



WHO Collaborating Centre for Pharmaceutical Policy and Regulation

Winter meeting 6 + 7 January 2016

Wednesday 6 January 2015

Venue: Faculty club 'Helios', Kanunnikenzaal, Achter de Dom 7a, Utrecht

Globalisation of clinical trials: policy, regulatory and ethical reflections

09:30-10:00	Registration, coffee
10:00-10:30	Welcome and introduction to the theme Bert Leufkens (UU, MEB) and Gilles Forte (WHO)
10:30-11:30	Facts and figures on global trials and clinical science Jarno Hoekman (UU) and Sander van den Bogert (UU) On tools to aid decision making under uncertainty in clinical trials Shyama Ramani (UNU-MERIT)
11:30-11:45	Coffee break
11:45-12:45	Globalisation of clinical trials: speed, relevance and quality issues Nicola Magrini (WHO) Ethical aspect within regulatory review lacks elaboration and attention Rose Bernabe (UMC Utrecht)
12:45-13:45	Lunch break
13:45-14:45	Industry/CRO perspective on globalization of clinical trials Henk Jan Out (University of Sunderland) Efficacy of mania drugs across geographic regions Carlijn Welten (AMC)
14:45-15:00	Tea break



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15:00-16:15 Plenary discussion with reflections from regulatory, industry, civil society, patient/study objects, academia etc
Moderator: **Bert Leufkens (UU, MEB)**

16:15-16:30 Wrap up and day closure
Gilles Forte (WHO) and **Bert Leufkens (UU, MEB)**

16:30 - Drinks

Thursday 7 January 2016

Venue: Faculty club 'Helios', Kanunnikenzaal, Achter de Dom 7a, Utrecht

Presentations of ongoing pharmaceutical policy analyses

From 8:30 Coffee

09:00-09:15 Welcome; introduction and overview
Aukje Mantel (UU)

09:15-10:45 Paper discussion - 2 parallel sessions
1a: Access to medicines
1b: Drug regulatory science (Opzoomerkamer)

10:45-11:15 Coffee break

11:15-12:45 Paper discussion - 2 parallel sessions
2a: Policy interventions
2b: Improving efficiencies in the health system (Opzoomerkamer)

12:45-13:45 Lunch break

13:45-14:15 Moderated poster presentations

14:15-15:00 Presentation of ongoing activities:
IMI ADAPT SMART – **Pieter Stolk (UU)**
The Global Initiative on Medication Safety (GIMS) – **Richard van Slobbe (GIMS)**
Lancet Commission on Essential Medicines Policies - **Hans Hogerzeil (RUG)**
Launch new website – **Rianne van den Ham (UU)**



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15:00-15:15	Tea break
15:15-16:45	Paper discussion - 2 parallel sessions 3a: HTA and public spending 3b: Qualitative policy research (Opzoomerkamer)
16:45-17:00	Wrap up and meeting closure Aukje Mantel (UU) and Gilles Forte (WHO)

Presentations of ongoing pharmaceutical policy analyses

Session 1a – Thursday 7 January 2016

9:15 – 10:45 - parallel session -

Access to medicines

Session Chairs: Geert Frederix (UU) and Hans Hogerzeil (RUG)

<i>Nr</i>	<i>Author</i>	<i>Title</i>
1	Vargas-Peláez	Causes and consequences of the litigation for access to medicines in Colombia
2	Perehudoff	A human rights approach to essential medicines: Tracking progress in 195 health systems
3	Achoki	The evolving burden of disease in Africa; are essential medicines lists keeping up?
4	Domnich	Accessibility to community pharmacies is associated with altitude: evidence from a mountainous region and implications for policy makers

Session 1b – Thursday 7 January 2016

9:15 – 10:45 - parallel session -

Drug regulatory science

Session Chairs: Marieke de Bruin (UU) and Alexander Doodoo (WHO CC for Advocacy and Training in Pharmacovigilance)

<i>Nr</i>	<i>Author</i>	<i>Title</i>
5	Coppens	A comparative analysis of regulatory frameworks for advanced therapies in Canada, European Union, United States, Korea and Japan
6	Ampadu	Factors facilitating Successful Pharmacovigilance Systems in Africa
7	Langedijk	Effect of generic introduction on clinical trial activities
8	Ferrario	From EU-wide marketing authorisation of new cancer medicines to patients access in Belgium, Estonia, Scotland and Sweden

