

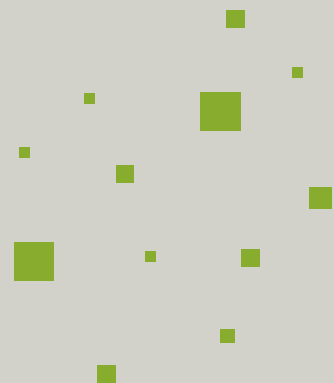


Biographies and presentations of the outcomes

Pharmaceutical Forum Delivering for Patients

How to move from agreed principles to good practice and positive change across Europe

25 March 2009, Brussels
Charlemagne Building



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Karin Johansson

Karin Johansson has a degree in Political Science and Public Administration from the University of Stockholm. In the eighties and beginning of the nineties, she pursued a career in various sales and marketing positions in the IT industry.

In 1993, Karin Johansson was given her first political assignment when she was appointed Political Advisor in the Prime Minister's Office. After the election in September 1994, she returned to the IT Industry and became Sales Director at France Telecom in Sweden. In 1999 she started her career at Microsoft and she left the company in 2006 as the Sales and Marketing Director.

Karin Johansson was appointed State Secretary with responsibility for healthcare and social welfare in October 2006.

Previously, she has also been chairman of the Board of Governors at the Swedish Broadcasting Corporation, chairman of the Board at the Blekinge Institute of Technology and member of the Board of non-Executives at the Swedish Lottery.

Karin Johansson is married to Per Egon Johansson, management consultant and former State Secretary. They have two children.



Georgette Lalis

Mrs Lalis is a Director in the European Commission's Directorate General of Enterprises and Industry (Directorate F). Her responsibilities include the cars industry, the pharmaceutical and medical devices industry, the cosmetics industry, biotechnology and the food industries. She is co-chair of the Steering Committee EPAA.

In relation to pharmaceuticals she is the Director responsible for the regulatory aspects, relation

with EMEA, market authorisation of centrally authorised medicines, as well as issues related to HTA, pricing and reimbursement.

Mrs Lalis joined the European Commission in 1981 and prior to her present job she has held several managerial and senior positions in different sectors of the Commission.

Mrs Lalis has studied law at the Universities of Athens and Strasbourg.



Anders Olauson

Anders Olauson was involved in the founding of the Agrenska Centre in 1989. He served as director until 2004 and since then has been chairman and chief executive officer. He is responsible for establishing The Agrenska Virtual International Academy, a research centre for rare disorders.

Anders is particularly concerned with the impact of rare conditions on children and their families. His work involves contact with both national and regional legislative bodies on the subject of rare disorders. He is also in contact with representatives of hospitals, education and labour unions as well as other key players in the field of rare diseases.

Anders is member of the board of Eurordis, and was president from 1999 to 2001. He currently

represents it as a member of the board of the European Patients' Forum (EPF). He has been president of EPF since June 2005. Anders represents EPF in both steering committee and at The Pharmaceutical Forum, which was established by DG Sanco and DG Enterprise in 2005. Agrenska was in 2005 appointed member of ECOSOC within United Nations, with "special consultative status".

Since 2006 Anders is a member of the advisory group for Health Research within DG Research. In 2005 Anders was accepted as a researcher within the PhD program at Gothenburg University.

The Swedish Government appointed Anders September 15th 2008, to be a member of the Advisory Council at The National Board of Health and Welfare.



Martin Benes

Mr. Martin Benes graduated at the Faculty of Pharmacy of the Charles University in the Czech Republic. Before he was appointed to the directorship of the State Institute for Drug Control, he had been working in the pharmaceutical sector. He is experienced as an expert scientist at the Institute for Medicinal Research in Brno and he also executed the office of the chief pharmacist at the Masaryk Oncological Institute. In January 2007 Mr. Benes joined the State Institute for Drug Control in the director's office and has been leading the Institute since then.

The Czech Republic acknowledges the huge effort that has been done within the three-year process of the Pharmaceutical Forum. In line with the Conclusions and Recommendations it is one of the priorities of the Czech Republic to improve patients' access to relevant health information. Patients are fully capable of finding different pieces of information. Member states should therefore ensure that they provide their citizens with high quality and accurate information. State Institute for Drug Control (Czech medicines agency) has recently launched a web site aimed at patients comprising relevant data about medicinal products and health. Furthermore it is as well important to provide healthcare professionals and decision makers with a quantity of reliable information in respect to the sustainability of healthcare systems. Therefore the Czech Republic welcomes the extension of the topic of relative effectiveness. A regular exchange of information among member states is highly valuable.



Richard Hudson

Rich has been a leading science and technology journalist in Europe for 25 years. He is CEO and Editor of a London-based media company, Science Business Publishing Ltd, a news and events service that covers early-stage investment in R&D, and helps academic researchers in Europe connect with industrial and private investors. Before that, he was with the Wall Street Journal for 25 years, as reporter, technology editor and managing editor of the European edition.

He is also co-author of a book on "fractal" analysis of financial markets with Yale/IBM mathematician Benoit Mandelbrot: *The (mis)Behavior of Markets: A fractal view of risk, ruin & reward*.

He is a graduate of Harvard College, a former Knight Fellow at MIT, and lives in Brussels.

I Panel, Information to Patients I



Ivana Silva

Ivana Silva is Adviser for Pharmaceuticals and Professional Affairs in the Pharmaceutical Group of the European Union (PGEU), a post she has held since March 2006. Her areas of responsibility encompass all issues relevant to pharmacy practice, including patient safety, pharmaceutical policy, e-health, education and continuing professional development. Ms. Silva previously worked for the Portuguese Pharmaceutical Society from 1999 to 2006, where she was the International Liaison officer.

Ms Silva current involvement on pharmaceutical policy includes, among other, developments related with medication safety, information to patients, pharmacovigilance, e-prescribing and electronic medication records. In the specific area of information to patients she coordinated PGEU's leadership on the work stream on access and dissemination of information to patients in healthcare settings at the High Level Pharmaceutical Forum – Working Group on Information to Patients. She is actively involved in the ongoing debate around legislative changes and is closely collaborating with other NGO's in advocating for a clear focus on health literacy.

Ms Silva is a pharmacist by training who studied at the University of Lisbon; she also holds an MBA in Information management from the Portuguese Catholic University; she speaks Portuguese; English; French and Spanish.

