Information folder

Brocher symposium

Equitable access to controlled medicine: between drug control and human rights in post-market access in low- and middle-income countries

8-9 October 2015, Geneva area

Contents

1 INVITATION

Utrecht University (UU, Netherlands) and Durham University (DU, England)
jointly organise the Brocher symposium:

Equitable access to controlled medicine: between drug control and human rights in post-market access in low- and middle-income countries

The pharmaceutical life cycle is underpinned by a notion of mutual benefit. Participation in clinical trials is justified by the greater good, namely developing medicines to address society's most pressing medical needs. In other words, drug development briefly equals drug availability. It would be unrealistic to state that every individual participating in a clinical trial should have direct access to all medicines this person needs on a lifelong basis for access to medicines is subject to a complex interplay of factors, which often set a resource intense or disadvantageous threshold for low- and middle income countries. Hence, especially in resource poor regions equitable access if far from reality despite the profound need for such care. The result being, millions of patients suffer in disabling conditions, which could amount to violating their human rights. These factors include restrictive trade agreements and patent laws, malfunctioning or slowly adapting health systems, or vastly administrative and strict control procedures. These so-called general barriers principally apply to all medicines, regardless of their classification. However, to a small sub-class of medicines - controlled medicines - additional barriers apply. Controlled medicines are those medicines of which the active substance is scheduled under the international drug control treaties. These additional barriers apply exactly because of their controlled nature, including the international drug control system, which is held to lead to a major public health deficit: many patients cannot access controlled medicines because of the restrictive and prohibitive nature of drug control regulation, which in itself is held to increase the number of patients in need of controlled medicines. In 2011, the Global Commission on Drug Policy labeled the 'war on drugs' as failed and issued a call for revision. In response to this call, Utrecht University organised the expert meeting: *"Human Rights and International Drug Control: Status quo, challenges, and interdisciplinary perspective"* in November 2012 in Utrecht, The Netherlands. The present symposium is a follow-up to this meeting. The set-up is to scrutinize the deficit from a multidisciplinary perspective in light of advancing post-market access in low- and middle-income countries as the equitable end-point of the pharmaceutical life cycle.

We hope to have compiled a stimulating and interesting multidisciplinary programme with ample time for discussion and debate. Please see below the draft programme.

The event is sponsored and hosted by the Brocher Foundation and co-sponsored by Utrecht University with a matching grant of the Dutch Medicines Evaluation Board. The Brocher Foundation is a Swiss private, non-profit organization supporting and encouraging multidisciplinary research into ethical, legal, and social implications of new medical developments. Its scientific board is composed of leading international experts.

Marie Elske Gispen (UU) and Deryck Beyleveld (DU)

2 OUTLINE & PROGRAMME

2.1 OUTLINE SYMPOSIUM

The purpose of the symposium is to bridge the gap between academia, policy and practice, by bringing together a multidisciplinary group of stakeholders to discuss and evaluate steps taken and re-set and advance the research agenda in this complex and fast developing field. The symposium is divided into four sessions:

Session 1 **Equitable access to controlled medicine: an introduction**
This session includes an introduction to the topic, as well as presentation of preliminary conclusions of the study 'Advancing Access to Opioid Analgesics' carried out at Utrecht University. The purpose is to elaborate and distinguish the main pending scientific questions from a multidisciplinary perspective by reflecting on the topic from particularly a law, ethics, and social sciences perspective.

Session 2 **Continuous constraints and challenges: international, regional, and local perspectives**
The focus of this session is to map the field and to identify current global, regional, and local constraints and challenges which potentially hamper the provision of controlled medication, but also constraints and challenges in drug enforcement efforts to grant a clearer and more global of how the two objectives to control and allow medical access to scheduled substances interplay in today's practice.

Session 3 **Mandates to advance access to controlled medicines under international law: an interplay of the human rights and drug control frameworks**
This session focuses on the interplay of international law in the field of access to medicines and drug control. In particular the interplay of international human rights law and the international drug control treaties is further elaborated by distinguishing actor specific responsibilities under both frameworks and aims to grant a better understanding of how the mandates of different actors should be interpreted such that states are supported to comply with their obligations under both systems of law.

Session 4 **Advancing a research agenda: theory and practice**
Given the niche area the field of controlled medication studies is often regarded as, this session focuses on mainstreaming access to controlled medicine studies into broader and related fields of work. As such, this session aims to reflect on drafting a research agenda from different disciplines and methodologies including theoretical, practical, and parallel aspects.

2.2 PROGRAMME DAY ONE

Thursday 8 October (Full day)			
Time	***Event/Title***	***Speaker/Affiliation***	***Location***
8.00	Shuttle bus Hotel Longemalle – Brocher Foundation		
8.30-8.55	Coffee and registration		
9.00-9.05	Welcome	Marie Elske Gispen, Netherlands Institute of Human Rights (SIM)/Ethics Institute, Utrecht University & Deryck Beyleveld, Durham University	
Session 1: Equitable access to controlled medicine: an introduction		**Moderator: Marcus Düwell**, Ethics Institute, Utrecht University	
9.05-9.20	*How drug control hinders access to controlled essential medicines*	Ruth Dreifuss, Global Commission on Drug Policy	
9.20-9.45	*Towards a human rights-based model of drug-control: introduction and preliminary conclusions*	Marie Elske Gispen	
9.45-9.55	*Critical legal questions: the interface between the right to health and international drug control treaties*	Brigit Toebes, University of Groningen	
9.55-10.05	*Critical ethical questions*	Deryck Beyleveld	
10.05-10.15	*Critical questions from a global health perspective*	Hans Hogerzeil, University of Groningen	
10.15-10.45	*Panel discussion: what is essential?*		
10.45-11.00	**Coffee break**		
Session 2: Continues constraints and challenges: international, regional, and local perspectives		**Moderator: Brigit Toebes**	
11.00-11.15	*Global and regional perspectives on drug control: access to medicines the useful enemy*	Damon Barrett, International Centre on Human Rights and Drug Control/University of Stockholm	
11.15-11.30	*Global perspectives on access to controlled medication*	Martha Maurer, Pain & Policy Study Group	
11.30-11.45	*Regional perspectives on access to*	Lukas Radbruch, Bonn	

	controlled medicine: lessons learned from the ATOME-project	University/ATOME-project	
11.45-12.00	*Regional perspectives on access to controlled medicine: implementing palliative care models in Africa*	Fatia Kiyange, African Palliative Care Association	
12.00-12.15	*Local realities of access to controlled medicine provision*	Mhoira Leng, Mulago Palliative Care Unit	
12.15-13.00	*Panel discussion: what's the state of play in practice?*		
13-00-14.00	**Lunch**		
Session 3: Mandates to advance access to controlled medicine under international law: an interplay of the human rights and drug control frameworks		**Moderator: Sandra Ratjen,** International Commission of Jurists	
14.00-14.15	*The role of the OHCHR special procedures branch*	Dragana Korljan, Office of the High Commissioner of Human Rights – Special Procedures Department	
14.15-14.30	*The role of the International Narcotics Control Board*	Bernard Leroy, International Narcotics Control Board	
14.30-14.45	*Programmatic actors: UNODC's role in creating change*	Elizabeth Mattfeld, United Nations Office on Drugs and Crime	
14.45-15.00	*Programmatic actors: the role of the WHO*	Gilles Forte, World Health Organisation - Essential Medicines and Health Products Department	
15.00-15.15	*Advocacy and the role of civil society*	Katherine Pettus, International Association Hospice & Palliative Care	
15.15-15.30	**Coffee break**		
15.30-17.00	*Panel discussion: towards a synergetic interpretation?*		
17.30	Transfer to Hotel Longemalle		
19.00	Restaurant Café Papon (Geneva down town)		1 rue Henry Fazy – 1204 Geneva.

