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.
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This Document is Sent By

Name of Committee Member	
Names of Assessors.....	
Date of comments.....	21/09/2017

This report concerns

Product name/No.	Quinolone and fluoroquinolone containing medicinal products
Procedure Number	EMEA/H/A-31/1452
Title of Report	FR Comments

General comments

We overall fully support this EU counterpart of the revision of the US B/R for (fluoro-)quinolones given the worrying safety profile of those antibacterial agents and all the more that those antibiotics are characterized by a high pressure of selection that mandates a restrictive use.
There are particular challenges in reaching a final position on the indications given the significant heterogeneity of the wording of indications across EU.

As proposed by the Rapporteur, the input of the SAG would indeed be highly critical for delineating the targeted populations where the safety concerns (notably long term disability) could be considered as being outweighed by the expected benefits.

To this purpose, it is noted that the Rapporteur has already made some attempts for removal of some indications and for indications that would deserve restrictions.
However, it is perceived that entering into this exercise at this stage might already raise some level of difficulties. Notably, it can be raised that acute bronchitis is nowadays considered as being a "non indication" for any antibiotic.
Therefore, while the efforts of the Rapporteur on those aspects are acknowledged, we would rather favour to raise more global questions to the SAG, that could be:

Given on the one hand the scientific knowledge accumulated so far through literature data and therapeutic guidelines to substantiate the benefit of (fluoro-)quinolones and on the other hand the level of concerns raised by the safety profile of quinolones with long lasting disabling and potentially irreversible ADRs, the SAG input is warranted on the type of infections where the safety profile of the (fluoro-)quinolones would be compatible with the use of those antibiotics.

This position should be discussed for each site of infections:

- Lower and upper respiratory
- Cutaneous
- Bone and joint
- Urinary
- Genital
- Abdominal
- Any other specific situations (such as prophylaxis of invasive infection due to Neisseria meningitides, neutropenic fever with suspected bacterial infections).

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