Firstly, the workshops constitute a major part of the program.

Secondly, you are expected to solve problems and cases rather than passively listening to lectures. The workshop moderators are asked to make sure that most of the time is spent on problem-solving activities.

Thirdly, the group size (max 30 attendants) is kept on a level where it is possible to work effectively and to create fruitful discussions. In this way the aim is for the attendants to learn something that they can take back and put into practice in their own places of work.

The symposium offers an extensive poster session including Oral Communications and Poster Discussion Forums with contributions from a number of countries from Europe and beyond.

As the focus is solely on clinical pharmacy, you have the opportunity to gain a fairly concise impression of research and practice in this important field of pharmacy for 2016.

The social program, created by the Organising Committee (OC) with Anne Gerd Granås as chair, is nearly a reason on its own to come to Oslo. On invitation from the Mayor of Oslo, Marianne Borgen, there will be a welcome reception at the City Hall, an iconic building that was built 1931 – 50 by the famous architects Arnstein Arneberg and Magnus Poulsson.

I hope that you will find the symposium professionally interesting and socially engaging, and that it will inspire you to further develop your own practice and reflect on the issues discussed.

Welcome to Oslo!
Who’s who? Frank Jørgensen

Mr. Frank Jørgensen graduated as a pharmacist from the School of Pharmacy, University of Oslo, Norway in 1987 and has since then worked within the hospital sector. He holds a postgraduate Clinical Diploma in Clinical Pharmacy from School of Pharmacy, Robert Gordon University, UK and is a Specialist in Hospital Pharmacy. In addition he holds the degree Master of Management from the Norwegian Business School, BI.

He has practiced within most areas of hospital pharmacy (procurement and distribution of medicines, manufacturing and compounding, ward and clinical pharmacy, and dispensing to in- and outpatients) including time spent as a manager. For the last 23 years he has worked at Haukeland Hospital Pharmacy, Bergen, which is based at Haukeland University Hospital. He has also worked for a few years at the Hospital Pharmacy in Skien, Norway and has had a brief engagement as a clinical pharmacist at Leeds Teaching Hospitals, UK.

Over the years, Frank has held a number of honorary positions nationally and internationally. Nationally, he has, among other things, served as President of the Norwegian Association of Hospital Pharmacists (NSF) since 2011. Internationally, he has served on the board of ESCP, both as board member and President (2007 – 2008) and he is currently serving as board member on the board of EAHP (European Association of Hospital Pharmacists).

He believes strongly that clinical pharmacy is an important part of pharmaceutical services which should be offered by pharmacists in the hospital and community sector. Through his daily practice at a surgical ward he experiences the breadth and width of medicines related issues and how well they can be identified and resolved by close collaboration between himself, patients, doctors, nurses and other healthcare practitioners.

In his clinical work at a hematological ward he is involved with the issues of access and prioritization related to the new and (very) expensive medicines within the specialty. Importantly, he experiences time and time again that he is able to bring new competencies to the therapeutic/economic team and thereby enable better medicines related decisions.

He thinks this is a common experience to most clinical pharmacists and to him this is the main reason for his clinical engagement.

Over the 30 years he has practiced pharmacy, clinical pharmacy in Norway has gained even more acceptance in hospitals and the primary care sector and is now on the brink of becoming main stream practice. This is partly due to research from Norway and Sweden where the therapeutic and economic benefits of medicines reconciliation and medicines review, performed by clinical pharmacists, in collaboration with doctors and nurses has been clearly shown.

It is also due to the relentless work of former and current pioneers based “on the shop floor”, in hospital pharmacy and community pharmacy management and in the national pharmaceutical associations, to promote the benefits of including the clinical pharmacist in the therapeutic team in discussions with patients, politicians, educators and fellow health professionals.

With these remarks, he thinks the future of clinical pharmacy in Norway looks bright.

Who’s who? Anne Gerd Granås

Professor Anne Gerd Granås has been a member of the ESCP General Committee for five years. When nominated, a personal daunting goal was to host the ESCP Symposium in Norway. Therefore, when the Norwegian Hospital Pharmacy Association agreed to jointly organise the event with ESCP, she had the biggest smile ever! “This is such an important event for the strengthening of clinical pharmacy practice and research in Norway! We will do our best to make this a memorable experience for our colleagues from all over Europe”.

