I would like to invite all colleagues who are involved in the development or promotion of clinical pharmacy worldwide, to the ESCP annual symposium in Prague.

Clinical pharmacy is developing slowly and in different ways worldwide. I, as many other opinions leaders, who try to develop clinical pharmacy think that clinical pharmacy is at heart of everything we do and that “all roads lead to Rome”. Some countries are more focused on pharmaceutical care during the dispensing of medicine in pharmacy, others develop stand alone clinical pharmacy services, whilst others practice clinical pharmacy without labelling it as such. Every activity, where pharmacists are involved in health care and utilise their knowledge and skills to help patients in prevention and treatment their health problems is beneficial for development of clinical pharmacy services. Therefore we should abandon the problem of “Babylon Tower” of differently labelled patient orientated pharmacy. Clearly for specialisation, for other health care professionals and for healthcare funding bodies it is better that we use only one label for our activities clinical pharmacy.

It is necessary to break old views about pharmacy and to understand the 5 requirements of a clinical pharmacy service. 1/ clinical experience, 2/ documentation, 3/ feedback on “my intervention”, 4/ information about patients and 5/ understanding of strategy of treatment and degree of risk acceptable to prescribing physicians. Clinical pharmacy needs a special system of education which is more focused on patient oriented education and implementation of clinical pharmacy into pharmaceutical care, in health policy, and in law. Clinical pharmacists and clinically oriented pharmacists have to be able to understand pharmacotherapy from point of view of pharmacology, clinical pharmacy (defined as a strategy for how to use and how to minimise risk of pharmacotherapy the acronym used in our faculty is “how to maximise effect and minimize the risk”), pharmaceutical technology and different specialist pharmaceutical disciplines which allow another views on pharmacotherapy.

We need to understand that pharmacists can do a lot of harm if they use theoretical knowledge only, have a shortage of skills and do not have any interaction with physicians, nurses and patients. We need to improve the quality of pharmaceutical care. Clinical pharmacy is full time job it cannot be done as a hobby. Clinical pharmacy is a self-standing pharmaceutical discipline which can be performed outside of the pharmacy. We have to be cautious of those pharmacy managers who support clinical pharmacy as a tool for increasing their income or image only and don’t allow their staff to actually optimise their practice of clinical pharmacy. Often they continue to prioritise dispensing of drugs in a routine way whilst claiming that they promote the development of clinical pharmacy.

Clinical pharmacy postgraduate education and research are very important elements for development of clinical pharmacy and its position in society. The absence of specialisation and research activities in any discipline will lead to its demise. We need to judge evidence based medicine information, to know how to receive evidence about validity of our expertise and evidence about clinical importance for particular patient.

An implementation of clinical pharmacy into the education, research and management and pharmacotherapy risk management are main topics of Prague symposium. It is the 3rd ESCP annual symposium managed in Prague. The Czech Republic has rich experience in development of clinical pharmacy in undergraduate education; and it is running post-graduate education in the form of PhD study opportunities, continuing education and specialised education in clinical pharmacy. Two professional organisations manage clinical pharmacy: the oldest one is the clinical pharmacy section of Czech Pharmaceutical Association (with more as 30 years’ experience). The second society is a new one which has been operating for two years only. Czech pharmacists would like to develop clinical pharmacy services and are looking for discussions on how to overcome particular barriers for development of clinical pharmacy. They would like to create a Central European network of clinical pharmacy. Therefore they call experts from Poland, Germany, Austria, Slovakia, Hungary, Slovenia and Croatia.

We are looking forward to welcoming all participants, invited speakers and experienced ESCP members to an exchange of skills and knowledge. We believe, that ESCP symposium will give you new impetus to create and develop clinical pharmacy. Let visit our website (http://www.escp-prague.eu) and let come to Prague.

Jiří Vlček
President of 42nd annual symposium on Clinical Pharmacy
jvlcek@faf.cuni.cz
Sara Bologna, born on July 24th 1977 in Parma, Italy

Education
Degree in Pharmaceutical Chemistry and Technology, University of Parma (2002); Ph.D. in Biochemical Sciences, University of Turin (2006); Hospital Pharmacy Specialist degree, University of Modena and Reggio Emilia (2008).

Work activity
In 2005, towards the end of my Ph.D., I started my training at University Hospital of Parma, Pharmacy Service, looking for the clinical aspects I was missing as a researcher. So I decided to engage with hospital pharmacy practice: the management of the best drug therapy for a patient, the selection of medications for local drug formulations and above all I was involved in the non-sterile compounding laboratory. After the first six months, I understood that was the way I wanted my career to develop.

