EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24th October 2016
EMA/478438/2016

Agenda – 1st Webinar on regulatory and procedural aspects of Type I variations

15 November 2016, 13:30 – 16:00 (GMT)

Chair: Alberto Ganan Jimenez

Item	Agenda	Time
1.	**Welcome / Introduction** Alberto Ganan Jimenez	13:30 – 13:40
2.	**General overview of validation issues for type IA and IB variations** Simona Villa-Colciago and Michalina Nadja	13:40 – 14:05
3.	**Electronic Application Form. Aspects to consider when preparing your submission.** Ioana Vitu	14:05 – 14:20
4.	**Documentation requirements. Aspects to consider when preparing your submission.** Blanka Zakutna, Birgitte Jorgensen	14:20 – 14:35
5.	**Update of safety product information for Generics** Birgitte Jorgensen	14:35 – 14:50
	Coffee Break	14:50 – 15:05
6.	**GMP and inspections related documentation** Laetitia Deguil	15:05 – 15:30
7.	**Applications affecting an Active substance Master File (ASMF)** Carlos Aicardo	15:30 – 15:50
8.	**Concluding remarks** Alberto Ganan Jimenez	15:50 – 16:00

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Speaker List

Alberto Ganan Jimenez – Head of Evaluation Procedures Service D – Human Medicines Evaluation Division, EMA

Birgitte Jorgensen – Procedure Manager – Human Medicines Evaluation Division, EMA

Blanka Zakutna – Procedure Manager – Human Medicines Evaluation Division, EMA

Carlos Aicardo – Procedure Manager – Human Medicines Evaluation Division, EMA

Ioana Vitu – Procedure Manager – Human Medicines Evaluation Division, EMA

Laetitia Deguil – Validation Officer - Inspections, Human Medicines Pharmacovigilance and Committees Division, EMA

Michalina Nadja – Procedure Manager – Human Medicines Evaluation Division, EMA

Simona Villa-Colciago – Procedure Manager – Human Medicines Evaluation Division, EMA