



THE MANAGED INTRODUCTION OF NEW MEDICINES

Second PIPERSKA workshop Lublijana, Slovenia, 19 – 21 March 2012

Provisional Programme (November 2011)

Monday 19 March	Day 1 – The Principles of Health Technology Assessment (HTA) and Horizon Scanning
8.30 – 9.00	Registration
9.00 – 10.00	Welcome and course outline – <i>Professor Lars L Gustafsson (Sweden), Professor Silvio Garattini (Italy) and Dr Jurij Fürst (Slovenia)</i> Course expectations – <i>All participants</i>
10.00 – 11.00	The need for managed introduction of new medicines – <i>Dr Brian Godman (Italy, Sweden and UK) and Professor Lars L Gustafsson</i> Principles of clinical pharmacology and pharmacoepidemiology – <i>Professor Lars Gustafsson</i> Principles for the rational use of drugs - <i>Dr Kees de Joncheere (WHO)</i>
11.00 – 11.30	Tea/coffee break
11.30 – 13.00	<u>HTA and managed entry practices in Europe</u> Practices across Europe including new developments and industry perspectives Managed entry of new drugs – Swedish experience Discussion (all) <i>Dr Brian Godman, Dr Gisbert Selke (Germany), Dr Rickard Malmström (Sweden) and Dr Richard Bergström (Director General EFPIA)</i>
13.00 – 13.45	Lunch
13.45 - 14.30	<u>Horizon scanning activities</u> Including identification, forecasting, critical drug evaluation and the development of pre-launch prescribing guidance with key stakeholder groups Discussion <i>Presentation led by Dr Roberta Joppi (Italy) supported by Dr Björn Wettermark (Sweden) and Professor Ken Paterson (Scotland)</i>
14.30 – 15.00	Activities and objectives of the workshop <i>Dr Roberta Joppi, Dr Björn Wettermark and Professor Ken Paterson</i>
15.00 – 17.15	Practical example of horizon scanning – workshop in four groups (Tea/coffee served in group session rooms)
17.15 – 17.45	Group feedback
17.45 – 18.00	Summary of Day 1 – <i>Professor Lars L Gustafsson</i>
18.00	Close
18.00	Welcome reception followed by free evening

Tuesday 20 March	Day 2 – How to carry out Health Technology Assessments
9.00 – 9.30	Review/evaluation of Day 1 (all)
9.30 – 11.00	<p><u>Review of the clinical evidence as part of introduction of new drugs</u> Indirect comparisons, extrapolation Superiority and non-inferiority trials and ways forward Critical evaluation of new drugs Discussion (all) <i>Professor Silvio Garattini and Dr Rickard Malmström</i></p>
11.00 – 11.15	Tea/coffee break
11.15 – 12.45	<p><u>Health economics (2 streams)</u></p> <p>Stream A - led by Dr Alan Haycox (for attendees those new/ relatively new to health economics)</p> <p>Brief overview of health economic principles and concepts Economic checklist – how do health economists carry out a review? How health economic evaluations are used in decision making Discussion</p> <p>Stream B – Dr Magda Władysiuka (Poland) and representative from SMC (Scotland) together with Professor Ken Paterson (for attendees routinely involved in health economic analyses – either with their health authority/ health insurance agency or commercial company)</p> <p>Practical session including guidance and concerns from those submitting health economic evaluations to payers, as well as guidance and key issues from HTA bodies evaluating health economic submissions on behalf of health authorities/ health insurance agencies</p>
12.45 – 13.45	Lunch
13.45 – 14.00	<p><u>HTA in action</u> Introduction to case history <i>Overview by Prof Ken Paterson, representative from SMC and Dr Alan Haycox</i></p>
14.00 – 17.00	<p>Discussions, parallel group working including feedback <i>All participants</i> <i>Feedback chaired by Prof Ken Paterson, SMC representative and Dr Alan Haycox</i></p> <p>(Tea/coffee served will be served during the group working sessions)</p>
17.00 – 17.30	Lessons learnt from the case history
17.30 – 17.45	Review/ evaluation of Day 2 (all)
17.45	Close
19.00	Drinks reception followed by
19.30	Gala Dinner

Wednesday 21 March Day 3 – Post Launch Activities

- 9.00 – 9.30 **'Risk sharing' arrangements – considerations for the future**
Jakub Adamski (Poland) and Dr Brian Godman
- 9.30 – 10.15 **Outcome and safety monitoring especially for new drugs**
Pharmacovigilance and registry programmes
Presentation led by Dr Eric van Ganse (France) supported by Dr Björn Wettermark
- 10.15 – 11.00 **Local formulary development**
Practical examples and challenges in primary and secondary care based on the 'Wise List' in Stockholm as well as approaches across Europe integrating formularies for hospital and ambulatory care to conserve resources
Discussion
Presentation led by Prof Lars Gustafsson supported by Dr Björn Wettermark, Dr Roberta Joppi and others
- 11.00 – 11.15 Tea/coffee break
- 11.15 – 11.45 **Influencing prescribing behaviour**
Presentation led by Dr Brian Godman and Dr Björn Wettermark
- 11.45 – 13.15 2 Streams around Prescribing/ Quality indicators
- Stream A (Pharma Company people plus Health Authority/ Health Insurance personnel not heavily involved with indicators)**
- Examples and their influence from France, Germany, Slovenia and Sweden
- Dr Saskia Van Der Erf/ Dr Eric Van Ganse (CAPI, etc. - France), Dr Gisbert Selke (WIDO indicators, Germany), Dr Jurij Fürst (Slovenia) and Dr Björn Wettermark (Sweden and Stockholm County Council)*
- Stream B – Health Authority/ Health Insurance personnel seeking to develop/ refine indicators**
- Workshop led by Dr Stephen Campbell (Australia, Germany and UK) and Dr Björn Wettermark (brief attendance at Stream A)*
- 13.15 – 14.00 Lunch
- 14.00 – 15.00 Continuing workshops and feedback sessions
- 15.00 – 15.30 Discussion on post-launch activities and lessons learned Day 3
Participants led by Dr Jurij Fürst and Professor Lars L Gustafsson
- 15.30 – 16.00 Workshop review/evaluation feedback and ways forward (including meeting expectations)
Participants led by Dr Jürj Furst, Professor Lars L Gustafsson, Professor Ken Paterson and Professor Silvio Garattini
- 16.00 Close and presentation of certificates of attendance