In 2006, I started at the School of Hospital Pharmacy and continued working at University Hospital of Parma for my specialisation training, in clinical pharmacy activities. During that period, the Pharmacy Service was at the very beginning the compounding of oncology IV admixtures in a centralised lab. I deepened my knowledge in the hemato-oncology inpatient setting, focusing on drug therapy improvement, clinical trials, management of adverse drug reactions. I participated in a project on the characterisation and surveillance of bisphosphonate-related osteonecrosis of the jaws in patients with cancer, that was also my thesis work for Hospital Pharmacy specialisation. In that period, I started my activity in the neonatal area, mostly in the management of parenteral nutrition for preterm infants.

After my specialisation in 2008, I gained experience also on providing optimising therapy for patients, collaborating in multidisciplinary groups (pharmacists, physicians, nurses, technicians) to guarantee quality, efficacy and safety of the therapies. I had a role in patient safety improvement projects, implementing recommendations and local procedures for pharmacovigilance, to minimize errors in therapy and for the safe handling of hazardous drugs (antineoplastic drugs, monoclonal antibodies).

Nowadays one of my main areas of interest is the paediatric setting, especially the hemato-oncology one: I find it is a very challenging area.

The month I spent in the US in September 2011 at UPMC Mercy Hospital in Pittsburgh (PA), thanks to a grant from SIFO (Italian Society of Hospital Pharmacy), this further opened up my mind towards pharmaceutical care. Since then, I can in the ward or, anyway, closely with clinicians and other health workers: I believe that multi-disciplinarity teams are the only way to put patients at the centre of our attention, giving them the best care.

I spend part of my time in education with university students and in tutoring for hospital pharmacy specialisation students: I firmly believe education is fundamental for us to have good clinical pharmacists in the future.

Sara Bologna
sologna77@gmail.com

Who’s who: Edwin van Aalten

Edwin van Aalten, born on April 19th 1963 in Hoek van Holland, The Netherlands.

Work activity and education:
I studied Pharmaceutical sciences at the Leiden State University (1981) and obtained my Master’s title in 1986. After that, I followed the postgraduate education as a pharmacist and finished in 1989.

After fulfilling my military duties I started as a community pharmacist in 1991 and have worked in different pharmacies. Almost from the beginning I have been active in either regional pharmacists’ boards or in working groups and committees, e.g. on individual patient information and on medication surveillance on patient characteristics.

With the change in the Dutch pharmacy market in 2003 my colleague and I have decided to sell our pharmacy. We continued our activities in the pharmacy and in addition besides that I started as a part-time pharmacy practice consultant at PharnaPartners, market leader in Dutch Pharmacy software. My task is to keep the company informed about developments in our profession, to specify user requirements for software to be developed for community pharmacies on these subjects and to perform acceptance testing.

In 2008 I decided that it was time for a new challenge. I changed pharmacies and am now managing an emergency pharmacy that is located next to a GP emergency practice in a hospital in Breda. Our opening hours are during the nights, weekends and public holidays. Besides having different dispensing profile from a normal community pharmacy a lot of communication is required between us and the prescribers, which are not only the GPs but also the specialists on the emergency ward of the hospital. Besides this we provide the hospital with information about the patients being admitted to the hospital during the hours we are open. We coordinate the electronic communication between the 25 community pharmacies in our region.

Furthermore, I am a Qualified Person (QP) for UCB which has an affiliate office in Breda. The regulations specify that no batch of medicinal product can be released for sale or supply prior to certification by a QP that the batch is in accordance with the relevant requirements.

ESCP activities:
In 2012, Erik Gerbrands, director of the International Office of ESCP asked me to join him in his activities running the Office and to see if I would be willing to be his successor in the near future. The international contacts and networking, and the promotion of clinical pharmaceutical care are elements that are very attractive to me. So I hope to see you on one of our events in the near future!