Anne has more than 15 years of work experience since her PhD graduation in 2000 at the School of Pharmacy, University of London. Her MSc Pharm degree is from the School of Pharmacy, University of Oslo. So what has been her main interest since her graduation?

“I have recently taken a post at the University of Oslo, after spending the last five years as Professor at Oslo and Akershus University College in Oslo. I have also worked at the Universities in Bergen (2008-2011), Tromsø (2001-2003) and Oslo (2001-2002). One great challenge was working as Director of Research at the Institute for Pharmacy Practice Research (Apopfors) (2003-2008), where we investigated a range of issues related to the pharmacists’ role in identifying prescribing errors, performing medication reviews and in reporting side effects. Occasionally stepping outside the academic world, and spending some time in Hospital Pharmacy, the Norwegian Directorate of Health (2011), and the Norwegian Medicines Agency (2000), has improved my skills as a pharmacy educator and researcher.”

Her research has been on multidisciplinary intervention to identify and resolve drug-related problems in various health settings, on the pharmacists’ role in reporting side effects, in resolving prescribing errors, and in providing pharmaceutical care services. She has a specific interest in patients’ understanding and management of their illnesses and medicines, often by combining quantitative and qualitative methods to address patient safety issues, in particular in the elderly population.


Anne also co-edited the first textbook in Pharmacy Practice in Norway. “Making this book was fun. I hope it contributes to a better understanding of pharmacy practice, professional and research ethics, policy developments, pharmacoepidemiology, pharmacoconomics, and the role of pharmacists in medicine use and information at an individual, national and global perspective. I just love it when students ask critical questions on the challenges of inequality in the world, poverty, falsified medicines and ethical dilemmas on drug patents and rising costs of medicines.

So what does the future look like? “Bright! This year I have been teaching for two months at the Université Paris Descartes, through an invitation by Professor Olivier Bourbon, the next president of ESCP. In my new job at the University of Oslo the main focus is to develop larger research projects that expand therapy and professions, somehow related to medication reviews and medication errors. And not to forget my latest passion: eLearning!”
Scientific information

The main theme of the symposium is “Clinical Pharmacy tackling inequalities and access to health care”. Clinical pharmacists are frequently asked to advise on appropriate therapies, from either pharmaceutical/medical or economic perspectives. It is ethically challenging to arrive at appropriate decisions, especially when the outcome is uncertain, the medicine expensive and the budget limited. The theme of our symposium reflects 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.

On Tuesday 4th October the program starts off with a Masterclass on qualitative research organised by the Research Committee of ESCP. In the evening there is a lecture on “Inequalities on access to information” presented by Dr. Magne Nylenna, bridging the theme of the ESCP Symposium last year “Medicines information – making better decisions”, and the focus of this year’s conference.

On Wednesday 5th October the main program commences with a plenary session where the first key note lecture, “Inequalities and access to health care: lessons to learn from experiences and challenges in Belgium” will give an overall impression of the situation concerning these issues in Europe as well as in Belgium. Possible ways forward to ensure equality of access to health care will be discussed.

The second key note lecture, “Pharmacist experiences of health and ethnic inequalities: a case study of diabetes management” will address the same issues from a clinical pharmaceutical perspective in a specific context.

The Steve Hudson Memorial lecture will be given by Dr. Rose Marie Parr, Scotland, UK. The presentation will build on Dr. Hudsons philosophy and practice of Pharmaceutical Care in NHS Scotland and highlight the current and developing roles of clinical pharmacy practitioners with the ability to undertake pharmaceutical care planning and review.

In the afternoon there are two plenary lectures on smoking cessation, and interactions between alcohol and medicines respectively. Here, two areas are highlighted where clinical pharmacists both in hospital and the community are making significant contributions towards reducing inequalities in health.

The program of Thursday 6th October is dedicated to issues concerning access to new and (very) expensive medicines. The aim of the day is to convey a glimpse into the complex landscape shaping the current and future accessibility to these medicines from the perspectives of the patient, the physician, the bill payer, the clinical pharmacist, the regulator and the pharmaceutical industry. This will happen through a number of lectures and a panel discussion. At the same time some of the relatively established, but expensive medicines, like infliximab, trastuzumab and rituximab, are meeting or will meet competition from biosimilars. As there are a number of controversies surrounding biosimilars, there will be a lecture entitled “Biosimilars – what should clinical pharmacists know?”.