Session 2a - Thursday 7 January 2016

11:15 – 12:45 - parallel session -

Policy interventions

Session Chairs: Gilles Forte (WHO) and Rianne van den Ham (UU)

<i>Nr</i>	<i>Author</i>	<i>Title</i>
9	Ivanovska	Antibiotic use in paediatric respiratory infections: national public awareness and OTC practice survey: work in progress
10	Kitutu	Effect of WHO/UNICEF integrated Community Case Management of childhood illness innovation on drug shop pediatric fever management in South Western Uganda
11	Mustafa	The effect of implementation of Standard Treatment Guidelines (STGS) in improving the antibiotics prescribing in Sudan in 2016
12	Santa-Ana-Tellez	Effect of mandatory substitution on generic medicines consumption in South Africa

Session 2b - Thursday 7 January 2016

11:15 – 12:45 - parallel session -

Improving efficiencies in the health system**Session Chairs: Aukje Mantel (UU)**

<i>Nr</i>	<i>Author</i>	<i>Title</i>
13	Bekker	Redispensing of medicines unused by patients: a qualitative study among stakeholders
14	de Rooij	Relevance and economic consequences of medicine waste in Vienna: analysis of a household garbage sample
15	Schneider	Policy transfer of health care initiatives – the example of self-care initiatives
16	Mwangi	Assessing the Viability of Pharmaceutical Technology Transfer: A Case of Kenya

Poster Session - Thursday 7 January 2016

13:45 - 14:15

Moderator: Aukje Mantel (UU)

<i>Nr</i>	<i>Author</i>	<i>Title</i>
17	Luiza	Access to medicines to non-communicable diseases treatment in Brazil: a multidimensional approach
18	Gebre	Assessment of drug use pattern using "WHO" prescribing and patient care indicators in Mekelle University Ayder Referral Hospital (ARH), Northern Ethiopia: A cross sectional study
19	Kibira	Monitoring access to UN Commission on Lifesaving Commodities in Uganda
20	Mehta	A Critical Analysis of Concentration and Competition in the Indian Pharmaceutical Market Catastrophic expenditure on medicines in Brazil
21	Yakubu	Implementing Nigerian National Drug Distribution Guidelines – re-modelling and strengthening Jigawa State drug distribution channel to set standards for replication
22	Schneider	Same problem, same solutions? – A survey of initiatives to reduce polypharmacy
23	Tetteh	Changes in creatinine clearance over time in a patient cohort on tenofovir as part of combined antiretroviral therapy
24	Sagwa	Linking treatment and laboratory databases to study biochemical abnormalities associated with multidrug-resistant tuberculosis treatment in Namibia

Session 3a - Thursday 7 January 2016

15:15 - 16:45 - plenary session -

HTA and public spending**Session Chairs: Alessandra Ferrario (LSE) and Anke Hövels (UU)**

<i>Nr</i>	<i>Author</i>	<i>Title</i>
25	Makady	What is Real-World Data? A review of definitions based on literature and stakeholder interviews
26	Leonardo Alves	The impact of Quality of Life data on Relative Effectiveness Assessments of new cancer drugs in Europe
27	Kalf	Use of Social Media to Assess Patient Perspectives on Health-Related Quality of Life in Melanoma Patients
28	Luiza	Catastrophic expenditure on medicines in Brazil

Session 3b - Thursday 7 January 2016

15:15 - 16:45 - plenary session -

Qualitative policy research

Session Chairs: Jarno Hoekman (UU) and Vera Luiza (Fiocruz)

<i>Nr</i>	<i>Author</i>	<i>Title</i>
29	Moye Holz	Affordability and Accessibility of Medicines in Mexico – a Policy Analysis. Preliminary Results
30	Moscou	Examining the impact of pharmacogovernance on drug safety in Kenya
31	Cole	Transparency in the pharmaceutical industry: A study using the Access to Medicine Index
32	Williams	Facilitating Access to Suitable Advanced Medical Devices in Ghana and Sierra Leone