2.3 PROGRAMME DAY TWO

Friday 9 October (half day)			
Time	***Event/Title***	***Speaker/Affiliation***	***Location***
8.00	Shuttle bus Hotel Longemalle – Brocher Foundation		
8.30-9.00	Walk in/coffee		
Session 4: Advancing a research agenda: theory and practice		**Moderator: Lukas Radbruch**	
9.00-9.25	*Controlled medicines as a strong learning case for pharmaceutical policy analysis*	Aukje Mantel-Teeuwisse, Utrecht University WHO Collaborating Centre on Pharmaceutical Policy Analysis, Utrecht University	
9.25-9.40	*Towards a theory of access to medicines*	Marcus Düwell	
9.40-9.55	*Conflicts and human rights aspects of access to medicines studies*	Brianne McGonigle Leyh, Netherlands Institute of Human Rights (SIM)/Utrecht University	
9.55-10.10	*Access to medicines studies in LMICs*	Tim Reed, Health Action International	
10.10-10.25	**Coffee break**		
10.25-10.40	*Lessons from access to diabetes medicines for controlled medicines*	David Beran, Geneva University Hospital and Geneva University	
10.40-10.55	*Practical aspects of implementing palliative care models in LMICs in future research*	Chitra Venkateswaren, Founder/Clinical Director MEHAC Foundation	
10.55-11.40	*Panel discussion: what's next?*		
12.25-12.55	*Drafting of research agenda, post-symposium planning*		
12.55-13.00	*Closure*	Marie Elske Gispen & Deryck Beyleveld	
13.00-14.00	**Lunch**		
14.00	Shuttle bus Geneva Cornavin Station – Geneva Airport		

3 LIST OF ABSTRACTS & SPEAKER INFO PER SESSION

3.1 SESSION 1

ABSTRACTS

How drug control hinders access to controlled essential medicines (Dreifuss) The international drug control system is stoking a global crisis of inequitable access to controlled medicines. Of the global population, an estimated 5.5 billion live in countries with poor to nonexistent access to opioid analgesics, in particular morphine, resulting in the avoidable pain and suffering of people around the world. At the last estimate, 92 percent of the world's supply of morphine was consumed by just 17 percent of the global population that consumption primarily concentrated in the global north. Terminal cancer patients, end-stage AIDS patients, and women in labor suffering from uncontrolled pain are among the key impacted groups, with the World Health Organization (WHO) estimating that tens of millions suffer from unrelieved pain annually due to a lack of access to controlled medicines. In addition, only a fraction of people globally who inject drugs are able to access controlled medicines for treating opioid dependence. Under international drug control law and international human rights law, States have an obligation to ensure controlled medicines are made available to their populations; any restriction of access constitutes a violation of the right to health. Though a number of factors impose barriers to access, including weak healthcare systems and the lack of training of clinicians working on the ground, the international drug control system has been responsible for perpetuating the continual undersupply of controlled medicines. With an increasing number of States and UN bodies drawing attention to the lack of access to controlled medicines, we are reaching a critical juncture, particularly with the United Nations General Assembly Special Session on drugs approaching in 2016. The time for concrete action on the issue is now.

Towards a human rights-based model of drug-control: introduction and preliminary conclusions (Gispen) In this presentation, the complexity of access to controlled medicines is mapped as being both a concern to human rights law and international drug control. The presentation contains a normative conceptual part and an applied practical component. Firstly, the normative foundation of a human rights-based approach to drug control is elaborated using ethics and the system of human rights law to reconsider the existing 'principle of balance' in which access to medicines and the control of diversion are understood as non-hierarchical norms the realisation of which is equally urgent. After having established the normative basis of a human rights-based approach to drug-control, the presentation secondly deals with whether or not such an approach could be implemented within the present features of the international drug control framework. In doing so findings of two case studies carried out in Latvia and Uganda are shared after which general preliminary conclusions of the study are presented.

Critical legal questions: the interface between the right to health and international drug control treaties (Toebes) This presentation will address the interface between international human rights law and the international drug control regime. Specific attention will be paid to how the right to health as a human right is to be balanced against the drug control treaties. An important component of the right to health is the so-called AAAQ, resulting in the State's duty to ensure that all health-related services are available, accessible, acceptable and of good quality. To what extent does the international drug control regime adequately reflect these notions? And to what extent are other human rights concepts, eg. the so-called minimum core obligation to provide essential medical medicines, reflected by the international drug control treaties? On the other hand, is the human rights regime sufficiently equipped and refined to address and to emphasize everyone's right to good-quality 'controlled medicines'? In this context, should the right to health be balanced against other human rights, including the right to life and the right to physical integrity? And as an individual human right, is the right to health a suitable tool for addressing a public health goal such as ensuring access to controlled medication to the population at large?

Equitable Access to Controlled Medicine: Critical Ethical Questions (Beyleveld) Three fundamental questions must be addressed: 1 What are the values the support access to controlled medicine? 2 What are the values that support restriction of access to controlled medicine? 3 How are these values to be ranked in case of conflict? These lead to the following questions that must be answered to have an equitable policy for access to controlled medicine: a) What are the causes of conflict between the two sets of values? B) Can conflict be avoided or at least reduced in an equitable manner? C) If so, how? Presuming that the criterion for equitable access is respect for human rights, I will argue that it requires application of the principle that persons have both positive and negative rights to agency needs under the 'will' conception of rights, and that equitable access can only be achieved by decriminalisation of opiate drugs.

Critical questions from a global health perspective (Hogerzeil) This presentation will critically reflect on access to controlled medicines and the interplay of human rights and drug control from a global health perspective. Inasmuch this contribution aims to distill key conceptual questions and elements which could be subject to further study and investigation in addition to the legal and ethical issues discussed as well.

SPEAKER INFO

Ruth Dreifuss (born in 1940, single) studied in Geneva where she received a degree in economics with special focus on econometrics in 1971. In her varied professional career she served as hotel secretary, editor of the weekly journal Coopération, social worker, assistant at the Geneva University. She then worked nine years for the Swiss Agency for Development and Humanitarian Aid (Federal Department of Foreign Affairs) and became in 1981 Secretary of the Swiss Labour Union Federation. In that capacity, she was responsible for sectors including social insurance, labour law, gender equality and relations with the International Labour Organization (ILO). Ruth Dreifuss was elected Federal Councillor (Member of the Swiss government) in 1993 by the Federal Assembly (Parliament), and was re-elected twice. From 1993 to her resignation in 2002 she was Head of the Federal Department of Home Affairs, the ministry responsible for public health, social insurance, scientific research, higher education, gender equality and culture, so as environment until 1997. During the year 1999, Ruth Dreifuss was President of the Swiss Confederation. As responsible for public health and social insurance, she implemented a new policy in the fields of drug addiction and prevention of HIV/Aids. She was also in charge with the introduction of the new law on health insurance, which guaranties a universal coverage for the Swiss population. After her retirement from government, she contributed to the WHO report on intellectual property rights, innovation and public health. Ruth Dreifuss is a member of the Global commission on drug policy and of the International commission against death penalty. She is Chancellor of the University for Peace (established as a Treaty Organization with its own Charter to support the central Peace and Security Objectives of the United Nations). Ruth Dreifuss is Doctor honoris causa of the Universities of Haifa, Jerusalem and Fribourg (Switzerland).

