Dear colleagues and friends

Three years the secretary has tried to organise the activities in order to form a good collaboration between all Pharmacists in Europe who are involved in Oncology.

We have made great success since we have founded our Society in Prague 2000. The needs have grown to foster the national groups in order to present Oncology Pharmacy at a national level to all responsible organisations in every European country but also to present our unique demands to the European government. Through 2 workshops in 2001 and 2004 at the European government in Luxembourg we have presented the status of our discussion of Quality Management in Oncology Pharmacy Services. The final documentation also from the last meeting is now available on CD and is be send to all members.

One country - one vote, under this motto we have supported all movements in all countries and in this MOL (Membership Online Letter) you will see the fruits of our work.

Our work is based on many national groups of Oncology Pharmacists and also on personal membership in smaller countries. Our presence at the ECCO 13 Conference in Paris has shown that the acceptance of our membership in the Federation of European Cancer Societies (FECS) is growing and that we are on a right way to work also as a Federal bases Society.

One year ago the ESOP delegates have stated: „A new time has come for Oncology Pharmacy in Europe“. They have been right.

yours
Klaus Meier

We are offering communication to all members in Europe through our newsletters and website www.esop.li as well as through our meetings and seminars. Take the opportunities to announce your Pharmacy as a Centre of Exchange and to give colleagues the chance to learn and also to teach.

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The fifth congress of the SFPO (French Society of Oncology Pharmacy) has been held during the 14 and 15th October, 2005 in Cannes Mandelieu, a very nice place in the famous Cote d’Azur (French Riviera). About 250 oncologist pharmacists and 50 industrial representatives were active participants. During the opening session, Dr Klaus Meier, has underlined the importance of the new federative organization for the ESOP. The president of the SFPO, Dr F. Pinguet, has emphasized the very positive role of an European network in oncology pharmacy and confirmed that our 300 members will be strong supporters of any initiative to develop oncology pharmacy services.

The scientific program was very dense, with several presentations about new molecules and new insights in pharmacogenomics and pharmacokinetics in oncology. Three round tables were devoted to oncology pharmacy in Quebec (Dr Gagné), state of art in preventing risks in oncology, and new aspects in handling cytotoxics.

About 75 posters and oral presentations mainly from young colleagues and of high scientific quality, were presented, covering all aspects of oncology pharmacy. Finally, our colleague, Irena Netikova, has offered a very appreciated presentation of the oncology pharmacy in Czech Republic. Obviously, for all attendants, this congress was a great success, confirming the vitality of oncology pharmacy in France.
News from the Czech oncology pharmacy working group

Irena Netikova, General Teaching Hospital, Prague, (Czech Republic)

Our working group has got now 36 members, pharmacists and pharmaceutical technicians and two new hospital pharmacies have started with central cytostatic preparation in our country.

The Czech oncology pharmacy working day took place on the April 29th in Prague.

Two foringer speakers from the ESOP, Kathleen Simons and Peter van Balen attended with very impressive presentations. The main topics were safe handling of cytostatics, a cytostatic contamination and risks for pharmaceutical staff. The meeting had a good response and discussion. Now we are in a negotiation with the only pharma company producing cytostatics in our country about a cytostatic contamination monitoring. An important part of this meeting was agreement all members about the integration as a national group in the ESOP and agreement with member fees.

This meeting had the reaction not only among oncology pharmacists, but among some medical oncologists and nurses and 2 other presentation on this topic were given, one for young medical oncologists group and one for nurses from oncological wards.

Thanks to invitation of the president of SFPO, Frederic Pinque, I had the opportunity to inform French colleagues about a situation in the oncology pharmacy in our country (Cannes, October 2005)

Two members from the Czech oncology pharmacy working group participated in the ESOP booth on the ECCO (Paris, October 2005). It was a good chance for us to present the ESOP to Czech medical oncologists and nurses. We met in particular with an interest about the QUAPOS.

By the traditional autumn meeting of the Czech Hospital Pharmacy Society (Brno, November 2005) one part of presentations was orientated on the oncology pharmacy. In this part informed other ESOP member, Vesna Pavlica, about important aspects in the oncology pharmacy and about the situation in Croatia. English colleagues, Christine Clark and Laurence A. Goldberg, as clinical pharmacists, gave the workshop about mistakes in hospital wards with accent to the oncology.

