EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 September 2017
EMA/406983/2017
Procedure Management Department

Agenda – Industry and assessors' joint training on how to improve the content of periodic safety update reports

22 September 2017, 9:00-11:00, Meeting room 3E

Chair: Menno van der Elst

Objective of the training: identifying key issues encountered by Industry and Regulators in the preparation of PSURS, sharing Best Practice (advice) on ways to address these key issues to achieve a common understanding of the quality standards needed to facilitate the EU PSUR single assessment.

High PSUR quality is essential to support the overall safety evaluation and integrated critical benefit-risk evaluation in the context of the life cycle of medicinal products and is therefore key in supporting public health.

Item	Agenda	Initials	Mins
1.	**Welcome** • Introduction to PSUR roadmap: explanatory note to GVP VII and Q&A for assessors • Purpose of the training: how to improve the content of PSURs	ME	5
2.	**Signals and close monitoring in the PSUR** **1.a) Preparing for a signal presentation / evaluation** (industry's perspective) Background + practical examples + solution **1.b) How to address requests for close monitoring** (industry's perspective) Background + practical examples + solution **2. What do assessors expect to receive in a PSUR?** (regulatory authorities' perspective) Background + practical examples + solution **3. Q & A** (all) **4. Summary of common understanding** (industry/network) Bullet points prepared in advanced in line with the papers agreed with	 CH VS UW	60

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3.	**Safety specifications** **1. How is the inclusion of safety concerns substantiated** (industry's perspective) Background + practical examples + solution **2. Request to review the safety specification** (regulatory authorities' perspective) Background + practical examples + solution **3. Q & A** (all) **4. Summary of common understanding** (industry/network) Bullet points prepared in advanced in line with the papers agreed with	KMB ME	20
4.	**Product information / Reference safety information** **1. QPPV oversight of the product information** (industry's perspective) Background + practical examples + solution **2. The role of the RSI and/or the PI** (regulatory authorities' perspective) Background + practical examples + solution **3. Q & A** (all) **4. Summary of common understanding** (industry/network) Bullet points prepared in advanced in line with the papers agreed with	MR ME	20
5.	**Use of summary tabulations** **1. How are they created** (industry's perspective) Background + practical examples + solution **2. Place in the assessment of PSURs** (regulatory authorities' perspective) Background + practical examples + solution **3. Q & A** (all) **4. Summary of common understanding** (industry/network) Bullet points prepared in advanced in line with the papers agreed with	DL ME	10
6.	**Close of training/Next steps**	ME	5

List of speakers' acronyms:

Menno van der Elst (ME)
Craig Hartford (CH)
Valerie Simmons (VS)
Ulla Wändel (UW)
Klaudija Marijanovic Barac (KMB)
David Lewis (DL)
Michael Richardson (MR)
Kora Doorduyn-van der Stoep (KDS)