Marie Elske C. Gispen obtained her LL.M. Degree in Fundamentals of Law focusing on International Human Rights Law from Utrecht University (NL) in 2011. An adapted version of her thesis is published as a report to the International Federation of Health and Human Rights Organisations: 'Poor Access to Pain Treatment: Advancing a Human Right to Pain Relief' (2012). Marie Elske presently works as a Ph.D. researcher at the Netherlands Institute of Human Rights (SIM) / Ethics Institute of Utrecht University analysing a human rights-based model of drug control with a special focus on advancing medical access to controlled substances. Marie Elske will finish her PhD in 2016. Prior to which she worked as a junior researcher on the nature and scope of the obligations as deriving from the UN Convention on the Rights of Persons with Disabilities, a project assigned to SIM by the Dutch Ministry of Health, Welfare and Sports. In the past, she interned at the World Health Organization's Essential Medicines and Pharmaceutical Policies Department, in Geneva (CH) and co-authored the report: 'Essential Laws or Medicines Access: A Pilot Study on National Legislation' (2014). She also interned at the Netherlands Institute of Human Rights (SIM). She is senior research-associate to the International Centre on Human Rights and Drug Policy—a research institute of Essex

University (UK), fellow of Global Health Law Groningen, a member of the Dutch Lawyers Association, and a member of the Working Group on Economic, Social, and Cultural Rights of the Netherlands School of Human Rights Research. She is also a past Editor-in-Chief of the Utrecht Journal of International and European Law. As part of her doctorate research, Marie Elske conducts field research in Uganda and Latvia. As such she has been a visiting fellow at both the African Palliative Care Association (UG) and the Latvian Centre of Human Rights (LV). Marie Elske has also been a visiting scholar / seconded project coordinator at Durham University (UK) from October 2013 until March 2014. As of September 2015, Marie Elske is working temporarily as university teacher at Tilburg Law School (NL).

Brigit Toebes, PhD, is Professor and Rosalind Franklin Fellow in International Health Law at the University of Groningen, the Netherlands. Her specialist areas are human rights, in particular economic, social and cultural rights, the definition of health as a right, the broader interface between health and human rights, (international) health law, medical ethics, international humanitarian law, and public international law more generally. She has written widely in these areas, including books with Intersentia Publising (The Right to Health as a Human Right in International Law, 1999; Health and Human Rights in Europe, 2012), and articles in leading human rights and health law journals. She is the founder of Global Health Law Groningen, a programme that pays attention to the protection of health from the perspective of international law. She is Co-Chair of the Global Health Law Committee of the International Law Association and Board Member of the Netherlands Society of Health Law.

Deryck Beyleveld BSc (Rand) MA (Cantab) PhD (UEA) FRSB is Professor of Law and Bioethics, Durham Law School, and Professor of Moral Philosophy and Applied Ethics, Ethics Institute, Department of Philosophy and Religious Studies, Utrecht University. His publications range over criminology, moral philosophy, legal philosophy, and many areas of substantive law, with particular emphasis on the regulation of medical research and the regulation of biotechnology. He founded the Sheffield Institute of Biotechnological law and Ethics (SIBLE) at the University of Sheffield, which he directed from 1993 until 2006. He was Vice-Chair of Trent Multi-Centre Research Ethics Committee in the UK from 1997-2006. His many publications include *The Dialectical Necessity of Morality* (University of Chicago Press, 1991), and with Roger Brownsword, *Human Dignity in Bioethics and Biolaw* (OUP, 2001) and *Consent on the Law* (Hart, 2007).

Hans Hogerzeil MD, PhD, DSc (*h.c.*), FRCP Edin is Professor of Global Health at Groningen University (Netherlands) and Co-Chair of the Lancet Commission on Essential Medicines. He is also member of the Supervisory Board of the Access to Medicine (ATM) Foundation and Chair of the Expert Review Committee of the ATM Index 2016. He was for five years a mission doctor in India and Ghana and joined the WHO in 1985. He has advised over forty countries, including S-Africa, India and China, and recently Morocco, Ghana, Uganda and Iran, on the development of their national medicines policy and programmes. From 1999 to 2008 he was the Secretary of the WHO Model List of Essential Medicines. From 2004 to 2011 he was WHO Director for Essential Medicines, being responsible for all WHO's global policies, nomenclature and standards on medicines, the prequalification programme, and all technical support to Member States. From 2001 to 2011 he was the Chair of the Interagency Pharmaceutical Coordination Group of all major UN agencies, the Global Fund, the World Bank and UNITAID. Dr Hogerzeil is editor of several WHO books and wrote over 60 scientific papers on essential medicines policies. His recent interests include essential medicines for reproductive health, and access to essential medicines as part of the fulfillment of the right to health.

3.2 SESSION 2

ABSTRACTS

Global and regional perspectives on drug control: access to medicines and the useful enemy (Barrett) This presentation considers challenges in access to medicines for people who require opioid substitution therapy. It will discuss regional and global access to methadone, buprenorphine and diamorphine for this purpose. Focusing on the social construction of people who use drugs it will invite the audience to consider contradictions within the UN drug control system and the recommendations of the International Narcotics Control Board – contradictions between people who use drugs as 'criminals' and 'patients'; and between access to certain opiates versus others. It will ask how efforts to ensure access to essential controlled medicines can help break down the artificial distinctions between deserving and undeserving patients, and whether the crisis in access can ever be resolved without simultaneously challenging the threat based narrative that has underpinned the drug control regime since its inception.

Global perspectives on access to controlled medication (Maurer) The adequate accessibility of many controlled essential medications is severely lacking throughout the world. This presentation will provide an overview of the current state of the global unmet need for controlled essential medications. Specific examples of the unmet need for controlled essential medications will be provided, such as the lack of: (1) opioids for the treatment of opioid dependence, moderate to severe pain and anesthesia, (2) barbiturates/ benzodiazepines for the treatment of epilepsy, and (3) the precursor medicines ephedrine and ergometrine used for emergency obstetrics. Finally, the presentation will discuss the overarching complex inter-related systemic factors that contribute to the global phenomenon of inadequate access to essential controlled medicines.

Regional perspectives on access to controlled medicine: lessons learned from the ATOME-project (Radbruch) The Access To Opioid Medication in Europe (ATOME) project was initiated by the Access to Controlled Medications Programme of World Health Organization (WHO)(funded under the 7th Framework Programme of the European Community in 2009, and has just come to an end after five years project work in November 2014. The project investigated why opioid medicines for moderate to severe pain and for the treatment of opioid dependence are not used adequately in twelve European countries, and developed tailor-made solutions for improved access to opioid medicines in these countries. In this presentation the key findings of this project are addressed as well as the broader implications of this study are discussed.

Regional perspectives on access to controlled medicine: implementing palliative care models in Africa (Kiyange, co-authored with Emmanueal Luyirike – Director African Palliative Care Association) Excellent pain and symptom control is one of the key goals of palliative care for people with life limiting illnesses. There is evidence that HIV, cancer and other chronic illnesses cause pain, and patients have a right to have it controlled. Opioids, which are controlled medicines are recommended by the WHO as the best option for managing moderate to severe pain. In 2012, the African Union (AU) adopted a common position on controlled substances and access to pain management drugs. AU urges member states to put in place a functioning system for managing the availability of narcotic drugs and psychotropic substances. The system must make such medicines available for the relief of pain and suffering by ensuring the safe delivery of the best affordable drugs to those patients who need them and, at the same time, prevent the diversion of drugs for the purpose of abuse. States must ensure an effective supply system through regulation, data management and reporting and should build capacity locally. Although improvements in the availability and access to opioids have been registered in several countries in Africa, the lack of such medicines continues to be a major barrier to the provision of palliative care services. The average morphine consumption per capita in Africa is 0.315mg, way below the global average of 6.28 mg. Seychelles, which tops the Africa morphine consumption list is below the global average according to the 2012 International Narcotic Control Board data, released in 2015 by the Pain and Policy Studies Group University of Wisconsin

Carbone Cancer Center WHO Collaborating Center. Recent studies and experiences on opioids estimation and consumption in Mozambique, Swaziland, Zimbabwe, Malawi and Botswana identify several challenges and barriers for the provision of controlled medicines. These include: stringent laws, lacking a balance between control and availability for medical use; inaccurate procedures for deriving annual consumption estimations rather than the use of morbidity and mortality data; fear of opioids use and attitude among service providers; stock-outs; inaccessibility in rural areas and distances to facilities with opioids; ignorance on part of the key players in the supply chain mechanism such as drug regulatory and enforcement personnel; inadequate interpretation of local medicines laws, user fees; inadequate numbers of prescribers and the lack of prescription knowledge and skills. Through a presentation and discussions, the speaker will elaborate this perspective further at the workshop.

