THE TIME OF PREVIOUS ASSESSMENT OF THE DDPS BEEN ADDRESSED?**

- Yes
- No  
(Please clarify).

**8. HAVE ALL PRODUCT/APPLICATION SPECIFIC INFORMATION/DETAILS BEEN PROVIDED AS AN ANNEX TO THE DDPS SUBMITTED WITH THE PRESENT APPLICATION (IF APPLICABLE)?**

- Yes
- No  
(Please clarify).

**9. DECLARATION BY APPLICANT: (Please complete the following declaration)**

The undersigned hereby declares that:

- the DDPS version submitted with this application is the same as that previously assessed and approved in <MR/DC/EU procedure number(s)> on <date of end of procedure(s)>.
- all issues raised during the previous assessment of this version of the DDPS <have been addressed / will be addressed at the time of next update of the DDPS>.
- all product/application specific information/details have been provided as an annex to the DDPS submitted with the present application.

**Name of the applicant/MAH:**

**Name of contact person:**

**Function:**

**Signature:**

**Date:**