- PGEU believes that one of the strengths of the Forum has been the range of voices around the table. In particular, as a result of the range of perspectives available we were able to identify areas of debate that were not initially on the Forum's agenda, but which have been shown to be highly relevant. PGEU is proud of its contribution to the work of this Working Group, in particular in helping to identify how accessibility to information can be improved in different healthcare settings such as community pharmacies, hospitals and general practice. The collection of good practices from around the EU, which are now available for future benchmarking, is a good example of the value of the Forum.
- We should also mention in this regard the quality criteria developed by the Working Group, which we believe will be of lasting value in helping to ensure that health information provided from diverse sources is appropriate for the needs of patients.
- We must ensure that the good work continues. The challenges we face in the sector transcend national boundaries. Working together there is much that we can achieve. Diversity, balance and an inclusive approach to all the interests in the sector are the key to ensuring that the work we do together truly bears fruit.
- PGEU supports that an EU strategy for information to patients is solidly based on developing health literacy, improving health professionals' and patients' communication skills and exploring the full potential of ICT without disregarding the traditional, non-electronic means of information.
- The challenge is how to ensure that information conforms to established quality principles (as the ones approved by the High Level Pharmaceutical Forum) and how information searchers will be prepared to distinguish credible high quality information from all the rest. It is of fundamental importance that public confidence in the integrity of information provided by any source is maintained.
- In the case of information on medicines, this means it is not just about the information on a specific medicine but is rather the information which is relevant and meaningful for a particular patient at a particular time of his/her life and evolution of his/her condition. Such tailored information, that several times also entails therapeutic patient education, is best achieved through a dialogue between the patient and a health professional.
- Another challenge is how to shift the paradigm from looking for information on medicines and diseases to looking for information and how to live healthily.



Susanna Palkonen

Susanna Palkonen works in Brussels as the Executive Officer of European Federation of Allergy and Airways Diseases Patients' Associations (EFA), member of the European Patients' Forum (EPF). As patient representative, she is a Member of the EU Consultative Forum on Environment and Health of the European Commission Directorate General (DG) Environment, DG Public Health and Food Safety (SANCO) Indoor Air Quality Expert Group and Allergic Rhinitis and Its' Impact of Asthma (ARIA) Initiative Guidelines Advisory Committee.

In her capacity as Vice President of EPF, she represented EPF 2007-2008 at the DG Enterprise and SANCO Pharmaceutical Forum Working Group on Information to patients and is now their representative in the European Medicines Agency (EMA) Working Group with Patient and Consumer organisations.

Being a patient with allergic rhinitis and atopic eczema herself, her special interests are prevention and environment and health from the patients' perspective.

Universal, approved quality principles to guide and test information targeted for patients are a very important and a welcome step forward – just as long as they are implemented. In 2008 European Federation of Allergy and Airways Diseases Patients' Associations (EFA), member of EPF, held a workshop for its' members as part of their involvement as patient representatives in a Network of Excellence 'Global Allergy and Asthma European Network GA²LEN' funded by the EU 6th Framework Programme for Research. The participants agreed that a European fact sheet on 'Aspirin induced asthma' need to be developed by EFA and the GA²LEN scientific work package on the topic to give the latest evidence based information on aspirin induced asthma and importantly, give the same message all over Europe through GA²LEN an EFA networks for patients and medical professionals alike. The researchers developed the first and excellent draft for EFA review. EFA used the quality principles developed by the Pharmaceutical Forum to check whether all aspects for quality were covered. As a result, rather than focusing on the content itself only, also the date of publication (principle Up-to-date), detailed references (principle Transparency) and contact information (principle Accessible) were added. The language was amended into more patient/lay-public friendly, medical terms explained and content relevant for patients, for example common fears and misunderstandings about aspirin-induced asthma explained. Even if this piece of work was on a very specific topic, the Principles helped to ensure that nothing important was forgotten. The quality principles are currently targeted for information providers, and not for individual patients' to check validity of patient information they come across, but could very well be developed into check list for patients as well.



Jeremy Mean

Jeremy Mean is the Information for Public Health Group Manager in the Vigilance and Risk Management of Medicines Division (VRMM) of the UK's Medicines and Healthcare products Regulatory Agency.

Jeremy is a career civil servant, having joined the service in 1984, and has worked in a succession of policy and management posts in the Department of Health. Within the MHRA, Jeremy headed up

the Agency's European Support Unit but in his current role is responsible for operational policy and delivery of the Advertising Standards and the Patient Information Quality Units as well as for policy development on cross Divisional/Agency issues.

Jeremy chaired the drafting group of the Pharmaceutical Forum's Information to Patients Working Group on non-statutory information.



Rita Kessler

Rita KESSLER is Project Manager at AIM – Association Internationale de la Mutualité – since 1998. She is in charge of European affairs including pharmaceutical policy. Between 2001 and 2004, she was also in charge of the management of the secretariat of the European Standing Conference of Co-operatives, Mutual societies, Associations and Foundations – CEP-CMAF (recently renamed SEE – Social Economy Europe).

Previously she worked for 8 years as Project Manager at ACME, European Association of Co-operatives and Mutual Insurers, in charge of studies and communication.

She holds a Master Degree in Psychology (1988), a Post-graduate in Business Management and Administration (1989) and studied Law (1993).



Hubertus Cranz

Dr Hubertus Cranz is the Director-General of the Association of the European Self-Medication Industry (AESGP).

After having received Masters Degrees in Pharmacy and Economics respectively at the universities of Tübingen and Hagen, he obtained a doctorate in natural sciences at the University of Kiel (Institute for Pharmacology).

Following different trainee programmes in pharmacies and the pharmaceutical industry (Ciba, Bayer) he joined the Institute for Health System Research in Kiel, a collaborating centre of the World Health Organization (WHO), where he carried out several research projects on healthcare systems, some of them particularly linked to the area of medicines and self-medication. He has written several books and numerous publications in scientific and health policy related magazines. He is also co-author of a book for patients on the use of self-medication products.

Between 1985 and 1988 he worked for the German Association of the Pharmaceutical Industry in Frankfurt. Since 1991 and in addition to his responsibilities at AESGP, Dr Cranz has been the Vice-Chairman for Europe and Africa of the World Self-Medication Industry (WSMI).

As a follow-up to the work of the European Pharma Forum in relation to information to patients the Association of the European Self-Medication Industry (AESGP) is participating in a project which aims at patients' empowerment by identifying and developing core self-care competencies required for general level European pharmacy practice and professional development. This shall allow for community pharmacists to provide the most adequate guidance on self-care related areas including new indications e.g. in the area of cardiovascular diseases. By that the growing expectations of patients with regard to the advisory role of pharmacists are addressed and shall lead to tangible results.

The partners in this project are the European Association of Faculties of Pharmacy, the European Pharmaceutical Students' Association, the London School of Pharmacy and AESGP. Representatives of the community pharmacists are closely associated. Key elements of the project include the development of online training modules with self-assessment questions and training material, which allows a targeted learning process. The first results of the project are expected to be made public by mid-2009.

| Panel, Pricing and Reimbursement |



Christoph **Thalheim**

Born in 1952 in Dresden, Germany, Christoph Thalheim spent the first part of his professional life in the German Air Force, where he got his university degree in pedagogies and left as Captain after 12 years of service.

A complete new orientation towards the field of "Intercultural Learning" followed, caused by a sabbatical year, which saw him travelling once around the world. Returned from this life-turning experience, Mr.Thalheim set up and run the EU-liaison office in Brussels of a major international NGO focussing on intercultural learning and international youth exchange programmes for 10 years.

In the beginning of 2000, the third new professional challenge in his life came up as EU affairs consultant, working mainly as Secretary General of the European Multiple Sclerosis Platform (EMSP), the European Advocacy Group representing the interests of 33 national MS Societies and more than 500.000 people affected by MS.

