PRAC Member Comments on PRAC Rapporteurs' and co-Rapporteurs Reports

Note

- Free text comments or short comments can be sent to CHMP/CAT/PRAC using secure e-mail.
- Use this template only if you wish to provide additional, more extensive comments.

This Document is Sent By

Name of Committee Member	
Names of Assessors.....	
Date of comments.....	03/07/2018

This report concerns

Product name/No.	Quinolone and fluoroquinolone containing medicinal products
Procedure Number	EMEA/H/A-31/1452- PRAC Rapporteur's 2nd Joint Assessment Report
Title of Report	FR Comments

General comments

FR supports the rapporteur's assessment report and has additional comments.

Regarding the update of RMP to include a follow-up questionnaire, some points need to be clarified notably for products without an RMP. Furthermore, it worth having clear of all the process around the questionnaire:

- Does it come in addition of usual spontaneous notification?
- What is the target (patients? Healthcare professionals?…)?
- What would be the dissemination methods triggered at national level?
- Is any cover letter necessary to reflect that this follow-up questionnaire is in agreement with the national authorities?
- …

Specific comments (including comments to draft questions)

Quality Aspects

Non-clinical Aspects

Clinical Pharmacology

Clinical Efficacy

Clinical Safety

Periodic Safety Update Report

Risk Management Plan/ Post-authorisation Safety Studies/ Conditions

Benefit-Risk Assessment

Summary of Product Characteristics, Package Leaflet and Labelling

Other Aspects