To give an insight into the opportunities and challenges ahead, the current and future medicinal treatment of rheumatoid arthritis will be addressed through an afternoon plenary lecture.

The place of the clinical pharmacist as a stakeholder in the crossfire between cost and benefit will be addressed in the afternoon plenary lecture “The role of the clinical pharmacist in advanced therapy”. In this presentation the emphasis will be on experiences from Grenoble, France, but the issues addressed are applicable to most other European settings.

On Friday 7th October, the focus is first on long-term conditions in children. The theme is addressed through a key note lecture on how to empower children as medicines users and two more on current treatment of diabetes type 2 and ADHD (Attention Deficit Hyperactive Disorder) respectively. The first lecture is on the need of education on medicines for children on chronic medication and how to meet this need, including the role of clinical pharmacists in this endeavour.

Diabetes type 2 and ADHD were chosen as themes as they are prevalent long-term conditions in children and at the same time there is a role for the clinical pharmacist in their management, especially in the community setting.

Secondly, antimicrobial resistance will be addressed through a key note lecture on how the gut microbiota may influence resistance patterns, and how the microbiota in the gut can be actively modulated by faecal transplantation. In recent years research on the role of the gut microbiota in health and disease has intensified within this important area.

The role of the clinical pharmacist in combating antimicrobial resistance will be covered in the second key note lecture. Opportunities and challenges for clinical pharmacists in addressing overuse, under-use and misuse of antibiotics in different settings will be discussed.

As in all ESCP symposia, afternoon workshops are an important element. This year there will be 18 workshops, some of them echoing the themes of the key notes. Nearly all the workshops will be run twice. Close to 400 abstracts have been accepted for presentation, either as a poster or an oral communication. In addition some of the posters will be highlighted through the poster discussion forums which this year will be on the “pecha-kucha” format.

We hope the program will support you in providing good pharmaceutical care, give insight in innovative clinical pharmacy developments, and inspire you to tackle challenges you meet in the arena of inequalities and access to health care.

Frank Jørgensen
Symposium President and Head of the Scientific Committee
frank.jorgensen@sav.no

Join the Masterclass of excellence in qualitative research!

The day before the Symposium in Oslo, the ESCP Research Committee organises a Masterclass on qualitative research “Getting started with qualitative research: from research questions to dissemination”. Qualitative research is increasingly important in pharmacy practice research. Qualitative findings may contribute to the design of more quantitative studies or the design of intervention studies. Moreover qualitative research helps to interpret the data obtained in quantitative studies or the (lack of) effects of interventions. Pharmacists are generally not familiar with qualitative research. In this masterclass we will give an overview of methods and how to they can be applied. We will use practical examples from qualitative studies. The masterclass will be facilitated by a social scientist and a pharmacist who both have experience with several types of qualitative research.

Marcel Bouvy is professor of pharmaceutical care at Utrecht University and part-time community pharmacist. His research focuses on patient adherence, medication safety, including observational methods and evaluation of pharmacy interventions.

Sofia Kälvermark Sparrong is associate professor and research group leader in social pharmacy at the University of Copenhagen. She has a social science background and has a versatile experience with qualitative research methodology. Her research focuses on the pharmacy professions e.g. pharmacy policy, pharmacy practice and drug communication.

Marcel Bouvy
on behalf of the Research Committee
m.t.bouvy@hs4at.nl
Abstracts reviewing
Approximately 22 reviewers have contributed to the review of the abstracts for the Oslo ESCP Symposium. The review was done according to new criteria, drawn up in 2015. For this conference, 407 abstracts were submitted, and as usual, each abstract was reviewed by at least 2 reviewers. The abstracts came from 39 countries, most from France and Spain. If the score of the reviewers showed a big discrepancy, then a third reviewer was assigned. At the end, 68 abstracts were rejected due to bad quality, or because the abstract was not about clinical pharmacy. Twenty-four abstracts were assigned to the oral communication sessions, and thirty-six to a poster presentation forum. There will be 330 posters on display in Oslo. If an abstract was considered to be out of scope, if the abstract could not be understood, if the project/abstract did not state an aim clearly, or if it was formatted inappropriately, it was automatically rejected. Not all abstract submitters understood the criteria, and therefore a podcast was made available on how to make and submit an abstract for the ESCP symposia. However, this year this did not seem to have influenced the rejection rate yet. The principal reasons for rejection had not really changed.