From 2000 to 2008, EMSP has emerged from an unknown "kitchen table business" starting with 21 member organisations, 1 sponsor, no major projects, very limited funds and one "multipurpose" part time staff to one of the key players in European patient advocacy, with member organisations in 33 European countries, 12 sustainable industry partners, several successful projects co-funded by the European Commission and /or other donors and sufficient funds to run a new Brussels based secretariat, currently consisting of the Secretary General, an Office Manager, an EU Project Coordinator, and an IT and Web specialist.



Thomas B. Cueni

Thomas B. Cueni is a member of the Board of the European Federation of the Pharmaceutical Industries' Associations (EFPIA) where he also chairs the Economic and Social Policy Committee (ESPC). He represented EFPIA on the Pharmaceutical Forum's Working Group on Pricing & Reimbursement. Mr. Cueni is Secretary General of Interpharma, the association of the Swiss pharmaceutical research companies.

He is also a member of the Council of the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) and serves on the Swiss Federal Medicines Committee, an Advisory Body of the Swiss Government. Prior to his appointment with Interpharma, Mr. Cueni had a career as a journalist and diplomat with postings in London, Paris and Vienna. Mr. Cueni studied at the Universities of Basle, the London School of Economics (LSE), and the Geneva Graduate Institute for International Studies, and has a degree in economics (University of Basle) and a post-graduate degree in politics (M.Sc.) from the LSE.

Finding a balance between reward for innovation, improved patient access to innovative medicines and controlling budgets remains a challenge for decision-makers, patients and industry in Europe. There are several problems which must be addressed in constructive dialogue involving all stakeholders:

(1) View health care spending as an investment not a burden: Today, Europe sees health care innovation too much as a cost rather than an asset. Not least thanks to the results of biomedical research we can not only expect to live longer but also enjoy old age with a higher quality of life.

(2) Incremental innovation must be rewarded: Without the acceptance of reward for incremental innovations, patients may not get many needed safer and more effective medicines. Medical progress rarely occurs in big leaps, small steps are the norm rather than the exception.

(3) Limit extraterritorial impact of national price controls: A similar price-level across Europe leads to a different level of affordability depending on the economic situation of each Member State. Adding to the pre-existing huge difference in purchase power across the EU, the financial market crisis and the resulting currency fluctuation make it even more important that national price controls be limited to the territory of the respective Member State concerned.

(4) Improve patient access to new medicines: Patients in Europe are faced with long variations and delays in access to new innovative medicines, including for life-threatening diseases. For example, cancer patients in some countries have to wait much longer till they have access, if at all, to modern therapies. This is unacceptable.



Greg Perry

Greg Perry established the European Generic Medicines Association (EGA) in 1993 and has been the association's fulltime Director General since 1999. He is a founding member of the International Generic Pharmaceutical Alliance (IGPA) and has served on its management committee since its creation in 1997. He served as Editor of the Journal of Generic Medicines from 2003 -2008 and was member of the SCRIP Awards Panel from 2004-2008. Greg is also CEO of GPA Ltd.

Greg was awarded the Golden Cross of Merit of the Republic of Poland in 2004 for his contribution

to industry and European integration. In 2005 he was granted Honorary Life Fellowship of TOPRA in recognition of his contribution to European pharmaceutical regulatory affairs.

Greg has over 20 years experience in European public affairs and business. He is a Member of various organisations including the International "Who's Who" of Professionals, the Institute of Directors (UK), Friends of the British Museum and Friends of the Royal Academy. Greg has an MA in European Integration, a BSocSc (Hons) in International Studies and a Diploma in Classical Studies.



René Jenny

Mr. René Jenny was elected GIRP President in June 2005 and re-elected for a second term in the summer of 2007. He holds a degree in Economics from the University of Fribourg, Switzerland and from the University of Stanford, USA. Before starting his career with the Galenica Group in September 1979, René Jenny joined Cooper Ltd as Head of Logistics and IT in 1974 and worked for the Swiss Scientific Council in Berne, Switzerland, from 1976 to 1979. Within the Galenica Group, he held different positions within the company, including Head of the Directorate General "Markets" and Head of the Division "Services". Until the end of August 2005 he was Member of the Corporate Executive Committee of the Galenica Group. René Jenny left the Galenica Group in August 2005 and took over various mandates as Board Member. René Jenny also is the President of the Swiss wholesalers' association pharma.ch. He is married and has two daughters.

GIRP, which is representing the European full-line wholesalers, has raised the awareness of the role of full-line wholesalers in the sustainable, safe and efficient delivery of the full range of medicines in Europe during the three years process of the Pharmaceutical Forum. The importance of this 'sustainable availability and delivery' of medicines has been highlighted in recommendation 7 of the Final Conclusions and Recommendations which, together with other recommendations, is very much welcomed by GIRP. However, the 'sustainable availability and delivery' of medicines is under threat from new distribution arrangements, which upset the well balanced full-line wholesaling system by taking profit making products out of the calculation, leaving full-line wholesalers with non profitable and many loss making medicines to distribute. One solution to this development has already been pointed out within the Working Group Pricing where an excellent paper on "Ensuring access to medicines in small markets in Europe" has been developed. In it the value of the public service function that full-line wholesalers fulfil by making all medicines available through pharmacies for the patients in Europe whenever and wherever they are needed is highlighted. We believe therefore that the best way for the Member States authorities to strengthen the sustainable availability and delivery of medicines as called for in recommendation 7, is to ensure that the public service function that full-line wholesalers already fulfill is recognised. GIRP encourages the European Commission therefore to enshrine the function of pharmaceutical full-line wholesaling in European legislation.

I Panel, Relative Effectiveness I



Anna Bucsics

Anna Bucsics was born in Budapest, Hungary and lives in Austria. She received her medical degree from the Karl-Franzens-University of Graz, Austria, where she did postgraduate research work in neuro-pharmacology at the Department of Experimental and Clinical Pharmacology. She was also an instructor there until 1991.

After completing her training in internal medicine at the Hospital of the Order of St. John of God in Graz, she received her diploma as a specialist for Pharmacology and Toxicology.

In 1991 she moved to Vienna where worked as a pharmacological consultant for the Main Association of Austrian Social Security Institutions and as auditor for pharmaceutical expenditures at the Viennese Social Health Insurance.

She is a Member of the MEDEV Committee since 1998 and was its Speaker from 2001 to 2005.

Since 2002 she is Deputy Department Head at the Department of Pharmaceuticals, Main Association of Austrian Social Security Institutions. In this position, she is responsible for management of applications for reimbursement of pharmaceuticals. She is also an instructor at the Center of Financial Services and Public Utility Management, University of Vienna.

She is grateful for the opportunity of representing ESIP at the Representative of ESIP in the Working Group on Relative Effectiveness of the Pharmaceutical Forum.

In the working group on information to patients, it was important for member states and health organisations to exchange their experience of existing projects in the field of patient information. However, ESIP can not support the Commission's proposal of 10 December 2008 to ease the restrictions of the current framework for pharmaceutical industry as regards information to patients on prescription-only medicines. We consider it crucial to ensure that the information provided to patients is balanced, unbiased, comprehensive, and not commercial. ESIP supports the ideas discussed in the Working Group on Pricing and would like to see further progress on how to increase price transparency and the need to make medicines available and affordable for all the countries of the European Union. Rewarding innovation in a way which helps strengthen the European pharmaceutical industry is also a topic which is best discussed in a forum such as the WG on Pricing, whereas determining what kind of innovation constitutes real added benefit for patients is best discussed in a more science-oriented context, such as the WG on Relative Effectiveness: how to make the best use of the available data and how to generate information which is more useful for assessing whether a new drug provides real added benefit for patients and just how large this benefit is. Whereas decisions on pricing and reimbursement are national, the WG on Relative Effectiveness showed just how useful international information exchange can be and identified networks for this purpose such as the official EUnetHTA, and MEDEV (the informal Medicines Evaluation Committee).