Edwin van Aalten
vanaalten@planet.nl

Prague conference: A new format for Pharmacotherapy update sessions

The next annual ESCP meeting in Prague will introduce a new format for Pharmacotherapy update sessions. These will be organized under the umbrella of the ESCP Special Interest Groups (SIGs) following the “Hot topics” format presented during previous annual conferences. The first Pharmacotherapy update (Thursday 17th October, 11:45 am) will be a joint session between ESCP, represented by the SIG Cancer care, and the European Society of Oncology Pharmacy (ESOP), which involves oncology pharmacists working in cancer care, in clinical and/or practical settings. Two lectures have been proposed: an update on pain management will be given by Stavroula Kitsi, from Ouprom. Indeed this area has seen the marketing of several new pain killers, especially innovative fentany presentations, that have modified the landscape of breakthrough pain management. Another update will concern breast cancer treatment, by Marta Tronciak from Italy. Here again, many new drugs have been marketed over the last years, particularly for HER2 positive breast cancer turnours (e.g., pertuzumab, TDM-1…), such modifying the treatment strategies. The second Pharmacotherapy update (Friday 18th October, 11:45 am) will be moderated by Moira Kinnear (SIG Education leader). Three SIG leaders will present recent data related to their expertise field, either from original articles or latest meetings: Bart Van Den Bernt, on patient adherence, Yolande Hanssens, on medicine information, and Louise Mallet, on geriatrics. We will be happy to welcome you do not hesitate to meet the SIG leaders at the end of these sessions. SIGs have been created for a long time within ESCP in order to network members who share specific topics of interest, and participation to SIGs is free, although reserved to ESCP members.

Mikael Daouphars
SIG Cancer Care leader
mikael.daouphars@chb.unicancer.fr

Who’s who: Sara Bologna

Who’s who: Edwin van Aalten

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Mikael Daouphars
SIG Cancer Care leader
mikael.daouphars@chb.unicancer.fr
The upcoming 42nd European Symposium on Clinical Pharmacy will be held on 16-18th October 2013 in Prague, the capital of the Czech Republic and Heart of Europe. It will focus on “Implementation of clinical pharmacy practice: Research, Education and Management” (www.escpvprague.eu) and will create an open platform for sharing different experience and ideas on the implementation of clinical pharmacy practice and advances in clinical pharmacy teaching, practicing and management. Plenary sessions of this Symposium will be organized around three main pillars (see www.escpvprague.eu).

Area I/ Experience with the implementation of clinical pharmacy practice in hospital and ambulatory care in the USA, Australia and Europe

Area II/ Approaches to individualized pharmacotherapy in patients at special risk of adverse drug events (particularly in complex older adults, psychiatric patients, patients suffering from pain and cancer)

Area III/ European perspectives and strategies for future development of clinical pharmacy education, research and management

Internationally renowned experts and excellent speakers from the USA, Australia and many European countries have accepted invitation to participate at the plenary sessions of this Symposium.

On Day 1 Prof. Barry L. Carter, PharmD., FACC, FAHA, FASH (Past President of the American College of Clinical Pharmacy and The Patrick E. Keefe Professor at the Pharmacy Department and Department of Family Medicine, University of Iowa, USA) will review factors that led to successful implementation of clinical pharmacy in the USA in inpatient hospitals, ambulatory care clinics and community pharmacies and will discuss how structural and educational features unique to the U.S.A. developed a large core of leaders of clinical pharmacy in this country. Key accreditation practices (accredited residencies, specialties) that increased the acceptance of clinical pharmacy services will be emphasised at the lecture with discussion of the threats and opportunities related to the expansion of clinical pharmacy in hospital and ambulatory care.

Many other excellent speakers will lecture on the Day 1 of the Symposium about the development and implementation of clinical pharmacy - Prof. Tim Chen, PhD, DipPH-Pharm, BPharm, MPS MSHP (Associate Professor at the University of Sydney, Australia), Prof. Kurt Hersberger, PharmD, PhD (University of Basel, Switzerland), Prof. Anne Spinewine, PharmD, PhD (Associate Professor at the Université Catholique de Louvain, Louvain Drug Research Institute, Belgium), etc. Prof. Chen is nationally and internationally renowned expert in medication review research and will speak about strategies to reduce medication harm and the successful research-based implementation of clinical pharmacy practice through Home Medicine Review Program funded by the Commonwealth Government in Australia. He will review experience and strategies for development of clinical pharmacy in ambulatory care. Prof. Anne Spinewine will summarize development of clinical pharmacy services in hospital setting in different European countries and will discuss results of European randomised control trials focused on optimization of pharmacotherapy by pharmacists and clinical pharmacists in different settings of care (with a special focus on care for older patients).

The 2nd Day of the Symposium will be devoted to individualized drug therapy. Morning plenary lectures will start with practical examples about important role of psychosocial and behavioral factors in pharmacotherapy appropriateness and quality. Results from the multicentric European studies on medication compliance will be presented, as well as studies analyzing role of psychosocial factors in the variation of patients’ response to pharmacotherapy. Importance of placebo and nocebo effect in clinical practice will be emphasized (speakers: Prof. Kardas (Poland), Prof. Horne (UK) and Prof. Benedetti (Italy)).

