



Work instructions

Title: How to create and revise the PhV inspections programme		
Applies to: P-CI-CNC		
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1. Changes since last revision

New WIN.

2. Records

All mentioned documents are saved electronically in DREAM in 04.Inspections/2.PHV/Planning and reporting/PhV Inspection coordination/PhV Inspection programme/ Relevant Year and quarter.

Abbreviations

- CAP Centrally Authorised Products
- CXMP Committee for Medicinal Products for Human/Veterinary Use.
- INN International Non-proprietary Name
- MAH Marketing Authorisation Holder.
- MS EU Member State
- P-CI-CNC Clinical and Non-clinical Compliance section, in the Compliance and Inspection Sector in the Patient Health Protection unit.
- PhV IWG Pharmacovigilance Inspectors Working Group.
- PhV Pharmacovigilance.
- PRAC Pharmacovigilance Risk Assessment Committee.



- PTL Product Team Leader.
- QPPV Qualified Person for Pharmacovigilance.
- V-PhV WG Veterinary Pharmacovigilance Working Group

3. Instructions

This WIN should be read in conjunction with the "Procedure for the preparation of a risk-based programme for routine pharmacovigilance inspections of MAHs connected with human centrally authorised products (CAPs)" INS/PhV/4 which can be found on the EMA public website: Home/Regulatory/Human medicines/Inspections/Pharmacovigilance/Inspections procedure

This WIN refers to the preparation of both, the human and the veterinary PhV inspection programme; therefore the steps described should be performed twice in order to complete both of them.

The programme should be prepared and revised at least twice a year (i.e. 1Q and 3Q).

Step	Action	Responsibility
1.	<p>The timing of the preparation and the frequency of the revision of the PhV inspection programme is determined by the "Procedure for the preparation of a risk-based programme for routine pharmacovigilance inspections of MAHs connected with human centrally authorised products (CAPs)" INS/PhV/4. To initiate the revision of the programme, request that a report is generated from SIAMED with all the human products with a valid Marketing Authorisation and another with all the veterinary products with a valid Marketing Authorisation.</p> <p>The reports, produced from SIAMED database, must include the following fields: EMEA number, Brandname, INN, Status, Commission Decision Date, Rapporteur, Rapporteur country, CoRapporteur, CoRapporteur Country, MAH, MAH country, PTL, PhV Contact Person, PhV Contact Person Address and PhV Contact Person Country.</p>	P-CI-CNC Adminsitrator
2.	Create a new folder name "<YEAR><Q1-Q2 or Q3-Q4>" to indicate whether it is the first or the second revision of the programme in the current year.	P-CI-CNC Assistant
3.	Save in this folder the correspondence related to the generation of the reports mentioned in step 1.	P-CI-CNC Assistant
4.	Create in this folder two sub-folders called "Human" and "Vet".	P-CI-CNC Assistant
5.	Save the report received under the relevant sub-folder and name it "Confidential H PhV Inspection Programme 20xx-20xx+3" and "Confidential V PhV Inspection Programme 20xx-20xx+2".	P-CI-CNC Assistant
6.	Rename the worksheet with the data, in both reports to "New Programme"	P-CI-CNC Assistant
7.	Copy from the previous adopted programme, version labeled "final all sheets", the worksheets called "New Programme" and "Legend".	P-CI-CNC Assistant