Local realities of access to controlled medicine provision (Leng) Appropriate policies, clear advocacy, educational initiatives, medicines procurement systems and effective implementation are essential in ensuring essential medicines are available and accessible to the end user. This end user is a person; who has a clinical problem; who is part of a family and a community; who is interacting with formal and informal health and social systems. This complexity and it's inevitable constraints and challenges will be illustrated from the perspective of the local setting using actual narratives from 3 continents (sub Saharan Africa, India and Chile). Key to these constraints is poorly functioning health systems and lack of integration within these systems. Medications may be theoretically available but not in the right place, or at the right cost, or with the right formulations. Many times attempts to change this involve making access to controlled medications a special case but this can further compromise the overall fragile procurement systems. Transport and logistics can also complicate the situation where lack of health care capacity including controlled medications prescribers is exacerbated by costs and availability of transport and lack of information. This can create significant inertia which results in denial of access to those suffering. In order to address these constrained health systems we need an approach that delivers values based change that is positioned as an integrated part of the health and social systems in order to improve functioning. Other issues that will be presented as contributors to these constraints include access to competency based health education that empowers the individual and community, addressing the realities of poverty and its causal relationship with chronic illness, understanding the underlying historical and cultural narratives and managing the impact of myths and beliefs. Ways of addressing these realities will be illustrated and include values based change at personal and systems levels, role of local champions, empowering communities, developing and implementing policy, mentorship and clinical modelling, working as effective teamwork, strategic approach to models of care, excellent advocacy and policy initiatives all underpinned by an appropriate evidence base.

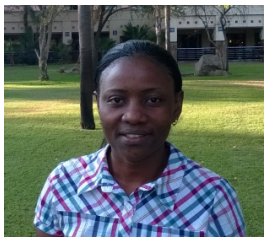
SPEAKER INFO

Damon Barrett is a Director of the International Centre on Human Rights and Drug Policy, which he co-founded in 2009. He is recognised internationally for his leading work in the areas of human rights and drug control, with a focus on systemic incoherence between these regimes; human rights and the international institutions of drug control; harm reduction and the right to health; and drug policy and the rights of the child. He regularly delivers lectures and publishes on these and other topics. Damon is currently a Visiting Fellow at the Human Rights Centre, University of Essex. He was a civil society member of the UK delegation to the UN Commission on Narcotic Drugs from 2008-2011 and from 2007-2014 he worked at Harm Reduction International, including as Deputy Director from 2012-2014. Damon is currently a PhD candidate at the School of International Studies and Faculty Law in Stockholm University, researching the international legal implications of drug policy reform. He lives in Göteborg, Sweden.

Martha A. Maurer MSSW, MPH, PhD is the Policy Program Manager and a Researcher at the Pain & Policy Studies Group (PPSG), a global research program at the University of Wisconsin Carbone Cancer Center within the School of Medicine and Public Health. The PPSG mission is to improve global pain relief by achieving balanced access to opioids in an effort to enhance the quality of life of people living with cancer and other painful diseases. The PPSG is nationally and internationally

recognized for its work and leadership to improve availability of opioid pain medicines, having been at the forefront of such efforts since its creation in 1996, since which time it has been the home of a World Health Organization (WHO) Collaborating Center (CC). Currently, it is the WHOCC for Pain Policy and Palliative Care. Throughout her 16-year career at the PPSG, Dr. Maurer has been involved in efforts to improve opioid availability and patient access to pain medications within the United States as well as globally. Early on in her tenure at PPSG, she gained experience in policy analysis and evaluation as a member of a team which performed content analyses of U.S. policies and integrated the results into an historical policy context. Dr. Maurer was instrumental in developing several editions of "Achieving Balance in Federal & State Pain Policy," reports which have been used by healthcare professionals and state policy-makers to improve their policy environment related to pain management. In the late 2000's, Dr. Maurer transitioned to focus on the PPSG global work. Since then, she has presented at numerous multi-country opioid availability workshops, been involved in individual country projects, and has been instrumental in the PPSG's International Pain Policy Fellowship (IPPF) program, becoming the IPPF program Co-Director in 2012. Initiated in 2006, the IPPF program empowers champion change-agents from low- and middle-income countries to work with their governments to evaluate and implement systems and policy changes to make opioid medicines available for patients receiving palliative care services in their countries. Since its inception in 2006, the IPPF program has trained 30 fellows from 25 countries around the world. Dr. Maurer completed her PhD in Social Welfare at the University of Wisconsin-Madison, where she had a concentration on aging and end-of-life care research. Her doctoral work involved examining a national dataset of hospice care patients looking at predictors of very short lengths of stay in hospice care programs. She also received a master's degree in Social Work and a master's degree in Public Health from the University of Wisconsin-Madison.

Lukas Radbruch holds the Chair of Palliative Medicine at the University of Bonn since 2010. He is president of the German Association for Palliative Medicine and chair of the International Association for Hospice and Palliative Care (IAHPC) since 2014. He was president of the European Association for Palliative Care (EAPC) during 2007-2011 and has been a member of the Steering Committee of the Research Network of EAPC since 1996. Dr. Radbruch attended medical school in Bonn, graduating in 1985. He completed his training in anaesthesiology at the University of Cologne. He chaired the pain clinic of the University of Cologne from 1995 to 2003, when he moved to Aachen where he set up the new Chair of Palliative Medicine at the University of Aachen. Since 2010 he is the Chair of Palliative Medicine at the University of Bonn and the director of the Centre of Palliative Medicine at the Malteser Krankenhaus Seliger Gerhard Bonn / Rhein-Sieg. He has published extensively, with his main research interests are symptom assessment, opioid treatment, fatigue, cachexia and ethical issues in palliative care.



Fatia Kiyange holds a Masters Degree in Social Sector Planning and Management of Makerere University, Kampala and a Bachelor of Arts Degree in Social Work and Social Administration of the same University. She also holds a Post Graduate Certificate in Health Protection with the University College Cork, Ireland, and is currently in the final stages of a Masters of Public Health Course with the same University. Ms Kiyange is the Programmes Director of the African Palliative Care Association (APCA), having served as the Training and Standards Manager of the same organisation until March 2010. Before joining APCA, Ms Kiyange worked with Hospice Africa Uganda as the Education Administrator for five years. She also served on the first Research and Ethics Committee of Hospice Africa Uganda and has fourteen years' experience working in the area of palliative care. Ms Kiyange has authored and co-authored several peer reviewed research papers on palliative care and contributed to palliative care reference books including the 2015 Oxford Textbook of Palliative Nursing. She serves on several boards including: Palliative Care Association of Uganda as board president till November 2014; International Palliative Care Children's Network, and the National Association of Social Workers in Uganda. Ms Kiyange has 15 years of experience working in the field of palliative care advocacy, programming, education and training, working closely with African ministries of health and other key stakeholders. Ms Kiyange has also accumulated a wealth of knowledge and skills in these key areas: programme development, management, implementation as well as monitoring and evaluation; programme and service reviews;

grant management; management and administration in Non-Governmental Organizations; Health Planning and Management including Health care systems, policy analysis and development, drug availability, national, regional and international frameworks; Social Work and as well as Research Methods.

