EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Enhancing PRAC engagement with patients and healthcare professionals –

Development of PRAC Points-to-Consider

PCWP and HCPWP September 2021

Presented by Priya Bahri
European Medicines Agency

PRAC Impact Strategy

- Active engagement and capacity-building with patient communities and healthcare professional bodies regarding effective risk minimisation
- Establish a process for involvement of patient and healthcare professional organisations/bodies and healthcare providers in evaluation of effectiveness of risk minimisation measures (RMM)

Presented by P Bahri at PCWP + HCPWP September 2021

Quantitative review of PRAC engagement event 2015-2019

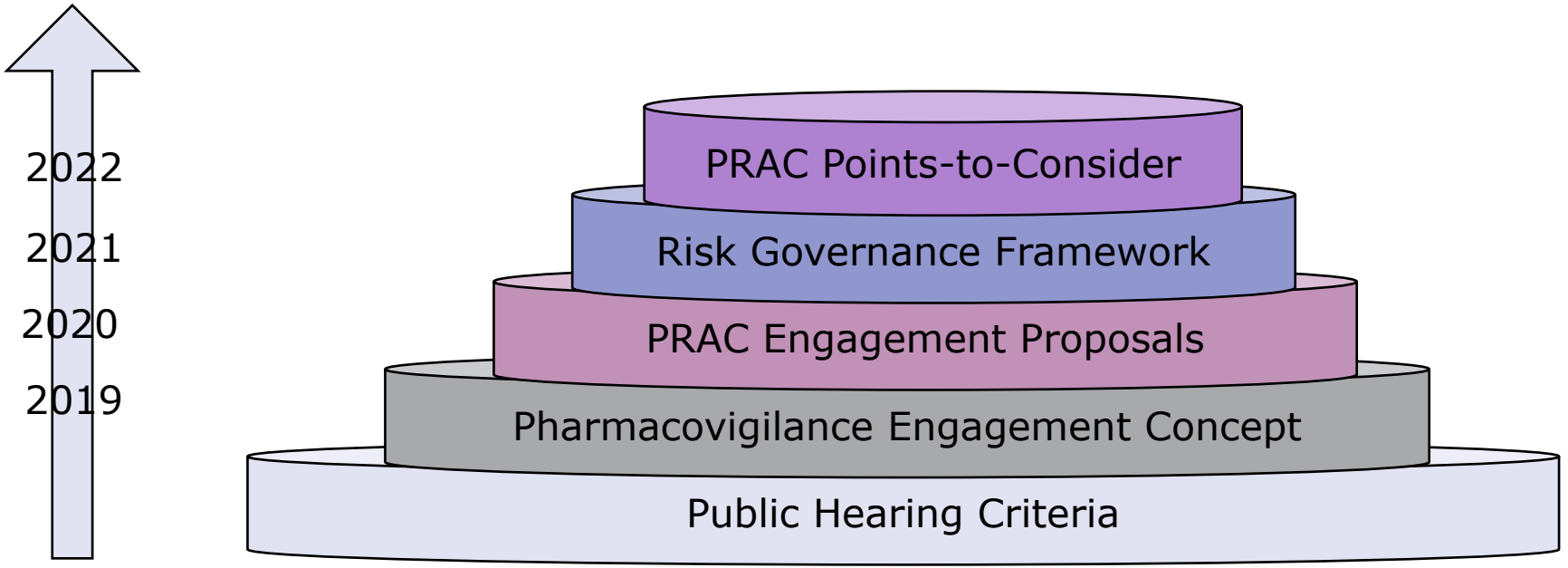
130 engagement events:

- Safety communication review: 50
- DHPC reviews: 36
- Written consultation: 22
- Scientific Advisory Group meeting: 4
- Ad hoc expert group meeting: 8
- Stakeholder meeting: 5
- Teleconference: 2
- Public hearing: 2
- Scientific publication: 1

