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Assessing Drug Effectiveness – Common Opportunities and Challenges for Europe

Post Conference Booklet, 29 July 2009



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THE DENTAL AND
PHARMACEUTICAL BENEFITS AGENCY



LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY



The Stockholm Conference on Assessing Drug Effectiveness – How do we go forward?

On July 29 2009 the conference “Assessing Drug Effectiveness – Common Opportunities and Challenges for Europe” took place in Stockholm with 120 participants from 27 countries under the auspices of the Swedish Ministry of Health and Social Affairs, Läkemedelsverket (Medical Products Agency) and Tandvårds- och läkemedelsförmånsverket (The Dental and Pharmaceutical Benefits Agency, TLV). During one intense day with plenary lectures, workshops and numerous informal discussions the challenges were reviewed. This booklet contains some preconference views but also summaries of lectures, workshops and summary conclusions.

The Conference was a step towards increased European cooperation on assessment of the effectiveness of medicinal products after approval. The ultimate objective is to provide greater assurance and safety for the individual patient by means of better knowledge based on information generated already when drug treatment is started. As a result of the conference the Swedish EU Presidency has now received the go-ahead from the delegates to initiate a pilot project to find ways of cooperating systematically at EU level on the collection and sharing of data on the effectiveness of drugs.

A meeting with the actors who have expressed interest in participating in the pilot project will be held 13th of November 2009 at the Permanent Representation of Sweden to the European Union, Square de Meeûs, 30 in Brussels.

Everyone interested in following the progress of the project, please, sign up before the 30th of October for s.hs@social.ministry.se. Contact person is Deputy Director Anne Nilsson at the Ministry of Health and Social Affairs.

A call for continued collaboration

By Karin Johansson

State Secretary to the Minister for Health and Social Affairs

Join us in promoting European collaboration on the follow-up of drug effectiveness in everyday clinical use.

The aim of the Swedish conference and the following pilot project is to find ways of cooperating systematically across Europe on the collection and sharing of data on the effectiveness of drugs. A better understanding of how well drug treatments work in everyday clinical use would benefit patients, pharmaceutical companies, government agencies and society as a whole. One reason that Sweden is committed to the issue of drug monitoring is our long experience of medical follow-up in different registers.

Examples of cooperation areas of particular interest include biologic agents for chronic inflammatory diseases, cancer drugs, and orphan medicinal products where individual countries often have too few patients to sustain comprehensive assessment programmes. The questions remaining now are, among others, who should be responsible for this pilot project, how long it should last and, last but not least, how it is financed. Other issues to be solved are creating a common routine for the collection and exchange of data, for example with regard to privacy, and which added effects of the medicines are chosen to review.

By your signing up for future interest in the topic and possibly participating in a planning meeting in Brussels in the 13th of November 2009, we will all come significantly closer to the goal – to launch a pilot project.



Karin Johansson, State Secretary to the Minister for Health and Social Affairs.



A Timely Effort to Advance European Collaboration

By Prof. Hans-Georg Eichler

Senior Medical Officer of the European Medicines Agency (EMA)

Pharmaceutical drugs have greatly contributed to public health in Europe and throughout the world. Yet, there is evidence that drugs may perform differently in everyday clinical practice than in the clinical trials which are the basis for licensing, reimbursement, and prescribing decisions. In its recent report, the EU High Level Pharmaceutical Forum has appropriately separated the concepts of efficacy (the extent to which an intervention does more good than harm under ideal circumstances) and effectiveness (the extent to which an intervention does more good than harm when provided under the usual circumstances of healthcare practice). Factors contributing to the often-quoted “efficacy-effectiveness gap” have been widely discussed, but effectiveness data that could guide policy decisions is sparse.

The initiative from the Swedish presidency to foster the collection and exchange of data on drug effectiveness across Europe is timely – over the past years the pendulum of public opinion on drugs has swung from often unrealistically high hopes to much more pessimistic expectations. This development highlights the need for reliable data to support the debate on drugs. On the bright side, increasing availability of drug utilisation and health outcomes data from electronic healthcare databases and other sources provides new opportunities for generating effectiveness information.