Mhoira E. F. Leng, Palliative care physician; MBChB, MRCP(UK), FRCP(Ed and Glas) is currently Medical Director Cairdeas International Palliative care Trust Head of Makerere University Palliative care Unit, Kampala *Ms. Leng's areas of interest are:* International palliative care and health system strengthening; working with partners to build capacity, offering mentorship, supporting curriculum development, contributing to evidence based practice and developing new models of integrated care. *Ms. Leng's Contribution to palliative is:* Background in internal medicine and working in palliative care for 24 years including10 years as head of palliative care in Grampian Region, Aberdeen, Scotland. I have been involved with international palliative care since 1998 in Africa, Eastern Europe and India; which I first visited in 1999 and continue to work alongside partners including Pallium India, Guwahati Pain and Palliative Care Society, Mental Health Action Trust and Emmanuel Hospitals Association. Life member of Indian Association for Palliative Care since 2001, mentor to the International Leadership Development Initiative, honorary academic in Edinburgh University and board member of the International Association for Hospice and Palliative Care. Medical Director and founder of Cairdeas International Palliative Care Trust (Scotland) which seeks to work with partners to build capacity for palliative care. Since 2008, first head of Makerere University and Mulago Hospital Palliative Care Unit (MPCU), Kampala. Key achievements include development and implementation of a model integrated clinical service in an national teaching hospital, building evidence based practise and research capacity, values based changes within undergraduate and postgraduate curriculum delivery including innovative MMed training and contribution to a BSc in Palliative Care run by IHPCA/ HAU, sustainable integration within a government setting and regional mentorship and support to RICK, Sudan. A major project working with MPCU, the University of Edinburgh and the African Palliative Care Association has been to build capacity for integrated palliative care in 12 hospitals hubs in 4 African countries (Uganda, Rwanda, Kenya and Zambia). This is through a grant from THET via DFID-UK and is currently being evaluation showing significant health systems change. www.cairdeas.org.uk, www.mhoiraleng.blogspot.com, dr@mhoira.net

3.3 SESSION 3

ABSTRACTS

The role of the OHCHR special procedures branch (Korljan) The special procedures of the Human Rights Council are independent human rights experts with mandates to report and advise on human rights from a thematic or country-specific perspective. The system of Special Procedures is a central element of the United Nations human rights machinery and covers all human rights. Special procedures undertake country visits; act on individual cases and concerns of a broader, structural nature by sending communications to States and others in which they bring alleged violations or abuses to their attention; conduct thematic studies and convene expert consultations, contribute to the development of international human rights standards, engage in advocacy, raise public awareness, and provide advice for technical cooperation. Special procedures report annually to the Human Rights Council; the majority of the mandates also reports to the General Assembly. The mandate of the Special Rapporteur on the right to of everyone to the enjoyment of the highest attainable standard of physical and mental health was originally established by the Commission on Human Rights in April 2002 by resolution 2002/31. Subsequent to the replacement of the Commission by the Human Rights Council in June 2006, the mandate was endorsed and extended by the Human Rights Council by its resolution 6/29 of 14 December 2007.

The role of the International Narcotics Control Board (Leroy) Several decades ago, the international community made a solemn commitment with the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol and the Convention on Psychotropic Substances of 1971 to make adequate provision to ensure, and not to unduly restrict, the availability of drugs that were considered indispensable for medical and scientific purposes. In recent decades, that promise has not been completely fulfilled. Too many people still suffer or die in pain or do not have access to the medications they need. Unnecessary suffering resulting from a lack of appropriate medication due to inaction and excessive administrative requirements is a scandal that shames us all. In such context, the International Narcotics Control Board (INCB) is promoting the consistent application of the international drug control treaties. Established in 1968 in accordance with the Single Convention on Narcotic Drugs, 1961, INCB includes 13 members who are elected by the Economic and Social Council. Among its functions, INCB : i)Ensures adequate supply of drugs for medical and scientific purposes. ii) Monitors Government's control over chemicals used in the illicit manufacture of drugs. iii) Assists Government's in preventing diversions from these chemicals into illicit traffic. iv) Identifies and helps to correct weaknesses in drug control systems. v) Determines which chemicals used to illicitly manufacture drugs should be under international control. vi) Converses with Governments to ensure adherence to provisions of the United Nations conventions. vii) Proposes appropriate remedial measures to Governments that are not fully applying the provisions of the treaties. viii)Conduct questionnaires to assess general consensus on State's attitudes towards efforts. For INCB, inadequate access contradicts the notion of article 25 of the Universal Declaration of Human Rights, including the right to medical care, which also encompasses palliative care. The data related to psychotropic substances show disparities among countries and regions in the levels of consumption of such substances. Inadequate availability and poor access to necessary medical treatment, as well as excessive availability and medically unsound use of psychotropic substances, all pose challenges to their control and use.

Programmatic actors: UNODC's role in creating change (Mattfeld) Patient care decisions must be made based on sound medical science and practice, within an effective policy framework that increases access to controlled drugs for medical purposes while preventing diversion and abuse. The complexities of this dynamic are often delicate and intricate at the country level as well as in local practice. Over the past three years, UNODC has worked to implement The Joint Global Program to support Member States as they create an environment in which the cancer patient is able to receive effective management of pain or palliative care measure and policies are in place to deter the misuse of medical prescriptions. This requires building the capacity of healthcare practitioners, engaging the community in advocacy efforts and engaging in policy practice that supports increased access to those in medical need. The

Joint Global Program ensures coordination and collaboration between three organizations to address this balance. The Resolutions of the 53rd and 54th sessions of the Commission on Narcotic Drugs (CND), the Discussion Paper prepared by UNODC for the 54th session of CND, the INCB's 2010 Annual Report, and particularly its Supplement 'Availability of internationally controlled drugs: ensuring adequate access for medical and scientific purposes',1 and the WHO's revised 'Ensuring balance in national policies on controlled substances: guidance for availability and accessibility of controlled medicines'2 provide the substantive background to move forward. Union for International Cancer Control (UICC) provides the valuable link to the community and advocacy initiatives since 1933. And, most recently the WHO has passed a ground-breaking resolution in 2014 to urge countries to integrate palliative care into healthcare systems, improve training of healthcare workers and ensure relevant medicines are available.

Programmatic actors: the role of the WHO (Forte) WHO has an unambiguous role in international law in terms of access to medicines and drug control, not least through its Expert Committee on Drug Dependence (ECDD). The preamble of the 1961 and 1971 international drug control conventions recognize that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes (1961); and that that the use of psychotropic substances for medical and scientific purposes is indispensable and that their availability for such purposes should not be unduly restricted (1971). Further mandate has been given to WHO in this regard through World Health Assembly resolutions (including 58.22, 67.19). A request for such a review can be initiated by a notification to the Secretary-General of the United Nations by a Party to the Conventions, or by WHO itself. WHO, through the ECDD, is required by both conventions to recommend if a substance should be placed under international control or if the level of control should be changed, after examining the risks of dependence and harm due to use of each substance and considers therapeutic usefulness of the substance. The ECDD makes recommendations through the WHO Director-General and UN Secretary-General to the Commission on Narcotic Drugs for further decision. With respect to control under the 1971 convention, WHO's assessment is determinative for scientific and medical matters, but CND may also take into account legal, administrative, economic, social and other factors in reaching its decision.