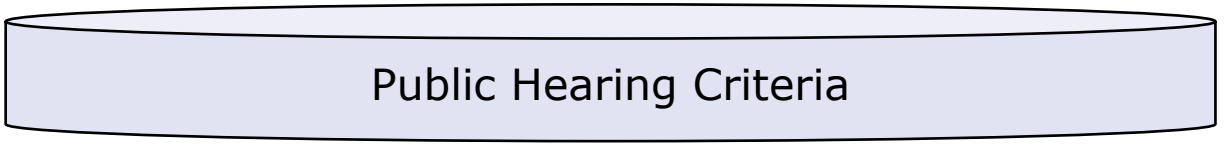
Thank you!

Engagement events total excluding DHPC and safety communications review: 44 (28 products)

Achievements and plans for evidence-based enhancement of PRAC engagement



- Feasibility to hold a public hearing in light of the urgency of the matter
- Nature and extent of the safety concern
- Therapeutic effect of the medicine and availability of therapeutic alternatives
- Potential impact of regulatory actions on therapeutic practice and availability of treatments
- Level of public interest



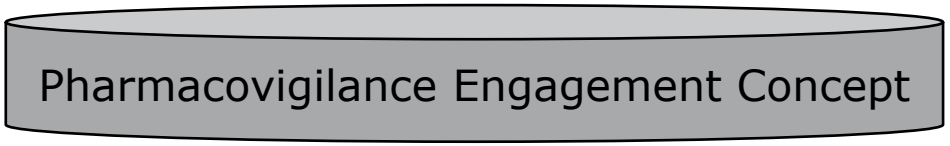
Pharmacovigilance engagement =

an ongoing knowledge exchange among stakeholders

- **Breadth** = Quantity and diversity of stakeholders being engaged
- **Depth** = Extent of knowledge exchanged between stakeholders and adopted for mutual understanding (information – consultation- participation)
- **Texture** = Interactive dynamics of what engagement 'feels' like, what does it mean, how it does shape motivations to engage and change behaviours based on values, emotions, (mis)trust and rationales

➢ These 3 dimensions are linked in complex manner, both in terms of processes and outcomes

[Brown & Bahri, 2019]



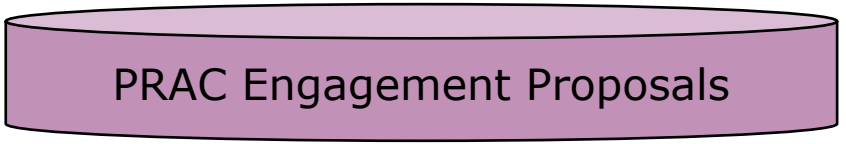
Proposals derived from valproate case study

A) Agreeing on appropriate RMM with stakeholders and catalysing healthcare leadership for RMM implementation

B) Building-up stakeholder input on all elements critical to RMM implementation

C) Collaborating with all stakeholders for monitoring implementation and evaluating RMM

[Bahri, Morales, Inoubli, Dogné & Straus, 2020]



International Risk Governance Council (IRGC) Framework

Simple risk, i.e. causality of risk and effectiveness of risk minimisation can be established

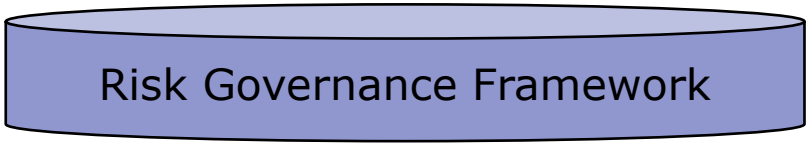
Complex risk, i.e. difficult to make a decision on action due to persisting complexity (e.g. certain assumptions must be made for causality assessment; evidence remains incomplete)

Uncertain risk, i.e. difficult to make a decision on action due to persisting complexity (e.g. certain assumptions must be made for causality assessment; evidence remains incomplete)

Ambiguous risk, i.e. divergent perspectives among stakeholders on the rationale for action