All stakeholders will benefit from more – and more reliable – drug effectiveness data. Patients, healthcare providers, and the general public, deserve the best possible information on a drug's benefits and adverse effects. Drug regulators would greatly benefit from such data to guide their continuous risk-benefit assessment throughout the life span of a drug.

Pharmaceutical companies would be able to demonstrate the value of their products for public health, and drug reimbursement bodies could consider, or refine, approaches to value-based drug purchasing.

While the goals of, and potential benefits from, systematic and structured follow-up of drug effectiveness are clear, there remains a plethora of practical challenges. These include the difficulties of initiating effectiveness studies, harnessing the potential of different healthcare databases across the EU, interpreting findings from studies that are outside the concept of the randomised controlled trial, and applying value judgements to heterogeneous clinical outcomes.

These topical and often controversial issues were intensely discussed at the Stockholm conference. I congratulate the organisers on a successful meeting and urge everyone to engage in the future collaboration.

Who benefits from European collaboration on follow-up of drug effectiveness in everyday clinical use?

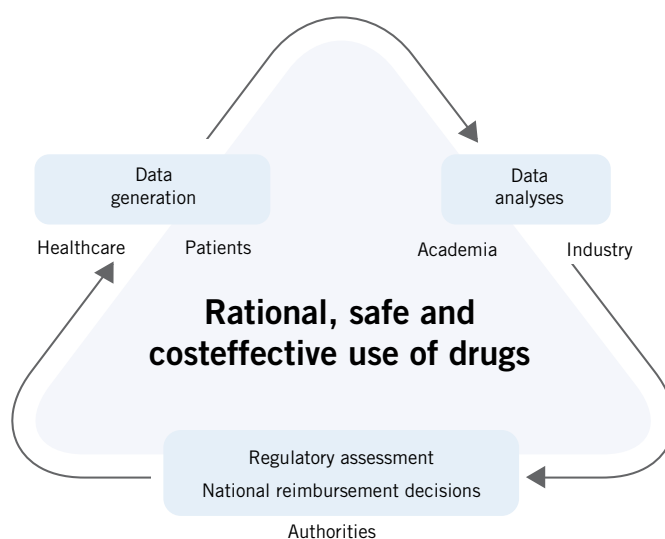
By the Conference Organizing Committee

When new medicinal products are introduced on the market, knowledge of their effectiveness in everyday clinical use is very limited.

The regulations governing the subsidising of medicinal products vary across the EU. However, regardless of the basis on which the subsidy status of a medicinal product is assessed, all countries need to know about the effectiveness of the product in everyday clinical use. This knowledge could be improved significantly if EU Member States were to pool some of the resources they already invest in separately into a collaborative data-gathering effort.

In the longer term, the information assembled in a collaborative European undertaking aimed at improving the collection of data on drug effectiveness could be made accessible to all EU Member States. It could also lead to medicinal products being used in ways better suited to the needs of patients and ensure that the resources invested in subsidies for medicinal products are used more efficiently throughout the EU.

Assessing effectiveness in clinical practice starts at the patient level by collecting relevant and validated data at the right time. These data are initially put together and analysed at individual and group level by health care professionals as a part of their daily work. Moreover, academic research groups, industry and other players have an interest in the collection and analysis of data which is of relevance to their own needs. Various agencies then make their assessments at national and European level according to their mandate. The conference aimed at identifying areas of improvement in the generation, compilation and analyses of data to facilitate the work of all concerned stakeholders.



Assessing effectiveness in clinical practice starts at the patient level by collecting relevant and validated data at the right time.

Summary of plenary lectures

Moderator Audun Hågå, Deputy Director General of the Ministry of Health and Care Services in Norway

Audun Hågå set the scene by presenting the agenda, the objectives of the meeting and giving the necessary clarifications to the sometimes confusing terminology regarding effectiveness by using the terminology stated by the Pharmaceutical Forum:

Efficacy: The extent to which an intervention does more good than harm under ideal circumstances.