Albert J. Jovell

Albert J. Jovell (Barcelona, 1962), married with two children, is a doctor specialising in Preventive Medicine and Public Health. He holds the degrees of Doctor in Public Health from Harvard University; Doctor in Sociology from the University of Barcelona; Master of Science in Health Policy and Management from Harvard University; Master of Public Health in Epidemiology from Harvard University; Doctor and undergraduate degrees in Medicine and Surgery from the University of Barcelona; an undergraduate degree in Sociology and Political Science from the Autonomous University of Barcelona; and a diploma in Data Analysis Methods and Techniques in Health Sciences from the University of Barcelona.

He is currently the General Director of the Josep Laporte Library Foundation's "Centre of knowledge management in health and life sciences"; an Associate Professor of Preventive Medicine and Public Health at the Autonomous University of Barcelona, President of the Spanish Patients' Forum and Director of the Universidad de los Pacientes (Patients' University). He is a member of the Board of Directors of the European Patient's Forum (2007-), Director of the Observatory of Health Professions; 2007-), member of the Governing Board of the Catalan Institute of Health (2007-), member of the Commission for the Modernisation of the Health Care System (2007-), member of the Counsel on the Medical Profession (2006-), member of the Bioethics Advisory Council of Catalonia (2005-).

Noteworthy accomplishments in his academic activity include directing several courses in the fields of health care policy, ethics, evaluation of health care services, public health and leadership, as well as courses for conference attendees at the University of Alcalá and on the campus of Harvard University. He has written over 190 scientific and journalistic articles, as well as several chapters and prologues in books. He has given various conferences at national and international institutions. He is currently an Academic with the Royal Academy of Medical Sciences of Catalonia, where he is a member of the editorial committee and reviewer of national and international scientific journals. He is a member of the planning and scientific committees for various national and international conferences. He sponsored the class of 2005-2006 at the Blanquerna University School of Nursing and Physiotherapy, and sponsored the Nursing graduation at the International University of Catalonia (UIC) 2008.

As regards research, worth highlighting are his grants from Fundació La Caixa-Indiana University, the Ministry of Education and Science, the Health Care Research Fund, Marató on TV3, the MAPFRE Foundation, Merck Foundation, and AMGEN Foundation-United Way. He has been and is the main researcher on multiple scientific research projects in the areas of the synthesis of scientific evidence, quality of life, economic analysis, public opinion, social capital, health care professions and patients.



Lisette Tiddens-Engwirda

Lisette Tiddens-Engwirda has been active as a lobbyist in many different policy areas. After finishing her Masters degree in Law and Political Science she worked for the Union of Local Authorities in the Netherlands.

From there she went to Bennis/BPR as a senior consultant in which capacity she handled a wide range of different client accounts. As managing partner of this PR/PA firm she was also responsible for the Public Affairs department. She was Secretary General of the European Organisation of Community Pharmacists, PGEU and since November 2001 she is Secretary General of CPME, the Standing Committee of European Doctors.

Lisette Tiddens-Engwirda is the co-author of different books on issues related to politics in the Netherlands.

Through the years she has been active as a politician and a member of a variety of different boards of national and international organisations. Recently she has been appointed by the European Commission as a member of the so called 'Stakeholders Dialogue Group' that advises DG SANCO on its relations with its stakeholders. She has been Board member and Treasurer of the Atlantic and Pacific Exchange.



Andrea Rappagliosi

Born in Rome, Andrea Rappagliosi received a law degree from the University of Rome "La Sapienza" and completed a post-graduate "Legislative Consultant Diploma" from the Istituto Superiore degli Studi Legislativi (ISLE).

He began his career in the early eighties, first in the Italian Government as a member of staff for the State Undersecretary of the Treasury, then for the Italian Senate focusing on drafting of legislative texts, comparative legal studies and public budget analysis. In 1992, he moved to The Ares-Serono Group as Head of the Institutional Affairs Department in charge of the Rome and Brussels offices. From 1995 to 1999, he was Public Affairs Director at Baxter Healthcare, part of the European Public Affairs team. In 1999, he joined Serono International, today Merck Serono, as Vice President Health Policy & Market Access Europe.

Recently, he was a member of the European Commission High Level Pharmaceutical Forum representing EuropaBio, the European Association for Bioindustry. He is Member of HTAi (Health Technology Assessment International Society) and founding member of its Policy Forum. He sits on the Board of the Foundation of the European Platform for Patients Organizations, Science & Industry (EPPOSI). He has been an Industry representative at the EMEA/COMP (European Medicines Evaluation Agency/ Committee for Orphan Medicinal Products) Working Group with Interested Parties in the first two terms 2000 to 2005. Additional information: Andrea is member of the British Institute of International and Comparative Law and is a member of the Editorial Board of the Journal of Commercial Biotechnology. He contributes regularly to European financial and legal publications.



Stanislav Primožič

Head of the Sector of Pharmacoeconomics at the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia, he joined the Agency in 2001. Prior to his present appointment, he pursued an academic career at the University of Ljubljana, Faculty of Pharmacy. While his scientific background is in pharmacokinetics and pharmacoepidemiology, his regulatory experience prior to joining the Agency included work on several national regulatory Committees. He took part in the Pan-European Regulatory Forum (PERF) in the areas of Telematics, Pharmacovigilance and Acquis Communautaire.

After Slovenia became EU Member State, he participated in the work of EMEA and European Commission bodies including the Transparency Committee, as well as the Steering Committee and Working Groups of the Pharmaceutical Forum. During Slovenian Presidency term in 2008 he was presiding the Council Working Party for Pharmaceuticals and Medical Devices and served as the Chairman of the Networking Meeting of Competent Authorities for Pricing and Reimbursement of Pharmaceuticals.

Relative effectiveness can be seen as head-to-head evaluation of medicines. It serves the patients by assessing their added value in a real setting. It does so by relying on specific scientific knowledge, predominantly on clinical pharmacology and outcome research. It should contribute to rational judgment of the added value of new medicines among themselves and in relation to existing medicines as well as other methods of treatment.

