# EuroDURG bulletin

**No. 27** **February 2017**

**NEWSLETTER OF THE EUROPEAN CHAPTER OF THE SPECIAL INTEREST GROUP OF DRUG UTILISATION RESEARCH (SIG-DUR) OF THE INTERNATIONAL SOCIETY OF PHARMACOEPIDEMIOLOGY (ISPE)**

***Editors*** *The Bulletin was mainly prepared by the EuroDURG board and the ISPE DUR/HSR SIG chair. See also contributors on behalf of national groups. Send reactions to: benkoria@gmail.com*

## *The Chair's message*

**Dear Drug Utilization researchers**,

Happy New 2017!

Time runs fast and one month has already passed since the new year arrived. So far, it has shown to be a year of political instability and uncertainty – all over the world. It makes scientific organizations like EuroDURG and ISPE even more important to bring people from different countries together for research and pleasure.

What can we expect from 2017? Many predictions have been made by various organizations. Many of them, address the continuous changes in our societies linked to the megatrends of the 21st century; **ageing populations, technological advances, digitalization, urbanization** and **sustainability**. All these trends have implications for drug utilization research and we can e.g. expect:

- an increasing focus on inappropriate drug use in the elderly and management of chronic diseases in the population.
- increasing difficulties for payers to manage health budgets with large numbers of new expensive biological drugs coming.
- digitalization of healthcare with many large number of new products coming for drug delivery to patients and various smartphones monitoring patients' activity or real-time alerting medical devices.

All these trends clearly show that the importance of Drug Utilization research will continue to grow.

During 2016, EuroDURG celebrated two birthdays - 40 years ago, in 1976, the first informal Drug Utilisation Research Group was formed, often referred to as the WHO-DURG. 20 years ago, in 1996, at a meeting at Lake Balaton, Hungary the EuroDURG was formally established.

The main happening during the year was our new textbook "Drug Utilization Research – methods and applications" that came from the publisher. The book compiles a lot of important knowledge of importance for our research field and I recommend you all to tell all people interested in drug utilization in your country that they should order a copy. More information about the book is presented in this bulletin.

During the year that passed, people from our society were also active in many conferences including the 32st ISPE conference in Dublin, Ireland as well as conferences held by EACPT, ESPACOMP? NORPEN, and MURIA conferences. Since EuroDURG is an eclectic discipline with linkage to many other scientific areas, participation in these events is important for learning as well as spreading the ideas and concepts of DUR. Reports of these meeting are found in the bulletin.

During 2016 we kept the same board for EuroDURG as we elected on the Groningen meeting in 2014, i.e.:

Bjorn Wettermark (Sweden) – chair

Ria Benko (Hungary) – secretary

Brian Godman (UK) – treasurer

Elisabetta Poluzzi (Italy) – webmaster

Robert Vander Stichele (Belgium) – liason with ISPE

Monique Elseviers (Belgium)

Vera Vlahović-Palčevski (Croatia)

Begler Begovic (Bosnia and Herzegovina)

Marion Bennie (Scotland)

Janet Krska (England)

Katja Taxis (The Netherlands)

Annabirna Almarsdottir (Denmark)

Cathrine Sermet (France)

Gabriel Sanfélix-Gimeno (Spain)

Paraskevi Voula Papaioannidou (Greece)

Gisbert Selke (Germany)

Jolanta Gulbinovic (Lithuania)

I want to thank all of you for the active participation and engagement in all the activities we have done.

Overall, 2016 was a good jubilee year and I would like to thank all our members for paying interest in our activities.
During 2017 it is time for our own Drug Utilization conference again and I really look forward to see you all in Glasgow in November!

*Björn Wettermark*
*Chair of EuroDURG*
*European chapter of*
*ISPE SIG DUR*


**European Drug Utilisation Research Group (EuroDURG) Conference 2017**
**15-17 November 2017; Glasgow, UK**

## DUR BOOK HAS BEEN LAUNCHED!

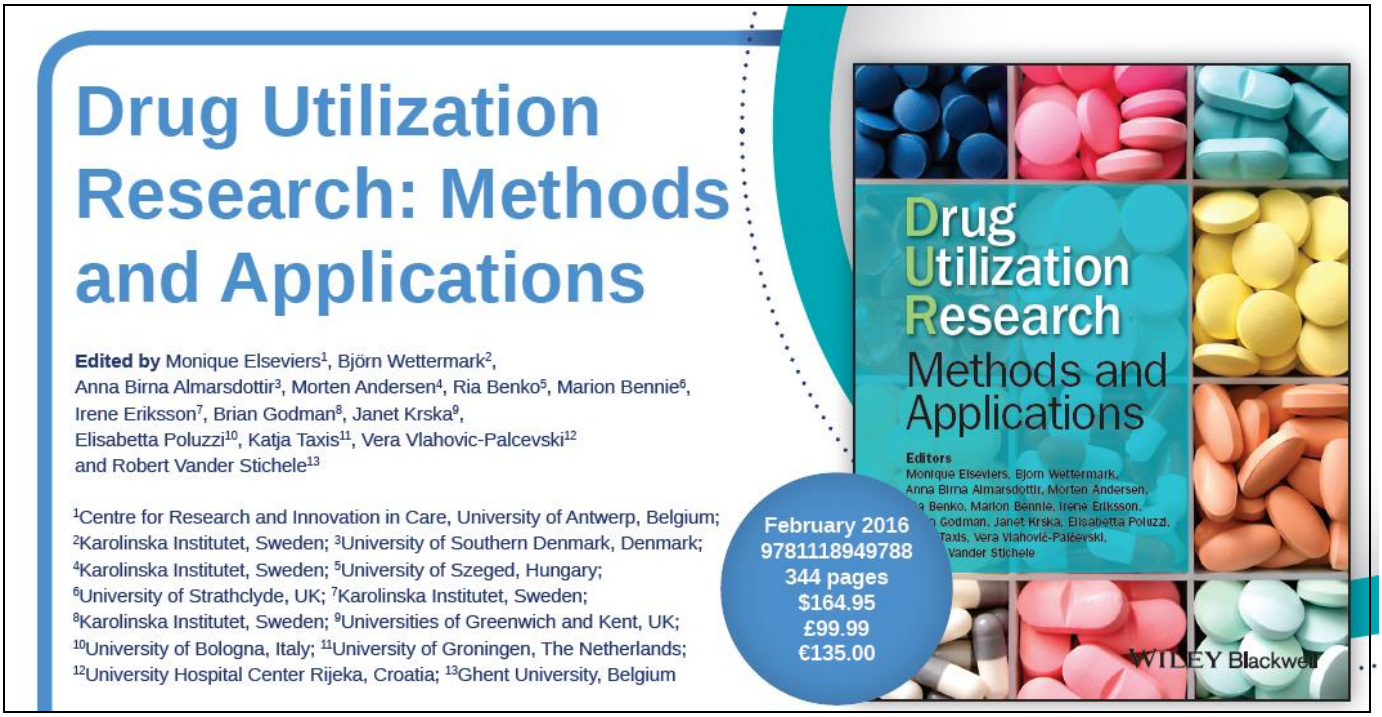
In the course of 2016, we were proud to announce the launch of our DUR book: Drug Utilization Research: Methods and Applications. During the ICPE meeting of last summer in Dublin, the book gained a lot of interest and the editorial board celebrated the launch during a special DUR book evening.