How to write an abstract - Workshop for enthusiastic Norwegian pharmacists
20 Norwegian pharmacists received useful tips for communicating their research results at an abstract workshop in Oslo, Norway.
Many pharmacists are new to writing scientific abstracts. Two members of the Organising Committee for the 2016 ESCP Symposium in Oslo, Liv Mathiesen and Anne Gerd Granås, invited aspiring pharmacists to an “How to write an abstract” workshop. By inviting pharmacists to write their own abstracts, they hoped to create interest in attending and presenting research projects the ESCP Symposium in Oslo, 5th-7th October. Any pharmacist interested in writing an abstract could attend. Before the workshop participants were told to bring draft copies of their abstract.

The aim of the workshop was to help the pharmacists with getting started with abstract work. - “We wanted to help the participants to increase their chances of getting their abstract accepted. For example, by considering what is important to include or leave out of an abstract” says Anne Gerd. “Most conferences receive more abstracts submission than they can accommodate. An abstract can also be seen as admission-ticket to participate in a conference, either with a scientific poster or a separate oral presentation”. At the workshop we explained how abstract reviewers use a quality scale when judging each of the submitted abstracts. It is often easier to criticise others than our own work. The participants were split into groups of four, reading each other’s abstract and giving feedback. In addition, Granås gave a lecture about what a good abstract should contain. A short introductory film could be viewed in advance, which is available on the ESCP website: http://www.escpweb.org/how-to-write-an-abstract.

Elevator pitch - what is your research really about?
It was important to emphasize that an abstract must be brief and to-the-point. All participants carried out a so-called elevator pitch. The idea is to pretend you meet someone in the elevator and in only one minute have to tell a person what your research project is about. What is the purpose? What did you find and what does it mean? “It was impressive what the pharmacists managed to sum up in only one minute, and it helped them pin-point the main focus for the abstract” says Anne Gerd.
20 pharmacists from all over Norway attended the workshop, many of which will attend the Symposium in Oslo in October 2016. The great national interest in publishing abstracts at ESCP Symposium in Oslo is very promising for the future of clinical pharmacy research. - “Our aim is that clinical pharmacists can build a stronger academic tradition and attend international conferences. As the ESCP Symposium is in our own country we hoped to lower the threshold to participate, especially for those who have not previously participated in international conferences”, says Liv Mathiesen. “There is a lot to learn and discuss for clinical pharmacists, but also community pharmacists, those working for wholesalers, for government agencies and the pharmaceutical industry. Everyone is welcome”.

“And I consider that writing an abstract is a litmus test on whether research should be published elsewhere”. She hopes that abstract the workshop will inspire more people to publish their research. –“I have attended ESCP Symposia where I can overhear participants looking at posters say; “But they have done something similar at home.” Then I think they should just to embrace the challenge to publish their own work!” smiles Mathiesen.
As a GC member in ESCP, Anne Gerd Granås also encourage clinical pharmacists in other European countries to run a similar workshop locally. “Maybe the short introductory film can give some inspiration for a local workshop? We certainly had a lot of good discussions and a lot of fun”.

Anne Gerd Granås
anne.granas@hioa.no

The ESCP Research Grant
The ESCP Research Committee was delighted with the interest shown in the ESCP Research Grant this year, receiving five applications for consideration covering a wide range of clinical areas:

<table>
<thead>
<tr>
<th>Area of Research</th>
<th>Collaborating countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Opportunistic screening</td>
<td>UK, Portugal, Belgium</td>
</tr>
<tr>
<td>2 Clinical outcomes assessment</td>
<td>UK, Ireland, Malta</td>
</tr>
<tr>
<td>3 Medication management</td>
<td>Croatia, Spain</td>
</tr>
<tr>
<td>4 Interventions in chronic polyphar-</td>
<td>Ireland, Germany, Switzerland</td>
</tr>
<tr>
<td>5 Survey of medication use</td>
<td>Norway, Hungary</td>
</tr>
</tbody>
</table>

The applications are being reviewed by a commission and the project leader of the winning application should be notified of their success by mid-September 2016.

Increasingly it seems that supervisors do not really teach their students how to write an abstract, but do require their name to be mentioned as an author. Especially in the case of a rejected abstract this can hardly be justified.

If you, as a potential author, are unsure if you can prepare a proper abstract, come to the workshop ‘Successful abstract writing’ (see below) which is held at least once during every ESCP Symposium, or look at the podcast.

