Livre des résumés / *Abstracts Book*

La Société Française d'Economie de la Santé
The French Society of Health Economics

en partenariat avec / with the partnership of:
La Fondation Robert Schuman

1st Euro Health Forum

Sous le haut patronage du Ministre de la Santé et de la Protection Sociale
Under the patronage of the French Minister of Health
Docteur Philippe Douste-Blazy

Le défi des réformes des systèmes de santé dans l'Europe élargie

The Challenge of Healthcare Systems Reforms Throughout the Enlarged Europe

First Euro Health Forum

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First Euro Health Forum

A few words of Welcome

Anne BARDOT, Chair of the Steering Committee

The objective of the European Health Forum is to create an environment for privileged exchanges uniting academics, health professionals, patient associations, health authorities and political figures from all of Europe.

The theme of the first edition of this forum organised in Paris came quite naturally to its organisers as a homage and message of welcome to the ten newest members of the European Union.

Also, the debates evolved around the reform of health systems in the enlarged Europe: what are the models? What are the objectives? What are the solutions for «finite systems faced with infinite demands?"* In what context can we speak of convergence?

The source of the participants and the defined framework within which the conference was developed illustrate the originality of a project characterised by insistence upon diversity and neutrality.

The support of the French authorities through its Minister of Health, the engagement of the French Society of Health Economics (SFES) - the organizing scientific body in partnership with the Robert Schuman Foundation, the involvement of the media Euractiv, the contribution of the sponsors who, for the first time, bring together both innovative – Lundbeck – and generic – Polpharma- industries attest to the novelty of this project.

To all – Mr Christian Poncelet, President of the Senate, Dr. Philippe Douste-Blazy, Minister of Health, European Ministers and Vice-Ministers, members of the Scientific Committee, Speakers, Partners, Sponsors, and Najaite Mazzoni ..., on behalf of the organising committee, I would like to offer my sincere thank you for having made possible in only a few months such an ambitious project.

To all participants, welcome and enjoy the Forum !

Anne BARDOT, Ph. D.

*Michel Foucault

First Euro Health Forum

Editorial

Robert LAUNOIS, Coordinator of the Scientific Committee

A FUNDAMENTAL QUESTION

Because of the increasingly fast emergence of new technologies, to which everyone considers they have the right, medical expenditure is absorbing an increasing part of the countries gross domestic products, to the detriment of other sectors which are also considered to be priority.

In the current state of development of medical technologies, so many treatment procedures are now recognised to be effective, that no country, even the richest, is able to provide them to all potential patients. We therefore, need to establish the ethical principles on which we can base the conditions of their use.

There are three different strategies.

- Some stress the need to preserve individual freedom, allowing everyone to use what they perceive as the fruits of their labour. This viewpoint would recognise anyone's right to define the amount of medical resource consumed and level of social protection within the bounds of their income.
- Others, in the name of equity, believe that we should serve the interests of the greatest number as best as possible within the constraints of limited resources. This concept of the closed budget necessarily involves choices based on systematic examination of the costs and benefits procured.
- A more subtle definition of equity involves introducing the concept of "adequate level of care". Supporters of this, point out that people with higher incomes can always access a higher standard of care from that offered to most of the population. Trying to impose equality in this area would, fatally in the context of free movement of people in Europe, lead to the geographical migration of wealthier patients.

All members of the European Union, new or more longstanding, are faced with the same dilemmas and troubled by the same questions.

The fundamental problem which any health service reforms raise, is clearly ethical. Should access to care be based on each person's ability to pay, or should it be the same for all within the limits of the combined purchasing potential of the country?

To what extent should the patient-consumer be involved in health decision making on a regional and national scale?

Prof. Robert LAUNOIS,
Vice President of the SFES

First Euro Health Forum

Wednesday October, 27, 2004

Morning

08:50 **Welcoming address / Discours de bienvenue**
Prof. Robert Launois (Vice-président, SFES), Jean-Dominique Giuliani (Président, Fondation Robert Schuman)

09:00 – 09:20 **Opening Remarks / Discours d'ouverture**
Dr. Philippe Douste-Blazy (Ministre de la Santé et de la Protection Sociale)
Mr Rafal Nizankowski (Vice Minister of Health, Poland)

09:20 – 09:40 **Introduction / Introduction**
Dr. Philippe Brunet (EU Commission, DG Enterprise, Head of Unit, Pharmaceuticals)

Why and How to reform Healthcare Systems in Europe
Pourquoi et comment réformer les systèmes de santé en Europe

Chairman:
Simon Stevens (President-Europe, United Health Group - former Health Policy Adviser to Prime Minister Tony Blair)
Rapporteur:
Dr. Borislav Borissov (former Head of the Bulgarian Drug Agency, General Manager of Prescriptia Ltd)

09:40 – 10:10 **The importance of Heritage in Central and Eastern European countries: resistance to change and roadmap to progress.**
Poids de l'héritage dans les pays d'Europe centrale et orientale : inertie et voies d'avenir.
Dr. Panos Kanavos (LSE Health and Social Care)

10:10 – 10:40 **Does the former Europe of 15 have models to propose and do the 10 newest members have solutions to share ?**
L'Europe des 15 a-t-elle des modèles à proposer et les 10 nouveaux membres ont-ils des solutions à partager ?
Prof. Robert Launois (Université Paris XIII)

10:40 – 11:00 Break / *Pause*

The Multiple Faces of Reform in the Europe of 25
Une mosaïque de réformes dans l'Europe des 25

Chairman:
Prof. Paul Corrigan (Special Adviser to the Secretary of State for Health, UK)
Rapporteur :
Dr. Borislav Borissov (former Head of the Bulgarian Drug Agency, General Manager of Prescriptia Ltd)

11:00 – 11:30 **Estonia:** Which model for the healthcare system reform in Estonia?
Estonie : quel modèle pour la réforme du système de santé en Estonie ?
Prof. Raul Kiivet (Health Care Management, Head of the Dept. of Public Health, University of Tartu, Advisor to the DG State Agency of Medicines)
Discussant: Hannes Danilov (Chairman, Estonian Health Insurance Fund)

11:30 – 12:00 **Great Britain: Current status and future of reforms of Healthcare System**
Grande-Bretagne : Bilan et avenir des réformes du système de santé
Prof. Alan Maynard (Prof. of Health Economics, Director of the York Health Policy Group at the University of York)
Discussant: Dr. Carole Longson (Appraisal Programme Director, National Institute for Clinical Excellence)

12:00 – 12:30 **Czech Republic: Healthcare system reform and the role of the health insurance companies**
République Tchèque : Réforme du système de santé et rôle des compagnies d'assurances
Ass. Prof. Karel Nemecek (Department of Drugs and Medical Devices, General Health Insurance Company of the Czech Rep.)
Discussant: Pavel Veprek (Chairman, NGO Citizen)

12:30 – 15:00 Lunch at "le Sénat" / *Déjeuner au Sénat*

First Euro Health Forum

Wednesday October, 27, 2004

Afternoon

The Multiple Faces of Reform in the Europe of 25
Une mosaïque de réformes dans l'Europe des 25

Chairman:
Dr. Josep Figueras (WHO - European Observatory on Health Systems and Policies)
Rapporteur:
Prof. Elias Mossialos (LSE Health and Social Care and WHO - European Observatory on Health Systems and Policies)

15:00 – 15:30 **France: Strategy of reform of the Healthcare System**
France : Stratégie de réforme du système de santé
Yves Bur (Député, Vice Président de l'Assemblée Nationale)
Discussant: Noël Renaudin (Président du Comité Economique des Produits de Santé)

15:30 – 16:00 **Poland: Between decentralized and centralized health systems, looking for the future of the Polish Health System ?**
Pologne : Système de santé centralisé ou décentralisé : quel futur pour le système de santé en Pologne ?
Andrzej Rys (Director of the Center for Innovation, technology Transfer and University Development - CITTRU - Jagiellonian University, Krakow)
Discussant: Mr Rafal Nizankowski (Vice Minister of Health, Poland)

16:00 – 16:15 Break / *Pause*

Towards a European health care « market »?
Vers un « marché » européen des soins de santé ?