Effectiveness: The extent to which an intervention does more good than harm when provided under the usual circumstances of health care practice.

Relative Effectiveness: Can be defined as the extent to which an intervention does more good than harm compared to one or more intervention alternatives for achieving the desired results when provided under the usual circumstances of health care practice.

The topic and focus on the conference will not be on relative effectiveness, but on effectiveness. A better understanding of how well drug treatment works in real life is what we will focus on during the conference and the pilot project.

Guest speakers

Thomas Lönngren, Executive Director European Medicines Agency (EMA)

Thomas Lönngren started by addressing what we know and what we don't know at the time of authorisation of a drug. Usually there is good evidence from clinical trials demonstrating efficacy and the most common adverse reactions in the specific indication. But the information on effectiveness of the product in normal clinical settings, as well as the full safety profile, for example delayed adverse drug reactions and adverse drug reactions in populations not in trials (children, very elderly), is not known at the time of authorisation. The initial authorisation decision is based on a favourable benefit-risk balance. This holds true for the entire life span of the drug, but the assessment of the benefit-risk balance is a continuous process and the outcome may change over time.



Thomas Lönngren, Director, EMEA (European Medicines Agency) and plenary lectures.

Examples of current post authorisation monitoring are routine pharmacovigilance, enhanced pharmacovigilance and further clinical trials studying effectiveness that are initiated by the companies or required by regulators. Thomas Lönngren stressed that a European collaboration on collecting and sharing of data on drug effectiveness is of great value in many ways. For example there would be larger populations from which to collect data, larger databases and reduction of cost for monitoring relative to the market size. Different health care systems allow comparisons of use and impact of risks minimisation measures.

There are proposals discussed in the European Parliament and the Council of Ministers to strengthen and rationalise EU safety monitoring. The new legislation will enable better data collection, better risk management planning, greater transparency and better information for users of medicines.

We need to monitor the safety and efficacy of medicines on the market and we have systems in place to do this. If we work together in European and international collaboration we can further improve this important post-authorisation monitoring.

Clare McGrath, Senior Director HTA Policy, Pfizer

Improved follow-up is needed for many reasons, for example to find out if evidence based decisions are implemented, reduce uncertainty in clinical results, reduce variation in utilization and outcomes, and to identify unmet needs that can be fulfilled with new medicines. Measures of effectiveness can be discussed at different levels: policy level, system level, provider level, and patient level.

Clare McGrath described the complexity of effectiveness management. Follow-up, as it is carried out today, consists of clinical trials, different registries, risk sharing schemes, medical audit, utilisation monitoring etc. Clare McGrath presented KIGS, a survey on growth hormone therapy in 60,000 children across 50 countries, where the treatment is individualised using predictor models.

Improving effectiveness management systems can further develop and improve the work. This could be done by for example by focusing efforts to collect more data on the areas where it will be of greatest value, facilitating cross country learning, engaging providers, health ministries and industry in design of effectiveness management systems and developing consensus on good data governance and analysis methods.



Clare McGrath, Senior Director HTA Policy, Pfizer.

Anders Olauson, President, European Patient Forum and Board Member, Eurordis (European Organisation for Rare Diseases)

The most important way to improve effectiveness assessments is to involve patients. Only patients can provide information about living with a disease and should be treated with equal standing as other stakeholders.

New thinking and flexibility can be achieved by risk sharing and conditional pricing. This is welcomed by patients and gives an opportunity for early access to new drugs. It will give early rewards for innovation as well as giving the opportunity to collect valuable experience about how the innovative medicine works in real life settings. In addition, funding authorities will have control over spending. Working together at EU level gives added value, such as coordinated post marketing requirements through EU level studies and registries, better targeting of patients with right treatment regimens and doses, and finally better value for money. Anders Olauson gave one example of strong patient involvement with Alzheimer's disease where dialogue with NICE created changes and concessions.

The European patients' forum is moving forward and on the agenda in 2010 is the European workshop on health technology assessment, compilation of accessible patient oriented materials on HTA information, and a joint event with HTA experts and patient leaders.