Advocacy and the role of civil society (Pettus) The role of civil society in improving access to controlled medicines for pain relief, palliative care, and opioid substitution therapy depends on the national and regional context, as well as the level at which the advocacy is exercised. Political and attitudinal constraints and supports differ in each country and each context. Partners on the ground Uganda, for example, are supported by the Ministry of Health, the national university, the church, and multiple NGOs. Partners in Pakistan and the Russian Federation, on the other hand, face more hostile environments and multiple constraints on advocacy. As someone working at the international level, particularly focusing on the upcoming UN General Assembly Special Session on the World Drug Problem, to be held in April 2016, my job is to support clinical partners on the ground in multiple countries, and raise "official" awareness at the national levels — in capitals, with Ministries of Health, Justice, Narcotics Control, Foreign Affairs, and so on. At the international level, the work is to both raise awareness at the UN bodies: the Commission on Narcotic Drugs, the Human Rights Council, the WHO, the Open Ended Working Group on Ageing, and among civil society groups working on health rights, the rights of women, older persons, indigenous groups, and children. It is very much a "joining up the dots" effort, identifying and activating already existing work plans and synergies that can be fruitfully directed towards achieving specific advocacy goals at the national, regional, and international levels. Knowledge translation and consistent advocacy can overcome the barriers and gaps generated by fear, fragmentation, and the inevitable silo mentality that characterises bureaucratic specialisation.

1 International Narcotics Control Board, 'Report of the International Narcotics Control Board on the availability of internationally controlled drugs: ensuring adequate access for medical and scientific purposes', New York 2011.
2 World Health Organization, 'Ensuring balance in national policies on controlled substances: guidance for availability and accessibility of controlled medicines', Geneva 2011.

SPEAKER INFO

Dragana Korljan Dragana Korljan is a human rights officer and Cooridinator of the Justice, Protection and Social Right Unit in the Special Procedures Branch. She is responsible for providing support to eight special Procedures thematic mandates dealing both with social, cultural and economic rights such as right to health, education, cultural rights, and civil and political rights, such as independence of judges and lawyers, human rights defenders , freedom of expression and transitional justice. With an academic background in law, she has significant experience in the field of human rights. She has worked with a number of international organizations, including different UN agencies, and the exposure to the work of different organizations has enabled her to gain an overall view of human rights and develop sound knowledge of human rights implementation at both international and national levels. Before joining OHCHR in 2005, she worked with the Ministry of Foreign Affairs of then Yugoslavia and was actively involved in preparation of monitoring reports on the fulfilment of its obligations related to human rights.

Bernard Leroy is born in 1948. National of France. Honorary Deputy Prosecutor General and Director of the International Institute of Research against Counterfeit Medicines. Degrees in Law, University of Caen, Institute of European Studies, Saarbrucken, Germany, and University Paris X. Graduate of the French National School for the Judiciary, 1979. Previously held positions of Deputy General Prosecutor, Versailles Court of Appeal, 2010-2013. Senior Legal Advisor, UNODC, 1990-2010. Advisor in charge of international, legislative and legal affairs in the French National Drug Coordination, 1988-1990. Investigating judge specializing in drug cases, Evry High Court, 1979-1988. Head of the Legal Assistance Programme, UNODC, and Coordinator of the decentralized team of legal experts, Bogota, Tashkent and Bangkok, 1990-2010. Leader of the legal assistance team assisting the Government of Afghanistan in the drafting process of the new drug control law, 2004. Co-author of the preparatory study to the law introducing Community Service Sentencing as an alternative to imprisonment in France, 1981. Co-founder of 'Essonne Accueil', a non-governmental organization providing treatment services for drug addicts, 1982. Member of the French delegation for the final negotiations of the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988. Chair of the study group on cocaine trafficking in Europe, Council of Europe, 1989. Author of the report resulting in in the first European Political Coordinating Committee to Combat Drugs, 1989. Chair of the World Bank and UNODC joint team (StAR Initiative) which organized the freezing and subsequent recovery in Switzerland of the assets stolen by the dictator Duvalier in Haiti, 2008. Organizer of the life-long learning programme on combating drug trafficking and addiction for members of the French judiciary, French National School for the Judiciary, 1984-1994. Lecturer for medical graduates in psychiatry in the field of forensic expertise and responsibility, School of Medicine, Paris-Sud University, 1983-1990. Lecturer in the field of social work, University of Paris 13, 1984-1988. Lecturer for second year Masters' courses in Security and Public International Law, Jean Moulin Lyon 3 University, 2005-2013. Member of the Executive Board of the international section of the National Association of Drug Court Professionals, 2006. External member of the Management Board of the French Monitoring Centre for Drugs and Drug Addiction, 2013. Member of the committee of the Reynaud Report, 2013. Member of the International Narcotics Control Board (since 2015).

Elizabeth Mattfeld has a M.S., in Community Psychology, with over twenty years of experience in public health, drug prevention and drug treatment. Currently she is a Project Coordinator with the United Nations Office on Drugs and Crime. In this capacity, she oversees two global programs, one specifically addressing the critical issue of increasing access to controlled drugs for medical purposes while preventing diversion, misuse and abuse. Her work includes a focus on legislation, policy, training of health professionals and increasing community awareness within a patient-centered

approach to controlled drugs for medical purposes, palliative care and pain management, at the local, national and global levels. Previous work in the United States as Executive Director of the National Liquor Law Enforcement Association, a Senior Consultant with Strategic Applications International, and implementation of national programs and grants through the Department of Justice as well as Health and Human Services provided valuable opportunities to implement large-scale coordinated projects with the field of addiction medicine.

Gilles Forte, Coordinator of Policy, Access and Use at the Department of Essential Medicines and Health Products, WHO, Geneva, has played a leading role in the development of global pharmaceutical and medicines policy over more than two decades. A trained pharmacist and public health specialist, he is responsible for developing WHO standards on medicines and medical devices policy, and for managing support to help countries strengthen their pharmaceutical systems, work that includes the EU/ACP/WHO Renewed Partnership and the WHO Good Governance for Medicines programmes. Dr Forte also leads the secretariats of the Expert Committee on Selection and Use of Essential Medicines and the Expert Committee on Drug Dependence. He is responsible for the department's work on WHO priority programmes, including antimicrobial resistance. Dr Forte holds a doctorate in pharmacy and a Master's degree in pharmacology and nutrition. From 1999 to 2005, he was the WHO focal point for pharmaceutical policies for the African Region at WHO headquarters. He contributed to the establishment of a network of WHO Medicines Advisers in 20 countries in Africa, which has now expanded to all WHO regions. Previously, he was based in the WHO Regional Office for Europe in Copenhagen, where he oversaw WHO pharmaceutical collaboration with countries of Central and Eastern Europe. During the break-up of the former Yugoslavia, he was based in Zagreb as Medicines Policy and Supply officer for WHO emergency operations. The first-hand insight into the cost to countries of inappropriate medicines donations during the crisis led him to co-author the first WHO Guidelines for Drug Donations and WHO Guidelines for Safe Disposal of Pharmaceuticals. He has also developed a series of emergency medical kits. Dr Forte has extensive experience in the NGO sector, having worked with a number of aid agencies involved in development and humanitarian programmes in Africa and Eastern Europe. He has also held senior posts in the French public health system.