Afternoon and evening plenary symposia will summarize “Standardized tools and indexes for clinical pharmacists used in resolution of drug-therapy problems” and “Approaches to individualized pharmacotherapy in psychiatric patients and patients suffering from pain and cancer” using applications of knowledge of clinical pharmacology and pharmacogenetics.

Third day of the Symposium is reserved for European plenary lectures and discussions on recent situation, experience and future directions of clinical pharmacy in three main areas: Education (pre- and postgraduate), Research and Management. Lectures of Prof. Bates and Chair of the Education SIG Committee (Dr. Moira Kinneear) and members of GC ESCP Committees (Dr. Anne Leendertse and Dr. Markus Lampert) will review the situation in Europe and future recommendations.

Do not miss the opportunity to participate at Prague Symposium interactive workshops and Master Class in Pharmacy Practice Research organized by ESCP Research Committee- Dr. Mara P. Guerreiro (Portugal) and Prof. Marcel Bouvy (The Netherlands) on October 15th, 2013 from 9 to 17.30 o’clock! On this day, a discussion meeting for Czech clinical pharmacists will be organized by the Department for Postgraduate Studies in Clinical Pharmacy, Institute for Postgraduate Education in Healthcare, Prague and several speakers of the 1st Day of the Symposium will participate at this event (October 15th, 2013, Hotel ILF Prague, from 14 to 17 o’clock).

All organizers cordially invite you to join important ESCP fall symposium in Prague! It will certainly expose you to many experiences and inspiration for the development of clinical pharmacy practice and clinical pharmacy services at your home country (registration is open at www.escpvprague.eu).

Fialová Daniela, PharmD, PhD
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An enthusiastic small group (~90 registered delegates) participated in an integrated programme of presentations and interactive workshops sharing experiences and exploring opportunities to work more collaboratively with colleagues across the professions.

Professor Hugh Barr (President of UK Centre for the Advancement of Interprofessional Education and Collaborative Practice (CAIPE)) encouraged us to learn about each other and to understand the contributions all members of the team make to patient care which may help us to work better together especially during times of service re-organisation and change when perceptions, attitudes and stereotypical behaviour may be counterproductive. There is a drive for Interprofessional Education (IPE) in undergraduate education to prepare professionals for collaborative practice and there’s a need to continue this type of learning after qualification. Often there’s an expectation that different professionals and specialists will work together but groups require time to form and to understand, trust and respect each other. The workshop facilitated by Hugh and Ruth Edwards (Senior Lecturer, Robert Gordon University) provoked participants to think out of their comfort zones and consider changes they could make in their own practice to improve relationships and team working to help achieve improvements in patient care. Discussion of evaluation of IPE focused on the Modified Kirkpatrick’s Model of Educational Outcomes for Interprofessional Education developed by Hugh and colleagues.

**Modified Kirkpatrick Scale**

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>1</td>
<td>Reaction Learners’ views on the learning experience and its interprofessional nature.</td>
</tr>
<tr>
<td>2a</td>
<td>Modification of attitudes/perceptions</td>
</tr>
<tr>
<td></td>
<td>Changes in reciprocal attitudes or perceptions between participant groups. Changes in perception or attitude towards the value and/or use of team approaches to caring for a specific client group.</td>
</tr>
<tr>
<td>2b</td>
<td>Acquisition of knowledge/skills</td>
</tr>
<tr>
<td></td>
<td>Including knowledge and skills linked to interprofessional collaboration.</td>
</tr>
<tr>
<td>3</td>
<td>Behavioural change</td>
</tr>
<tr>
<td></td>
<td>Identifies individuals’ transfer of interprofessional learning to their practice setting and their changed professional practice.</td>
</tr>
<tr>
<td>4a</td>
<td>Change in organisational practice</td>
</tr>
<tr>
<td></td>
<td>Wider changes in the organisation and delivery of care.</td>
</tr>
<tr>
<td>4b</td>
<td>Benefits to patients/clients</td>
</tr>
<tr>
<td></td>
<td>Improvements in health or well being of patients/clients.</td>
</tr>
</tbody>
</table>

Collaborative practice was illustrated by Gordon Thomson (Pharmacist, NHS Tayside) who described the Scottish Patient Safety Programme (SPSP) which requires all team players to have a clear understanding of systems of patient care to enable the model of improvement to be applied. Medication safety is one of several work streams within this national programme and is where pharmacists are engaged in collaborative practice to improve the safe and effective use of medicines. Gordon used medicines reconciliation to illustrate a collaborative approach to safe systems of work and provided shared outcome data illustrating improved quality of patient care. A further collaborative project in Tayside between quality improvement teams and information technology has developed an electronic discharge document to improve communication between clinicians across care boundaries with the intention of reducing prescription errors and delays for the patient when they move settings.

