

PRAC Member Comments on 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	(FR)
Names of Assessors.....	
Date of comments.....	28/08/2018

This report concerns

Product name/No.	Fluoroquinolones
Procedure Number	Not applicable
Title of Report	EPITT 18651

General comments

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

We strongly support and recommend to have a combined DHPC (PRAC signal and Art. 31) in order to avoid multiple communications to HCPs at a short interval.

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

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