Chairman:
Kees de Joncheere (Regional Advisor for Pharmaceuticals and Technology, WHO Regional Office for Europe)
Rapporteur:
Prof. Reinhard Busse (Technische Universitaet Berlin, Dpt Health Care Management - European Observatory on Health Systems and Policies)

16:15 – 17:30 Round Table / *Table ronde*
How to assure equitable access to medications throughout Europe?
Comment assurer un accès équitable aux soins à travers l'Europe ?
Jim Murray (Director, The European Consumer's Organisation), Greg Perry (Director, European Generic Medicines Association), Dr. Dagmar Stara (Consultant in Regulatory Affairs and Pharmacoeconomics), Albert van der Zeijden (Chair, The International Alliance of Patients' Organisations)

17:30 **Questions - Answers** / *Questions - Réponses*

18:00 **Closing address** / *Discours de clôture*
CEE Ministers

18:30 **End of the debates** / *Fin des débats*

20:30 **Dinner** /*Dîner*
Hôtel de la Monnaie

Prof. Robert LAUNOIS

Université Paris XIII, Vice President of the SFES

Robert LAUNOIS a fait ses études à Rennes, Paris et Cambridge Mass. Agrégé des facultés de Sciences Economiques, diplômé de l'Institut d'Etudes Politiques de Paris et Harkness Fellow du Commonwealth Fund of New York (Harvard University), il enseigne l'Economie Médicale à la Faculté de Médecine de l'Université de Paris XIII. Directeur scientifique du Réseau d'Evaluation en Economie de la Santé (REES France), il est consultant pour le compte des administrations et des industries de santé. Ses recherches portent sur l'étude des stratégies diagnostiques et thérapeutiques, l'évaluation pharmaco-économique, l'analyse des systèmes de protection sociale français et étrangers. Il s'est tout spécialement préoccupé de la nécessaire réintroduction de mécanismes de marché dans le domaine de la Santé. Il a été membre de la commission de la Nomenclature Générale des Actes Professionnels (NGAP Ministère de la Santé 1991-1994), membre de la commission de surveillance de l'hôpital Laënnec, Assistance Publique des Hôpitaux de Paris (1994-1999). Il est actuellement membre de la commission des comptes de la santé depuis 1993 et Vice-Président de la Société Française d'Economie de la Santé (SFES).

Jean-Dominique GIULIANI

Président, Fondation Robert Schuman

Jean-Dominique Giuliani Préside, depuis 2000, la Fondation Robert Schuman, dont il est l'un des fondateurs.
Licencié en droit et diplômé de l'Institut d'études politiques, Jean-Dominique Giuliani est ancien auditeur de l'Institut des Hautes Etudes de Défense Nationale.
Secrétaire général du groupe de l'Union centriste du Sénat entre 1981 et 1992, il fut, de 1992 à 1998, le directeur de cabinet de M. René Monory, Président du Sénat. Il a démissionné du Conseil d'Etat où il a été nommé Maître des Requêtes en 1995.
De 1998 à 2001, Jean-Dominique Giuliani a été Directeur à la direction générale du groupe Taylor Nelson Sofres puis, en 2002, Special Policy Adviser pour Fleisman-Hillard (Groupe Omnicom). Cette même année, il fonda JD-G.Com International Consultants.
Jean-Dominique Giuliani est l'auteur de « Marchands d'influence » Les lobbies en France, Le Seuil (1991) ; « Pour l'Europe réunie » - 2 tomes Collection « Les Notes » de la Fondation Robert Schuman (2002) , « Quinze + Dix : Le grand élargissement », Albin Michel (Paris 2003), « L'élargissement de l'Europe, PUF, collection « Que sais-je », Paris, mai 2004.

Dr. Philippe BRUNET

Head of Unit "Pharmaceuticals. Regulatory framework and marketing authorisations." Directorate-General Enterprise. European Commission, Brussels

Doctor of Medicine and Doctor of law.
Joined the European Commission in 1988 as Administrator in Directorate-General V (Social affairs), firstly in the Unit "Health and Safety at work" then in the Unit "Public Heath".
Moved in 1993 to Directorate-General III (Industry) now Directorate-General Enterprise, Unit "Pharmaceuticals" where he integrated the task force in charge of the setting up of the European Medicine Evaluation Agency and the new marketing authorisations procedures.
From 1995 onwards, in the same Unit, in charge of new legislation, legal issues and management of the Commission Decision making process for marketing authorisations.
Appointed Deputy Head of Unit of the Unit "Cosmetics and Pharmaceuticals" in 1998.
Appointed Head of Unit in 2000. One year later the Unit became "Pharmaceuticals: regulatory framework and marketing authorisations"

Since 1993 he has worked to set up the new Community Marketing authorisation system, in particular through the adoption of numerous implementing measures. In 1998, under his responsibility, a draft Communication was prepared to determine the overall framework for ensuring full implementation of the directives adopted in 1993 and in particular of the mutual recognition procedure. The final Communication was adopted in July 1998. In the meantime a huge Codification exercise of the EU legislation was launched (more than 30 texts) under his supervision which was concluded with the adoption in November 2001 of these Community "Codes" relating to medicinal products (human and veterinary). The year 2000 saw the launch of an audit of the functioning of the Community Marketing authorisation system and 3 proposals to reform the system were drafted under his responsibility.

In November 2001, based on these proposals, the Commission proposed the famous "Review Package" on which a final agreement was finally reached in December 2003. During this legislative process, the action of Ph. Brunet and his team has been decisive.

Ph. Brunet has regularly participated in DIA events. On numerous occasions, he has made critical presentations: the content of the 98 Commission Communication, the presentation of the Review Package, the Content of the Council common position on these texts and recently the challenges of the European Parliament Second Reading have been presented and explained for the first time at DIA meetings.

Since 1999, Philippe Brunet has been a Member of the ICH Steering Committee where he represents the EU.

In addition to numerous articles, he has published a "Dictionary of the principal terms in European Pharmaceutical law" (Editions de santé - Paris 2000).

First Euro Health Forum

Introduction

Dr Philippe BRUNET, EU Commission

LE DÉFI DES RÉFORMES DES SYSTÈMES DE SANTÉ DANS L'EUROPE ÉLARGIE
PRODUITS PHARMACEUTIQUES : CADRE LÉGISLATIF ET AUTORISATIONS DE MISE SUR LE MARCHÉ

Monsieur le Ministre,
Monsieur le Président de la Société Française d'Economie de la Santé,
Monsieur le Président de la Fondation Robert Schuman,
Mesdames, Messieurs,

Tout d'abord, permettez-moi de remercier la Société française d'Economie de la Santé et la Fondation Robert Schuman de m'avoir invité à cette première conférence internationale « Euro Santé ».
Mes nouvelles missions au sein de la future Commission européenne m'empêchent malheureusement d'être physiquement parmi vous aujourd'hui.
C'est néanmoins un honneur et un plaisir pour moi de partager avec vous ces quelques réflexions sur le défi essentiel que pose la réforme des systèmes de santé au sein de l'Union européenne, et qui se pose avec d'autant plus d'acuité que l'Europe d'aujourd'hui représente 25 Etats-membres et plus de 450 millions d'habitants, c'est-à-dire l'équivalent du troisième « pays » le plus peuplé au monde !
Pour le fonctionnaire de la Commission européenne et le citoyen d'un Etat-membre que je suis, cette problématique s'analyse nécessairement dans une perspective double, à la fois nationale et communautaire. Car au-delà des particularismes nationaux et des spécificités régionales, c'est bien la question de l'Europe de la Santé, l'« **Europe blanche** » dans sa définition la plus large, qui est ici en jeu.