Foppe van Mil
Chair Communication Committee
jwfvmil@vanmilconsultancy.nl
In the February issue of the International Journal of Clinical Pharmacy (Int J Clin Pharm) an interesting study on medication therapy management (MTM) for patients with Parkinson’s disease (PD) was published (1).

The authors did show that even in a well-informed active group of patients with PD, MTM significantly improved quality of life (QoL), measured by the Unified Parkinson’s disease rating scale (UPDRS) and the Movement Disorder Society Unified Parkinson’s disease rating scale (MDS-UPDRS). This result is remarkable for several reasons: PD has a high psychological strain and symptoms mostly improve quickly after administering adequate medication. Therefore, medication adherence is higher compared to other diseases like hypertension. In addition, patients were recruited by a support group. Hence, the participating patients were very well informed and interested in their pharmacotherapy. Against this background, the results are remarkable showing that medication management improves disease control, although antiparkinson drugs were not the main focus of the intervention.

Moreover, a slight deterioration in UPDRS and MDS-UPDRS would have been expected due to the progression over time most common in PD.

The results of Henrichsmann et al. are supported by a more recent study from Brazil (2). Although these authors could not detect a statistically significant improvement in QoL using the Parkinson’s Disease Questionnaire (PDQ-39), they could improve the appropriateness of the medication in general. Another earlier study, also compared to other diseases like hypertension, the results are against this background, the results are remarkable showing that medication management improves disease control, although antiparkinson drugs were not the main focus of the intervention.

Further research should focus on longer observation times in this patient group with the goal of avoiding hospital admissions and reducing treatment costs. This would enable pharmacists to offer this service to more patients worldwide.

Ref:

Martin Schulz
On behalf of the Research Committee

In the April issue of the International Journal of Clinical Pharmacy (Int J Clin Pharm) an interesting study by Willeboordse F et al. compared the differences between using a questionnaire (Q) or a patient interview to undertake a clinical medication review (CMR) in elderly patients (≥55 yrs). By way of background, the authors highlighted there was no gold standard for collecting data on medicines and drug-related problems (DRP), and that face-to-face (F2F) interviews were generally time consuming. Once Q was developed, it’s potential place in the provision of CMR was explored.

Data was obtained from 97 patients with mean age of 75.9 yrs (SD 7.1). The reported number of medicines used was higher in the F2F group than the Q group (7.3 SD 3.2 versus 6.8 SD 2.7) with an observed agreement between Q and F2F of 87% for all medicines. Also, patient taking < 10 medicines showed significantly greater agreement than those taking ≥ 10 medicines (91.1% versus 78.4% at medication level; 55.7% versus 18.5% at patient level; both p<0.05).

DRPs were categorised as; adverse events, effectiveness problems, adherence, user or practical problems. More DRPs were identified through F2F than the Q (116 versus 76) with greatest level of agreement for the Q against F2F being around adverse events (78.4%, 95% CI 70.0 – 86.7) and effectiveness (79.4%, 95% CI 71.2 – 87.6). The results reported in this study show that the use of F2F will generate more information on medicines and DRPs than the developed Q. However, there may be merit in considering the use of this type of Q in patients taking <10 medicines with relatively few chronic diseases or to help standardise the process of CMR with the potential to reduce the time required for F2F assessment. Further work may be required to further optimise the Questionnaire.

Ref:

The ultimate aim of conducting and reporting clinical and pharmacy practice research is that the findings may be implemented to impact and improve the care of patients and clients. To achieve this aim will require that the research is designed and conducted as robustly and rigorously as possible and that the findings are disseminated widely. Furthermore, those reading and potentially translating the findings to their own practice must be able to consider the appropriateness, or otherwise, of any study.

The June 2016 volume of the International Journal of Clinical Pharmacy (Int J Clin Pharm) intends to highlight key issues in clinical and pharmacy practice research and is appropriate for all with an interest in research. It is aimed at novice researchers, those undertaking research related studies to those leading research within the profession. Each article has been written by experts in their respective field, followed by an extensive process of peer review prior to publication. Articles cover a broad range of topics and are clustered into aspects of literature, specific methodologies and methods, and the complexities of selecting appropriate outcome measurements. The following describes just a few of the articles.