In European Union, it is based on a legal framework giving the competence to Member States. From a societal angle, purpose of relative effectiveness assessment of modern medicines is to act as a bridge between drug regulatory area and decision making in pricing and reimbursement. The former has structurally become a part of EU law, while the latter is organized nationally and calls for networking and cooperation. Pharmaceutical Forum deliverables can be instrumental for Member State authorities, regardless of stage of their development and the size of their human or financial resources, and help them to cope with the advent of new technologies and the pressures posed by different stakeholders, only in a tight mutual cooperation. They should take on board the initiatives developed over recent years in Europe. At the current stage, such cooperation should be in principle non-binding however involving a high degree of professional standards and information exchange. I should maintain also a high degree of transparency toward different groups of professionals as well as patient groups.

| Focus, Information to Patients |



Lars-Olof Hensjö

MD since 1972. Specialist of Internal medicine and Family medicine. 1972, I worked as an internist at Nacka Hospital and at the Intensive Care Unit of Södersjukhuset, in Stockholm. 1977-2000, I worked as a family doctor in a suburb of Stockholm, Gustavsberg, which is beautifully situated in the archipelago of Stockholm. 1986 - 2001, I also worked in the Drug & Therapeutic Committee in a leading position. Part time I then also worked with "Academic Detailing" - together with a pharmacist I visited more than 25 Health Care centres twice a year, teaching rational and drug use and rational prescribing on behalf of the D&T Committee (*). During the same period I also worked part time as a teacher at the Karolinska Institute. 2000 - to date, I am working as the Chief medical officer at Sjukvårdsrådgivningen SVR AB "Health Care direct online".

(*) Ref:

- C. Stålsby Lundborg, L-O Hensjö, LL Gustafsson, "Academic Detailing: from project to practice in a Swedish urban area", Eur J Clin Pharmacol (1997) 52:167-172
- Folke Sjöqvist, Ulf Bergman; Marja-Liisa Dahl, Lars L Gustafsson, Lars-Olof Hensjö, feature article "Drug and therapeutic committees: a Swedish experience", WHO drug information Vol 16, No 3, 2002

The presentation concerns drug treatment information for the public in two different channels

- 1177.se = a web site on diseases, investigations, treatment, drug treatment etc.
- 1177 Sjukvårdsrådgivningen = telephone advice nursing (i.e. the phone number is 1177 all over Sweden)

The purpose of this package of different ways of giving drug treatment information is to support drug consumers and those nearest. Background: In our society there is a lot of drug information for the public to be found on the Internet and elsewhere. The information is often difficult to evaluate for the laymen and hard to understand. It therefore often is not useful, sometimes it rather makes the reader more confused than well informed. Also information in Product Information Leaflets (PIL) is, to be honest, often difficult to understand, in spite of the purpose of the PIL. Furthermore isolated drug information lacks the context of information on the disease or symptom treated, which is necessary to understand the purpose of the treatment. The information at the web site www.1177.se is produced in a strict quality process in cooperation with pharmacists, clinical experts in different fields. The texts are edited by journalists in order to make them easy to read, easy to understand, relevant to and in the perspective of the reader. All texts are revised once a year or at need. The drug information for the public on the web site consists of three components.

- Single drugs
- Diseases and symptoms, part of the texts has a chapter on treatment
- How to treat... hypertension/pain/ atrial fibrillation/ psychosis etc - the choice of drug treatment step by step, explained in a pedagogic way

Questions that are answered in these texts are for example: What is the benefit of the drug? How does the drug work? What are the most common adverse drug reactions or important ones to know? Links to useful and reliable sources like FASS (PDR), SPC:s etc are presented. The information on diseases and symptoms and treatments etc is also used as a quality assured source in a professional electronic counselling support used by the nurses giving telephone advice. The context with drug information close to information of the disease treated is essential and necessary to support good understanding and empowerment. This is important for good compliance and promotes safe use of drugs. The reader must be comfortable, feel safe and rely on the information. 1177.se is owned and run by the 21 county councils of Sweden.



Per Manell

Per Manell is chief technology officer at the Swedish Association of the Pharmaceutical Industry, LIF. He is also a registered pharmacist. Per has been at LIF since 1999.

Per graduated from the Faculty of Pharmacy, Uppsala UNIVERSITY in 1971.

Per Manell has been working for 17 years at the Swedish Medicines Agency (at present the Medical Products Agency).

Per has been CEO of PharmaSoft Inc, a global medicines information technology company.

He has also been advisor to the World Health Organisation, WHO, regarding regulation of medicines and medicines information in developing countries.

Per Manell had a fundamental role in the establishment of the WHO Collaborating Center on international drug monitoring in Uppsala in 1978.

Per has been on the Board of several professional organizations.

Fass has been developed by the Swedish Association of the Pharmaceutical Industry (LIF) and uses the advanced and modern XML (Extensible Markup Language format), which offers an array of functions for the use of information stored in a database. More than 140 pharmaceutical companies are online with the database and update it daily. Regardless of whether you are using a hand-held computer, making a search in Fass.se, or using an electronic prescription writing system to seek information, you will always be up to date and you will be alerted about important changes. The same is valid for patients. Although an essential part of the development of Fass has been the active participation of health-care professionals and patient organisations, it is also a product of several Private Public Partnerships (PPPs). A printed directory of medicines known as Patient-Fass has been available to the public since 1983. It was therefore a natural step to create Fass.se, the medicines information portal, which came online in August 2001. Today Fass.se has more than 4 million visitors every month. It has various functions designed to promote better use and knowledge about medicines. Of those who have visited the Fass.se medicines information portal, 90% say that they are satisfied with the information.* The Swedish trade journal Internet World has ranked Fass.se as Sweden's best healthcare website. Fass.se is adapted for users with functional disabilities, and an automated dictionary has been added for reader assistance. Fass.se provides only product information that is approved by the authorities – no promotional texts or advertising. On Fass.se you can create your own customized medical compendium using the My Fass function, a tool for personal involvement to follow and better understand your own medications. After storing a personal medicine information log, you can request dosage intake reminders to your mobile phone (via instant messaging) or via e-mail.

| Focus, Pricing and Reimbursement |



Hildrun Sundseth

Hildrun Sundseth heads the Brussels office of the European Cancer Patient Coalition (ECPC).

ECPC is a patient-led umbrella organisation, bringing together over 200 cancer patient groups from the large cancers such as lung, colon, breast and prostate to the rarer cancers, to speak with a single voice in the European healthcare debate. Hildrun is responsible for ECPC's strategy and communication on all EU policies, legislation and measures that affect cancer patients and their care. She provides the Secretariat for MAC "MEPs against Cancer" the Forum that brings together 68 MEPs who have pledged to make the fight against cancer a priority for EU and Member State action. Hildrun has been campaigning to have patients considered partners for change in health policy and care and has written a chapter about this in the Slovenian Cancer Policy book "Responding to the challenge of cancer in Europe".

No stranger to the European political and policy landscape, before retirement in 2004, Hildrun has had 20 years' experience of working with the EU institutions as Director of European Community Affairs for one of the world's leading pharmaceutical companies. Within the Company and the European Pharmaceutical Industry and Associations' (EFPIA), she pioneered improved communication with patient groups and health NGO based on shared interest, transparency and trust.

Access to innovative medicines is especially critical for patients with a life-threatening disease or a disease where there are currently few treatment options. These medicines come at a price, putting pressure on healthcare budgets. Cancer patients, however, want access to these innovative medicines.

Cancer patients are painfully aware of healthcare budgets and understand that governments need to maintain sustainable financing of healthcare for all patients. The company has spent time and capital to develop the medicine and is looking for a reward. Patients are interested in the company's continued ability to invest in further research. This presents patients with a dilemma, all the more reason why we need new thinking and more flexible approaches.

