Läkemedelsakademin
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	**Welcome** 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	**Veterinary medicinal products: Labelling- opportunities and challenges from an industry perspective** Christelle Exbrayat, Merial SAS, Lyon, France
15:05	Break
15:25	**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
16:25	**Q&A**
16:55-17:00	**Closing**