Authors conducting and reporting literature reviews often term these ‘systematic’ in that a systematic and ordered approach has been undertaken. While this is correct, these are not necessarily ‘systematic reviews’ and this issue is described by MacLure et al., followed by a detailed guidance on conducting and reporting systematic reviews. Mohammed et al. extend this with their coverage of meta-synthesis of qualitative research data.

The United Kingdom Medical Research Council Framework for developing and evaluating complex interventions (defined as those with several interacting components) and its application to pharmacy practice is described by Hughes et al., with a complementary article by Stewart et al. describing the need to embed theory in quantitative and qualitative research. Mixed methods studies which combining qualitative and quantitative research elements, either in sequence or parallel, are being used increasingly within health related research hence require greater consideration in clinical and pharmacy practice research. Hadi et al. describe and justify several different approaches and their application. While many factors, such as the availability of resources, may limit the scope and extent of clinical and pharmacy practice research, it is still essential that the design, methodology and method are as scientific as possible. This will include consideration of aspects such as robustness in quantitative studies (e.g. issues of validity and reliability) and rigour in qualitative studies (e.g. issues of trustworthiness). The articles presented in this volume of International Journal of Clinical Pharmacy should assist all in achieving these ambitions.

Derek Stewart
On behalf of the Research Committee
Improving safety of first-in-human clinical trials: EMA starts EU-wide reflection on the necessary changes to best practices

Severe adverse reactions in healthy volunteers such as those observed in the trial in Rennes are extremely rare during clinical trials. The trial led to the death of one participant and hospitalisation of five others. Since 2005, approximately 14,700 phase I clinical trials (with participation of 305,000 subjects) have been conducted in the EU, including 3,100 first-in-human studies. Only one other severe incident has been previously reported in that time in the EU.

The European Medicines Agency (EMA) has started a review of the guidelines that describe first-in-human clinical trials and the data needed to enable their appropriate design and allow initiation. This is being done in cooperation with the European Commission and the Member States of the European Union (EU). The review will identify which areas may need to be revised in the light of the tragic incident.

EMA’s review will take into account the findings from two in-depth investigations into what went wrong during this trial, one carried out by the Temporary Specialist Scientific Committee (TSSC) set up by the French medicines agency ANSM and the other by the Intervention Générale des Affaires Sociales (IGAS), the inspectorate for social affairs in France. Both reports include a series of recommendations regarding the requirements for authorisation and conduct of first-in-human clinical trials for further examination by the international regulatory and public health community.

EMA’s work will focus on best practices and guidance. The aim is to agree a concept paper by July identifying areas for change and proposals to further minimise the risk of similar accidents. The concept paper will form the basis for an EU-wide review of the guidelines. This process will include targeted discussions with stakeholders and a public consultation on proposed changes later in 2016.

Gazyvaro approved for rare white blood cell cancer

Follicular lymphoma and chronic lymphocytic leukaemia are both rare types of cancer that affect certain white blood cells that fight infection, called B-lymphocytes. In follicular lymphoma, the body produces abnormal B cells that build up in lymph nodes. While effective treatments exist for follicular lymphoma, the disease often comes back and becomes increasingly aggressive and resistant to existing treatment options.

Patients whose disease has become aggressive often die after one to two years.

The active substance in Gazyvaro is a monoclonal antibody that targets B-lymphocytes and triggers the death of cancer cells through the activation of the immune system. Gazyvaro was first authorised in the European Union (EU) in July 2014 for use in combination with chlorambucil in patients with previously untreated chronic lymphocytic leukaemia. Because follicular lymphoma is rare, Gazyvaro was designated as an orphan medicine in 2015.

In April 2016, the European Medicines Agency (EMA) has recommended extending the authorised indication of Gazyvaro, (obinutuzumab) to treat patients with follicular lymphoma. The medicine is to be used in combination with bendamustine in patients who were previously treated with chemotherapy.

The recommendation from EMA’s Committee for Medicinal Products for Human Use (CHMP) is based on the results of a phase III trial that compared the effects of Gazyvaro given in combination with bendamustine and followed by Gazyvaro as a maintenance treatment, with the effects of bendamustine alone, in 321 patients with follicular lymphoma who did not respond to or whose disease progressed with chemotherpay. In this study, patients treated with Gazyvaro in combination with bendamustine lived longer without their disease progressing compared to patients treated with bendamustine alone (on average about 29 months compared to 14 months).

The most common side effects reported with the combination of Gazyvaro and bendamustine were consistent with the known safety profiles of the individual medicines.