Han de Gier (Professor of Pharmaceutical care, University of Groningen, Netherlands) reported the need for more pharmacist engagement in information and communication technology projects and the need for these projects to be more patient centred. Literature suggests patients are willing to share personal health record information and they want to control their information available to specific people. In their workshop, Han and Edwin van Aalst (Community Pharmacist, Netherlands) facilitated discussion around the web based pharmaceutical care plan designed for sharing information among patients, community pharmacists and general practitioners in the Netherlands. The challenges and benefits of sharing information in this way and also using social media was explored.

Dr Margaret Whoriskey (Director, Joint Improvement Team, Scottish Government) emphasised the need for wider collaboration to achieve the vision to enable people to live longer healthier lives at home. Margaret highlighted how pharmacists could help reshape the care of older people in Scotland by working in a more integrated way with health care and social care providers. Existing initiatives included polypharmacy reviews with carers and patients, supporting self medication whilst patients are in hospital, and pharmacists working with a home care service to better enable patient independence in taking their medicines. A linked workshop led by Annamarie McGregor (Professional Support Pharmacist, Royal Pharmaceutical Society) focussed on a wider approach to assessing the pharmaceutical needs of the patient, and the importance of information from social care providers (family/friends, neighbours, formal carers) in making decisions around the need for a medicines compliance aid. Issues around intentional and unintentional compliance were explored, and how the patient’s home environment can give useful information on how the patient is using their medicines. A patient’s social activities can also affect their independence and quality of life, as can those medicines known to cause cognitive impairment that can be prescribed or purchased over-the-counter.

This holistic approach to care was continued in an interactive workshop facilitated by Louise Mallet (Pharmacist) and Tammy Abramovitch-Ostreff (Physiotherapist) from McGill University Health Centre, Montreal. They used a case study to illustrate how a pharmacist and a physiotherapist work together in the evaluation of falls or risk of falling in elderly people. Collaborative working and understanding each other’s roles was illustrated through patient assessment to prevent admissions to hospital and injuries such as hip fracture. Falls prevention activities were proposed including multifactorial risk assessments such as medication review and physical assessment to evaluate gait, strength and balance.

Louise also presented an oral communication illustrating observations and learning from a patient’s home visit by a multidisciplinary team and how this may support continuity of care and prevention of recurrent hospitalisation. Perceptions of collaborative working between pharmacists and other professionals were explored and reported in the other oral communications. All the presentations and workshops were thought provoking and synergistic in the way the different themes fed into each other and provided participants with several take home messages about improving patient care through collaborative practice. Thanks to everyone for participating and contributing to a successful workshop.

Networking continued and friendships were kindled with a final group challenge to walk along the path under Salisbury Crags on Friday evening, taking in great views of Holyrood Palace, the Scottish Parliament and further afield to the Firth of Forth. (Insert picture 010)

Please access the webcasts and further reading as recommended by the speakers (ESCP website).

Moiraa Kinnear
Chair of Workshop
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Each year, ESCP is invited to assist at the DUPHAT meeting, the Dubai International Pharmaceuticals & Technologies Conference and Exhibition. The DUPHAT meeting has developed to be one of the most recognized and significant pharmaceutical event in the Middle East and North Africa. This year, the 19th edition took place 10-12 March 2013 in Dubai.

Speakers from USA, UK, Australia, Japan, Europe and the Middle East were invited to present their latest perspectives on pharmaceutical science in the 3-day program. The program encouraged the pharmaceutical professionals to evolve and to enhance their education levels for an improved understanding of pharmaceutical care through the following themes: redefining pharmacists role, upgrading quality standards, social pharmacy practice, health economics, ensuring quality use of medicines, pharmacoeconomics, medication management, protecting public health, perspectives on new technologies, quality, safety and research and clinical challenges in oral drug therapy. DUPHAT scientific program also comprised pharmacy workshops, managerial skills workshop, parallel scientific presentations, professional faculty and student poster session, student poster competition and student short oral presentation competitions. The latest technical information from the pharmaceutical industry was highlighted in the Pharmaceutical Technologies Exhibition.

To assist at the DUPHAT gave me the opportunity to meet and to discuss with speakers from all over the world. As an invited speaker at the conference, I provided a plenary lecture in the theme of mental health pharmacy but I also got involved in several activities, such as student oral presentations and marking students and professionals posters. All of them enthusiastically explained their findings. A much appreciated social program was offered to the speakers including a desert safari and gala dinner during which all speakers received a memorable gift as appreciation for their contributions to the 19th DUPHAT meeting.