The realization of the book was an initiative of EuroDURG and the 13 editors are all closely related to the EuroDURG board. It took us more than three years from the first discussions on the content till the submission of the last chapters of the book. Exactly 100 authors contributed to the writing of the 48 chapters. After internal review, an additional 75 external reviewers were involved to bring the book to the final version.

The methodology section of the DUR book provides guidance on the wide range of methods used in the field. The principal aim of drug utilization research is to facilitate the safe and effective use of medicines in populations. This may be achieved in a variety of ways. Descriptive drug utilization studies can be used to stimulate discussions on potential over or underuse of medicines. Prescribing patterns may be compared with current recommendations and guidelines to identify areas for improvement. Analytical studies may be conducted to explore factors potentially influencing patterns of drug prescribing, dispensing or consumption. Qualitative studies are also needed to gain an understanding of the perceptions of prescribers, pharmacists and patients.

The applied drug utilization research sections are designed to illustrate recent developments in drug utilization research from different perspectives. The chapters of this applied part are grouped under the following headings:

- Section A: Comparative drug utilization research
- Section B: Drug utilization and health policy
- Section C: Drug utilization in specific populations
- Section D: Drug utilization in specific therapeutic areas



- Section E: Determinants of drug utilization
- Section F: Adherence and drug utilization research
- Section G: The role of drug utilization within the field of pharmacoepidemiology
- Section H: Assessment and improvement of the quality of medicine use

The complete Introduction chapter of the DUR book with more detailed information about the content is available at the ISPE/EuroDURG website and is accessible using the following link: http://pharmacoepi.org/pub/be6e050a-b69c-2a74-4c4a-4cf8f3dae421

The DUR book can be ordered directly via the publisher Wiley at: http://eu.wiley.com/WileyCDA/WileyTitle/productCd-1118949781.html

Should you be interested to promote the DUR book at a national or international meeting, please contact someone of the editorial board members to obtain flyers and a powerpoint announcement of the book.

*Monique Elseviers*
*chief-editor*



ISPE ANNUAL MEETING

## General summary of DUR related sessions

Many members of EuroDURG family travelled to the 32nd International Conference on Pharmacoepidemiology and Therapeutic Risk Management, held in Dublin from August 26-28, 2016. It was an opportunity to meet our friends from around the world.

**Thursday**

The conference officially kicked off on Friday 26th August within the futuristic walls of the Dublin conference centre. During this preliminary day, an introductory course and an advanced workshop on drug Utilisation Research was held. Thursday evening saw the academic showcase; a chance for delegates to chat to relevant institutions about their research and courses.

**Friday**

Sunny Friday morning started very early with a session on Cross-National Comparison guidelines and a meeting of the Latin American Chapter. ISPE organized a very lively poster session with also DUR walking tour. There were two plenary sessions: in the morning on representative sampling in Pharmacoepidemiology, and in the afternoon on the future of real world data. There were sessions on adherence and on drug utilisation in older populations. In the evening many EuroDURG friends from Europe and around the world gathered for a crypto-event on a river-sided boat to celebrate the launch of the DUR book.

**Saturday**

Saturday morning psycho-tropic use was all over the agenda, in pregnancy, attention deficit hyperactivity disorder (ADHD), Pain treatment, with a strong emphasis on the multinational perspective. In the afternoon, again adherence sessions, and focus on antipsychotics and biologicals. The impact of the advent of Big Data was the issue for the late afternoon sessions. In the early evening, the meeting of the SIG-DUR, with the involvement of different chapters (e.g. EuroDURG) was held (see below in this bulletin). The day ended with an unforgettable evening at the Guinness Storehouse with great bear and traditional Irish dancing, leading to collective frenzy.

**Sunday**

In the morning, Drug Utilisation Research was present in the session on diabetes and cardiovascular health. In the afternoon, there was a session on the development and introduction of innovative medicines and the role for pharmaco-epidemiology,risk management planning, and observational drug utilisation data. There were interesting sessions on

pattern recognition of drug use in longitudinal observational research, and on risk-benefit assessment.
In the afternoon, the sessions were on disease burden from clinical databases, the adverse outcomes of the glucocorticoid and immune-modulator use, and the transition to oral coagulants.