Treatment of renal cell carcinoma to be added to Opdivo’s approved uses

Renal cell carcinoma is the most common form of kidney cancer in adults. Advanced renal cell carcinoma includes both metastatic disease and locally advanced renal cell carcinoma that cannot be resected (removed by surgery). Patients with advanced renal cell carcinoma have a poor long-term prognosis therefore new medicines are urgently needed for patients.

The European Medicines Agency (EMA) has recommended extending the use of Opdivo (nivolumab) to include the treatment of adult patients with advanced renal cell carcinoma (a type of kidney cancer who have received prior therapy).

Opdivo was first authorised in the European Union (EU) in June 2015 for the treatment of advanced melanoma (a type of skin cancer) and already had its use extended (in October 2015) to treatment of the advanced stages of a type of lung cancer, squamous non-small cell lung cancer (NSCLC).

The active substance in Opdivo – nivolumab – is a monoclonal antibody. Nivolumab attaches to and blocks a receptor called ‘programmed death-1’ (PD-1). By blocking the usual receptor interactions, Opdivo leads to activation of the immune system against cancer cells.

The recommendation from EMA’s Committee for Medicinal Products for Human Use (CHMP) is based on the results of a randomised phase 3 study evaluating Opdivo versus another type of kidney cancer treatment called everolimus. 821 patients with locally advanced or metastatic renal cell carcinoma whose disease worsened during or after treatment with anti-angiogenic therapy were included in the study.

The median survival time after starting treatment in patients taking Opdivo was 25 months compared to just under 20 months in patients treated with everolimus.

In addition, about 22% of patients taking Opdivo saw a complete or partial shrinkage of their tumors compared to 4% of those taking everolimus; on average the effect lasted around 12 months for both groups.

The most common side effects of Opdivo reported during the clinical trial were similar to those observed in the already approved indications of Opdivo. These include fatigue, nausea, rash, diarrhoea and decreased appetite.

The recommendations adopted by the CHMP at its November 2016 meeting are an intermediate step on Opdivo’s path to patient access. The CHMP opinions will now be sent to the European Commission for the adoption of a decision on EU-wide marketing authorisations.

PRAC recommends that Fusafungine nose and mouth sprays are no longer marketed

Fusafungine is an antibiotic and anti-inflammatory nose and mouth spray used to treat upper airway infections such as rhinopharyngitis (common cold).

The majority of the serious allergic reactions occurred soon after the use of the medicine and involved bronchospasm (excessive and prolonged contractions of the airway muscles leading to difficulty breathing). Although the PRAC review found that serious allergic reactions are rare, they can be life-threatening, and the PRAC considered that no measures had been identified to sufficiently reduce this risk.

With regard to the benefits, the PRAC considered that the evidence for beneficial effects of fusafungine is weak. Taking into account the mild and self-limited nature of upper airway diseases such as rhinopharyngitis the PRAC considered that the benefits of fusafungine did not outweigh the risks.

Gert Laekeman
Past President ESCP (2006-2008)
Co-opted member of the Herbal Medicinal Product Committee (EMA)
gert.laekeman@kuleuven.be
Clinical pharmacy tackling inequalities and access to health care

45th European Symposium on Clinical Pharmacy, jointly organized with NSF
Oslo, Norway, 5-7 October 2016

Clinical pharmacy tackling inequalities and access to health care

We are proud to announce the Programme and Workshops for the ESCP Symposium 5th-7th October 2016 in Oslo, Norway.

• Clinical pharmacy tackling inequalities and access to health care

Clinical pharmacists are frequently asked to advise on appropriate therapies, from either pharmaceutical/medical or economic perspectives. It is ethically challenging to arrive at appropriate decisions, especially when the outcome is uncertain, the medicine expensive and the budget limited.

The theme of our symposium reflects 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.

We invite you to Oslo in October for an exciting programme, 18 different workshops, and a pre-conference masterclass in qualitative methodology (4th Oct). All information can be found at www.escpweb.org/oslo.

The deadline for abstract submission for a poster or an oral communication is 11th July.

The Symposium venue is the historic Dragon Building at Scandic Holmenkollen Park Hotel, 350 m above the Oslo City Centre.

The Mayor of Oslo will welcome us at the Oslo City Hall. The Conference dinner includes a visit to the Holmenkollen Ski Museum & Tower.