Following the NICE decision that Velcade for the treatment of multiple myeloma is not cost-effective, the NHS and the Company, who developed the drug, agreed to a "risk-sharing scheme". They agreed that Velcade would be made available for patients with relapsed multiple myeloma when bone marrow transplant was not an option. After 4 cycles, impact was measured and if there was a 50% reduction in serum M-protein, treatment was considered effective and NHS continued funding. If however, the drug did not work the Company would refund the cost.

There are clearly benefits with this risk-sharing approach. The patient for whom the drug works is given the medicine. Such flexible approaches of risk-sharing or conditional pricing are welcomed by patients. If agreed before the NICE evaluation, it would have avoided one year of delay, and gathered clinical experience and the therapeutic value in controlled settings while the patient had access. For patients with a life-threatening cancer this is critical.



Yann Le Cam

Mr Le Cam has over 20 years of professional experience, and personal commitment, in health and medical research non-governmental organisations in France, Europe and the United States in the fields of cancer, HIV/Aids, genetic disorders and rare diseases.

Chief Executive Officer of EURORDIS since 2001, of which he is a co-founder in 1997 (Paris). EURORDIS is the largest European non-governmental and not-for profit organisation in the health area.

EURORDIS is an umbrella organisation of 360 patient advocacy and support associations in 39 countries, active in the field of research, drug development, centres of care, information, social support, through capacity building of patients and patient representatives and advocacy.

Member of the European Commission DG SanCo Rare Diseases Task Force (Luxembourg), board member and Treasurer of the European Platform of Patient Organisation Science and Industry – EPPOSI (Brussels), board member of the Drug Information Association – DIA – (Zurich), board member and President-Elect of the International Council for Orphan Drugs and Rare Diseases – ICORD (Stockholm), founding member, Vice President and Acting President of the International Alliance of Patients Organisations – IAPO (London). Executive Board Member of the French National Health Authority – ANAES and later HAS (Paris).

Education: Executive MBA, HEC, Jouy-en-Josas, France, 2000, MBA, Institut Supérieur de Gestion, Paris, France, 1984. Family: He has three daughters, the oldest (18 years) being affected by cystic fibrosis.



Huib Kooijman

After completing a Msc in Biomedical Science at Leiden University in 1996, Mr. Kooijman worked in the international pharmaceutical industry in the discipline of clinical research. From 2003 on he held positions as Senior consultant and Director business development in an international research consultancy firm in Pharmacoeconomics and Pricing & Reimbursement offering strategic services to both pharmaceutical industry and health care authorities.

Mr. Kooijman subsequently joined the local office of a major pharmaceutical company in the business unit corporate affairs/governmental affairs.

In 2007, Mr. Kooijman accepted a position as Senior policy advisor at the Dutch Ministry of Health, dealing with Pharmaceutical Affairs in general and pricing & reimbursement in particular.

| Focus, Relative Effectiveness |



François Meyer

Dr. Meyer received his MD from the University of Montpellier Medical School in France in 1984. He worked to become a specialist in Endocrinology and Metabolic Disorders.

In 1979 he became a Resident at the Montpellier Teaching Hospital. From 1984 to 1988, he worked as Registrar (Chef de Clinique – Assistant) in Montpellier hospitals and university; the first two years he spent in the Endocrinology and Metabolic Diseases Unit at Lapeyronie Hospital, while in 1986 through 1988 he was in the Internal Medicine Unit at Saint Eloi Hospital.

In 1989, he started his own private practice in Endocrinology and Metabolic Disorders and worked part-time as a hospital physician. From 1992 to 1997, he worked in the R&D department of a pharmaceutical company, initially as a medical sponsor and, from 1994 on, as Group Leader of Oncology.

In 1997, he became Deputy Director in charge of Medical Affairs in the Medicines Evaluation Department at the French Health Products Safety Agency (Agence Française de Sécurité Sanitaire des Produits de Santé - AFSSAPS). From 2000 to 2002, he was member, as the French representative, of the EMEA's Committee for Orphan Medicinal Products (COMP).

In 2005 he joined a new public independent body, the French National Authority for Health (Haute Autorité de Santé, HAS). HAS was set up by the French government in order to bring together under a single roof a number of activities designed to improve the quality of patient care and to guarantee equity within the Health Care System. Dr. Meyer is currently Director of the Health Technology Assessment Division at HAS.



Andrew Chidgey

Andrew Chidgey is Head of Policy and Public Affairs and Programme Director for National Dementia Strategy Implementation at the UK Alzheimer's Society where he has worked for 7 years. In that time he has been responsible for developing public policy and campaigning for a National Dementia Strategy, mental capacity legislation, access to drugs and changes to the system of charging for care.

Andrew has advised politicians, policy makers and commissioners on the needs of people with dementia and their carers and has appeared as a spokesperson for the Alzheimer's Society on many occasions.

In 2005-2006 Andrew was seconded to the Department of Health where he worked on the White Paper Our Health, Our Care our Say and the comprehensive spending review. From 2007 to the present Andrew has acted as the Alzheimer's Society's head policy lead working with the UK Department of Health to develop a National Dementia Strategy for England and continues to work with Government, the National Health Service and councils to ensure better information, support and care for people with dementia and their carers.

Patient organisations have a vital role to play in ensuring that the patient voice is heard in health technology assessment. In the technology appraisal for dementia drugs that took place from 2004-2007 in the UK, the Alzheimer's Society gathered evidence from over 4,000 people with dementia and carers to offer an expert patient view on the benefits of treatment, to complement the submissions made by others to the UK National Institute for Health and Clinical Excellence. When it was appropriate, the Society also mounted public and political campaigns to explain the benefits of treatment and where the view of patients and the public was not adequately being reflected in the health technology appraisal process.

Information to Patients

Information to Patients Pharmaceutical Forum Outcome of the 3 year process

Conference The Pharmaceutical Forum, Delivering for Patients
How to move from agreed principles to good practice and positive change across Europe
25 March 2009

1. Information to Patients What are the challenges?

Information to Patients What is at stake?

Multiple information existing:

- ♣ Different providers
 - ♣ Diverging objectives
 - ♣ Diverse channels
- Challenge in terms of **Quality** and **Access**

Focus

- Disease and treatment option information:
Core element/ production/ validation
- Electronic and non-electronic dissemination of information
- Availability of information in healthcare environments

2. Information to Patients WG Mission statement and areas of reflection from 2005

Mission Statement

- To advise the Commission on ways to **improve the quality of information** on authorised medicines available to European patients. This will supplement the key role of health professionals in providing information to patients **on medicines and health issues more generally**. Patients are increasingly loaded with different information, provided by multiple parties with differing objectives and sent through multiple channels (E.g., the internet).
- This initiative will cover **different topics that could help improve electronic and non-electronic information** for patients and, in particular, develop a **model for a Public Private Partnership** that could implement the recommendations in an effective and sustainable way.
- It will also explore the **feasibility of establishing a database of comprehensive and easily accessible information**.