*Robert Vander Stichele*


The Drug utilization / Health Service research Special Interest group met during the 2016 ICPE conference in Dublin on Friday August 26th 2016. A record number of 68 people attended our SIG meeting. Currently, the Executive Committee consists of:

**Chair:**
Katja Taxis, Netherlands
k.taxis@rug.nl

**Past Chair:**
Lisa Pont, Australia
lisa.pont@sydney.edu.au

**Chair-Elect:**
Veronika Wirtz, United States
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**Educational Program:**
Douglas Steinke, UK
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Andy Gilbert, Australia
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**Communications:**
Gillian Caughey, Australia
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We summarized the DUR activities at ICPE 2016 which included the pre-conference educational sessions (coordinated by Doug Steinke), Introduction and Advanced course on Drug Utilisation Research, a Symposium – Drug Utilisation in Older Populations: The Irish View on Knowing Right from Wrong, the DUR Poster Spotlight Session. Overall, DUR was very well represented in both oral and poster Presentations. More on the content of ICPE 2016 in Dublin can be found vide supra in the Bulletin.

All chairs of regional networks present at the meeting gave an update on activities of their networks. For EuroDURG Bjorn Wettermark informed about the DUR Book, the development of the CNC guidelines and the next EuroDURG conference in 2017 (see also below). For Australia Lisa Pont informed about recent activities including: National Medicines Symposium, Medicines Use Research Australia (MURA) and 2017 ISPE's 10th anniversary Asian Conference on pharmaco-epidemiology to be held outside Asia: in Brisbane, Australia 2017 (Chair of the conference will be Frank May). Opioid Drug Utilisation Study Collaborative - an international working collaborative to examine global drug utilisation: opioid use and misuse with the aim to conduct multi-country study which should be examining amongst others, type of opioids available, policies around access and restrictions. Data so far, has been collated from UK (Li-Chia Chen and Teng-Chou Chen) and Australia (Gillian Caughey), to date. Any persons interested in being part of this group please contact Gillian Caughey (see email above).
For Latin America – LA DURG Marcella Jiron was present (mjiron@ciq.uchile.cl).

For Africa – Ilse Truter (Ilse.truter@nmmu.ac.za) informed about the establishment of MURIA (Medicines Use Research in Africa) and a working collaborative of about 18 people supported by Karolinska Institute and University of South Africa and facilitated by Brian Godman (see MURIA news below). For North America,Ingrid Sketris (ingrid.sketris@dal.ca) informed about a recently funded project from Canadian Government that includes DUR and that the next ICPE will be in Canada.

Finally, a number of researchers from Asia raised the question to establish a Asian DUR Network. The goal is to establish this by next years' ICPE. Those interested in helping to establish and be part of this group please email Gillian Caughey.

If you have any suggestions, comments, feedback or ideas

for the DUR SIG please contact Katja Taxis or Gillian Caughey (see emails above). Thanks!

*Katja Taxis*

## Report on the ESPACOMP meeting

For the 20th time, the ESPACOMP meeting on adherence was held, this time in Lisbon, 17 to 19 November, 2016. This society brings together the European researchers on the subject of patient adherence (formerly patient compliance) and a number of international guests from other continents.

The meeting was preceded with two educational courses. The first was on implementing and sustaining of adherence interventions in real world settings – A practical guide. The second was the start of an interprofessional course in optimizing patient's adherence to treatment in healthcare, which will be continued during 2017 by four 1.5-hour webinars.

A tribute was held for the recently deceased Prof. Dr. John Urquhart, a founding father of ESPACOMP, and a pioneer in electronic monitoring of compliance. His contribution to the field was remembered in a brilliant memorial lecture by Prof. Bernard Vrijens.

Keynote sessions addressed adherence in HIV and the patient and policy perspective. Views were presented on the impact of audit of the appropriateness of poly-pharmacy on adherence, and on the role of labeling. Two plenary speeches were devoted to motivating adult patients and children (and their families). From 89 abstracts a number of oral presentations were presented in 4 two by two parallel sessions.

Finally, the work of the EMERGE Group were presented as guidelines to report studies on adherence.

*Robert Vander Stichele*

## Report on the 45th ESCP conference

This was the annual meeting of the European Society of Clinical Pharmacy which was organized in cooperation with the Norwegian Association of Hospital Pharmacists (NSF) in Oslo, Norway. The title of the congress was Clinical pharmacy tackling inequalities and access to health care. The conference took place on a hill overlooking Oslo in bright and sunny autumn weather. Travelling to this beautiful place was worth the trip. The majority of participants were pharmacists working in clinical practice: hospital or community and academia.

The symposium's theme reflected the increasingly widening gap between what is technologically possible to achieve with medicines, their increasing cost, and what is affordable to society and individual patients. There were a number of high profile speakers covering this topic from various angles. Also the conference covered long-term conditions in children and antimicrobial resistance as two major public health issues where appropriate use of medicines is vital to achieve good outcomes for patients and the society. The congress also included a masterclass on qualitative research and many workshops on a range of topics relevant to clinical pharmacy practice and research. Research projects of participants were presented during oral presentation sessions and poster presentation sessions.

More information is available at the society's website: http://www.escpweb.org/

*Katja Taxis*

## Report on the NORPEN meeting

The Nordic Pharmaco-epidemiological Network (NorPEN) had is annual meeting in Stockholm in November 2016. The meeting focused on cancer pharmacoepidemiology and different speakers from the Nordic countries were invited to provide insight into the topic. A pharmacoepi-slam session was held where members from the Nordic countries were invited to present their research in three

minutes. A workshop facilitated important discussions of different topics on how to conduct research. See details also under Swedish national news.
The next NorPEN meeting will be held in Helsinki in November 2017 and the focus will be on safety of drugs and vaccines.

*Lotte Rasmussen*

## MURIA GROUP

MURIA (Medicines Utilisation in Africa) group was founded in Port Elizabeth, South Africa in January 2015 with the help of Ilse Truter. It was agreed there needs to be a multidisciplinary network of healthcare professionals in Africa to stimulate national and cross-national drug utilisation research to enhance the appropriate use of medicines in Africa, with an agreed vision and mission (1).
MURIA to be based on groups such as EuroDURG and PIPERSKA (2). This vision of MURIA to be achieved through training, collaborative research, information sharing and facilitation of access to data to address current challenges, with a mission to be fully functioning and publishing within 2 years of its inception. This is already happening with 2 symposia/ workshops held in the University of Botswana in July 2016 and 2017. Both were well attended with good feedback from participants (3, 4).
More details can be found on the MURIA group website: **http://muria.nmmu.ac.za/**.