Deborah Symmons, Professor of Rheumatology and Musculoskeletal Epidemiology, University of Manchester and Anders Olauson, President, European Patient Forum and Board Member, Eurordis.

Bengt Jönsson, Professor of Health Economics, Stockholm School Economics

The introduction of new drugs means decision-making coupled with uncertainty. There are two alternatives to reduce uncertainty: doing more studies before the introduction, which reduces risks of making wrong decisions but delays potential benefits; or doing follow-up studies which could be done after introduction. Bengt Jönsson pointed out that lack of effectiveness by necessity means loss of money and consequently loss of health, since resources have alternative uses within health care budget.

Assessing cost-effectiveness before market authorisation is difficult. Clinical trial data is helpful but not conclusive and cost-effectiveness is often based on estimations from models. Requests for follow-up studies are common; to secure that the drug is used for the right patients and to verify predicted effectiveness and/or cost-effectiveness. Bengt Jönsson discussed different new models for reimbursement: coverage with evidence development, risk sharing (if predicted goals are not met payment will be adjusted), and pay for performance, where payment per patient treated is adjusted for outcome.

Up to now, there have been about 60 different reimbursement models, the majority of which are used in the EU, with numbers increasing all the time. Coverage with evidence development is most common and TLV (Swedish Dental and Pharmaceutical Benefits Board) and CMS (US) are the most active. From a health economic perspective experiences with patient registers have some shortcomings: data collection is too costly and complicated, lack of variables related to patient outcome and resource allocation, limited access for “outsiders”, and registers are not used to their full potentials.

Finally, follow-up data is the key to the development of rational and accountable decisions relating to resource allocation. Apart from more efficient allocation of resources for health in the short run this provides incentives for more cost-effective innovations in the long run.

Guido Rasi, Executive Director, AIFA (Agenzia Italiana del Farmaco)

In Europe we have got one unified licensing system but more or less 27 different pricing and reimbursement systems, none of which communicate with any of the others. Consequently, when identifying the objectives of an EU-collaboration it is necessary to agree on some common principles.

Prof. Rasi described the two schemes for reimbursing expensive and potentially innovative drugs that AIFA practices; conditional payment (risk-sharing agreements with ex-post evaluation) and conditional reimbursement (time-limited reimbursement under special conditions). An example of risk-sharing agreement is especially drugs against cancer. The payment is conditional and the treatment is reimbursed only for responders. For non-responders the treatment is stopped and previous reimbursement is paid by the MAH.



Guido Rasi, Executive Director, AIFA and Moderator Audun Hågå.

Such a scheme facilitates a quicker access to the drug after approval for those patients who might gain by the medication and a possibility to collect data from real use. The conditional reimbursement is aiming at collecting additional information on the use of a specific drug and facilitates controlling the use of that drug. Conditional reimbursement in Italy includes 25 drugs used by 40 000 patients. It is possible to transfer the data that is gathered to a single database for common use in the future.

National initiatives are seldom systematical but EU-initiatives present great opportunities for cooperation and coordination of national activities by improving exchange of information. Joint initiatives on HTA and relative assessment as well as EMEA-led early dialogue on the need to establish common endpoints are ways of achieving useful results in this field.

Deborah Symmons, Professor of Rheumatology and Musculoskeletal Epidemiology, University of Manchester

Drug safety signals can be detected from clinical trials, pharmacovigilance and observational cohorts. They all have their strength and weaknesses. Registries are one form of large observational study. In Europe there are three major Biologics Registers for Rheumatic Diseases which collaborate in a systematic way namely, BSRBR in UK, ARTIS in Sweden, and RABBIT in Germany.

Prof. Symmons emphasized that there are important methodology issues such as the need for a comparison cohort not treated with biologic agents, definition of exposure period at risk, (e.g. if whilst on the drug or forever), and the serial exposure to multiple biological agents. Differences in study design may account for differences in the results between observational studies. The importance of collecting information regarding comorbidity and comedication was also emphasized.