Un premier constat s'impose : les systèmes de santé européens sont marqués par une forte **diversité des structures**, à laquelle se superpose **une disparité des niveaux de ressources.**

Diversité des structures : le modèle assurantiel de gestion corporatiste, où les cotisations sociales financent les soins, côtoie, dans d'autres pays, le système dit « beveridgien », où les soins sont gérés par une administration publique et financés par un impôt. Certains pays, comme la France depuis l'introduction de la Cotisation Sociale Généralisée, ont même développé une sorte de 'troisième voie', hybride. En outre, les modalités de mise en oeuvre de ces systèmes (centralisé, décentralisé...) varient selon les Etats, de même que les rôles respectifs des différents opérateurs économiques : hôpitaux et médecine ambulatoire, médecine libérale et salariée...
A cette mosaïque des systèmes et des pratiques s'ajoutent de fortes disparités en termes de ressources allouées par les Etats. Le niveau moyen de dépenses de santé, de l'ordre de 8 à 8,5% du PIB en Europe, masque mal une hétérogénéité encore accentuée par le dernier élargissement. Au final, les dépenses de santé par habitant peuvent aisément varier du simple au triple au sein de l'Union.
En première approximation, cette diversité me paraît résulter de trois facteurs : d'une part, l'histoire politique et sociale des Etats, déterminée par les contingences historiques et dont dépend, in fine, la flexibilité du système ; d'autre part, le stade de développement économique qui conditionne pour partie les dépenses, et enfin, les caractéristiques socio-démographiques du pays, en particulier la pyramide des âges.
Une telle diversité des systèmes de santé, tant au plan des structures que des ressources, peut apparaître en contradiction avec l'un des principes fondateurs de l'Union : **le principe de solidarité.** Comme cela est rappelé dans

la Charte des Droits Fondamentaux, l'Union se doit en effet de promouvoir la cohésion économique et sociale entre les États membres, et d'assurer dans la définition et la mise en oeuvre de ses politiques un niveau élevé de protection de la santé. Or, très concrètement, comment assurer à tous un niveau élevé de protection lorsque le PIB par habitant en France vaut trois fois celui de la Lituanie ?

Face à ce constat, deux niveaux d'action, qui ne sont d'ailleurs pas exclusifs, s'offrent au politique : le niveau communautaire, et le niveau national.
Au plan communautaire, et à titre d'exemple, l'un des succès les plus retentissants est sans conteste la mise en place progressive, depuis 1965, d'un cadre legislatif harmonisé pour l'évaluation et l'autorisation des médicaments. Cette harmonisation a pour but d'éliminer les obstacles techniques et scientifiques au marché intérieur dans le secteur pharmaceutique, tout en assurant un haut niveau de protection de la santé publique. Elle est le reflet d'une dynamique communautaire -désormais classiqued'intégration croissante, qui vise à garantir le respect, à l'échelle européenne, des mêmes normes de qualité, de sécurité et d'efficacité des médicaments. Or, définir des standards européens dans un secteur, c'est évidemment, à terme, faciliter l'harmonisation des systèmes nationaux connexes à ce secteur.
Cette évolution du « **marché intérieur de la Santé** » (ou plus précisément des produits de santé) a aussi permis la création, en 1993, d'une procédure dite « centralisée » qui conduit à une autorisation unique de mise sur le marché du médicament (dite AMM centralisée), octroyée par la Commission européenne, et valable dans toute la Communauté. Dans le cadre de cette procédure, c'est donc la Commission qui autorise la mise sur le marché du produit, en se basant sur un avis scientifique émis par l'Agence Européenne des Médicaments. Elle dispose de ce fait d'une compétence exclusive qui, là encore, devrait favoriser certains niveaux de remboursement, en les exposant tous au mêmes contraintes. J'ajouterais que cette procédure centralisée, si elle reste peu importante en termes de nombre de médicaments autorisés, concerne néanmoins ceux dont l'enjeu économique est le plus remarquable, comme par exemple les médicaments d'origine biotechnologique. Tout récemment, la révision générale de la législation pharmaceutique européenne, qui a été adoptée par les institutions communautaires en avril dernier, a permis d'élargir, d'affiner et de compléter ce cadre réglementaire. Bien qu'indirect, l'impact de cette révision sur le versant « économique » du secteur des médicaments dans les Etats-membres sera tout à fait significatif.
Je m'explique.
Prenons par exemple le cas des **génériques**. Alors que les coûts des soins de santé sont en augmentation en Europe, le recours aux médicaments génériques est un des facteurs importants pouvant assurer la pérennité des systèmes de remboursement. L'utilisation accrue -et légalement clarifiée- des médicaments génériques, parce qu'ils peuvent représenter des économies substantielles pour les systèmes de soins, contribuera donc à améliorer la viabilité des modes de financement. Elle définira aussi un marché où l'innovation, toujours plus chère, pourra recevoir une juste rétribution. Or, le nouveau cadre législatif communautaire pour les produits pharmaceutiques, en définissant des règles précises et harmonisées notamment vis-à-vis de la protection des données, va probablement favoriser le développement des génériques dans les pays où leur taux de pénétration du marché est encore faible, sans pour autant constituer un frein à l'innovation, bien au contraire.
Ainsi, l'harmonisation du cadre réglementaire pharmaceutique dans le domaine technique, scientifique et administratif constitue sans doute une évolution positive sur laquelle toute réforme future des systèmes de santé pourra s'appuyer. Rappelons que cette harmonisation est largement due à une compétence communautaire explicite et reconnue. Or, en ce qui concerne les aspects socio-économiques, la ligne de partage des compétences est tout à fait différente. Pour citer un arrêt célèbre de la Cour européenne de Justice : non, certes, « la sécurité sociale n'est pas un îlot impermeable aux règles du marché intérieur ». Mais force est de constater que l'intégration européenne reste, à ce niveau et à l'heure actuelle, limitée.
Limitée, par construction, dirais-je. En effet, le Traité stipule clairement qu'en matière de politiques de santé publique, l'action de la Communauté « complète les politiques nationales » ; la Communauté « encourage la coopération entre les Etats membres (...) et, si nécessaire, elle appuie leur action ». Mais elle ne saurait s'y substituer. Quant au volet socio-économique, il est établi que les dispositions relatives au remboursement ou au paiement des médicaments soumis à prescription relevant d'une compétence essentiellement nationale. Certes, une Directive européenne prévoit que les décisions dans ce domaine sont prises en toute transparence, sans discrimination et dans des délais précis. Mais point d'harmonisation. Il va sans dire cependant que l'exercice de ces compétences nationales n'est pas « immunisé » vis-à-vis des règles générales du Traité ; le contrôle de cet exercice national par la Commission est à ce titre déterminant.
Si action il y a, l'essentiel semble donc devoir se faire par la méthode de cooperation intergouvernementale, ou mieux, par la méthode dite « de Lisbonne », qui implique une approche harmonieuse des compétences nationales et communautaires, considérées non plus comme antagonistes ou exclusives, mais bien synergiques et complémentaires. Dans cette optique, on aurait tort de négliger l'apport des institutions de la Communauté. Ainsi, c'est à l'initiative de la Commission européenne qu'a été mis en place, en mars 2001, le « Groupe de haut niveau sur l'innovation et la fourniture des médicaments » dit « **G10 médicaments** ». Composé de représentants de pays de l'Union, du secteur pharmaceutique, des associations de patients et des mutualités européennes, le G10 a émis un