There was also a separate symposium in February 2016 to stimulate antibiotic research (5) as well as country training programmes, e.g. Swaziland. There have also been numerous publications, acceptances and submissions in the past 2 years. Subjects include (i) ways to optimise antibiotic use in hospitals and improve adherence to antimalaria treatments, (ii) ways to improve adherence to anti-infective prescribing guidance as well as combine multiple guidelines into one coherent guideline to reduce confusion, (iii) researching ways to reduce inappropriate self-purchasing of antibiotics as well as improve adherence to HIV and non-communicable disease treatments; (iv) researching current anti-hypertensive utilisation patterns and knowledge to improve care as well as ways to improve Drugs and Therapeutic Committee functions/ HTA assessments to promote rational use of medicines and (v) strengthening DU capabilities generally to influence future policies. This will continue with the third MURIA conference in Namibia 26-28 June 2017. Anyone interested in DU studies in Africa should attend as well as be part of the group. Further details on the conference and membership application forms can be found on MURIA's website.

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1. Massele A, Godman B, Adorka M et al. Initiative to progress research on medicine utilization in Africa: formation of the Medicines Utilization Research in Africa group. Expert review of pharmacoeconomics & outcomes research. 2015;15(4):607-10.
2. Garattini S, Bertele V, Godman B et al. Enhancing the rational use of new medicines across European health care systems. European journal of clinical pharmacology. 2008;64(12):1137-8.

3. Massele A, Burger J, Katende-Kyenda NL et al. Outcome of the first Medicines Utilization Research in Africa group meeting to promote sustainable and rational medicine use in Africa. Expert review of pharmacoeconomics & outcomes research. 2015;15(6):885-8.

4. Massele A, Burger J, Kalemeera F et al. Outcome of the second Medicines Utilisation Research in Africa Group meeting to promote sustainable and appropriate medicine use in Africa. Expert review of pharmacoeconomics & outcomes research. 2016.

5. Massele A, Tiroyakgosi C, Matome M et al. Research activities to improve the utilization of antibiotics in Africa. Expert review of pharmacoeconomics & outcomes research. 2017;17(1):1-4.

*Brian Godman*


Below we list all forthcoming international or European, English language conferences and their abstract submission deadlines that may interest people engaged in DU research. For national conferences please see country specific news below.

## EuroDURG conference 2017

The scientific (chair Katja Taxis) and local organizing (chair – Marion Bennie) committees would like to invite you to join us in Scotland for the next EuroDURG conference to be held November 15-17th 2017 in Glasgow. We have designed an exciting program (attached flyer) which aims to bring together:
Digital Health - how this capability can transform data into intelligence to enrich clinical decision support tools
Big Data - informatics driving new evidence generation from routine patient level health data.
Policy - global perspective on drug utilisation and health policy

This will be underpinned by familiar and new drug utilisation topics including: adherence; anti-infectives; children; elderly; patient reported outcomes; citizen science. We will also be running half day educational sessions for all levels on DUR.

Come and join us in Glasgow for a great scientific programme in our new conferencing facilities at the University of Strathclyde. Enjoy some Scottish hospitality including a visit to the Glasgow Science Centre for dinner and a ceilidh dance, sample our national drink and take the opportunity to extend your stay and explore Scotland.

Registration and Abstract submission is now open at www.EuroDURG2017.com

**Deadline for abstract submission: 15 April, 2017.**

*Marion Bennie*

## ISPE 2017

The ISPE Mid-Year Meeting will be organized in Royal College of Physicians London, U.K., April 1-4, 2017.

**Abstract submission deadline has passed.**


**Deadline for abstracts submission 15 February, 2017.**

The 33rd International Conference on Pharmacoepidemiology & Therapeutic Risk Management will be held in the Palais de Congres de Montreal, Montreal, Canada, between August 26-30, 2017. The agenda will be available in the coming weeks.

**Deadline for abstracts: 15 February, 2017.**

For more information and submission of an abstract: https://www.pharmacoepi.org/meetings


International Society of Pharmacovigilance

The ISoP Mid YearTraining Course "Developing risk management capability: Maximising opportunities from global Pharmacovigilance experience." Will be held in Bangkok, Thailand during 25-26 May 2017. Venue: Mandarin Hotel Bangkok.

This two day-course has been designed to help interdisciplinary groups to learn and work together in contributing to patient safety when medicines are used. At the end of the course, the participants are expected to understand current local and international legislative frameworks, and how they are expected to develop over the coming years. Participants will gain an understanding of considerations when developing strategies to increase volumes of adverse drug reactions (ADRs), and how they might be handled through different signal management systems. The second part of the course will focus on risk management and minimization approaches. Participants will gain hand on experience of development of Risk Management Plans (RMPs) and the conduct of Benefit-Risk assessments.

For more information visit: http://isoponline.org/training/midyear-training-bangkok-25-26-may-2017/

The 17th ISoP annual meeting: "Pharmacovigilance in the 21st Century", will take place in Liverpool, UK, from 15-18 October 2017. The theme of the conference will capture innovations that are occurring in many domains, and focus on how they can bring about benefits for patients. The draft program includes topics such as use of social media, signal detection strategies, patient involvement in pharmacovigilance, linking pharmacovigilance to health informatics and genomic sciences, big data approaches to improving drug safety, and education and training. Venue: ACC Liverpool, Kings Dock, Liverpool Waterfront.

