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Polish Pharmacoeconomic Society activities review

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The Polish Pharmacoeconomic Society was created in 2001 by 26 founding members. Since January 20, 2006 Polish Society has been a Chapter of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR).

The mission of the Polish Pharmacoeconomical Society is to promote the development of theoretical knowledge and practical application of pharmacoeconomics and to popularize best practices in the evaluation of the effectiveness of treatments. It is also important for the Society to promote initiatives, attitudes and activities leading to the development of pharmacoeconomics and the assessment of the effectiveness of treatments and research results utilization in order to shape the social and health policy.

According to its mission the Society aims at translating the results of scientific research in the field of pharmacoeconomics and treatment effectiveness studies into practice to ensure fair and effective use of limited resources allocated by the society for health care. Last year among others, the Society's activities centered on organizing pharmacoeconomic conferences, workshops, competitions for students, working on the Polish pharmacoeconomical guidelines update. In 2010 the Society established 5 sections or task forces in order to fulfill its mission and to create a platform for close cooperation of the society members in the fields they are particularly interested in.

Those sections were:

- Epidemiology and cost of disease
- Health Technology Assessment
- Health Related Quality of Life
- Methodology of pharmacoeconomical analysis
- Therapeutic Programs and Pharmaceutical Care

Finally, four started their activities and during the General Meeting in December 2011 it was decided that the Methodology of pharmacoeconomical analysis task force will become part of the Health Technology Assessment section. Members of all of the task forces meet regularly (usually once a month) and work on the areas agreed, according to a pre-specified plan. Every year each section should present the yearly report of activities to the General Meeting. The reports from each section's meetings are available on the Polish Pharmacoeconomical Society website.

The Therapeutic Programs and Pharmaceutical Care section (TPPC), since it was established by the Polish Pharmacoeconomical Society in 2010, has had 16 members involved in the task force activities. The scope of interest has been the therapeutic programs area and the pharmaceutical care issues. The Therapeutic Programs constituted one of the possible ways of drug reimbursement in the Polish health care system by the end of 2011. Predefined inclusion criteria of the programs allowed qualified patients to be treated according to the program description and it was one of the ways to reimburse drugs assuring good efficacy and safety monitoring. The treatment was delivered to those patients for whom certain treatment would be really beneficial, it was frequently a targeted therapy. The eligible patients' population was possible to define due to clear inclusion and exclusion criteria, also including diagnostic procedures. The public payer could plan and control spending from the health care budget in an efficient way. Apart from those positive results there are still areas for improvement in order to facilitate better access to treatment within those Programs for patients especially with innovative therapies.

In Poland, until the third quarter of 2011 there were 39 defined, diligently described and operating Therapeutic Programs. According to the Polish law the Minister of Health announced implementation of a new Program after the AHTAPol President issued a positive recommendation for the reimbursement of a newly introduced drug and, if applicable, for the whole amended Therapeutic Program. Due to the changes in the legal regulations in the health care sector, the project of the new Reimbursement Legal Act was presented for public consultations at the beginning of 2011. Immediately the TPPC task force initiated work on the comments to the new Reimbursement Legal Act. Those comments and proposals for new solutions were submitted to the Polish ISPOR Chapter Board as one of the voices in the public discussion. The hurdles that the new law could cause for patients' access to treatments were pointed out. Also a need to set up registries for different disease areas was underlined.

Among other changes, according to the new act, since 2012 the Therapeutic Programs have been to be replaced by the Drug Programs which could result in significant changes, that were seen as needing further discussions. One of the major changes is that drug manufacturers will be involved in the process of creating Programs and now will have possibility or even obligation to submit proposals of new Drug Programs to the Ministry of Health. The new approach to Programs provoked a discussion within the TPPC task force about the future approach to biosimilar drugs, on how they will be defined, what requirements there will need to be fulfilled to form part of a Drug Program. The TPPC task force investigated the approach to the biosimilar drugs in the European Union and at the EMA. Among other aspects discussed, the task force concentrated on the production process of original drugs and a biosimilar drug seeking differences. Finally an agreement was reached that there is a need to define a biosimilar drug in the Polish legal environment. The TPPC task force agreed on the following definition: A biosimilar drug is a drug produced using biotechnological methodology and it is similar in terms of medicinal product design, pharmacological and pharmacokinetic properties, safety and efficacy, but not identical with the original registered and an authorized reference biological medicinal product. This definition was presented to the Board at the Polish ISPOR Chapter meeting in December 2011 as the proposals to be included in the future acts regarding reimbursement and HTA assessments.

Concurrently, the TPPC task force worked on the pharmaceutical care issues such as financing. The current financing model was discussed and activities were initiated to look for possibilities of financing pharmaceutical care from health care budget. A special meeting to learn from others and to share experience with an invited nurse (an experienced educator in diabetology) was organized. Further steps are planned for 2012. In November 2011 the TPPC section was the factual patron of the Polish National Pharmaceutical Care Competition organized by the Students Chapter "Social Pharmacy" and the students' Scientific Association from the Medical University in Lublin. The competition was addressed to Pharmacy students in Poland.

The Health Technology Assessment section (HTA) concentrates its activities on broad aspects of HTA. The main aim of the HTA Section is to review the official HTA guidelines issued by AHTAPol in 2009. The task force plans to provide AHTAPol with constructive and detailed comments and to propose solutions on how to improve and to adapt the guidelines into real life setting after several years of experience with HTA reports preparations.

Among other activities, a lecture about pharmacovigilance was presented in February 2012 and the safety issues were discussed as being a requirement in the guidelines part of the health technology assessment report. The members of the HTA Section considered the possible sources of data about drugs safety and discussed the possibility of using data such as Eudravigilance and documents like SPC, PSUR in the safety assessments. One of the issues discussed by HTA section members was the newly implemented by the Reimbursement Legal Act rationalization analysis. It is an addendum to the previously established HTA requirements, but without any specified details on how it should be carried out or what the expectations towards it are. As a result of the discussion the HTA section has prepared a list of questions that need to be answered and clarified by the decision maker.

The Health Related Quality of Life section (HRQoL) started its activity in 2012 and there are two main objectives for 2012. Firstly the Section

will work on a dictionary of quality of life and utility related terms. The other objective is to review the part of the HTA guidelines that are related to the quality of life (clinical efficacy analysis) and utilities (economic analysis) and to prepare a statement on it. The epidemiology and the cost of a disease section has taken up activities in the epidemiology area as well as aims at preparing the basis for the assessment of the cost of a disease

The sections' activities presented above are ambitious and require special dedication of all the teams working on the projects. The results of the annual work of each section will be presented at the following General Meeting scheduled for December 2012.