certain nombre de propositions visant notamment à réduire les délais de décision en matière de fixation des prix et de remboursement, à une échelle communautaire, et dans le respect des compétences nationales.
Par ailleurs, la Commission a réuni à plusieurs reprises le Comité pour la transparence des mécanismes de fixation des prix des médicaments, dit « **Comité Transparence** », afin de mener une sorte de « dialogue préventif » avec les États-membres, et aider à résoudre les problèmes rencontrés ou à trancher les questions d'interprétation. La constitution d'une base de données actualisées sur les usages administratifs actuellement en vigueur dans les États-membres constitue un premier résultat tangible de ces efforts.
A mon sens, ces deux exemples illustrent comment la Communauté, à travers la Commission, et ce malgré une compétence limitée, peut néanmoins favoriser l'harmonisation des systèmes nationaux de santé en jouant un rôle de **promoteur d'idées, de courtier, d'intermédiaire** vis-à-vis des Etats-membres.
On l'a vu, la réforme des systèmes de santé, et plus globalement la question de l'Europe blanche sensu largo, se heurte à la difficulté de concilier l'action communautaire, à visée d'intégration et d'harmonisation mais au champ d'action circonscrit, avec les disparités nationales. Mais, pour citer Beaumarchais, la difficulté de réussir ne fait qu'ajouter à la nécessité d'entreprendre ! Nécessité d'autant plus pressante qu'en dépit de traditions socioculturelles et institutionnelles diverses, les Etats-membres de l'Union européenne (y compris les 10 « nouveaux ») me paraissent aujourd'hui confrontés à des défis, des évolutions dont la nature et la portée sont tout à fait similaires. La « globalisation » de l'industrie, de la recherche, des media, des attentes des patients pour ne pas dire des maladies, se soucie peu des particularités « constitutionnelles ».
Dans ce cadre, je citerais trois défis : le vieillissement des populations, le coût croissant de l'innovation, et les exigences sociétales en matière de santé.
La population européenne vieillit. Quoique hétérogène au niveau local, ce phénomène affecte l'Europe dans sa globalité. Fait remarquable et sans précédent, c'est la tranche des plus de 80 ans qui, sur les 20 prochaines années, connaîtra vraisemblablement le plus grand taux d'accroissement démographique ! Quant aux moins de 25 ans, leur nombre diminuera de plus de 11 millions sur la même période. Les services médicaux devront donc faire face à une demande de soins quantitativement plus importante, et qualitativement différente, car recentrée sur les maladies spécifiques du troisième âge.
Une seconde évolution convergente concerne **le coût croissant de l'innovation**. Le développement de nouveaux médicaments, la mise aux points de nouvelles technologies de santé, tout ceci a un coût. Or, ce coût connaît depuis un certain nombre d'années une augmentation régulière et significative, qui se répercute sur les niveaux de prix des médicaments et pose de nouvelles questions en termes d'accès aux soins, de financement des prestations, et d'accroissement de l'offre.
Enfin, et c'est peut-être l'une des évolutions les plus significatives de nos sociétés sur ces cinquante dernière années, **les exigences des patients** vis-à-vis des systèmes de santé ont considérablement augmenté. Le patient d'aujourd'hui ne se contente plus de dire "Docteur, je vous fais confiance". Le patient d'aujourd'hui souhaite connaître les détails de sa maladie, de son traitement. Il souhaite connaître les différentes options thérapeutiques à sa disposition, les différences de qualité, de sécurité et d'efficacité entre les différents produits. A une obligation de moyens se substitue peu à peu une obligation de résultats, dictée par un impératif de transparence.
Ces évolutions trans-européennes impliquent probablement une transformation des systèmes de santé vers plus de flexibilité, plus de proximité, et plus de lisibilité.

Mesdames, Messieurs,
Il me semble important de souligner que ces évolutions, en ce qu'elles affectent tous les Etats de l'Union, appellent un rapprochement, une convergence des systèmes nationaux. Si **se comparer, c'est être intelligent**, comme le notait le philosophe Alain, alors il est probable qu'une réforme « intelligente » passera par la mise en commun des expériences à l'échelle communautaire et la comparaison des différentes stratégies de réforme. L'élargissement de l'Union Européenne ne fait pas qu'ajouter un niveau supplémentaire de complexité à la problématique de la réforme des soins santé ; il offre sans doute aussi des solutions, en nous permettant d'échanger, de comparer, d'étalonner.
A l'heure où cet élargissement et les élargissements futurs soulèvent questions et inquiétudes, je voudrais rappeler ce mot de Robert Schuman : « L'Europe ne se fera pas d'un coup, mais par des réalisations concrètes, créant une solidarité de fait ».
Ce 1er forum international « Euro-Santé » constitue, je le crois, l'illustration des bienfaits d'une telle approche. Et si l'Europe de la Santé est encore un vaste et fascinant chantier, votre présence aujourd'hui prouve que le mot de R. Schuman, y compris dans ce domaine, n'est pas resté lettre morte.
Je vous remercie de votre attention.

Dr Philippe BRUNET

Why and How to reform Healthcare Systems in Europe
Pourquoi et comment réformer les systèmes de santé en Europe

Morning

Chairman

Simon STEVENS

■ President-Europe, United Health Group
former Health Policy Adviser to Prime Minister Tony Blair

Simon Stevens is European President at UnitedHealth Group, and visiting professor of health policy at the London School of Economics. UnitedHealth Group aims to support European social insurers and tax based systems improve chronic disease management and enhance consumer responsiveness. From 1997-2004 Stevens was the UK Government's Health Policy Adviser - first at the UK Department of Health, and then as the Prime Minister's Health Adviser at 10 Downing Street.

His background is in healthcare management and he was educated at Oxford University, Strathclyde University, and Columbia University, New York.

Rapporteur

Borislav BORISSOV

■ Former Head of the Bulgarian Drug Agency,
General Manager of Prescriptia Ltd

■ Education

1990 MD
1997 Medical Faculty of Sofia ; PHD in parenteral nutrition
2002 Medical Faculty of Sofia ; MBA for executives / US

■ Appointments

1990 - 1998 Medical University of Sofia
June 1998 - 1999 National Drug Institute of Bulgaria
2000 - May, 2004 Bulgarian Drug Agency
Present - Founder and General Manager of Prescriptia Ltd.

■ Foreign experience

1992 Ste. Marguerite University hospital, Marseille
1993 - 1994 CHU La Pitié-Salpêtrière, Paris, France
1997 Addenbrooke's hospital, Cambridge, UK

Dr. Panos KANAVOS

LSE Health and Social Care

Panos Kanavos is a lecturer in International Health Policy and Research Fellow in Pharmaceutical Economics at the London School of Economics and Political Science. His research interests comprise health policy from a comparative perspective, health reform, and pharmaceutical economics and policy. He has published extensively in the peer review literature and has acted as advisor to over 17 governments and most international organisations in his areas of expertise.

The importance of Heritage in Central and Eastern European countries: resistance to change and roadmap to progress.

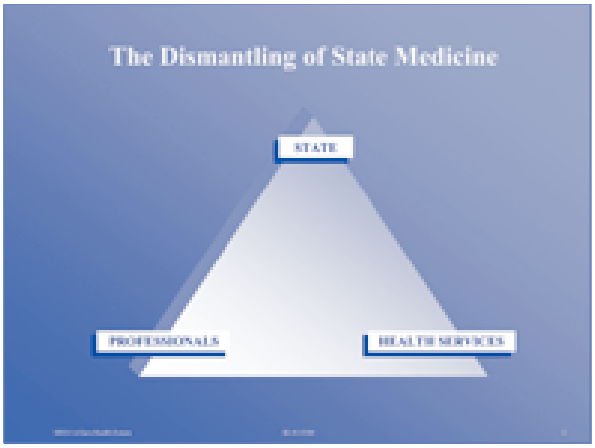
Poids de l'héritage dans les pays d'Europe centrale et orientale : inertie et voies d'avenir.

