

Swedish Academy of Pharmaceutical Sciences

## Nordic Regulatory Affairs Meeting 2018 - Nordic Multilingual Packages for Human and Veterinary Medicinal Products

May 3, 2018, Stockholm

## **Preliminary Program**

08:45	Registration
09:15	<b>Welcome</b> Moderator: Lena Vågberg, AstraZeneca, Mölndal, Sweden
09:25	The Nordic Package Group – our work, our achievements and our mandate Lene Havsteen, Danish Medicines Agency, Copenhagen, Denmark
09:40	Questions, questions and some answers! Ylva Satrell, Swedish Medical Products Agency, Uppsala, Sweden
09:55	Frequently asked questions about safety features Niina Makkonen, Finnish Medicines Agency Fimea, Helsinki, Finland
10:25	Human medicinal products: Labelling- opportunities and challenges from an industry perspective Victoria Ericsson, AstraZeneca, Södertälje, Sweden
11:10	Break
11:30	Mock-ups & specimens review – process and challenges Alexios M. Skarlatos, European Medicines Agency, London, UK
12:15	Are we too stubborn? Jóhann M. Lenharðsson, Icelandic Medicines Agency, Reykjavík, Iceland
12:45	Lunch
14:00	HPRA's initiatives to maintain medicine supply, post Brexit Una Moore, Health Products Regulatory Authority, Dublin, Ireland
14:20	Common Nordic Assessment of Mock-ups – The smart course of action Pia-Maria Grandell and Tobias Rydgren, Swedish Medical Products Agency, Uppsala, Sweden Elin Søndenå Sanne, The Norwegian Medicines Agency, Oslo, Norway
15:20	Break
15:40	Veterinary medicinal products: Labelling- opportunities and challenges from an industry perspective Andrew Gubb, Zoetis Belgium SA, Zaventem, Belgium
16:25	Q&A
16:55- 17:00	Closing