EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Feedback from PRAC

March 2020

Pharmacovigilance Risk Assessment Committee
Representatives from each member states
+ 6 independent experts +

Members representing healthcare professionals

Raymond Anderson

Pharmaceutical Group of the European Union (PGEU)

Alternate

Roberto Frontini

European Association of Hospital Pharmacists

Members representing patients' organisations

Cathalijne van Doorne

European Federation of Neurogical Associations (EFNA)

Alternate

Virginie Hivert

EURORDIS - Rare Diseases Europe

PRAC Workplan 2020
& involvement of civil society representatives

1.1.2. Life-cycle approach to pharmacovigilance and risk management (Cathalijne & Raymond)

*By ensuring robust, feasible and risk proportionate **planning of pharmacovigilance activities** including **risk minimisation** and further collection of data and information, the work of the PRAC supports the **protection and promotion of public health**. The work of PRAC also underpins **innovation** throughout the product lifecycle thereby and supporting the delivery of new treatments to patients, fulfilling **unmet medical needs**.*

1.3.1. Information from real-world clinical use of medicines (Virginie & Roberto)

*Collection and analysis of data from the **real-world use of medicines** is important in supporting assessment and decision-making on how medicines are used, their effectiveness and their safety. Use of **epidemiological approaches** is key and enablers include access to **electronic health and insurance records**, clear governance, and collaboration across stakeholders including academia. Data and information from the real-world use of medicines is a key enabler for **access to new treatments** and will support the PRIME scheme and Adaptive Pathway initiatives.*

1.5.3. Measuring the impact of pharmacovigilance activities (Cathalijne)

*Systematically measuring **patient-relevant health outcomes** of major regulatory interventions (e.g. post referral procedures) and key pharmacovigilance processes enables the **focus of pharmacovigilance** to fall on those activities and regulatory tools that **make a difference in daily healthcare**. → Improve pharmacovigilance through feedback on impact of regulatory actions*

2.3.1. Engage patients and healthcare professionals, communication with stakeholders (PRAC topic leader: Raymond + Cathalijne, Virginie and Roberto as participants)

*The **engagement** of patients and healthcare professionals is important for effective pharmacovigilance. Patients and healthcare professionals can be involved **throughout the process** from **risk management planning**, through **reporting of suspected adverse drug reactions**, **assessments and decision** e.g. through PSURs and referrals and on benefit-risk communications. For PRAC, key engagement has included membership of the **committee**, patients' and healthcare professionals' **reporting**, involvement in **ad-hoc expert groups** and **scientific advisory groups**, **public hearings and targeted written consultations**.*

PRAC Statistics September '19 to February '20

Number of Safety Signals assessed	77
Number of Periodic Safety Update Reports (PSUR's) reviewed	424
Number of Risk Management Plans for centrally authorized products reviewed	328
Number of Post-Authorisation safety studies reviewed	151
Number of Referrals reviewed	8

<u>New Communication on EMA Website</u>

Direct Healthcare Professional communication will be regularly published on the EMA website from February 2020. DPHC's inform HCP's about new safety information on a medicine and will be published on the EMA website at the time of national dissemination. The new webpage will also include links to national registers of DHPC's.

Key Recommendations from the PRAC

Estradiol Creams (High-strength): Recommendation limiting use to a single treatment period of up to four weeks to minimize risk of side effects e.g. blood clots & strokes

Lemtrada (Used in M/S): Recommendation to restrict use due to rare but serious side effects (including death) from immune-mediated conditions and serious disorders of the heart, circulation and bleeding.

Xeljanz (Used in active RA): Recommendation to be used with caution in patients at high risk of blood clots.

Picato (Used in actinic keratosis) Recommendation patients stop using Picato while review into possible link with skin caner is ongoing

Cyproterone: Recommendation medication containing 10mg or more should only be used in certain conditions once other treatments have failed (or not suitable) and not used in people who have or have had a meningioma