Prof. Symmons concluded that the risk of adverse events from biologic agents is highest in the first few months of treatment. She emphasized the advantage of academic-led studies that give not only pharmacovigilance focus but also enable the development of new statistical methodologies. Many other long-term outcomes, effectiveness data, and health economic evaluations have been published from the Registers. She also stressed the value of collaboration such as harmonization of reporting, replication of results, exploration of reasons for different results and pooling of rare events.

Wim Goettsch, PhD Deputy Secretary of the Medicinal Products Reimbursement Committee Health Care Insurance Board (CVZ)

The General objective of EUnetHTA is to establish an effective and sustainable European Network for Health Technology Assessment – EUnetHTA - that informs policy decisions. The general strategic objective of the network is to connect public national HTA agencies, research institutions and health ministries, enabling effective exchange of information and support policy decisions by the Member States.

After three years of an intensive project work (2006–2008) the EUnetHTA has delivered products such as: an HTA Core Model that will allow transparent shared work of producing HTAs across borders, an HTA Adaptation toolkit for better use of existing HTA reports and adapting them to local contexts and a system facilitating evidence development and exchange of information for promising technologies. Between 2010 and 2012 the EUnetHTA will start a new network phase that will be financed by the European Commission using a Joint Application. An important part of this new phase will be a work package on the relative effectiveness assessment (REA) of pharmaceuticals. In this work package, in the period 2009-2012, an exploratory phase will be initiated leading to a proposal of relevant tools and methods and a definition of a framework for REA of pharmaceuticals. On the basis of a pilot test, assessing our concept model, the model will be adjusted and definitive methodology and toolbox for REA will be developed.

How to design a European pilot project on collecting and sharing drug effectiveness data

Assoc. Prof Nils Feltelius, Swedish Medical Products Agency

Performing a European pilot project on collecting and sharing drug effectiveness data is planned as a continuation of the conference. Dr Feltelius discussed possibilities and problems with this. He presented some criteria for selecting one or more pilot projects that may serve as good examples in the development of optimal ways to collect and share effectiveness data. The following feasibility criteria were suggested:

- Therapeutic areas where drugs recently have been or are about to be launched or where new indications are underway.
- A functioning clinically based network with the ability to collect data relevant to assessment of drug effectiveness.
- Scientific/analytical competence at several sites within the EU.
- Transparent financing safeguarding scientific independence.
- Willingness to share effectiveness data with others.

As relevance criteria the following were suggested:

- Significant post-approval drug efficacy/safety issue that requires a large sample size or otherwise multinational data collection.
- Substantial impact on health economics.
- Differences in availability within the EU.
- Widespread off-label use.
- Stimulating EU cooperation (clinical networks, academic centres/ENCePP, etc) or methodological development.
- Potentially supportive of innovative drug development.

To give the participants in the workshops a reasonable scope for discussion three therapeutic areas had been chosen i.e. cancer, chronic inflammatory disease and orphan diseases. These choices were based on medical, health economics and methodological reasons. The importance of creating a representative committee for overseeing the project and of regular feedback to all interested parties was emphasized. Given this background the participants were prepared for the afternoon workshop session.

Reports of workshop discussions

The summaries from the workshops are based on notes made during the discussions and have not been authorized by the participants. Brand name for drugs and other specialized terminology relating to the subjects discussed are referred to as they were used by the delegates.

Workshop 1: Biologic agents for chronic inflammatory diseases

The Panel in this workshop consisted of: David Magnusson, Swedish Rheumatism Association; Tomas Cueni, EFPIA Economic & Social Policy Committee; François Meyer, French National Authority for Health (Haute Autorité de Santé, HAS) and Lars Klareskog, Karolinska Institutet.

The Moderator was Hans-Georg Eichler, the European Medicines Agency (EMA) and the Rapporteur was Ruxandra Draghia-Akli, Directorate General for Research, European Commission.

The discussions were intense and covered topics from general aspects on drug safety, efficacy and effectiveness to more concrete issues regarding specific projects. Initially two main candidates were discussed, namely multiple sclerosis and rheumatoid arthritis. These are therapeutic areas where new biologic drugs have been developed in recent years and where safety, efficacy and cost-effectiveness need particular attention.