Siaka Desplenter
ESCP President
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The International Journal of Clinical Pharmacy is the association journal of the ESCP. It has a rather small Editorial board, which consist of the editor in chief (Foppe van Mil), a representative of ESCP (Marie Caroline Husson), a representative of the Dutch title-owner KNMP (Peter de Smet) and a representative of the managing editing company Springer SBM (Peter Butler). This board meets at least annually, and the last meeting was on 17th of June 2013 in Dordrecht, the Netherlands. Below you can find examples of what is discussed during such meetings.

ESCP abstracts and poster
ESCP poster and abstract access were briefly being discussed. French clinical pharmacists would like direct access to the ESCP posters. ESCP members have free access to the abstracts, but that is one of the benefits of their membership. Real full posters have never been published. There is currently no system in place in ESCP for reproducing all posters, and it is not within the current scope of Springer SBM to offer such a service.

Impact factor
This is an important topic, which is always discussed. Due to the recent name change of the journal, the impact factor released in 2013 (0.83) is not a good representation of reality, since it does not cover the cites in 2010 (when the journal was still called Pharmacy World & Science). A remark to this extend needs to be placed on the journals web site. Peter Butler, from Springer SBM, will come to Prague for a small workshop on Impact Factors for the ESCP board and Communication Committee.

Editor-in-chief and publisher reports
It is again remarkable that there a 20% annual increase of contributions. We have a kind of “overflow of papers”. Language in the contributions remains a problem as is finding good active reviewers. The reviewers database needs to be regularly maintained. We should send all reviewers an annual letter, checking their email and asking them to adapt their key words, if necessary.

There is a general tendency in publisher’s land to pay more attention to ethical issues around medical research and publishing. Should IJP add more ethical considerations? The Board decided to add an extra obligatory standard header “Ethical Approval” (before the Method section) to all relevant publication types.

The publication speed of the journal is still OK and comparable to similar journals. Most subscriptions are institutional or corporate, and electronic. There are few subscribers for the printed edition left. All in all, the title change seems to have worked OK for the journal, although the influence on the Impact Factor only becomes clear in 2014.

Language editing, Edanz and relation with Springer.
There is an editing service affiliated with Springer (Edans, www.edanzediting.com), and they offer their services to authors for Springer journals at a reduced rate. We should somehow advertise this, although the quality does not always seem as good as may be expected. For people who cannot afford a professional editing service, the journal has a language editor who occasionally helps to edit an already accepted manuscript.

Top 5 reviewers
As in other years, Springer offers gifts to those reviewers that have done the most reviews. To find the very good reviewers, we should, of course, look at completed reviews, and not at the invitations.

J.W. Foppe van Mil
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PRAC recommends the same cardiovascular precautions for diclofenac as for selective COX-2 inhibitors

On the 14th of July, EMA disseminated a press release on possible cardiovascular risks of diclofenac. Within EMA there is a Pharmacovigilance Risk Assessment Committee (PRAC). The PRAC review of diclofenac was started in October 2012 in response to findings from the 2012 review of NSAIDs, which identified a small increased risk of these cardiovascular side effects with diclofenac compared with other NSAIDs - an increase similar to that seen with the COX-2 inhibitors. The absolute cardiovascular risk with any NSAID depends on a person’s underlying risk factors, such as high blood pressure and cholesterol levels. For diclofenac, the overall number of heart attacks would be expected to increase by approximately 3 cases per year for every 1,000 people at moderate risk, treated (from 8 per 1,000 people per year normally, to 11 per 1,000 people per year taking the medicine) (1).

As diclofenac-containing medicines are all authorised nationally, the PRAC recommendations will be forwarded to the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), which will adopt a final position. The CMDh is a medicines regulatory body representing the EU Member States. It is more than 10 years since, the outcomes of clinical trials pointed to an enhanced cardiovascular risk by diclofenac. All NSAIDs should be considered as enhancing cardiovascular risks (2). Most probably the Summary of Product Characteristics (SPC) of the marketed medicines containing diclofenac will have to include extra warnings.

Bibliographic references

PRAC recommends restricting the use of codeine when used for pain relief in children

The PRAC has recommended a series of measures to address safety concerns with codeine-containing medicinals when used for the management of pain in children. This follows the PRAC’s review of reports of children who developed serious adverse effects or died after taking codeine for pain relief. Most of the cases occurred after surgical removal of the tonsils or adenoids for obstructive sleep apnoea (frequent interruption of breathing during sleep).