We prepare next spring Oncology pharmacy working day in Prague (21.4.2006) now and try to built better conditions for a central cytostatic preparation in our pharmacies.
In November 2005, the Slovenian Chamber of Pharmacy organized, jointly with the Institute of Oncology Ljubljana (Slovenia) and the European Society of Oncology Pharmacy (ESOP), organized a workshop on preparation of antitumor agents.

The aim of the workshop was to inform the Slovenian pharmacists about the standards required in producing and preparing antitumor agents, in providing a proper equipment for the work place, in selecting proper preparation and documentation methods, and in recording and reducing the number of errors.

The workshop was organized on the initiative of ESOP, the European Society of Oncology Pharmacy, founded 10 years ago. ESOP is an organization that gathers the delegates of different professional profiles as well as cancer patients from 17 European countries. The aim of the society is to determine, via different levels of activity, the optimal medical treatment for cancer patients. The motto of the society is to think globally and act locally. Apart from developing drug use and administration methods and strategies, their mission is also to promote knowledge of the pharmacists from European countries on the standards for the production and preparation of antitumor agents, thereby assuring higher safety and quality of medical treatment of cancer patients.

The workshop was study-oriented and was attended by the pharmacists and heads of the pharmacies in Slovenian hospitals who are involved in the treatment of cancer patients with antitumor agents. This is a new work approach in the field of pharmaceutical activities that requires a high quality of work as well as the use of the most up-to date work methods. The members of the society are regularly attending international and local seminars and congresses and are invited to enroll in postgraduate study programs for specialization in pharmacy that are organized in some countries, e.g. USA and Germany. The specialization in pharmacy includes also the basics of medical treatment in oncology (epidemiology and diagnostics), handling with cytostatics (SOP) and oncology pharmacists involvement in clinical studies in oncology.

The participation in the workshop was rather high; so was also the participants’ interest in the standards. Their concern for further progress and development in this field was as much obvious as urgent. The workshop was therefore the first step towards an up-to-date approach to antitumor agent preparation and towards acquiring the knowledge of the related recommendations and standards.

The President of the society, Mr. Klaus Meier, attended the workshop as invited speaker. Mr. Meier has rich and long-standing experience in introducing standards into pharmaceutical practice and high merits in introducing quality standards into the preparation of antitumor agents.
He was also one of the founders of ESOP. In his opening speech, Mr. Meier particularly stressed the need to improve the quality of work. In his opinion, a close and mutual cooperation of all members of the expert team is of paramount importance, specifically the cooperation of the pharmacist with the physician. He also emphasized that it would be necessary to set up a computer network in order to facilitate a better flow of information, thereby allowing greater data accessibility to all the personnel involved in the cancer patient treatment. He mentioned the need for cooperation between the hospital and the patient. He also reminded of the risk of errors and reported of the endeavors to avoid them, suggesting the introduction of quality assurance standards. In his opinion, this may be achieved only by establishing an appropriate training system and by acquiring the responsibility or giving the authorization. He drew particular attention to the risk that errors may be committed at different levels of hospital work involved in handling with cytotoxic drugs.

At the workshop, Ms. Andreja Čušar, MSc (Pharm.), President of the Slovenian Chamber of Pharmacy, presented the currently valid quality assurance standards in the oncology pharmacy. She informed the participants that the first uniform standards valid in EU were adopted in 2001 in Luxembourg and summarized their contents.

The second invited speaker, Ms. Vesna Pavlica, MSc (Pharm.) from Croatia, gave an excellent lecture on the errors putting at risk the success of medical treatment of cancer patients with antitumor agents.

My presentation dealt with the systems assuring safety at hospital work related to the handling with antitumor agents, the standards to be met at this work, and possibilities of improvement and upgrading of work methods.

Ms. Petra Tavčar, MSc (Pharm.) from the Institute of Oncology Ljubljana, made an account on the recommendations for dissolving antitumor agents. She highlighted some specific requirements and recommendations.

Ms. Marijana Fortuna, MSc (Pharm.) and Mr. Igor Virant, MSc (Pharm.) both from the Institute of Oncology Ljubljana, made a review of the tasks required in handling with antitumor agents in practice – a sum-up of the preparations applied as safety instruments or dissolving agents.