For more information visit: http://isop2017liverpool.org/committee/


European Society of Clinical Pharmacy

The 2017 ESCP Spring Workshop: "Extended responsibilities for pharmacists in the treatment of acute and chronic conditions" will take place in Leiden, The Netherlands, 15.-16. June 2017

**Deadline for abstracts submission: 15 March, 2017**

For more information visit: http://escpweb.org/content/escp-international-workshop-2017-leiden

-The 46th ESCP Symposium: "Science meets practice - towards evidence-based clinical pharmacy services." in Heidelberg, Germany, October 9th-11th, 2017 (Venue: Kongresshaus Stadthalle).

The programme aims at attracting both scientists and practitioners sharing the mission to develop clinical pharmacy and its role in health care.

During the conference, ideas and concepts on how integrate evidence in clinical pharmacy services, how generate evidence for clinical pharmacy services and how education and training can promote quality in clinical pharmacy practice will discussed and developed.

**Deadline for workshop proposals: 15 March, 2017**

**Deadline for abstracts submission: 01 July, 2017**

For more information visit: http://escpweb.org/content/46th-escp-symposium-clinical-pharmacy-heidelberg


European Association for Clinical Pharmacology and Therapeutics

The 2017 EACPT Meeting will focus on the role of clinical pharmacology in personalized pharmacotherapy, both a priori – pharmacogenetics – and a posteriori (therapeutic drug monitoring). It will be held between 6 February 2017 in Prague, organized by the Czech Society for Clinical Pharmacology in cooperation with the European Association for Clinical Pharmacology and Therapeutics (EACPT). Venue: Clarion Congress Hotel Prague.

The objective of this year's conference is to show, especially to younger clinical pharmacologist, the future potential and fundamental role clinical pharmacology plays in modern health science.

For more information visit: http://eacpt2017.org/


Health Technology Assessment International

The HTAi 2017 Annual Meeting: "Towards an HTA Ecosystem: From Local Needs To Global Opportunities", will take place in Rome, Italy, from June 17-21, 2017, at Ergife Palace Hotel in Rome.

The 2017 HTAi annual meeting is aimed at collecting experiences to promote a deeper understanding of the potentials and challenges of different approaches and foster collaboration in HTA and integration between HTA and regulatory systems.

**Abstract submission deadline has passed.**

For more information visit: http://www.htai2017.org/

## *European projects*

Electronic assessment of the quality of pharmacotherapy in old age

In 2014, experts from 8 European countries assembled in Ghent, Belgium, for an ESF (European Science foundation) workshop. The international multidisciplinary team of experts (mostly EuroDURG members) focused on the quality and safety of pharmacotherapy in old age aiming to define the requirements for an electronic assessment tool based on available explicit lists of Potentially Inappropriate Medications (PIMs). A summary of the workshop and the recommendations formulated are published in the European Journal of Clinical Pharmacology (see Azermai M et al, 2016). The Heymans Institute of Clinical Pharmacology of the University of Ghent, Belgium, launched an application for a

3-year PhD studentship on this topic. Ivana Ivanova, a MD of Macedonia, applied and started her exploratory studies using an electronic repository of PIMs. EuroDURG members are invited to offer secondary databases of medication use in old age (all or not containing also clinical data) for validation studies of the electronic PIM tool.

*Monique Elseviers*

## Good practice guidelines for conducting and reviewing cross-national comparison (CNC) drug utilization studies

In 2015, ISPE launched a call for proposals for manuscripts that could be used for guidelines development or reference documents for pharmacoepidemiology. The EuroDURG working group on CNC studies submitted a proposal to ISPE and was very pleased to obtain the ISPE granting.

The work intended to develop a methodology to assess the validity of cross-national drug utilization studies and to develop Good Practice Guidelines for designing, conducting, reporting and reviewing CNC studies. These guidelines will assist researchers by highlighting the most common and potential biases and limitations of this type of studies as well as to recommend procedures to overcome them. The work was divided to three parts:

1. A systematic review of Cross National Comparison (CNC) Studies. A first attempt to produce a review of European CNC studies was presented during the EuroDURG meeting in Antwerp in 2011. We continued our efforts under the lead of Yared Santa-Ana-Tellez and Aukje K. Mantel-Teeuwisse from the WHO Collaborating Centre for Pharmaceutical Policy & Regulation of the Utrecht University, The Netherlands. The new global review focused on methodological approaches to perform CNC studies aiming to evaluate the comparability of included DU data.

2. A checklist to evaluate CNC studies. Mainly based on the experiences of the CNC systematic review, a checklist was developed aiming to systematically evaluate all sources of bias that could jeopardize the validity of the comparison. Draft CNC checklists were used by internal and external reviewers to evaluate published CNC studies and to study inter-observer variability

3. Good practice guidelines for conducting and reviewing CNC studies. The guidelines focus on the specific comparative aspects of DU studies giving DU researchers and reviewers a practical tool for designing, conducting, reporting and reviewing CNC studies. The general aim is to improve the overall quality of the comparison by documenting and evaluating all sources of bias related to this particular kind of studies.

Apart from several skype meetings, the CNC working group assembled during a 2-day plenary meeting organized in April 2016 in Utrecht. During this meeting the CNC checklist for evaluation of CNC studies was corrected and completed with instructions and a glossary. During the ISPE conference in Dublin the results of an external review round of the CNC checklist were discussed and the checklist was adapted accordingly. A second plenary meeting was held in October in Utrecht again with the development of the framework of the CNC guidelines. The final report including the literature review, the CNC checklist and the guidelines will be submitted to the ISPE Planning Committee within the next 4 months. The documents will be made publicly available on the ISPE/EuroDURG website.

*Monique Elseviers*

# *News from NATIONAL DURGs*

## Austria

During 2016, Gesundheit Österreich (GÖG/Austrian Public Health Institute) has been developing an information platform targeted at physicians with the aim to support a more rational and safe prescribing. The aim of this service is to provide practical information. The platform that will be provided as a section of Austria's official public health portal https://www.gesundheit.gv.at/ will go online during the first months of 2017. The first focus topic will concern tools for prescribers to better deal with polypharmacy.

The WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies at GÖG organised its first summer school on Pharmaceutical Pricing and Reimbursement Policies from 29 August till 2 September 2016. 33 participants of public and non-for profit institutions working in the field of pricing and reimbursement of medicines of 18 different countries attended the course in Vienna. Alongside the Summer School, a public panel debate was organised: high level speakers discussed about strategies to deal with high cost medicines. For further information on this summer school see: http://whocc.goeg.at/SummerSchool. The next summer school is planned for the period from 28 August till 1 September 2017.

***Sabina Vogler***

## Denmark

The Danish Society for Pharmacoepidemiology (DSFE) has had as one of the most important foci this year to prepare a position paper on the role of database validation projects in epidemiological research. The background for the work is that several members have experienced being refused permission to medical records in projects that contained elements of validation.
The society's position is very clear: Validation of health care databases is research, and is cannot solely be regarded as quality work. A new regulation in this area is being drafted in Denmark and we will be followed very closely by the DSFE.

***Anna Birna Almarsdóttir***

## France

Access to French Health Data
After the National Health Data System (Système National des Données de Santé-SNDS) was created by the Health System Modernization Law in January 2016, two decrees published in December 2016 organize the access to health data for studies, research and evaluation of public interest. Sanitary agencies such as French National Agency for Medicines and Health Products (ANSM) or French National Authority for Health (HAS), academic hospitals researchers, the French National Institute of Health and Medical Research (INSERM) and other public research institutes will have permanent access to the SNDS.

Other public or private bodies must obtain prior approval from the CNIL (National Commission of Information and Liberties). The single access point will be the National Heath Data Institute (INDS). The first release of the SNDS in April 2017 will gather anonymized data from National Health Insurance (SNIIRAM database) and hospital data (PMSI database). Death causes will be added in June 2017, data on handicap in 2018 and data on private complementary insurances in 2019.
We have observed a significant mobilization of the scientific community in France around these new conditions of access to health data with the creation of two research consortium endorsed by ANSM (French National Agency for Medicines and Health Products): the PEPS consortium (pharmacoepidemi

ology of health products) in Rennes and Villejuif (http://ansm.sante.fr/content/download/77731/985561/version/1/file/CP_CHU-Rennes_05-06-2015.pdf ) and the DRUG-SAFE consortium in Bordeaux and Marseille. Both aim to develop research by using the SNDS data base for pharmacoepidemiology and pharmacovigilance. In addition, INSERM will be in charge of the national coordination of the research infrastructures using health data.

**Upcoming events 2017**

Inserm organizes a four days' workshop on methodological challenges for drug surveillance". The workshop will provide a comprehensive coverage of the latest advances in pharmacoepidemiological research for drug safety evaluation. "Inserm Worshop 244: methodological challenges for drug surveillance, 8-10 March and 13-14 March 2017 in Bordeaux.
https://ateliersinserm.dakini.fr/atelier.244.defis.methodologiques.pour.la.surveillance.des.medicaments-66-21.php

A 2 days meeting will be organized by the PEPS consortium on Monday 26 June and Thursday 27 June in Rennes on the use of SNIIRAM database for health research.
https://project.inria.fr/rennesdonneessante2017/

The 6th edition of the Pharmacoepidemiology Festival will be held in Bordeaux from Wednesday 10 May to Friday 12 May 2017. The program consists of six half day conferences covering various topics on pharmacoepidemiology, pharmacoeconomics and pharmacovigilance. The program is available at http://pharmacoepi.bordeaux-festival.eu/pdf/bordeaux_pharmacoepi_festival_2017_programme.pdf

*Catherine Sermet*

## Germany

In November 2016, the German national DURG "Society for Drug Utilization Research and Drug Epidemiology (Gesellschaft für Arzneimittelanwendungs-forschung und Arzneimittelepidemiologie GAA) held its 23rd Annual Meeting in Bochum. Details of the meeting including the abstracts are to be found under:http://www.egms.de/dynamic/de/meetings/gaa2016/index.htm?main=1.

The 23rd annual meeting had three main themes: nursing, medication safety and the federal standard medication plan, and social inequality in medication therapy.
The first theme comprised of medication safety in nursing education and training. The main focus was on nursing in nursing homes context and in community health. The next themes were on the federal standard medication plan, which is regulated by laws of the Federal Ministry of Health. Further presentations were on medication safety (AMTS) and communication, medication safety and opiod use, and optimization of the medication plan for geriatrics inpatients. The third part of the annual meeting was about social inequality. Drug prescription and medication adherence correlated negatively with income and socio-economic status.

*Andrea Truemner*

For 2017, the 24th Annual Meeting of the GAA is planned to be held from 2017 November 30th - December 1st Erfurt. Please contact Katrin Janhsen (Katrin.Janhsen @uni-wh.de) or see our website for further information: http://www.gaa-arzneiforschung.de.

*Katrin Janhsen*
*Chair of German –DURG*

## Italy

In Italy several DUR related activities were organized and several DUR related report have been published during 2016.
The annual report on drug utilization in Italy (Rapporto OsMED - Osservatorio dei Medicinali,http://www.aifa.go

v.it/it/content/rapporti-osmed-luso-dei-farmaci-italia) was presented by the Italian Medicine Agency (AIFA).
Main results: (a) Each Italian inhabitant took on average 1.8 doses of medication in a day;
(b) off-patent drugs accounted for 70% of overall consumed doses, with an increase of biosimilars, especially of epoetins (+ 49% vs. 2014) and somatropin (+22%); (c) consumption and expenditure of antibiotics decreased (vs. 2014: -2.7% and -3.2%, respectively), however their inappropriate use was still > 30%, although in constant decline.

National Institute of Health (ISS) organized two events on the appropriate use of drugs (http://www.epicentro.iss.it/farmaci/2016.asp). "Different faces of the appropriate prescription" compared
(a) points of view of General Practitioner (GPs) and drug committee members (regional or hospital), (b) quality indicators in pediatric population and in the elderly,
(c) main issues of drug prescription in outpatients vs. inpatients.