Step	Action	Responsibility
	Paste them in the new programme and re-name the worksheet "New Programme" to "Previous Programme".	
8.	Format the "New Programme" worksheet in the same way as the "Previous Programme" worksheet.	P-CI-CNC Assistant
9.	Arrange the columns of the "New Programme" in the same order as in the "Previous Programme".	P-CI-CNC Assistant
10.	Sort both worksheets selecting "custom sort" in the "sort and filter", choosing the date of the columns "Commission decision" (ascending) as first option and "Brand name" as the second option.	P-CI-CNC Assistant
11.	Check which was the last product in the "Previous Programme" worksheet and highlight in yellow all new products at the end of the "New programme" worksheet.	P-CI-CNC Assistant
12.	Sort both worksheets selecting "custom sort" in the "sort and filter", choosing the date of the columns "Commission decision" (ascending) as first option, "Brand name" as the second option and "INN" as the third option.	P-CI-CNC Assistant
13.	Copy the columns "Brand name" and "INN" from the "previous programme" worksheet and insert those in the "New Programme" worksheet next to the columns with the same name. It is recommended to highlight the columns coming from the "previous programme" worksheet to avoid confusion.	P-CI-CNC Assistant
14.	Align in both the order of the two fields called "Brand name" and "INN" going product by product, deleting duplicate entries, withdrawn products and taking any other measure needed. For any change you make in order to align the order of the products in the columns always remember that the rest of the information in both sheets should stay within the right product/row. If you need to move the products up or down in the brandname/INN columns in order to align the order remember to first insert a row and then cut and paste the names. It is recommended to write your actions (i.e. deletion of products). Repeat the alignment check in both worksheets in order to ensure that the order is exactly the same before you copy and paste the programme information from the "Previous programme" worksheet to the "New programme" worksheet.	P-CI-CNC Assistant
15.	Copy and paste the programme information from the "Previous programme" worksheet to the "New programme" worksheet once the products/rows in both worksheets are aligned.	P-CI-CNC Assistant
16.	Check for changes in the "MAH", "PhV Contact Person" or "PhV Contact Person Country" by comparing the information in the "Previous programme" and "New programme" worksheets.	P-CI-CNC Assistant
17.	Highlight in orange products that have changed "MAH", "PhV Contact Person" or "PhV Contact Person Country".	P-CI-CNC Assistant
18.	Update changes in the "PhV Contact Person Country" and the field "MS to lead the inspection". It is recommended to make a note of those changes in order to alert the concerned MSs in the cover note when the programme is sent for PhV IWG review.	P-CI-CNC Assistant

Step	Action	Responsibility
19.	Sort the "New programme" worksheet by "MAH" as first option, "Brand name" as the second option and "INN" as the third option.	P-CI-CNC Assistant
20.	Highlight in red any discrepancies that need to be solved (i.e. different QPPV for different product of the same MAH). Contact the MAH or the PTL to solve the issues and correct in the programme if needed.	P-CI-CNC Assistant
21.	<p>Check and update the fields "Year of scheduled inspection", "Year of previous inspection". For inspections that took place in the previous year or have already taken place in the current year, suggest a new date (year of inspection +2 years for Vet inspection with non-significant findings, +3 years for Human inspections with non-critical findings and follow the inspector recommendation for Vet inspections with significant findings or Human with critical findings.</p> <p>For new MAHs, a risk assessment process based on the "Procedure for the preparation of a risk-based programme for routine pharmacovigilance inspections of MAHs connected with human centrally authorised products (CAPs)" should be performed to decide on date of inspection.</p>	P-CI-CNC Assistant
22.	Sort the worksheet by "MS to lead the inspection" as the first option, "MAH" as second and "Brandname" as third option, before its circulation to the PhV IWG.	P-CI-CNC Assistant
23.	Send the programme for agreement to the first or third quarterly meeting of the PhV IWG in the mailing. Please give enough time for the inspectors to revise the programme before the meeting.	P-CI-CNC Assistant
24.	Once comments have been included and the programme has been agreed by the PhV IWG, save the document with the label "<date>agreed by PhV IWG".	P-CI-CNC Assistant
25.	Edit the document by adding a new worksheet named "For adoption". The format of the new worksheet (document title, reference, version, date and date of adoption) can be copied and edited, as applicable from the last version of the previous programme).	P-CI-CNC Assistant
26.	Sort the worksheet "New programme" by "Year of scheduled inspection" as the first option, "MAH" as second and "Brandname" as third option and copy to the "For adoption" worksheet the columns for MAH, Brand Name, INN, Rapporteur country, Co-rapporteur Country, MS proposed to lead the inspection, Requestor of the inspection, year of schedule inspection, year of previous inspection and findings in the previous inspection.	P-CI-CNC Assistant
27.	Send for agreement to the PRAC and V-PhV WP.	P-CI-CNC Administrator
28.	Once comments have been included and the programme has been agreed by the PRAC and the V-PhV WP, update the programme with the relevant dates of PRAC/V-PhVWP agreement and save the document with the version label "final all sheets"	P-CI-CNC Assistant

Step	Action	Responsibility
29.	Delete all worksheets except the one named "For adoption" and send the document to the CXMP for adoption. The programme must be adopted by June for the first revision and by December for the second revision.	P-CI-CNC Administrator
30.	In case comments are received by CXMP and changes are needed before adoption, go to the version marked "final all sheets", make the requested changes to the "New programme" worksheet and repeat step 26 and save the document with the version label "final all sheets".	P-CI-CNC Assistant
31.	Delete all worksheets except the one named "For adoption" and re-send the document to the CXMP. Save the adopted document as "Final".	P-CI-CNC Administrator