22 November 2017
EMA/CHMP/BWP/149179/2017
Human Medicines Research and Development Support Division

AGENDA:
Joint BWP/QWP workshop with stakeholders in relation to prior knowledge and its use in regulatory applications

23 November 2017, European Medicines Agency, London

Purpose

Prior knowledge has always been an important tool in designing both manufacturing processes and control strategies for medicinal products. In recent years, it has gained more focus in EU guidelines (e.g. process validation for biotech drug substances; process validation for finished products). Making use of such prior knowledge in regulatory application dossiers, to support manufacturing and control strategies, could be justifiable in certain circumstances. For prior knowledge to be used in this way, good understanding among regulators and industry of the expectations of how it should be documented in regulatory application dossiers is essential.

This workshop will address what prior knowledge entails and how it can be used to support product development, manufacturing and control strategies. These general discussions will be further elaborated through a number of specific industry case studies and a discussion of experiences to date of accelerated access schemes. The conclusions from the workshop will be captured in a report, which will be published. Further follow-up guidance may be considered.

Location

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Agenda: Thursday, 23 November 2017, Time: 09:00-17:30

Timings	Topic
8:30 – 9:00	Arrival and registration
9:00 – 9:05	**Welcome, Introductions & Goals of Workshop** *Veronika Jekerle, EMA, BWP secretariat, Quality Office* *Brian Dooley, EMA, Quality Office*
9:05 – 9:45	**1. What is Prior Knowledge?** What is (and isn't) considered to be prior knowledge, how can such prior knowledge be used in regulatory submissions, how to justify its use and how to present it in the dossier. *Session Chair: Mats Welin, BWP, MPA, Sweden*
9:05 – 9:20 9:20 – 9:35 9:05 – 9:45	General considerations from regulators *Mats Welin, BWP, MPA, Sweden* General considerations from industry *Markus Goese, EBE/EFPIA/Vaccines Europe, Roche* Discussion
9:45 – 11:15	**2. Using prior knowledge in product development/design?** How to justify applicability of prior knowledge of active substance, excipient or packaging properties from similar products to support formulation design and how to apply prior knowledge from similar products or different product classes to a product in development (e.g. platform technologies, identifying CQAs, informing risk assessments). *Session Chair: Keith Pugh, QWP Chair, MHRA, UK*
9:45 – 10:00 10:00 – 10:15 10:15 – 10:25 10:25 – 10:35 10:35 – 10:45	Regulator's perspective *Keith Pugh, QWP Chair, MHRA, UK* General considerations from industry *Keith Watson, EBE/EFPIA/Vaccines Europe, Abbvie* Case Study 1: FIM to commercial for a lyophilised (NBE) product *Michael Siedler, EFPIA, Abbvie* Case Study 2: Development of a lower dose paediatric strength IR tablet *Matt Popkin, EFPIA, GSK* Case Study 3: Use of platform technologies for Adenovirus-based vaccines *Mark van Ooij, Vaccines Europe, Janssen*

Timings	Topic
10:45 – 11:15	Discussion
11.15 – 11:30	Coffee
11.30 – 13:00	**3. Using prior knowledge in process development & manufacturing strategy?** Using prior knowledge when selecting starting materials and manufacturing processes, supporting design space development, determining validation approaches and criticalities and supporting scale up. *Session Chair: Seán Barry, BWP, HPRA, Ireland*
11.30 – 11:45	Regulator's perspective *Seán Barry, BWP, HPRA, Ireland*
11.45 – 12:00	General considerations from industry *Ron Ogilvie, EFPIA/EBE/Vaccines Europe, Pfizer*
12.00 – 12:10	Case Study 1: Application of prior knowledge to process parameter definition *Bob Kuhn, EFPIA/EBE, Amgen*
12.10 – 12:20	Case Study 2: Validation Efficiencies from QbD & Prior Knowledge *Frank Zettl, EFPIA/EBE, Roche*
12.20 – 12:30	Case Study 3: Prior knowledge to streamline viral safety and resin lifetime studies *Marie Murphy, Eli Lilly & Company (EBE) Nancy Cauwenberghs, MSD Inc (Vaccines Europe)*
12.30 – 13:00	Discussion
13.00 – 14:00	Lunch
14:00 – 15:45	**4. How to use prior knowledge in defining the control strategy?** How prior knowledge can be used to define an integrated control strategy by using prior knowledge of CQAs when assessing risk to safety and efficacy and clinical experience when setting specifications. *Session chair: R. Martijn van der Plas, BWP, MEB, The Netherlands*
14:00 – 14:15	Regulator's perspective *R. Martijn van der Plas, BWP, MEB, The Netherlands*
14:15 – 14:25	Case Study 1: Specification Setting for a Multivalent Vaccine *Nancy Cauwenberghs, Vaccines Europe, MSD Inc*
14:25 – 14:35	Case Study 2: Oligonucleotide Control Strategy *Rachel Orr, EFPIA, GSK*

Timings	Topic
14:35 – 14:45	Case Study 3: Prior Knowledge in the Control Strategy for Biotechnology Products *Darrin Cowley, EFPIA/EBE, Amgen*
14:45 – 14:55	Case Study 4: Prior Knowledge for Setting Acceptance Criteria *Thomas Stangler, Medicines for Europe, Novartis*
14:55 – 15:10	General considerations from industry *Andrew Lennard, EBE/EFPIA/Vaccines Europe, Amgen*
15:10 – 15:45	Discussion
15:45-16:00	Coffee
16:00 – 17:00	**5. Experiences of accelerated access approaches (i.e. PRIME)** Sharing industry and regulator's perspectives and experience with accelerated access approaches (i.e. PRIME), and exploring when and how prior knowledge could be used in this context. *Session chair: Veronika Jekerle, EMA, BWP secretariat*
16:00 – 16:10	Regulator's perspective & experience on prior knowledge and accelerated access *Veronika Jekerle, EMA, BWP secretariat*
16:10 – 16:20	Considerations for Accelerated CMC programs *Ronald Imhoff, EBE, Janssen / Richard Keane, EBE, Biogen*
16:20 – 16:30	Case Study 1: Atezolizumab: A Case Study of Accelerated Development *Andrea Challand, EBE, Roche*
16:30 – 16:40	Case Study 2: Avelumab integrated Mab example *Isabelle Colmagne-Poulard, EFPIA, Merck*
16:40 – 17:00	Panel discussion *Panel Chair: Peter Richardson, EMA, Head of Quality* *Sol Ruiz, BWP chair, CHMP, CAT, AEMPS, Spain* *Nanna Kruse, BWP vice-chair, CAT, DKMA, Denmark* *Marie-Hélène Pinheiro, EMA, Industry Stakeholder Liaison* *Jordi Llinares Garcia EMA, Head of Scientific and Regulatory Management Department* *Ronald Imhoff, EBE, Janssen* *Richard Keane, EBE, Biogen* *Mairéad Duke, EBE, BioMarin*

Timings	Topic
17.00-17.30	**6. General discussion, summing up and way forward** The lessons learned from the workshop and next steps will be summarised at the end of the meeting. *Brian Dooley, EMA, Quality Office* *Mats Welin, BWP, MPA, Sweden* *Keith Pugh, QWP chair, MHRA, UK* *Markus Goese, EBE, Roche* *Isabelle Colmagne-Poulard, EFPIA, Merck*
17.30	**Meeting ends**