The "25th Conference on Drug Utilisation and Drug Safety" discussed (a) challenges of big data in health research, (b) appropriate use of new oral anticoagulants (NOACs) and of drugs for COPD, (c) use of biosimilars and (d) gender differences in use of medications.

The Public Health Agency of Tuscany (ARS) published its first drug utilisation report (https://www.ars.toscana.it/en/pubblicazioni/collana-documenti-ars/pubblicazioni-2016/3373-rapporto-sull-uso-di-farmaci-in-toscana-2016.html). Special focus was done on (a) gender and age (women were the most frequent drug users among young adults, whereas the prevalence of drug use in the elderly was similar between males and females), and (b) adherence (< 60% for anti-hypertensive drugs, < 40% for anti-osteoporosis drugs, < 25% for antidepressants, < 20% for respiratory drugs).
The Lazio Department of Epidemiology (DEP) organised the first annual meeting of "4words - the words of innovation in health" (http://forward.recentiprogressi.it). Availability of healthcare big data and opportunities generated by them for both research and management of health systems were discussed.
The Italian College of General Practitioners and Primary Care presented the 9th Health Search Report (https://report.healthsearch.it/) , based on electronic health records of > 1 million of adult patients in charge of 800 Italian GPs.
The Italian Society of Pharmacology addressed drug utilization within two different events: "The real world evidence in Italy: state of the art in Italy in 2016" ( http://www.3psolution.it/dettaglio-evento.asp?id=115) and "The Role of Clinical Pharmacology in Italy: the way forward in the context of the NHS" Web access: http://www.sifweb.org/eventi/2016/sif_conv_monot_farm_clinica_na_151216.pdf). The following topics of DU were specifically presented: use of depot antipsychotics, off-label drug use in pediatric population, pattern of use of Direct Oral Anticoagulants (DOACs), inappropriate prescriptions among the elderly.
The Italian Epidemiology Association (AIE) discussed pharmacoepidemiological topics in a specific session of its annual meeting (web access: http://www.epidemiologia.it/wp content/uploads/2016/10/programma_definitivo-3.pdf): efficacy and safety of DOACs, use of NSAIDs in the elderly population, relation-ship between antipsychotic exposure and mortality, antidepressants and risk of diabetes.

*Elisabetta Poluzzi and Carlo Piccinni*

## Kosovo

The Kosovo National EuroDURG group during 2016 has performed several activities related to drug consumption, as are listed below:

The Kosovo team signed the contract to participate in a project entitled: Prospective observational study to assess the risk factors, clinical management and outcomes of hospitalized patients with serious infections caused by carbapenem-resistant Enterobacteriaceae and Acinetobacter baumannii (Protocol Code: FIS-ATB-2015-01). This is multicentric clinical trials with different study objectives and one of the objectives is the antibiotic use related to these patients.

The Kosovo utilization team collected the data about the antibiotic consumption at Surgey Clinic of University Clinical Center of Kosova in period of 15 years (2001, 2011 and 2016). The results of this survey is planned to be published during 2017.

Using the PPS method developed by the European Surveillance Antimicrobial Consumption (ESAC) project we have collected the data in 2016 and we will continue during next coming years.

In 16th November 2016 the Ministry of Health of Kosova organized the European Antibiotic Awareness Day.
The Kosovo Medicinal Agency will publish the data about imported drug in Kosovo in one report using the ATC/DDD methodology).

***Shaip Krasniqi***

## Russia

To optimize antimicrobial usage and restore nosocomial pathogens resistance levels in multi-profile hospitals in Russia we are currently developing an expert system based on clinical decision support algorithms. Such systems have been widely adopted throughout the world in recent decades but none has been implemented in Russia yet as up to quite a recent time Russian healthcare institutions had no necessary resources. Ministry of Health initiative of country-wide adoption and incorporation of new IT solutions, including electronic health records, in the healthcare institutions generates opportunities for introduction of supporting information products such as expert systems specifically designed to meet Russian multi-profile hospitals needs in the field of antimicrobial therapy.
Working in integration with hospital electronic medical records the system will collect, combine and analyze clinical, laboratory and pharmacy data to develop the medical logic and provide clinical decision support in infectious diseases management (including bacteriological testing, clinical observation and antimicrobial agents' choice) based on data obtained from patient's health records, hospital experience with infections as well as relevant professional information.
The system will respond in timely manner by issuing alerts (significant laboratory findings, including isolation of pathogens, adverse drug reaction occurrence, drug interactions, etc.), correcting tactics of infectious diseases management and proposing improved diagnostic and therapeutic approach in compliance with up-to-date healthcare standards, providing decision support in antimicrobial agents choice in accordance with local antimicrobial stewardship program, recognizing and bringing to relevant healthcare professional's attention information of possible hospital acquired infections and reportable infectious diseases, isolation of significant pathogens and incorrect use of antimicrobials.
Implementation of the system is expected to improve antimicrobial therapy quality and safety in multi-profile hospitals in our country, decrease selective pressure of antimicrobials, facilitate hospital-wide adoption of antimicrobial stewardship and improve clinicians' knowledge of antimicrobial therapy.

***Svetlana A. Rachina*** **(Moscow),** ***and Yulia A. Belkova*** **(Smolensk)**

## Scotland

2016 has been a busy year for our pharmacoepidemiology

researchers in Scotland. We published for the first time a data profile on our new national community prescribing dataset covering the total Scottish population of 5.3million from 2009 (Alvarez-Madrazo S et al. Int J Epidemiol 2016; *doi: 10.1093/ije/dyw060. pmid:27165758).*
We have been preparing and publishing studies using this dataset as part of our Farr Scotland pharamacoepidemiology workstream including use of methadone, antimicrobials and direct oral anticoagulants (DOACs) nationally. Also our collaborations internationally are expanding with an established program in Brazil and also exploratory work with Malaysia, hosting a visit in October, and with Kenya and South Africa in development of drug utilisation to support communicable and non-communicable disease surveillance and stewardship. We had a good profile with our students/researchers presenting at multiple conferencing including the International Population Data Linkage Network Conference in Swansea and ICPE in Dublin. A new key area of development for us in 2016/17 is the commencement of a new Cancer Medicines Outcome Programme (CMOP) which will focus on exploring the use of our routinely captured cancer treatment data for the first time at scale to better understand the intended and unintended consequences of our more recently approved cancer treatments. We will also be starting to examine PROMs (Patient Reported Outcome Measures) and how they maybe incorporated into routine cancer care.