This workshop was the first seminar-of-its-kind in Slovenia. It presented up-to-date methods of work with antitumor agents, possible errors, standardization requirements, i.e. the topics that are routinely applied in Western-European countries. The workshop was attended by the pharmacists and heads of the pharmacies in Slovenian hospitals who are involved in the treatment of cancer patients with antitumor agents.

The workshop closed with a general conclusion that the possibilities for a standardized preparation of antitumor agents are complex.
We are happy to announce that we were able to produce a CD-Rom of all presentations and workshop summaries of the 2nd Conference on Quality Standard of Oncology Pharmacy Service in Luxemburg which was held in 2004.

It was attended by 80 participants of 20 different countries who were actively involved in 5 different workshops and who had the possibility to follow 5 different presentations. The slides and the sound of all workshops and of four of the five presentations were recorded during the meeting.

After processing the material The CD-Rom documentation was created which is dedicated to spreading the advances and results of the work which has been done in Luxemburg also to those who could not attend.

The entire work at the Conference was based on the multidisciplinary approach to oncology and split into 20 categories. ESOP, as the European umbrella association of oncology pharmacists, was present at the Conference.

It was represented, as instructed by Klaus Meier, by Alain Astier, France (host), Monika Sonc, Slovenia, Irena Netikova, Czech Republic, and Vesna Pavlica, Croatia. As the ESOP presentation area was in a highly visible spot, between the exhibition area and the Conference hall, there were numerous and intense contacts and communication between our representatives and physicians, nurses and colleagues from the industry and business. It was through them that we gained knowledge and insight into the development of oncology pharmacy on all continents.

We exchanged information and filled in questionnaires, providing detailed information on our work. Further communication is expected to follow novelty, compared with the Copenhagen Conference, through a 3-day Patients’ Programme, whereby patients’ representatives, physicians, and policy-makers discussed in an open and straight forward manner the key issues pertaining to the care of oncology patients in all European countries. ECCO Conference was attended by 12000 delegates.

Our days passed in getting to know each others, exchanging views, knowledge and experience, along with the sightseeing of Paris in the evening hours.
Over 100 pharmacists took part in traditional annual meeting of oncology pharmacy held on 13 – 15 October 2005 in Warsaw. An opening lecture on Ethical aspects of clinical studies of drugs was delivered by prof. Krystyna Orzechowska-Juzwenko from Clinical Pharmacology Department of Medical Academy in Wroclaw. Other interesting lectures which were prepared by specialists from National Centre of Oncology in Warsaw included following topics: Facts and myths of clinical studies of antitumor drugs (dr. P. Siedlecki), Treatment of cancer pain (dr. E Hagmajer), Head and neck cancers (dr. B. Jagielska) and Actual epidemiological situation of neoplastic diseases in Poland (dr. W Chmielarczyk).

In another session participants of the Meeting had an opportunity to present their communication concerning different practical experiences from their practice as oncology pharmacists.

On the second day of the Meeting Polish Quality Standards in Oncology Pharmacy drawn up by members of the Section of Oncology Pharmacy of the Polish Pharmaceutical Society (dr. K. Chmal-Jagiello, dr. H. Jankowiak-Gracz and H. Kuzniar) has been presented and discussed. The standards has been edited in a form of printed edition by pharmaceutical company EBEWE and were disseminated to all participants.

During a special workshop dr. Karla Domagk reminded European Quality Standards of Oncology Pharmacy QUAPOS.

Unfortunately our good friend, Klaus Meier could not join us because of healthy problems, but he has sent us a paper Patients need information which was presented by dr. Lazowski.

There was an exhibition of pharmaceutical companies sponsoring the Meeting and some attractive social meetings which enabled discussion and an exchange of experience as well as spend free time in a very pleasant atmosphere.
It is now well recognised that most anticancer drugs are potentially hazardous substances, since they are mutagenic, teratogenic and/or carcinogenic (CMR).\(^1,2\) For this reason, the healthcare workers who are involved in the preparation and manipulation of anticancer drugs can, if they are not adequately protected, absorb potentially harmful quantities of such compounds\(^1,2\).

Therefore, it is important that all people involved with cytotoxic drugs (medical, nursing, and pharmacy staff as well as cleaners, transporters, …) must receive appropriate training relating their level of involvement. They must be aware of the dangers associated with the accidental spillage of cytotoxic drugs. Consequently, procedures and protocols should be developed by a multidisciplinary team in each institution and should correspond to appropriate risk management guidelines.