Codeine is an opioid that is authorised as painkiller in adults and children. It is converted into morphine in the patient’s body. The children who had suffered severe side effects had evidence of being ‘ultra-rapid metabolisers’ of codeine. In these patients, codeine is converted into morphine in the body at a faster rate than normal, resulting in high levels of morphine in the blood that can cause toxic effects such as respiratory depression.

The PRAC recommended the following risk-minimisation measures to ensure that only children for whom benefits are greater than the risks are given the medicine for pain relief:

Codeine-containing medicines should only be used to treat acute (short lived) moderate pain in children above 12 years of age, and only if it cannot be relieved by other painkillers such as paracetamol or ibuprofen, because of the risk of respiratory depression associated with codeine use.

Codeine should not be used at all in children (aged below 18 years) who undergo surgery for the removal of the tonsils or adenoids to treat obstructive sleep apnoea, as these patients are more susceptible to respiratory problems.

The prescribing information should carry a warning that children with conditions associated with breathing problems should not use codeine.

The PRAC further recommended that, as the risk of side effects with codeine may also apply to adults, codeine should not be used in people of any age who are known to be ultra-rapid metabolisers nor in breastfeeding mothers, because codeine can pass to the baby through breast milk.

The prescribing information for codeine should also include general information for healthcare professionals, patients and carers on the risk of morphine side effects with codeine, and how to recognise their symptoms.

During the review, the PRAC assessed all available data on the benefits and risks of codeine when used for pain relief, including pharmacokinetic data, clinical studies, post-marketing data in Europe and other published literature. The Agency also invited stakeholders, including healthcare professionals, patients’ organisations and the general public, to submit data relevant to the procedure. The Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) will adopt a final position.

The Belgian Medicines Agency has put codeine containing cough preparations on prescription only since May 2013. Formerly these preparations were OTC, also for children over 2 years old. This decision was taken independently from the PRAC investigation and seriously influences the actual counselling practice in community pharmacies.

PRAC recommends measures to minimise risks of thromboembolism: the case of Diane®

The PRAC has concluded that the benefits of Diane® 35 (cyproterone acetate 2 mg, ethinylestradiol 35 micrograms) and its generics outweigh the risks, provided that several measures are taken to minimise the risk of thromboembolism (formation of blood clots in the veins and arteries).

These medicines should be used solely in the treatment of moderate to severe acne related to androgen sensitivity and/or hirsutism (excessive unwanted growth of hair) in women of reproductive age. Furthermore, Diane® 35 should only be used for the treatment of acne when alternative treatments, such as topical therapy and oral antibiotic treatment, have failed.

The Europe-wide review was initiated at the request of the French medicines regulatory agency (ANSM), following the announcement of its plan to suspend the marketing authorisations for Diane® 35 and its generics in France. This was the result of a national benefit/risk review by ANSM of the product. This review highlighted serious thromboembolic events and extensive off-label use of these medicines as a contraceptive only.

Based on all available data, the PRAC concluded that Diane® 35 and its generics have a place as a treatment option for certain women suffering from the above-mentioned conditions. It also acknowledged that there is a need to take further measures to better address and minimise the risks of thromboembolism associated with these medicines.

Gert Laekeman
Past President of ESCP (2006-2008)
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Masterclass in Pharmacy Practice Research

Tuesday, October 15, 2013, 9.00 – 17.30.

The day before the ESCP Symposium Prague there will be a Masterclass of Excellence in Pharmacy Practice Research, organized by the ESCP Research Committee.
Program:
9.00–9.45 Introduction and Pharmacy Practice Research; Mara P. Guerreiro (PT)
9.45–10.15 Defining your research question; Marcel Bouvy (NL)
10.15–11.00 Overview of quantitative methods in pharmacy practice research; Marcel Bouvy
11.00–11.15 Coffee break
11.15–12.00 Overview of qualitative methods in pharmacy practice research;

Mara P. Guerreiro
12.00–13.00 Outcomes research: measuring clinical, economic and humanistic endpoints; Mara P. Guerreiro
13.00–14.00 Lunch
14.00–14.30 Proposals of research projects by participants and selection of projects to further elaborate on in small groups
14.30–16.00 Group work: Defining a research question and deciding on research methodology
16.00–16.30 Coffee break
16.30–17.15 Presentation of group outputs and discussion
17.15–17.30 Wrap-up session
Venue: Clarion Congress Hotel Prague, same venue as the ESCP Symposium.