This year we have also made good progress with preparing for hosting the EuroDURG 2017 conference which will be in Glasgow 15th -17th November 2017. The social program will include a Scottish ceilidh, a visit to our Science Centre and always lots of opportunity to sample our national drink! This will all complement the excellent Scientific Program organised by EuroDURG. Come and join us in Glasgow.

***Marion Bennie***

## Spain

In October 2016, the XXIX Congress of the Spanish Society for Clinical Pharmacology was held in Barcelona. The programme included two round tables regarding the introduction and health outcomes of new medicines and the impact and challenges of "real world evidence" on medication use and pharmacoepidemiology and the potential of Spanish electronic datasets to provide useful information for health care management. Conference abstracts can be accesed at: http://onlinelibrary.wiley.com/doi/10.1111/bcpt.2016.119.issue-S1/issuetoc.

A study entitled Antibiotic Use in Children – A Cross-National Analysis of 6 Countries has been published in the Journal of Pediatrics, showing huge variations in antibiotic use in children (up to 7.5 fold) across several industrialized countries from Europe, Asia, and North America (http://www.jpeds.com/article/S0022-3476(16)31256-2/abstract). This study that includes Spain has had an enormous impact on Spanish media.

**Gabriel Sanfélix-Gimeno**

## Sweden

A three-day NorPEN-meeting (Nordic Pharmaco-epidemiological Network, www.norpen.org) was successfully held in Stockholm under the auspices of Centre for Pharmacoepidemiology, Karolinska institute, in November 2017. International and Nordic researchers, and PhD-students chaired experiences during days and not-so-early nights. A special thank to Professor Til Stürmer, USA, who spoke about screening and diagnostic detection of pre-clinical cancer. Of special interest was the discussion about possible synergies between pragmatic randomized register studies and pharmacoepidemiology based on experiences from

Uppsala Clinical Research Center (UCR).

Two reviews over the first decade of the Swedish Prescribed Drug Register were published during 2016. One study covered all 338 identified studies, and the second one focused on the 24 effectiveness-studies published 2005-2014. It is a very positive trend with increased output (90 articles during 2014), and an increase in the fraction of studies utilizing record linkage with other register and databases (89% in 2014), over time.

In the updated action plan of the National Pharmaceutical Policy there is an increased emphasis on the importance of follow-up on the use and effects of drugs, with pharmacoepidemiology as one key component. However, there are as of now no increased funding suggested.

Links to the two review articles:

Wallerstedt S, Wettermark B, Hoffmann M. The First Decade with the Swedish Prescribed Drug Register – A Systematic Review of the Output in the Scientific Literature.
Basic & Clinical Pharmacology & Toxicology. 2016;119(5):464-9.
DOI: 10.1111/bcpt.12613
http://onlinelibrary.wiley.com/doi/10.1111/bcpt.12613/full

Wallerstedt S, Hoffmann M. Evaluating beneficial drug effects in a non-interventional setting. A review of effectiveness studies based on Swedish Prescribed Drug Register data. British Journal of Clinical Pharmacology. 2016 ahead of print.
DOI: 10.1111/bcp.13206
http://onlinelibrary.wiley.com/doi/10.1111/bcp.13206/full

***Mikael Hoffmann and Björn Wettermark***

## United Kingdom & Ireland

The 2016 PRIMM conference, held in January at the Health Foundation in London, maintained its usual high standard of high quality of invited speakers and submitted abstracts. We were yet again treated to three excellent and highly thought-provoking presentations.
Dr David Watson, from the Association of British Pharmaceutical Industry, shared interesting data on the uptake of new medicines in different countries, which showed that the UK is generally very slow to take up new products compared to other countries, but eventually are high consumers of medicines, with the change frequently being related to price reductions. Prof David Gerrett, from NHS England Patient Safety Division, described the network of 381 Medicine Safety Officers, distributed across NHS and private health organisations, who both report incidents of harm or near misses, and help implement and monitor change to reduce harms from medicines. Prof Chris Newdick, from the University of Reading, asked us to consider what is the future of the NHS, if the costs of treating diseases related to lifestyle factors, such as obesity, continue to rise and productivity savings continue to be required to save money? Should people who are ill because of lifestyle retain their autonomy to do as they wish or should decisions be made by others on their behalf?
There were 24 posters presented, plus four oral presentations. The winner of the Hugh McGavock bursary, was Dr Wasim Baqir, from Northumbria Healthcare NHS Foundation Trust, for his work on evaluating models of medicines optimisation in care homes. The winner of the poster prize was Kieran Walsh, from University College, Cork, for his work on patterns of prescribing in older people with and without dementia on admission to Irish hospitals.
The PRIMM committee has expanded! New members are: Dr Wasim Baqir (Northumbria Healthcare NHS Foundation Trust), Prof Nina Barnett (Northwick Park Hospital) and Prof Philip Routledge (University of Cardiff).

PRIMM also now has a Twitter account. Follow us on @PRIMM_UK_IRL.
Chris Diaper has stepped down as PRIMM administrator. Our new administrator is Sally

Bragg. PRIMM contact details are: primmad17@gmail.com.

Website: www.primm.eu.com

The 2017 PRIMM conference was on Friday 27th January with the theme of Deprescribing – is less more? We will report on this in the next Bulletin.

*Janet Krska*

We invite other national groups to report on their activities in the next years' Bulletin!


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