Areas of Reflection

- Sources of information
- Quality of the information
- Dissemination of the information
- Sustainability

3. Information to Patients WG

The outcomes

Endorsed by the High Level Pharmaceutical Forum
on 2 October 2008

Information to Patients

General Conclusions

- Urgent challenge to invest in **high quality** and **accessible** information on diseases and treatment options considering the **shared responsibility** of all
- The Members of the Forum recognised:
 - ✦ Role of **national authorities** to make the best information available
 - ✦ **Healthcare professionals** and **competent authorities** as the primer sources of information
 - ✦ Added value of **common principles**, **European methodologies** and **specific requirements**
 - ✦ Benefit of **mobilising the knowledge and resources from different partners**
 - ✦ The role of **existing partnerships** and other collaborative approaches
- The Members of the Forum invited for consideration of :
 - ✦ **Sound cooperation** fostered by the wealth of national initiative
 - ✦ The launch of a **European information library** of existing high quality information to patients.
 - ✦ The development of **strategies to ensure coherent approaches both at national and at European level.**
- **New approaches** to be developed in a coordinated manner, with stakeholders, promoting health literacy and health information in the broadest sense.

Information to Patients

Final Recommendations of the Pharma Forum

- Recommendation 1: Enhance **quality** of information
- Recommendation 2: Increase **Accessibility** and **Dissemination** of Information
- Recommendation 3: Generation of information by making the **best use of all actors**
- Recommendation 4: **Continued momentum** on information to Patients

Information to Patients

1. Recommendation to enhance the quality of information

- ✦ Using the **core quality principles** and their **methodology of use** for the development of information, and to identify poor quality information.
- ✦ Using the identified **key elements for information to patients** on medical conditions and treatment options
- ✦ Using the **DARTS-principles** to identify good quality web-sites
- ✦ Continue the **ban on advertising of prescription medicines**

Core quality principles

- Objective and unbiased
- Patient-oriented
- Evidence-based
- Up-to-date
- Reliable
- Understandable
- Accessible
- Transparent
- Relevant
- Consistent with Statutory Information

DARTS - principles

1. **D**ate (When was the information updated?)
2. **A**uthor (Who is the writer? Is he/she qualified?)
3. **R**eferences (Are the references and sources of content valid?)
4. **T**ype (What is the purpose of the site?)
5. **S**ponsor (Is the site sponsored and, if so, by whom?)

Information to Patients

2. Recommendation on access and dissemination

- ♣ **Effective Communication format** taking account of local traditions, healthcare systems and languages
- ♣ Identification of **best practices** and promote cooperation among MS
- ♣ Further develop **EMEA database** on medicinal products authorised in the EU

Recommendations for Access and Dissemination

for MS

- Review existing tools and see how far they are adequate with patients needs
- Awareness campaigns for patients
- Promotion of education for health professionals.
- Promotion of Information Communication Technology / literacy initiatives

for the Commission

- Support bodies promotion capacity building
- Facilitate exchange of information between health care settings

for stakeholders

- Map education needs
- Promotion of best practices in healthcare settings
- Promotion of multidisciplinary approaches among health professionals

Information to Patients

3. Recommendation for the generation of information by making the best use of all actors

- ♣ **Exchange information** about different approaches and consider whether **further collaboration** can be created
- ♣ Implement the **ethical requirements** (transparency, disclosure of financial and other support and definition of responsibilities) as to collaborations and Public Private Partnerships
- ♣ Possibly refer to the overview of existing partnerships in the EU and raise the **visibility of existing partnerships**

Information to Patients

4. Recommendation for a continued momentum

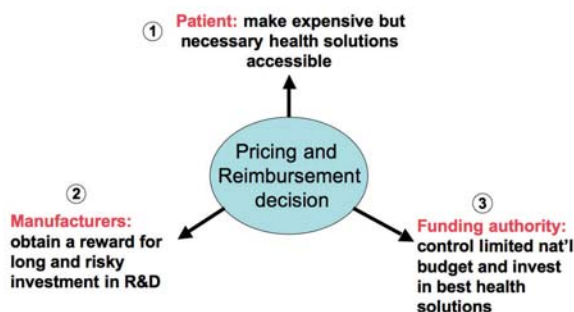
- Implementation by all **interested parties**
- **First review in 2 year** by the Commission
- **Further cooperation** and **sharing of experiences** at EU level

Presentation of the outcomes on pricing and reimbursement

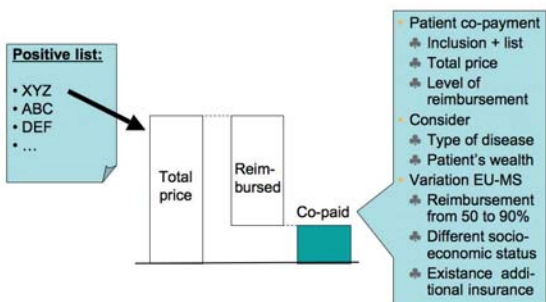
Outcomes of the Working Group on Pricing and Reimbursement

The Pharmaceutical Forum
Delivering for Patients
25 March 2009, Brussels

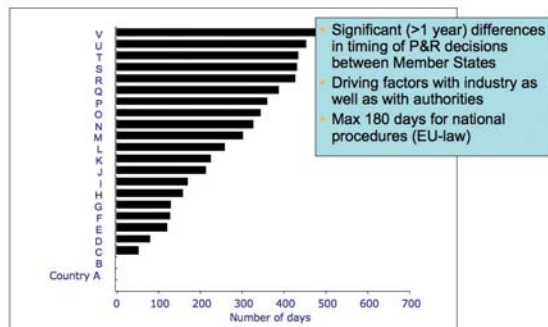
EXPECTATIONS FROM A PRICING AND REIMBURSEMENT DECISION



P&R-DECISIONS DEFINE ECONOMIC ACCESS / AFFORDABILITY FOR PATIENTS



MOMENT OF P&R DECISION DEFINES AVAILABILITY Time between Market Authorisation and P&R decision



* Defined by when medicine gets a pricing and reimbursement decision in a MS
Source: IMS, Marketing Authorisation 30/6/2000 to 30/6/2004

FINAL RECOMMENDATIONS OF THE HLPF

- Recommendation 7: **Access** to medicines for EU citizens
 - Fasten access, apply Directive 89/105/EEC
 - Improve availability in small markets
 - Ensure equal access to orphan medicines
- Recommendation 8: Expect, identify and **reward** valuable **innovation**
 - Set common and clear expectations
 - Be consistent with recognition and reward
 - Align all elements in national P&R systems
- Recommendation 9: **Optimal use of resources**
 - Keep the patient focus
 - Align all elements of P&R practices
 - Exchange experiences between Member States
 - Further development of knowledge

KEY DOCUMENTS ADOPTED IN THE WG PRICING

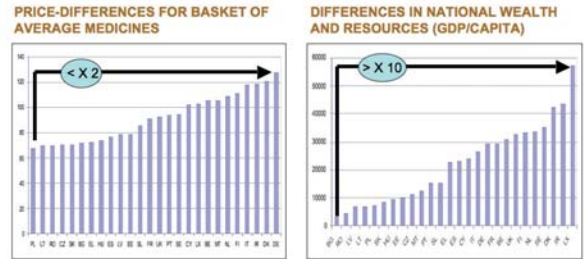
- "Guiding principles" for good practices implementing a pricing and reimbursement policy
- 1. On Access for patients:
 - Ensuring access to medicines in small national markets in Europe
 - Improving access to orphan medicines for all affected EU citizens
- 2. On Reward for innovation:
 - Characterisation of the value of innovative medicines
 - From assessing innovative value of pharmaceuticals to pricing and reimbursement decisions
- 3. On Control of expenditure:
 - Risk sharing practices and conditional pricing of pharmaceutical
 - The Toolbox exercise