Prof. Robert LAUNOIS

Université Paris XIII, Vice President of the SFES

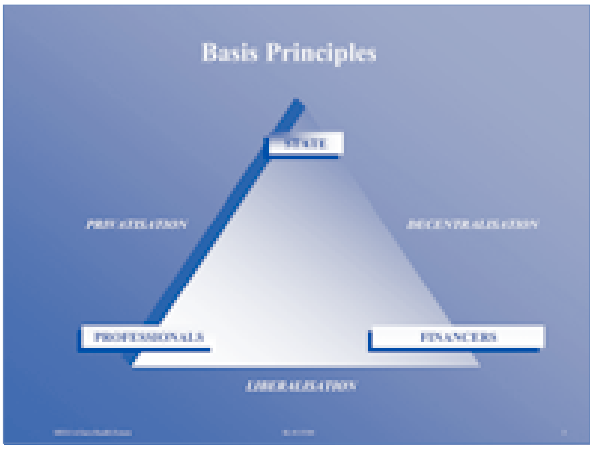
Does the former Europe of 15 have models to propose and do the 10 newest members have solutions to share ?

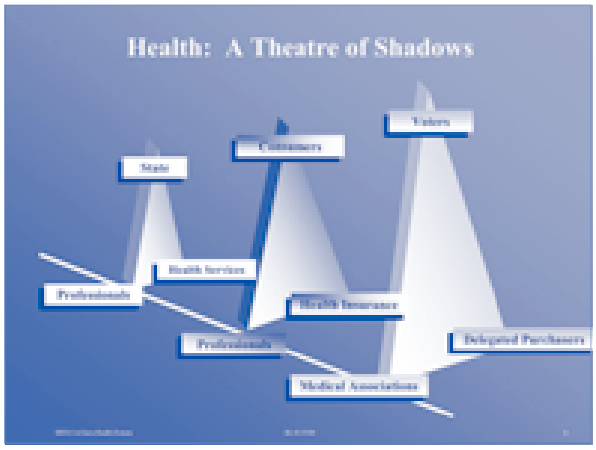
L'Europe des 15 a-t-elle des modèles à proposer et les 10 nouveaux membres ont-ils des solutions à partager ?

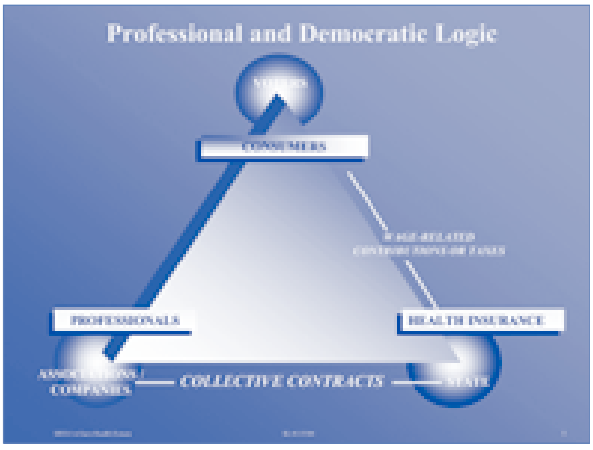


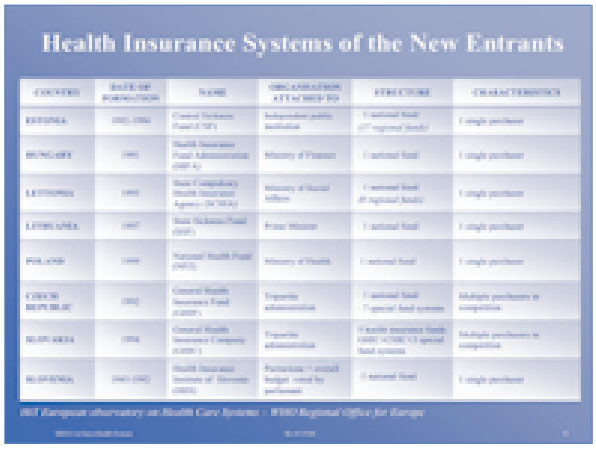
Why and How to reform Healthcare Systems in Europe
Pourquoi et comment réformer les systèmes de santé en Europe

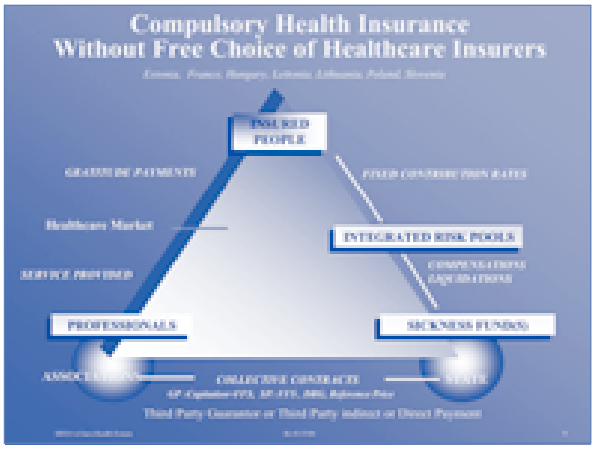
Prof. Robert LAUNOIS, next

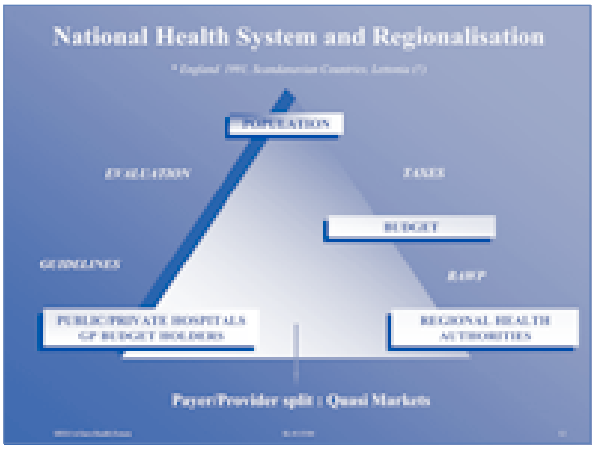


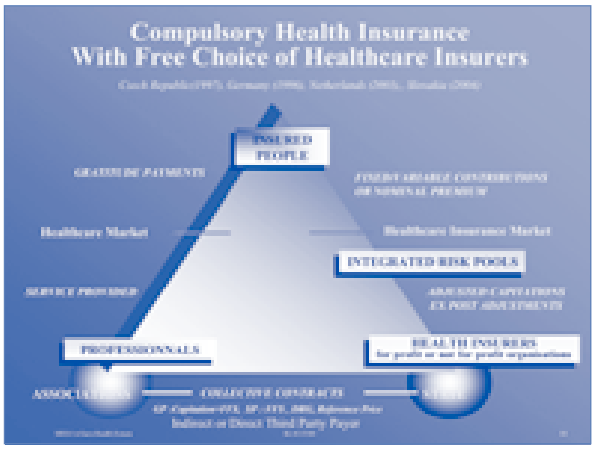


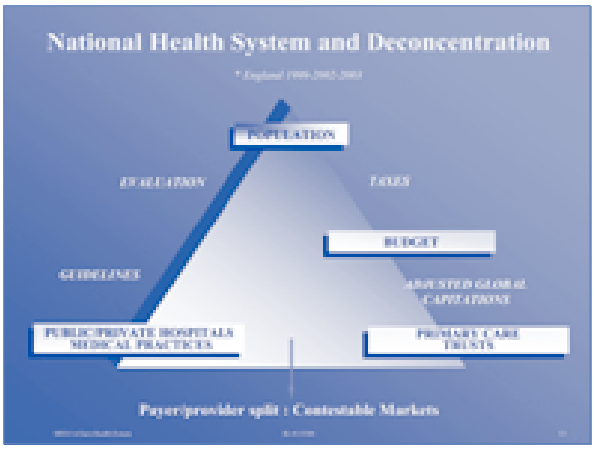












Competition by Quality
« Clinical Governance »

Converging Dynamics of Change

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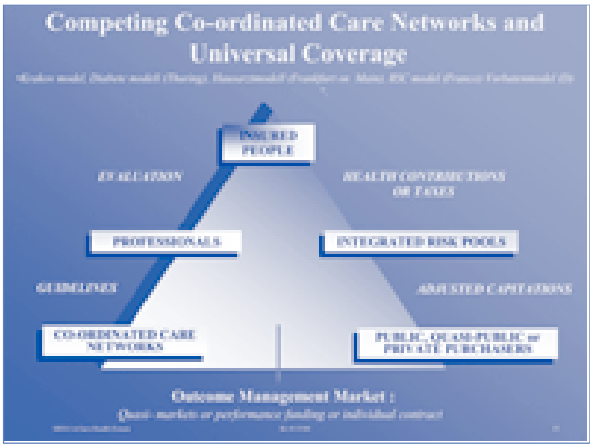