From left: Rapporteur Ruxandra Draghia-Akli, Lars Klareskog, Moderator Hans-Georg Eichler, Tomas Cueni, François Meyer and David Magnusson.

After some debate rheumatoid arthritis, with focus on existing and upcoming drug, was selected as candidate for the project. The delegates agreed on that the structure should be based on existing registry network in Germany, Sweden and UK. Possibly the project could be performed with a “two-level design”. Level one would be of short-term duration with the main objective to identify gaps in infrastructure: whereas level two would be a registry-based follow-up of patients with a long-term perspective. The group suggested that the project be financed through a public-private partnership. The expectations and goals of the project are to identify predictors of different degrees of effectiveness that subsequently could be translated into rules for patient treatment or therapy management strategies. Finally, it should also identify eventual safety issues that can be seen only in large populations and/or after long term use.

Workshop 2: Orphan drugs

The panel in this workshop consisted of: Yann Le Cam, European Organisation for Rare Diseases; Andrea Rappagliosi, EFPIA Economic & Social Policy Committee; Kerstin Westermark, Committee for Orphan Medicinal Products; Segolene Aymé, INSERM (Institut National de la Santé et de la Recherche Médicale), and the WHO Topic Advisory Group on Rare Diseases; Josep Torrent-Farnell, Autonomous University of Barcelona, Spain and Ad R. Schuurman, Dutch Health Care Insurance Board (CVZ) and the Medical Evaluation Committee (MEDEV).

The Moderator was Stanislav Primožič, Agency for Medicinal Products and Medical Devices of the Republic of Slovenia and the Rapporteur was Giulia Del Brenna, Directorate General for Enterprise and Industry, European Commission.



From left: Yann Le Cam, Ségolenè Aymé, Kerstin Westermark and Andrea Rappagliosi.

One part of the discussions focused on conditions of success and can be summarised in the key words feasible, relevant and innovative. Some examples of ways to achieve conditions of success is to keep it simple (use existing knowledge in a transparent way) and to share agreed and accepted methodologies by all stakeholders. The project should also be “hands on” and “learn by doing” with continuous follow-ups, combining and connecting academic, industry and regulatory registries and using existing methodologies.

Four different Project candidates were identified. Highest priority was given to Cluster of Lysosomal disorders (16 disorders, 7 drugs). The reasons why the group chose these disorders for the project were that there are existing registries, expensive drugs, heterogeneous population, life-long treatment and a good network.

Cryopirin-associated Periodic Syndromes was another alternative that was discussed by the delegates. Reasoning for proposing this project was the fact that two new drugs recently were approved for these indications. There is already a multinational network (PRINTO) with experience of performing clinical trials as well as observational studies in this therapeutic field that could take the task as pilot project. Also there are no alternative treatments available for the patient groups in question.

Thirdly Rare cancers was suggested as a pilot project. One reason behind this proposal was the lack of alternative treatments in these patient groups in contrast to the availability of standard cancer treatments in larger cancer populations.

Finally Pulmonary Arterial Hypertension was suggested with the argument that there are new drugs in the pipeline, the existing network is good and the disease is very complex.

The delegates also discussed the structure, financing, feedback process and project duration. The group suggested that the EU Presidency (SE) or the European Commission should be responsible for surveillance and that the project should last for 3-5 years. Stakeholders constitute a broad platform (EMA, centres of reference, NCA National Competent Authorities, P&R, HTA, academia, patients, HC professionals, industry, and third party payers). It was suggested that EU funds (Public Health Project/ Co-financing) finance the project. Everyone was in agreement that the stakeholders are critical for a successful feedback process and that the project should give feedback to everyone in yearly reports.



Isabel de la Mata, Principal Adviser, Directorate General for Health and Consumers Affairs.