Katherine Pettus, Phd serves as the Advocacy Officer for Palliative Care and Human Rights for IAHPC (International Association for Hospice and Palliative Care), a global non-governmental organisation based in Houston, TX (http://www.hospicecare.com). She participates in meetings and conferences in Geneva at the Human Rights Council, and in Vienna at the Commission on Narcotic Drugs, interacting with mission representatives and building constructive relationships to further advance palliative care globally. Katherine holds a Doctorate in Political Theory from Columbia University in New York and a Masters' Degree in Advanced Studies in Health, Law and Policy from the University of California San Diego and California Western School of Law.

3.4 SESSION 4

ABSTRACTS

Controlled medicines as a strong learning case for pharmaceutical policy analysis (Mantel-Teeuwisse) Medicines are among the most regulated products in society. From the earliest pre-clinical stages onward, policy makers want to foster the development of safe, effective and affordable medicines for patients in need of pharmacotherapy. When a drug reaches the market, it is the beginning of a process of complex interactions between patients, prescribers, insurers, pharmaceutical companies and governments. Furthermore, the inequity in access to medicines is still a defining characteristic of the global pharmaceutical market place. The aim of this presentation is to give an overview of different phases in pharmaceutical policy analysis and existing frameworks for access to medicines and provide insight into current developments, complexity and diversity in (methods for) pharmaceutical policy analysis. Examples from the field of controlled medicines will be used as illustrations.

Towards an ethics of access to medicines (Düwell) The development of medicine and their availability is increasingly complex in a globalised world. Complicating factors are e.g. the diversity of relevant actors, the mismatch between national regulations and global pharmaceutical markets, and growing global inequality. This is increasingly complex for access to controlled medicines. On a global scale, human rights are forming the basic framework for regulation. Human rights, however, are insufficiently prepared to deal with the contemporary challenges to ensure access to medicines, partly because drug policy is not taking the human rights framework sufficiently into account. An ethical assessment of access to medicine is required. Such an assessment will therefore have to reflect on the conceptual and normative starting points of the human rights framework in order to investigate how human rights should inform contemporary law and policy. In relation to controlled medicines, such analyse should also include an ethical assessment of drug policy in general as well.

Conflicts and human rights aspects of access to medicines studies (McGonigle Leyh) While the public debate with regard to access to medicine is often limited to patent regulations and the pharmaceutical industry, a very real problem, inadequate healthcare and health infrastructure, often remains under exposed. A major aspect of healthcare and health infrastructure concerns access to medicine. Indeed, access to medicine is an established element of the right to health as enshrined in the International Covenant of Economic, Social and Cultural rights. Since the right to health is non-derogable, States also have an obligation to safeguard minimum essential levels of the right to health even in times of conflict. This is of paramount importance since conflict affects health both through direct violence as well as the breakdown of social structures and healthcare systems. Specifically, access to medicine can be affected since States deploy numerous physical barriers for victims and healthcare providers during times of conflict. Conflict thus increases the need for healthcare while it at the same time affects the access to essential medicines. Moreover, access to medicines can restrict the destructiveness of war, strengthen the social fabric, and thus contribute to the management of conflict and peace building efforts. The human rights implications are clear. This presentation will examine the legal framework of the right to health in times of conflict, including its limitations and contributions, and address what can be done to better understand and tackle the issue of access to medicine in times of conflict, highlight some examples that can serve as best practices.

Access to medicines studies in LMICs (Reed) Over 100 medicine price and availability surveys, using the WHO/HAI methodology, have been conducted in low- and middle-income countries, but few have concerned morphine. Data from these surveys will be presented concerning the availability and patient price of morphine in facilities in the public sector and in private retail pharmacies, as well as government procurement prices of this medicine. This data will then be compared with availability and price data for other medicines. The problem that remains concerns the limited data available and that more needs to be done to really understand the barriers to access – regulatory, supply chain or price.

Lessons from access to diabetes medicines for controlled medicines (Beran) Lessons from HIV/AIDS show that it is possible to deliver care and medicines for a complex chronic disease in LMICs. The difference between anti-retrovirals and medicines for Noncommunicable diseases (NCD), is that the medicines needed to treat cardiovascular disease, cancer, chronic respiratory diseases and diabetes present four distinct categories of challenges in terms of access: i) Oral medicines which are available in generic form, which are available cheaply on the international market yet are still not available in countries and are often of uneven quality; ii) Asthma inhalers and insulin – these are available at higher costs and to a certain extent are more complicated to manufacture. However, it is important to note that these medicines cost less than most antiretroviral regimens; iii) Some NCD medicines, especially those for cancer, are still under patent and price means they are accessible only via expanded access programmes of individual companies which lead to varied accessibility; iv) Effective and affordable pain management and opioid analgesics such as morphine, which are essential for palliative care and are of limited access in a series of countries due to regulatory limitations. Research using a standardised Rapid Assessment Protocol (RAP) in Kyrgyzstan, Mali, Mozambique, Nicaragua, the Philippines, Vietnam and Zambia led by the International Insulin Foundation found a variety of barriers to insulin access. This presentation will look at the issues identified for insulin and link these with issues relative to pain control and palliative care as well as presenting how the RAP approach might be of use for pain control and palliative care in low and middle income countries.

Practical aspects of implementing palliative care models in LMICs in future research (Venkateswaren) Reliable access to strong opioids, such as morphine, is a prerequisite to delivering quality palliative care. However, despite its designation as a World Health Organization essential medicine, morphine is drastically limited, or absent, in many low- and middle-income countries (LMICs), including India. In this context, identifying the gaps in the development and implementation of service delivery models is of significant importance. This should be underpinned by an understanding of the deeply embedded social and cultural dynamics, which are fundamental to the development of appropriate health policy and clinical practice. One glaring issue is the lack of reliable evidence generated in LMICS. Research has not been a priority when compared to clinical practice and organizational interests. Similarly what research there is tends to focus on general clinical research rather than policies and access to controlled medications. This again is influenced by the culture of medical education and practice in a country like India. The status and availability of research in this context will be outlined especially related to its outcomes and impact on policy or education. The session will also focus on information gathered from experience at the ground level in a clinical role, delivering services and its structural difficulties; and conducting educational programs including research workshops. It will also reflect the experience in palliative care across specialties and role in community based initiatives and will include the oft -neglected one of mental health. Models which have integrated research will be highlighted. This will help identify the gaps encountered in practice; relevant questions and possible options in research will be generated.

SPEAKER INFO

Aukje Mantel-Teeuwisse obtained her PharmD in 1998 at Utrecht University. After a few months working as a community pharmacist in Delft (Apotheek Tanthof), she started her PhD studies at the Division of Pharmacoepidemiology and Clinical Pharmacology of Utrecht University (promotores: prof. dr. A. de Boer and prof. dr. A.J. Porsius). After completion of her thesis in 2004 she started to work as an assistant professor at the same Division, a position she currently still holds. In the period 2005-2010 she worked part-time at the Dutch Medicines Evaluation Board as a liaison between UU and the MEB. Aukje has been appointed Director of the School of Pharmacy since 1 July 2014. At present, she is also the Managing Director of the WHO Collaborating Centre of Pharmaceutical Policy and Regulation. The Centre works closely together with WHO HQ and participates in the TI Pharma Escher project and EU ATOME (Access To Opoid Medication in Europe) project, among others. Her research interests include drug regulatory science, pharmacovigilance, pharmaceutical policy analysis and variation in medicines use across countries. She is involved in the bachelor and master Pharmacy programmes as well as in the master Drug Innovation programme.