Drugs are not only conveyed by trained personnel such as those of pharmaceutical companies and wholesalers but can be sent by postal services thus exposing unwillingly other professionals to cytotoxic drugs. This is especially true for small quantities and clinical trial drugs ordered in emergency situations. Another safety issue is that the danger warning is not always indicated on the outer packaging, and there is no cautionary information concerning CMR effects.

Table 1 shows that a consensus has not been found between the different institutions and at present there are four ways of labelling\(^3-7\):

- Use of a warning written in letters such as “CARE : cytotoxic drugs”
- Use of a colour code.
- Use of a specific sign.
- No specific labelling.

Implementation of an unique cytotoxic label, at least in Europe, is now necessary to insure the safety of all people involved in the flow of cytotoxic drugs. The international colour to indicate danger is yellow so it would be wise to choose it for labelling. It would also be of great help if the commercial packaging could notify that the drug has CMR effects. Pharmaceutical firms, pharmacists and the European governments should mutually collaborate in this safety issue.

It is important to have an international recognised label, so that in case of a spillage, everybody would be able to understand the meaning of the warning and to act correctly without being exposed to a CMR drug.

References

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<th>Country</th>
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<th>Comments</th>
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| Australia[3] | Guide of the Community Services industry Workplace Health and Safety Committee | ![Purple symbol](image) | • Purple symbol, which represents a cell in late telophase.  
• Alternatively, a purple label with the word “Cytotoxic” may be used.  
• Purple is the recognised colour denoting the presence of cytotoxic substances or waste and is generally used wherever possible for containers, plastic bags and printing generally.  
• This label should be used to identify transport containers for cytotoxic drugs. |
| Canada[4]    | Guidelines of the Canadian Society of Hospital Pharmacists             | ![Purple symbol](image) | • A white C in a red triangle, in a blue rectangle.  
• Cytotoxic drugs are considered as hazardous chemicals.  
• Hazardous chemicals shall not be transported by Canada Post.  
• For transportation Outside the Heath Care Facility, packaged cytotoxic drugs shall be labelled appropriately for transportation in order to alert the handler to the hazards of the package’s contents.  
**Remark:** this sign is also used on commercial waste containers in Canada and USA. |
| Cyprus       | Bank of Cyprus Oncology Centre in Nicosia                              | ![Yellow symbol](image) | • Yellow symbol                                                                                                                                                                                          |
| Germany[5]   | Merkblatt M 620, TRGS 525                                            | No guidance   | Packaging of CMR drugs should be identified with a warning such as “Care, Cytostatic drugs”.                                                                                                                |
| Germany      | GRY-Pharma GmbH                                                        | ![Yellow symbol](image) | Sign used on packaging for transport                                                                                                                                                                    |
| Switzerland  | Sanofi-Avantis                                                         | ![Yellow symbol](image) | In yellow, because this is the international colour for danger                                                                                                                                          |
| Switzerland[6] | SUVA                                                                    | No guidance   | Packaging must be clearly identified                                                                                                                                                                |
| Switzerland  | University Hospitals of Geneva                                         | ![Yellow symbol](image) | Packaging must be identified with this label.                                                                                                                                                           |
| UK[6]        | Scottish guidelines                                                    | No guidance   | Packaging must be labelled to identify of the nature of the contents  
Procedures should be available for dealing with spillage during transport.  
Cytotoxic chemotherapy is classified as prohibited or restricted material by Postal Service and should therefore not be sent by routine post. Special arrangements are required – with the carrier being made aware of the hazardous contents.  
Storage handling and packaging requirements need to be agreed. For further information contact Royal Mail International Headquarters. |
| UK[7]        | Glasgow hospital                                                       | ![Yellow symbol](image) | Packaging must be labelled to identify the nature of the contents along with a cytotoxic symbol.                                                                                                          |

Cytotoxic chemotherapy is classified as restricted material by the Royal Mail and must not therefore be sent by routine post. Special arrangements must be made with the Royal Mail by contacting the Customer service Centre.
Oncology patients in Spain are usually treated in general hospitals, belonging to our National Health Service (public hospitals). There are very few specific cancer centres in the country (San Sebastian, Valencia, Barcelona, La Coruña, Madrid). Some of these are private hospitals but they usually have some kind of agreement with the National Health Service and treat patients through the National Health Service insurance.