Require

Different types of discourse



Applicability of IRGC Framework

Risk of lipodystrophy with medicines used for highly active antiretroviral therapy (HAART): First-time engagement of patient and healthcare professional representatives in a multi-stakeholder oversight committee for research requested by EMA for an adverse reaction suspected and notified by patients themselves (1999)

Risk of carcinogenicity with contaminated nelfinavir-containing products: First-time engagement of EMA where a patient representative was contacted by EMA immediately after a marketing authorisation holder's notification of a quality defect and before the risk assessment could be started (Note: The risk assessment demonstrated that the exposure of patients had been below the toxic threshold) (2007)

Risk of teratogenicity with thalidomide: First-time engagement of EMA where victim and patient representatives were brought together by EMA at a dedicated meeting (2007)

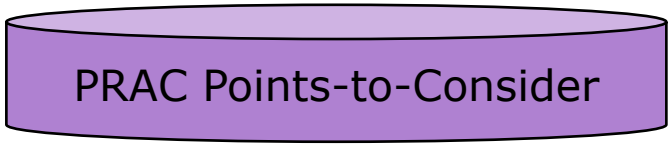
Risk of progressive multifocal leukoencephalopathy (PML) with natalizumab: First-time invitation of patient representatives in a Scientific Advisory Group (SAG) meeting regarding a risk of an authorised medicine (2008)

Risk of venous thromboembolism (VTE) with combined hormonal contraceptives (CHCs): First-time dedicated meeting with patient and healthcare professional representatives for Pharmacovigilance Risk Assessment Committee established in July in 2012 under then new legislation (2013)

Risk of teratogenicity with valproate: First-time public hearing at the Pharmacovigilance Risk Assessment Committee (PRAC) (2017)

[Bahri & Pariente, 2021]

- To support PRAC for systematic consideration of engagement options and questions to stakeholders
- To achieve consistent, risk-proportionate and effective engagement
- Support to PRAC decision on RMM



Risk scenario **defines** **Engagement objective**

Simple risk

RMM Implementation

Agree on how to put RMM into practice

Complex risk

Evidence gathering

Input to support PRAC decision on risk characteristics, best risk estimates and proportionate RMM

AND

RMM Implementation

Agree on how to put RMM into practice

Uncertain risk

Evidence gathering

AND

Precautionary action

Input to support PRAC decision on proportionate precautionary RMM

AND

RMM Implementation

Agree on how to put RMM into practice

Ambiguous risk

Evidence gathering

AND

Consensus

Find agreement across stakeholders and support PRAC decision on RMM

AND

RMM Implementation

Agree on how to put RMM into practice

Risk scenario **defines** **Engagement objective** **defines** **Engagement event**

Stakeholder events
Written consultations
Dedicated meetings
Scientific Advisory Groups (SAGs)
Public hearings

Considerations for prioritising and optimising:

- Discourse type and texture
- Focussed questions
- Breadth
- Depth
- Timelines
- Privacy vs publicity and other stakeholder preferences

and taking into account the regulatory procedure

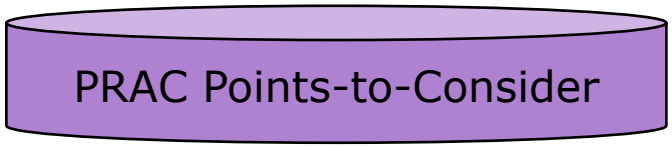
[Bahri & Pariente, 2021]

Develop together and pilot!

- PRAC Impact Group – engagement workstream
- PRAC
- PCWP + HCPWP

Status and next steps:

- Draft of July 2021 available
- Presented to PRAC Impact Group and PRAC, and discussion by PRAC to be continued in Q3/Q4 2021
- Further development with PCWP, HCPWP and PRAC input at PRAC Impact Group – engagement workstream Q4 2021/Q1 2022
- Piloting in 2022



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Thank you

Further information

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