Marcus Düwell (born in 1962) holds a chair for philosophical ethics at Utrecht University. He is director of the *Ethics Institute* of Utrecht University and director of the *Utrecht Research Institute for Philosophy and Religious Studies*. From 2005-2012 he was director of the *Netherlands Research School for Practical Philosophy.* Düwell studied Philosophy, German Literature and Theology in Tübingen and Munich. His PhD-thesis at the university of Tübingen was a philosophical investigation about the relationship between ethics and aesthetics. From 1993-2001 he was academic coordinator of the Interdepartmental Center for Ethics in the Sciences and Humanities at the University of Tübingen. His research interests include bioethics, ethics of climate change and general topics of moral and political philosophy, particular the ethics of human dignity and human rights. His current research projects are: Human Dignity as the Foundation of Human Rights? (Vici-Grant, NWO 2011-2016); What Can the Humanities Contribute to Practical Self-understanding? (director of the Horizon-Programma, NWO 2011-2016); *Rights to a Green Future* (director of the ESF-Thematic Network, 2011-2015); *Human Dignity in the Context of Bioethics – China and the West (*China Exchange Programme, CASS-KNAW, 2012-2016).

Brianne McGonigle Leyh, PhD is an assistant professor with the Netherlands Institute of Human Rights (SIM) / Utrecht University where she specializes in human rights, victims' rights and transitional justice. She is also a member of the Montaigne Centre for Judicial Administration and Conflict Resolution, an executive editor of the Netherlands Quarterly of Human Rights and co-directs the Utrecht Centre for International Studies (UCIS), which is a centre supporting and encouraging study and research on international issues across the humanities and law at Utrecht University. In addition to her academic work she co-directs the Netherlands Office of the Public International Law & Policy Group (PILPG).

Tim Reed, PhD has more than 30 years of experience in NGO management and medicines policy research. After directing a national UK-based charity for a decade, in 1997 Tim was awarded a BA Hons (first class) in Sociology with Development Studies from the University of Sussex in the UK and specialised in the Sociology of Health and Development and the Politics of Pharmaceutical policy. In 2003, he obtained his doctorate from Sussex for his thesis "The regulation of medicines in Central and Eastern Europe". He is one of the few holders of a PhD specifically in the politics of medicines regulation, and it led him to became a lecturer in health policy, medicines and development from 2003 to 2006. His work on related issues has been published in a number of books and peer-reviewed journals including *Science, Technology, Society*; the *British Medical Journal*; *Health Risk & Society*; *Social Studies of Science* and *Social Science and Medicine*. He also presented his work on medicines issues at numerous international conferences. Tim's commitment to social equality in health led him to Health Action International's European office in Amsterdam in 2005, where he became coordinator. First re-structuring the organization's governance and accountability, and then re-building a vibrant global network, in 2007 he was appointed as the organization's Global Director to manage global projects such as those conducted in partnership with WHO and the DFID sponsored Medicines Transparency Alliance (MeTA) international secretariat.

David Beran MSc, PhD is a Researcher and Lecturer at the Geneva University Hospitals and University of Geneva within the Division of Tropical and Humanitarian Medicine. Before this David was the Project Coordinator of the International Insulin Foundation based at University College London (UCL) where he developed and implemented a health systems tool to assess to access to diabetes care. This work was carried out in Kyrgyzstan, Mali, Mozambique, Nicaragua, Vietnam and Zambia and led to the development of specific policies and projects to address the barriers identified. David is a Swiss national who grew up in Geneva. He holds a BSc in Management with an Emphasis in Marketing. Following his first degree, he worked for a leading Swiss Biotech Company in both Health Policy and Government Relations and Public Relations. He then obtained his MSc in Public Health at the London School of Hygiene and Tropical Medicine. David's PhD at UCL researched the needs of people with Type 1 diabetes in 13

countries. His research interests include: health systems and health systems research; management of chronic diseases; diabetes; patient needs; access to insulin and the issue of multi-morbidity.

Chitra Venkateswaran (MD Psychiatry) is the founder/Clinical director of Mehac Foundation which is a not for profit organization working towards improving the quality of lives of mentally ill people and their families in Kerala and India incorporating principles of palliative care. They strive to deliver exceptional care focussing on strengthening mental health services and access to medications in the community and improving quality of care. She holds the post of Professor in Psychiatry in Department of Psychiatry and is faculty at the Department of Oncology and Palliative Care of Amrita Institute of Medical Sciences, Kochi. She devotes her time to the palliative care issues especially looking at psychosocial issues and in training and research. She has been focusing on identifying psychological distress in palliative care population as part of research and has carried out projects both in India and UK. She is a contributor for the development of Palliative Tool kit by Help the Hospices, UK. She was an UICC International Research Fellow from 2006 - 2008. As part of this fellowship she has been doing research on screening tools for psychological distress in palliative care in Leeds, UK. She initiated Psycho Oncology clinics in Pain and Palliative Care Society, Calicut, 2003 and in Amrita Institute of Medical Sciences, 2008. She is a National Faculty in Palliative Care in India, Indian Association of Palliative Care and Faculty/Consultant for Cairdeas, International Palliative Care Trust, Scotland, UK. She is a Leader in the International Palliative Care Leadership Development Initiative, The Institute for Palliative Medicine at San Diego Hospice, San Diego, CA, USA, 2012-2013.

4 INFORMATION FOR SPEAKERS & MODERATORS

4.1 POWERPOINT FACILITIES

All speakers are advised to bring a USB stick and make sure their presentations are uploaded before the start of each session.

4.2 TIME & SIGNS

All speakers are kindly asked to strictly observe the time allocated to their presentation (see programme). We seek the power of the symposium in a well-informed discussion hence we developed a programme in which speakers are allocated a fairly short period of time to briefly elaborate on an issue from their particular position or field of expertise. However, the key to success is to a large extent in hands of the moderators! Moderators are urged to keep a strict eye on time. Therefor we kindly ask all moderators to use the following sequence of sings, if necessary, to indicate to speakers the amount of time left: five minutes left (green); 2 minutes left (yellow); no time left, please wrap up (red). The signs will be available in the conference room.

5 LIST OF PARTICIPANTS

Name	Affiliation
Barrett, Damon	International Centre on Human Rights and Drug Policy/Stockholm University
Beyleveld, Deryck	Centre for Ethics and Law in the Life Sciences Durham University/Ethics Institute Utrecht University
Beran, David	Geneva University Hospital/Geneva University
Dreifuss, Ruth	Global Commission on Drug Policy
Düwell, Marcus	Ethics Institute Utrecht University
Ettinger, Kate	Mural Institute
Gispen, Marie Elske	Netherlands Institute of Human Rights (SIM)/ Ethics Institute Utrecht University
Hogerzeil, Hans	Groningen University
Kiyange, Fatia	African Palliative Care Association
Korljan, Dragana	Office of the High Commissioner of Human Rights special procedures branch
Leng, Mhoira	Mulago Palliative Care Unit, Makerere University, Kampala/Cairdeas International Palliative Care Trust
Leroy, Bernard	International Narcotics Control Board
Mantel-Teeuwisse, Aukje	Division of Pharmacoepidemiology and Clinical Pharmacology of Utrecht University
Mattfeld, Elizabeth	United Nations Office on Drugs and Crime
Maurer, Martha	Pain and Policy Study Group/University of Wisconsin
McGonigle Leyh, Brianne	Netherlands Institute of Human Rights (SIM) Utrecht University
Meer, van, Peter	Dutch Medicines Evaluation Board
Perehudoff, Katrina	Groningen University
Pettus, Katherine	International Alliance of Hospice and Palliative Care
Radbruch, Lukas	Bonn University
Ratjen, Sandra	International Commission of Jurists
Reed, Tim	Health Action International
Toebes, Brigit	Groningen University
Venkateswaren, Chitra	MEHAC Foundation

N.B. See for a most updated list of participants the Brocher website.