Hospital Pharmacists in Spain have a quite complete and huge background, which includes:

- University studies: 5 years of university including 6 months of practice (7 hours/day).
- Hospital Pharmacy Specialisation: obtained through a 4 years Residency programme. To work as a hospital pharmacist in the country it is compulsory to get this certificate. This specialisation programme has a totally practical orientation; there are no theoretical lessons at university. The pharmacist stays all the time in the hospital and receives a salary for his work. The introduction of the fourth year of specialisation is quite recent (2003). The main objective of this year is to provide a more clinical background to specialists and it includes rotations in different clinical areas.

Focusing on Oncology, according to data from year 2000, 80% of hospitals prepare cytotoxic drugs in the pharmacy service. In our country cytotoxic drugs are prepared in Biological Safety Cabinets; the use of isolators is not widespread. In recent years pharmacists have payed special attention to the quality of the preparation facilities and environmental issues.

71% of the Pharmacy Services use computerised programmes for the preparation and 11% have computerised oncology prescription programmes.

In the recent years hospital pharmacists are increasing their visibility and participation in the oncology team. They collaborate with oncologists and nurses in many activities with a final goal: to offer a better therapy and care to the oncology patient. His/her activity has been very well accepted by both patients and health professionals.

At a national level, oncology pharmacists have GEDEFO (Spanish Group for the Development of the Oncology Pharmacy). The group was founded as a cooperative working group in 1995 after ISOPP IV in Hamburg. In January 2003 the group was transformed into a Foundation in order to get an appropriate legal frame of action. It works closely with the Spanish Society of Hospital Pharmacists (SEFH) and develops some projects in collaboration.

GEDEFO integrates more than 130 hospitals and 225 oncology hospital pharmacists in the country.

According to its constitution, the main aims are:

- To promote appropriate education and training for pharmacists who work or are interested in oncology.
To develop pharmacist’s integration in the health team in order to improve oncology care of the patients.

To foster and develop cooperative projects in oncology.

To provide an appropriate frame for the collaboration and the exchange of experiences among its members.

Among its activities, I would outline:

- Working groups

- Educational projects:
  
  In 2003 GEDEFO and SEFH (Spanish Society of Hospital Pharmacists) started an important educational project in order to help pharmacists working in oncology to get the BPS certificate (Board of Pharmaceutical Specialties of the American Pharmaceutical Association).
  
  They offered 20 grants for Oncology Pharmacists with at least 3 years of experience in oncology. The grants provide and facilitate all arrangements for the exam. The grant includes a programme of teaching activities: at least 3-4 intensive educational weekends are organised in order to prepare the exams. High-qualified teachers (pharmacists and physicians) are contacted for this purpose.

  In the 1st edition held in 2003, 13 pharmacists passed the exam (65 % success). In the 2nd edition in 2004, 14 pharmacists passed the exam (70 % success). The results for the 3rd edition (2005) are not available yet. Considering the results of these 2 years, Spain is at this moment the 2nd country, after USA, in number of Certified Pharmacists. It is even ahead of other English speaking countries (Spain: 27, Canada: 7, Australia: 5, UK: 4, Jordan, Korea, Saudi Arabia, etc: 1). The experience with this project has been really successful in all aspects as the certified pharmacists refer it. They specially appreciate the level of knowledge and confidence in clinical aspects acquired throughout the programme. This background helps them to integrate into the multidisciplinary oncology team.

- Investigational projects 2000:
  
  - Use of Taxanes: multicenter study
  - Ondansetron versus granisetron (meta-analysis)

2005:


  Presented in different professional meetings (ASCO, SEOM, SEFH, FESEO)

  Data of the study were obtained from chemotherapy prescriptions throughout 1-week period. 110 hospitals participated in the study and 2134 patients were enrolled, representing 70% of patients receiving chemotherapy for breast cancer during that period.

- Publications

  2005: Ovarian, colorectal and lung protocol guides (in press)

  2004: Breast protocol guide

  2003: Hazardous drugs

  2002: Oncology therapy guide, Oncology patient information

- Consensus documents

  - Consensus document for medication prevention errors in oncology
  - Consensus documents for the usage of oncolgy drugs for “compasive use”

- Scientific courses, meetings, congresses, etc.

Nowadays Oncology has become an important field in the hospital pharmacist activity. GEDEFO is a very active group and provides an adequate platform of support for hospital pharmacists interested in oncology.
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