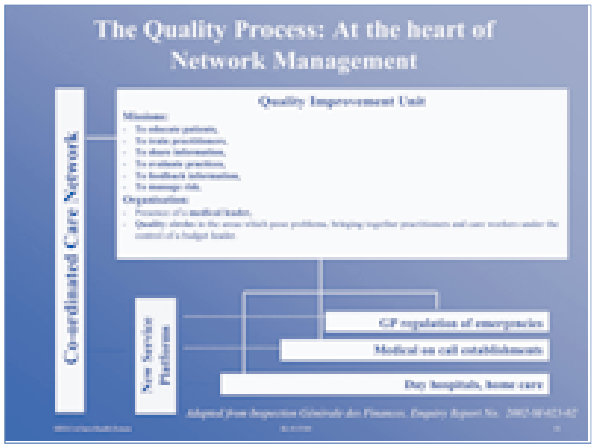

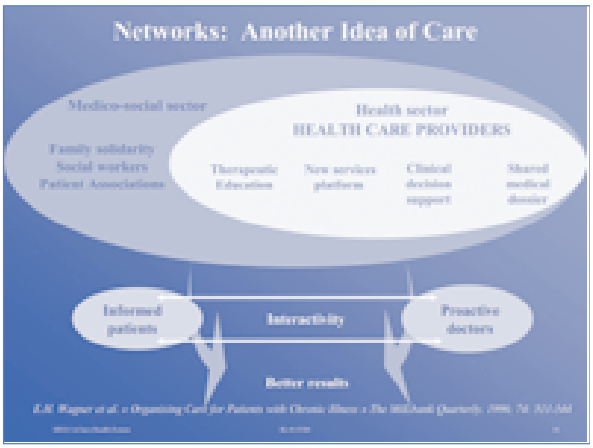

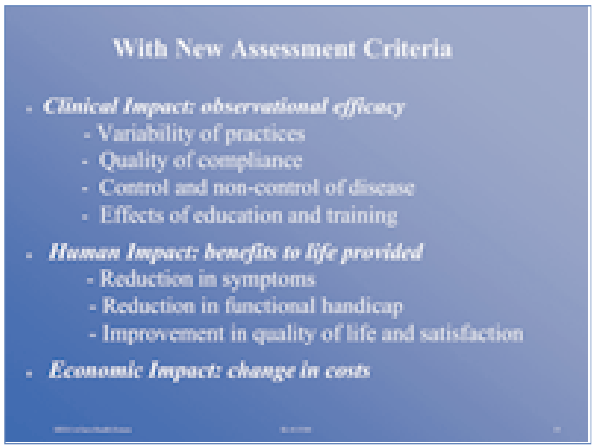

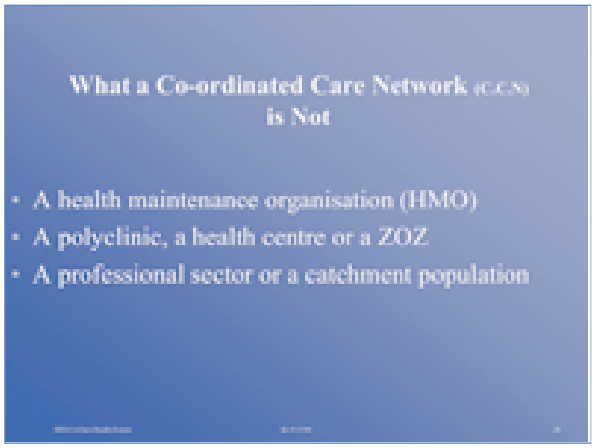

What it is

« The network is a structure grouping together healthcare professionals, facilitated by the family doctor chosen by the patient, who dispenses all of the care required by a population the amount of which is quantitatively set in advance;

in return for an overall annual sum, set in advance, financed in part by the Social Security and in part by the insured person ».

R Launois : « les Réseaux de soins coordonnés, un projet de réforme du système de soins français » Assemblée générale de l'Association de Genève. The Geneva Paper on Risk Insurance 1987; 12: 345-349

Solidarity

The *monopoly* of the Social Security system is *maintained*. Only the methods of payment of services are changed.

TRIPLE SOLIDARITY:

- Solidarity *within* a class of risk between the well and the ill
- Solidarity *between the classes* of risk within the network
- Solidarity between the *rich* and *poor* on a community basis.

How is it Financed?

- Each network freely sets the price for the overall management of a subscribing member
- The National Health Insurance Funds pay an Annual Health Sum which varies depending on the age and sex of the person
- The subscribing member pays the difference between the total price and the National Health Insurance Funds sum. He or she pays this in advance. This establishes a competing dynamic situation.

R Launois : « les Réseaux de soins coordonnés, un projet de réforme du système de soins français » Assemblée générale de l'Association de Genève. The Geneva Paper on Risk Insurance 1987; 12: 345-349

Contestability

- Between the CCN for their potential subscribers. The CCN which has the best quality/personal contribution ratio attracts the clientele.
- Between health care professionals for the CCN. If a producer is too expensive the network will have to increase its prices.
- Between the CCN and the rest of the health care providing system; nothing is imposed.

Accountability

- Cost constraint is introduced at the level where decisions are made,
- Procedures for managing the clientele are changed,
- The responsibility of providers is clearly established: gains or losses at the end of the year are shared.

Expenditure on Consultations in the Control Group and in the Experimental Group Before and After Experiment, Per Consumer, Per Year

(Atlantic Pyrenees Region 1)

	Control Group (n=1116)			Experimental Group (n=1573)		
	1999	2000	%	1999	2000	%
GP	151.69	163.73	7.9	135.25	122.11	- 10.1
SP	325.48	293.92	- 9.7	292.55	278.07	- 5
TOTAL	477.17	457.55	- 4.1	428.38	400.80	- 6.4

Source : REES France - Mutualité Sociale Agricole des Pyrénées Atlantiques-Groupama Partenaires Santé

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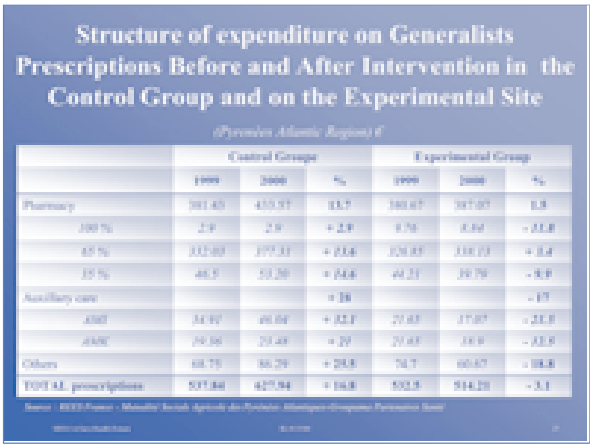
Prof. Robert LAUNOIS, next



Structure of expenditure on Generalists Prescriptions Before and After Intervention in the Control Group and on the Experimental Site