Registration: [http://www.escp-prague.eu](http://www.escp-prague.eu)
Registration fees:
Masterclass only for ESCP members, and for members of Czech Pharmaceutical Society or Czech Society for Clinical Pharmacy: 150 euro
Masterclass only for non-ESCP-member: 250 euro
Additional fee for the Masterclass if also registered for the ESCP Symposium: for ESCP members, and for members of Czech Pharmaceutical Society or Czech Society for Clinical Pharmacy: 120 euro; for non-ESCP-member: 150 euro.
The number of participants is limited to 30.

Symposium President
Jiří Vlcek, Czech Republic
Organizing Committee
Chair: Irena Netíková
Members OC ESCP
Olivier Bourdon, France
Siska Desplenter, Belgium
Erik Gerbrands, Netherlands
Members OC Czech Republic
Šárka Kozáková
Roman Gončů
Marie Zajícová
Jitka Bačová

Scientific Committee
Chair: Daniela Fialová
Members SC ESCP
Anna Carollo, Italy
Mara Guerreiro, Portugal
Yolande Hanssens, Qatar
Marie-Caroline Husson, France
Marcus Lampert, Switzerland
Members SC Czech Republic
Petra Matoušková
Petr Čerwený
Dalibor Černý
Martin Vodička
Martina Maříková
Aleš Mareček

New GC members
As you might know, the members of the General Committee of ESCP are elected for 4 years and the term in office can be extended by the General Assembly for another 2 years. At the General Assembly in Prague, October 18th, 2013, Piera Polidori, representing Italy, will step down from the General Committee of the ESCP and is not eligible for re-election.

As the International Office has received only one nomination, of Daniela Scala, she is elected to represent Italy in the GC.

The term of office for General Committee members is four years, with the option of a further two years. By accepting the nomination, the nominee declares, if elected, to be an active member of the GC and an active member, representing the GC, in one of the following committees: Research Committee, Education Committee, Communication Committee, or SIG council. The GC has two meetings a year: one the day before the Autumn Symposium, and the other usually the day after the Spring Workshop. Some conference calls can take place during the year, and there is (almost daily) email exchange.

For the full text of the Constitution, visit the website: [www.escpweb.org](http://www.escpweb.org).

For the election-process for GC-members: see Art. 10.
For Your Diary

2013

16-18 October Prague (CZ) 42nd ESCP Symposium on Clinical Pharmacy « Implementation of Clinical Pharmacy Practices: Research, Education and Management »

2014

22-23 May Palermo (Italy) ESCP-Sifo International Workshop

22-24 October Copenhagen (Denmark) 43rd ESCP Symposium on Clinical Pharmacy « Patient Safety - Bridging the Gaps »

New Members

ALGERIA
Yamina Benelfoul ....................... Blida

CZECH REPUBLIC
Daniela Fialova ............ Hradec Kralove

FRANCE
Lise Bernard ........... Clermont Ferrand
Daniel Bourdeaux ..... Clermont Ferrand
Magali Bourdelin 
........................ Villefranche sur Saône
Lionel Brisseau ................. Nantes
Solène Collin .............. Nancy
Farida Dolarid ................ Rouen
Magali Heilot Guersing ........ Vienne
Sandrine Joly ............. Venissieux
Cécile Jonneaux ...................... Lille
Nhom Lam ....................... Pfostatt
Aurélie Marquet .............. Nantes
Zoubir Ramjaun ............... Trebes

Anne Rouault ..................... Paris
Lakshmi Rughoon ............... Nancy
Saadia Skali ..................... Pierre Benite
Laurence Spiesser-robelet .... Angers
Si Mohamed Yassine ....... Ivry sur Seine
Sophie Bonn-Louve ....... St Nicolas du Port
Clau de Brunet ............. Lille
Chantal Gueyouche .......... Chantilly
Alain Guilleminot ........... Rézé
Claudine Hequard .......... Caen
Michel Luycks .............. Lille Cedex
Jacky Maillet ............ Saint Aout
Katalin Toth .............. Briss sous Forge
Etienne Cousein .......... Valenciennes
Stéphane Honoré .......... Marseille
Francois Lemare ........ Villejuif
Jean Louis Cazin .......... Lille

INDONESIA
Dyah Perwitasari .......... Yogyakarta

Woyo Supadmi .............. Yogyakarta

MOROCCO
Rachid Benaddia .......... Ksar Al Kabir

NETHERLANDS
Siska Kool ....................... Chaam

NETHERLANDS ANTILLES
Wandikay Matowe ............. Dutch Lowlands St.Maarten

NORWAY
Holm Hilde ...................... Gjøvik
Reidun Kjome ................. Bergen

SWITZERLAND
Catharine Haenni .......... Fribourg
Lea Bruehwiler ............... Baden