See: http://ec.europa.eu/pharmaforum/pricing_en.htm

KEY ELEMENTS TO IMPROVE ACCESS TO MEDICINES

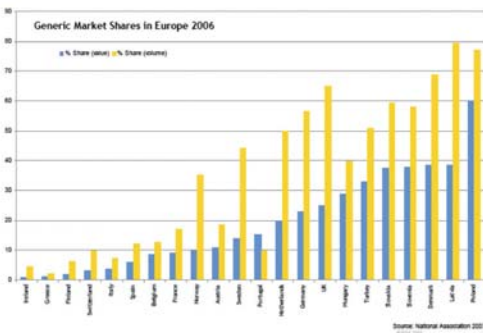
1. Affordability differences over the European Union
2. Good use of generics policies
3. Good use of conditional pricing/risk sharing practices
4. Access to orphan medicines
5. Availability in small Member States

AFFORDABILITY HAS A TRANS-EUROPEAN DIMENSION



Source: Eurostat-OECD, IMF

GENERICS ALLOW SIMILAR TREATMENTS AT LOWER PRICES



Source: European Generics Association

RISK SHARING AND CONDITIONAL P&R ALLOW FACILITATED ACCESS IN UNCLEAR SITUATIONS

Situation

- Complex situation due to:
 - Potential strong benefits...
 - ... but not yet prove, doubt about value
 - ... and very high prices
- Solution in a conditional agreement
 - Limited time period
 - Controlled number of patients/maximum costs
 - Study setting
- Comforts all parties
 - Patients have an early use/access of medicine
 - Control of budget for funding authorities, with certainty that knowledge on the value will soon be better known
 - Early reward for innovation for companies

Increasing use

- UK – Velcade
- IT – Performance risk-sharing (Bayer)
- UK – MS
- BE – Conditional reimbursement
- NL – Conditional reimbursement in hospitals
- LT – Conditional reimbursement
- ...

**IMPROVE EU-WIDE ACCESS TO ORPHAN DRUGS
SPECIFIC BOTTLENECKS DUE TO RARITY**

Key bottlenecks

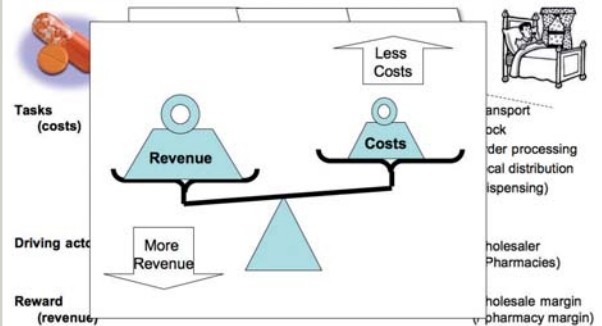
- Risky development of orphan drug
- Assessing uncertain clinical value
- Difficult pricing/reimbursement deals
- Limited awareness and skills

Potential Ways forward identified

- EC Regulation* + National incentives
- Early Dialogue
- Flow information on orphan drugs
- Bundle fragmented know-how
- Promote conditional pricing/reimbursement
- Monitor/study utilisation
- Standardised patient registers
- Network centers of expertise

*: (EC)No 141/2000, (EC) No 847/2000

NECESSARY STEPS TO GET A MEDICINE TO THE PATIENT INTO A SMALL NATIONAL MARKET



Presentation of the outcomes on relative effectiveness

Relative Effectiveness Pharmaceutical Forum

Outcome of the 3 year process

Conference The Pharmaceutical Forum,
Delivering for Patients

*How to move from agreed principles to
good practice and positive change across
Europe*

25 March 2009

1. Relative Effectiveness What is it?

Relative Effectiveness – explained

- Agreed working definitions:
 - **Efficacy**: is the extent to which an intervention does more good than harm under ideal circumstances.
 - **Relative efficacy**: can be defined as the extent to which an intervention does more good than harm, under ideal circumstances, compared to one or more alternative interventions.
 - **Effectiveness** is 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**.

Relative Effectiveness – explained

- In plain language:
 - Which one of two or more medical interventions (medicines) is more effective for treating sick persons in every day life?
- Relative Effectiveness Assessments
 - Try to help decision makers understand how this can and should be measured

2. Mission statement and mandate from 2005

Why did the Forum want to
work on this issue?

Mission statement

- *To support Member States apply Relative Effectiveness systems in order to allow containment of pharmaceutical costs as well as a fair reward for innovation.*
- *Relative Effectiveness systems are relatively new for many Member States and rather complex. Nevertheless the outcome of relative effectiveness is promising as they will help allow identify the most valuable medicines, both in terms of clinical efficiency as of cost-effectiveness, and will help set a fair price for these medicines.*
- *The Working Group will bring experiences of different Member States and of industry together in order to further develop this promising field.*

Expected outcomes

- Identification of areas of interest where Member States could benefit from sharing best practices and from building common approaches.
- Develop mechanisms for sharing best practices and/or for building common approaches

3. The deliverables of the Relative Effectiveness WG

Endorsed by the 27 MS and the stakeholders on 2 October 2008

General conclusions

- Decisions on pricing and reimbursement lie with the national competent authorities
- **But** members of the Forum agreed on:
 - The importance of exchanging information
 - The added value of common working definitions and good practice principles
 - The added value of information on data available, needs and methodologies used

More substantial work remains

Recommendations (1)

- **Common definitions and core principles**
 - Efficacy/relative efficacy of drugs
 - Effectiveness/ relative effectiveness (RE)
 - Relevant distinction RE/cost-effectiveness assessment (CEA)
 - RE most appropriate at national level but EU cooperation can bring added value for developing data on RE and dealing with methodological challenges
 - **All actors involved invited to promote the use of the definitions**

Recommendations (2)

- **Cooperation should focus on:**
 - Strengthening the **methodological** quality and rigour of RE assessment
 - Consolidating **scientific evidence** on RE
 - Better understanding the barriers for the generation of the data
 - Better understanding transferability limitations

Recommendations (3)

- **Involvement of all actors**
 - Competent authorities make the final decisions on Pricing/ Reimbursement but:
 - Need to listen to the views of stakeholders: patients, health professionals, industry, payers

Recommendations (4)

- Explore avenues for **early dialogue** between Market Authorization holders and decision makers, during the drug development process
- Make best use of the **EPAR** (European Public Assessment Report) and **NPAR** (National Public Assessment Report)
- Identify any **scope for common approaches**, as appropriate

| Notes |

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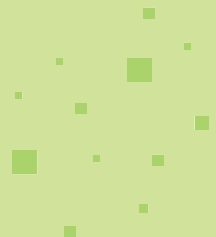
European Commission
Enterprise and Industry



europatientsforum



Directorate-General for
Health & Consumers



<http://ec.europa.eu/pharmaforum/>