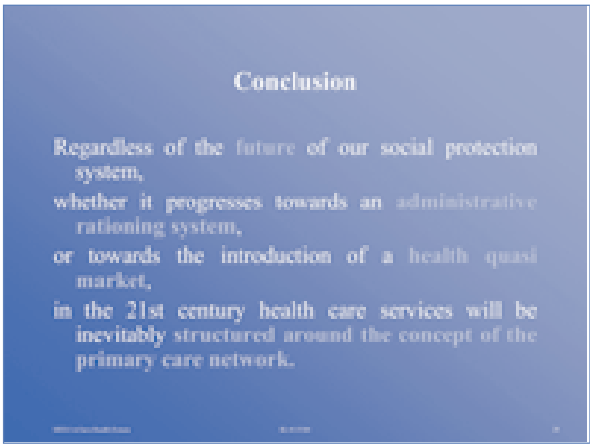
(Pyrenées Atlantic Region) €

	Control Groupe			Experimental Group		
	1999	2000	%	1999	2000	%
Pharmacy	381.83	433.57	13.7	380.67	387.07	1.8
100 %	2.9	2.9	+ 2.9	3.74	5.04	+ 35.8
65 %	332.03	377.33	+ 13.6	326.85	330.23	+ 1.4
35 %	46.5	53.30	+ 14.6	49.21	51.79	+ 5.9
Auxiliary care			+ 38			- 17
ASD	34.97	46.04	+ 32.2	27.87	17.07	- 23.5
ASDE	39.56	51.48	+ 29	31.65	14.9	- 52.9
Others	68.75	86.29	+ 25.5	74.7	60.67	- 18.8
TOTAL prescriptions	537.84	627.94	+ 16.8	552.5	514.21	- 3.1

Source : IRES France - Monthly Social Aperçu des Pyrénées Atlantiques-Groupama Partenaires Santé

The Advantages of the Co-ordinated Care Networks

- Cost-consciousness for the user
- Making producers financially responsible
- Maintaining quality through competition
- Solidarity safeguarded



Conclusion

Regardless of the future of our social protection system,

whether it progresses towards an administrative rationing system,

or towards the introduction of a health quasi market,

in the 21st century health care services will be inevitably structured around the concept of the primary care network.

Notes

The Multiple Faces of Reform in the Europe of 25
Une mosaïque de réformes dans l'Europe des 25

Chairman

Prof. Paul CORRIGAN

■ Special Adviser to the Secretary of State for Health, UK

Paul Corrigan gained his first degree in social policy from the LSE in 1969, his PhD at Durham in 1974 and has been appointed Visiting Professor of public policy at the University of North London since 1995.

For the first twelve years of his working life he taught at Warwick University and the Polytechnic of North London- he was Head of Department of applied social studies in the latter. He taught, researched and wrote about inner city social policy and community development.

In 1985 he left academic life and for the next 12 years he worked in local government – mainly in London but also as a member of staff in the local government Unit of the Labour party.

In 1997 he started to work for himself as a local government consultant working on issues of modernisation and in 1999 started to work for the Office for Public Management. That year through Kogan Page he published Shakespeare on Management.

From July 2001 he has been working as a special adviser to the Secretary of State for Health.

Rapporteur

Borislav BORISSOV

■ Former Head of the Bulgarian Drug Agency,
General Manager of Prescriptia Ltd

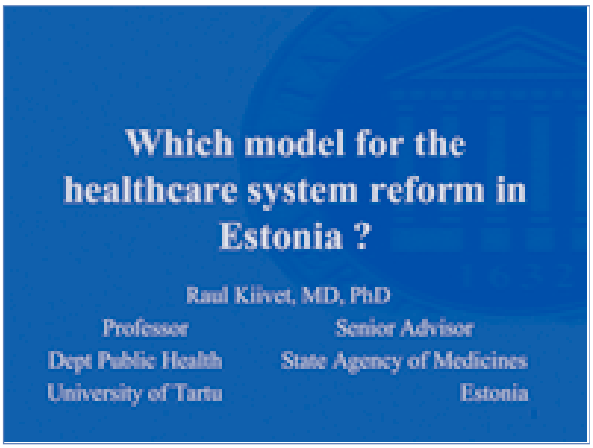
The Multiple Faces of Reform in the Europe of 25
Une mosaïque de réformes dans l'Europe des 25

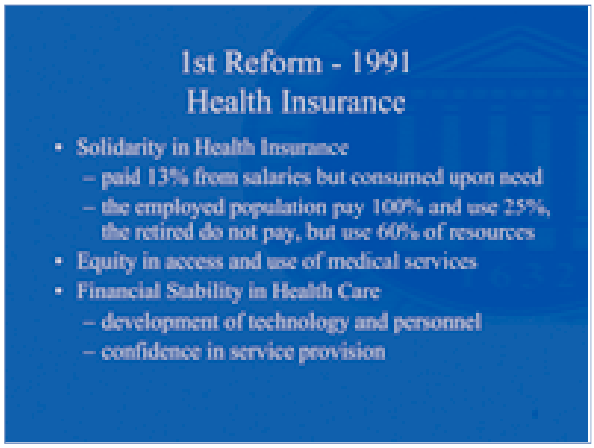
Prof. Raul KIIVET

Health Care Management, Head of the Dept. of Public Health, University of Tartu, Senior Advisor to the DG State Agency of Medicines

Estonia: Which model for the healthcare system reform in Estonia?

Estonie : quel modèle pour la réforme du système de santé en Estonie ?





- Hospital treatment and ambulance services are free of charge
- Health Insurance budget per 1 insured in 2003:
  - family physician service 22 euros
  - dental care 16 euros
  - specialist care and hospital treatment 130 euros
  - reimbursement of medicines 35 euros
- Average annual increase of Health Insurance funds have decreased from 20% to 10%

Aims of the 2 reforms

- In financial reorganisation
  - stability and sustainability
  - accountability
  - solidarity
- In primary care
  - quality and continuity of care
  - equity and access
  - patient-oriented services

2nd Reform 1996-2000
Primary Care - Family Physicians

- Reorganization of primary health care – from polyclinics to family physicians
  - training of health care personnel
- Introduction of public health concepts to primary health care – disease prevention and health promotion to support medical care, patient-oriented services
  - Per capita payments for each person enlisted

Lessons From the Decade

- Independent decision-making and planning on all levels of health care
- Quality in patient-doctor relationships
- Growing awareness about costs

Recognition that ones health is not a responsibility of medical professions but of oneself and the society

Family Physicians

- Everyone has his "own" family physician
  - freedom of choice and personal compatibility
- Responsibility for the patient
- Cooperation with patient for health
  - supporting life-style that spares and values health
- Continuity of medical care
  - information on ones disease and treatment collected and kept by family physicians

The Future for Health Care

- Emerging treatment possibilities increase expectations and have to be met by limited resources
- Equity in health and access to services will remain high on the agenda
- Medical services have limited impact on population health
- Therapy will be supported with rehabilitation, nursing and support for self-care

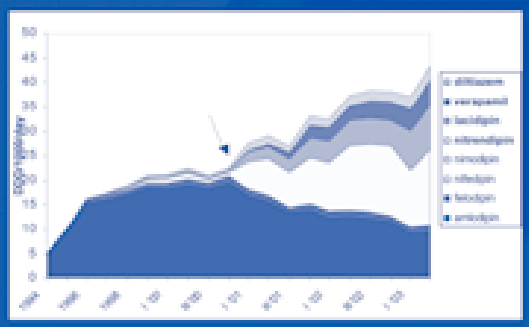
The Multiple Faces of Reform in the Europe of 25
Une mosaïque de réformes dans l'Europe des 25

Raul KIIVET, next

Health Insurance Drug Costs

	'98	'99	2000	'01	'02	'03
Total budget (million EEK)	315	367	438	624	731	758
Annual increase	37%	16%	19%	42%	17%	4%