Workshop 3: Cancer drugs

The panel in this workshop consisted of Hildrun Sundseth, European Cancer Patient Coalitions (ECPC); Meni Styliadou, EFPIA Economic & Social Policy Committee; Gunnar Juliusson, Lund University Hospital in Sweden; Bengt Jönsson, Stockholm School of Economics; Jolanta Gulbinovic, Vilnius University Hospital in Latvia and Wim Goettsch, the Medicinal Products Reimbursement Committee Health Care Insurance Board (CVZ).

The Moderator was Thomas Lönngren, European Medicines Agency (EMA) and the Rapporteur was Isabel de la Mata, Directorate General for Health and Consumers, European Commission.

The project candidates were presented as “Methodology”, “Registry of breast cancer treated with Avastin” and “Paediatric population”. The project candidate called Methodology was suggested to focus on methodology development for treatment outcome and personalised medicine/biomarkers. This would be carried out in a network of comprehensive academic cancer centres and institutes of public health. Suggested financing was FP7 (the Seventh Framework Programme for Research and Technological Development). Stakeholders will be crucial in the feedback process reporting to government institutions and healthcare providers. The project duration was suggested to be four years.

The group came to the conclusions that there are many reasons why breast cancer treated with Avastin should be chosen for the project. There is a high prevalence of breast cancer, there is an ongoing debate on the effectiveness of the drug, the treatment is very expensive and the treatment strategies differ between countries. Stakeholders are identified as industry, patients, payers, and clinicians. Government funds and industry were presented as financing alternatives. The stakeholders will get feedback on feasibility after six months and following that, long-term feedback.

A pilot project in the paediatric cancer population was discussed and was supported by the following facts: it is a small population, it gives good added value, treatment approaches may vary among countries, and it is possible to treat paediatric cancer with orphan drugs. The delegates decided to concentrate on a specific project candidate, myeloma. Surveillance should be carried out in network (SIOP) and financing could be covered by FP7, health programmes and cancer registries. Stakeholders are determined by the choice of financing. The pilot is planned as a 3 year project with the possibility for further extension.

Policy conclusions

By Karin Johansson, State Secretary to the Minister for Health and Social Affairs, Gunilla Hulth-Backlund, Director General TLV and Christina Åkerman, Director General, Medical Products Agency.

We cannot emphasize strongly enough the importance of developing cooperation on monitoring of medicines in everyday clinical use. In Sweden, as in the rest of Europe, we need to optimize the usage of our healthcare resources, improve the follow-up of methods available to us and prioritize the medicines which offer the best value.

During the process of the recently concluded Pharmaceutical Forum it was made clear that the authorities throughout Europe have noticed the same lack of data. We all have a need to know as much as possible in the regard to the true effect of drugs in clinical use and over the long-term.

Today there are large gaps in the data available on the effectiveness of pharmaceuticals in clinical setting. A better understanding of how drug treatments work in everyday clinical use would benefit patients, pharmaceutical companies, government agencies and society as a whole.



*Christina Åkerman, Director General, Medical Products Agency,
Karin Johansson, State Secretary to the Minister for Health and Social Affairs,
Gunilla Hulth-Backlund, Director General The Dental and Pharmaceutical Benefits Agency.*

One desired outcome of the conference was an agreement by the participants to start a pilot project on collective gathering of data on drug effectiveness. The topic was discussed during the conference in three working groups and by delegates representing Member States, EU candidate countries, patient organisations, the pharmaceutical industry and health services. All groups were in favour of the idea to start a pilot project. We hope to jointly develop a model for systematic and structured follow-up for initial testing on an orphan drug.

Karin Johansson invited all who are interested in taking part in this important European cooperation, i.e. the pilot project, to notify their interest at the URL: s.hs@social.ministry.se in Ministry for Health and Social Affairs.

It is our belief that the fruitful discussions we had at the meeting in July will be an important contribution to an improved European cooperation in the collection and sharing of data on drug effectiveness.

**Do not forget to register your interest
to attend the meeting in Brussels.**

URL: s.hs@social.ministry.se, the 30 October at the latest.



This booklet was edited by
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Photo: Scanpix Sweden AB.