Please feel free to follow ESCP on Facebook.

King regards from

Markus Lampert
ESCP President
Frank Jorgensen
President, NSF
Anne Gerd Granas
Head of Organizing Committee

76th FIP World Congress of Pharmacy and Pharmaceuticals Sciences 2016
Buenos Aires, Argentina, 28 August - 1 September 2016

Reducing the Global Burden of Disease-Rising to the Challenge

During the 76th FIP World Congress of Pharmacy and Pharmaceutical Sciences 2016 in Buenos Aires, Argentina from 28 August to 1 September 2016, more than 1700 participants from 92 different countries, both pharmacists and pharmaceutical scientists, rose to the challenge to reduce the global disease burden.

The question was: Are you prepared to take this challenge?

Of the top 10 causes of death around the world, nine are diseases. Heart disease, stroke, HIV/AIDS, chronic obstructive pulmonary disease, lung cancer, diabetes and diarrheal diseases are among this list.

However the burden of disease is not just about the years of life lost due to early death; it is also about years lost due to living in less than full health.

As a result, there has been an effort to change from a sickness care model to a health care model. Our role in improving the outcomes of treatments is the essence of the pharmacy profession and of pharmaceutical scientists. Creating, preparing and providing medicines is based on this role.

Moving from a sickness model to a health model means that pharmacy is also now about disease prevention and health promotion.

Pharmaceutical scientists, pharmacists and pharmacy educators are dedicated to integrating evidence-based practice to improve the use of medicines. Innovation that creates new treatment options with medicines, collaborative practices (not only within health professionals, but also individuals and communities themselves), practices that improve the use of medicines, prevention (of both diseases and complications from existing disease) and public health programmes all have the potential to reduce the global burden of disease.

In addition, interprofessional education must meet higher quality criteria in order to increase impact and create new context for health care professionals.

The professional symposia at this congress have explored “guidelines for emergency response to disease” and the challenges of tomorrow in the field of chronic pathologies. In addition they explored developments to ensure the proper use of the drugs and minimising the impact of supply disruptions, and counterfeiting of medicines. Further discussions looked at new challenges: integration of digital technology which imposes a new perspective on health care. And of course the vital global issue of antibiotic resistance.

Many ways exist to respond to global health care needs, through practice, science and education, with the aim of reducing the burden of disease and improving quality of life.

Dr Anna SARFATI
Membre du Bureau du Conseil National de l’Ordre des Pharmaciens (National Chamber of Pharmacists)
For Your Diary

2016

5-7 October
Oslo (Norway)
45th ESCP Symposium on Clinical Pharmacy
"Clinical pharmacy tackling inequalities and access to health care"

2017

15-16 June
Leiden (Netherlands)
ESCP International Workshop

9-11 October
Heidelberg (Germany)
46th ESCP Symposium on Clinical Pharmacy

New Members

Australia
Sally Harding

Belgium
Stijn De Maeyer

France
Jean-Meidi Aili
Helene Charlot

Germany
Anna Laven

Italy
Silvia Vecchio

Netherlands
Sander Borgstede
Bart Winters

Norway
Hege Therese Bell
Christina Brekke
Renate Elenjord
Kjell H. Halvorsen

Kristin Larsen
Liv Marit Lundstad
Liv Unni Naalsund
Margareth Wilk
Irene Haugen Ødegård

Switzerland
Karen Maes
Sandra Unfer
Valerie Wentzky

Membership 2016 & 2017
Address: http://www.escpweb.org

2016 Membership fees
1 year Full Membership ................€ 85
3 years Full Membership ..............€ 215
5 years Full Membership ..............€ 340
Student Membership ..................€ 25

Dual Membership (SFPC or SIFO)
SFPC: see http://sfpc.eu/fr/
SIFO: contact the Italian office

ESCP News is published by ESCP
Editor: Marie Caroline Husson (France)
Page Layout: Conniel Tollier (France)
Language editing: Ian Miller (UK)

Copyright: The contents of this publication are compiled in good faith. The publisher accepts no responsibility for omissions or errors.

ESCP International Office
Sil Institute for Pharmacy Practice and Policy, The Netherlands
Tel: +31 645 985 891; Fax: +31 71 572 2431
Email: info@escpweb.org / international.office@escpweb.org
www.escpweb.org

Deadline for the submission of material:
for issue number 174 is 15 December 2016.