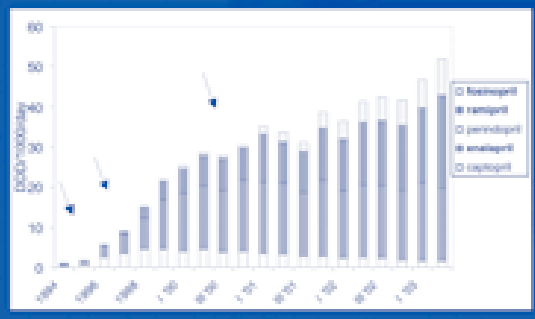
Calcium Antagonists



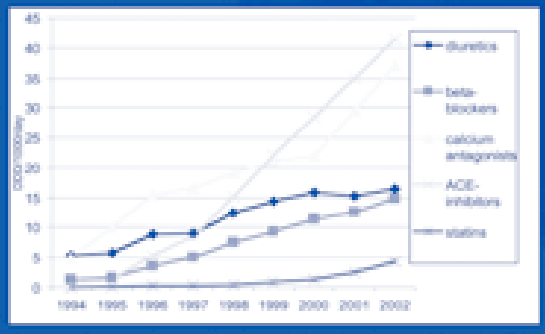
Use of medicines (DDD/1000/day)

	'95	'99	2003
Total	201	374	507
Ulcer	4,2	7,6	12,5
Diabetes	8,1	13,5	19,1
Hypertension	18,2	48,1	116,3
Antibiotics	13,8	13,8	13,9
Antipsychot.	3,6	3,7	4,5
Asthma	9,5	14,8	16,2

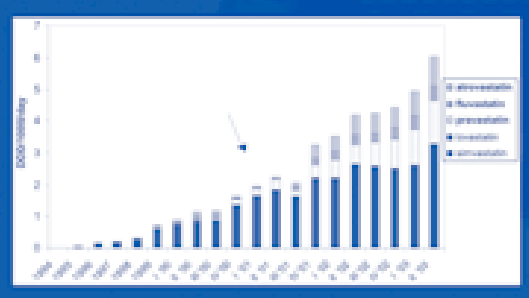
ACE-inhibitors

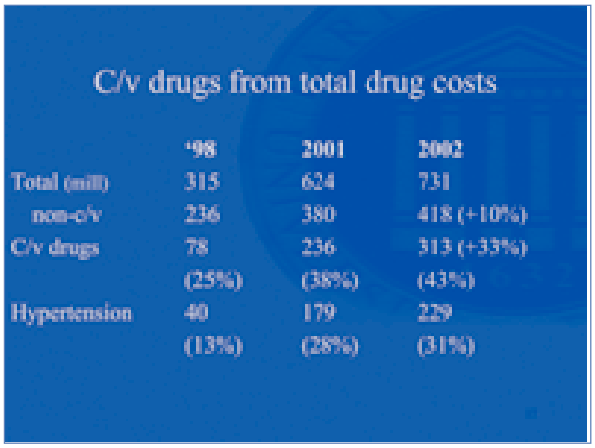


Use of Cardiovascular Drugs



HMG CoA reduktase inhibitors




C/v drugs from total drug costs
'98 2001 2002
Total (mill) 315 624 731
non-c/v 236 380 418 (+10%)
C/v drugs 78 236 313 (+33%)
(25%) (38%) (43%)
Hypertension 40 179 229
(13%) (28%) (31%)


4th Reform
Hospital Masterplan 2001-2015
Purpose – high quality acute treatment should be followed by professional continuous treatment and nursing, adjusted according to individual needs
• Introduction of rehabilitation services and modern principles of nursing and basic care
• Concentration of high-tech medical care
– to improve the quality of medical care
– for more effective use of resources

Notes

Discussant

Hannes DANILOV

Chairman, Estonian Health Insurance Fund

Education

1972 - 1977 University of Tartu - Estonia, undergraduated
Subject: Chemistry

Vocational Training

1996 Dalhousie University Baltic Economic Management Training Programme
2000 Harvard University Executive Program for Leaders in Development

Work experience

1993 - 1994 Deputy mayor of Haapsalu: in the field of social security, education and culture

1994 - 1999 County governor of West - Estonian county: Social security matters on the county level

1999 - 2002 Secretary general of ministry of social affairs of Estonia: Social security, social insurance, health care, public health and labour matters

2002 Chairman of board of health insurance fund of Estonia: Secure the access and the quality of the health services

Estonia: Which model for the healthcare system reform in Estonia?

Estonie : quel modèle pour la réforme du système de santé en Estonie ?

Management

Electronical DATA processing – " PIPE "

- Claims of providers
- Prescriptions for the reimbursment of pharmacies
- Electronical registering and unregistering employees in database of EHIF by employers
- Electronically modelled price list using activity based costing methodology

Near future

- Electronic prescription
- Electronic incapacity of work leave

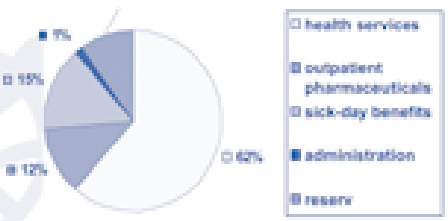
Reimbursement

- Family physicians reimbursed through capitation fees
- Special care – per diem, fee for service and DRG payments

Quality

- Random control of claims and prescriptions
- Clinical audits
- Guidelines
- Patient complaint handling systems for providers
- Control over the accessibility
- Next step – establishing quality award for health care providers, based on EFQM model

EHIF budget 2004 – 390 milj. euros



Contracting

- All special care providers are publicly owned, but under the private law
- Global budget contract, planned cases by specialities, separately outpatient and inpatient cases.
- Budget for provider is capped, No of cases x cost of case = budget, risk corridor 5%
- Capitation contract for family physicians, 20,5% above of calculated sum of contract pays EHIF to the hospital for the examinations prescribed by FP

Notes

The Multiple Faces of Reform in the Europe of 25
Une mosaïque de réformes dans l'Europe des 25

Prof. Alan MAYNARD

Prof. of Health Economics, Director of the York Health Policy Group at the University of York

Alan Maynard is Professor of Health Economics and Director of the York Health Policy Group in the Department of Health Sciences, University of York. He is also an Honorary Professor of Health Economics at the University of Aberdeen, Visiting Professor at the London School of Economics and Adjunct Professor, Centre for Health Economics Research and Evaluation, University of Technology, Sydney, Australia. He was Founding Director of the Centre for Health Economics at the University of York (1983 – 95) and Founding Editor of Health Economics, a specialist journal. He has worked as a consultant for the World Health Organisation, the World Bank, and the UK Government's Department for International Development in countries such as China, Cyprus, Chile, Brazil and South Africa. He has published widely in books, specialist journals and the media. He is Chair of the York NHS Health Services Trust and has been involved in NHS management since 1983.

Great Britain: Current status and future of reforms of Healthcare System

Grande-Bretagne : Bilan et avenir des réformes du système de santé

Abstract

Health Care Reform in the United Kingdom

After two years of initial parsimony in the funding of the NHS (1997-99), the Blair Government is increasing rapidly public expenditure on the NHS, with the goal of reaching the EU average amount of spending by 2008. The UK is now a federal state in the health care sphere, with Scotland, Wales, Northern Ireland and England adopting very different policies and having different NHS structures. For instance Scotland has abandoned the Thatcher purchaser-provider split whilst England has not. The following discussion focuses on English policy.

The following issues will be discussed:

> The Labour Government abolished Trust status for NHS hospitals and General Practice Fund holding in 1997-99 as they had "failed" according to their rhetoric. Subsequent evidence does not support this rhetoric with regard to GP fund holding. In 2004 Blair restored (Foundation) Trust status to NHS hospitals and rebranded and reintroduced a weak form of GP fund holding, now called practice level budgets in October 2004.

> Large and rapid increases of expenditure in health care funding have to be translated into increased employment of doctors and nurses in particular if waiting times are to be reduced and service quality increased. Medical school intake has been increased by 30 per cent and doctors and nurses are being imported from abroad. Both GPs and hospital specialists (consultants) have been given large pay increases, with some emphasis on increasing the fee for service element in existing mixed payment systems. As ever the risks with such policies is the nature of the incentive effect (what is not incentivised is marginalised) and the potentially inflationary effects.

> In exchange for large increases in expenditure, Blair required the NHS to "act smarter" A range of policies was introduced to police compliance. The National Institute for Clinical Excellence (NICE) reviews new technologies, identifies their cost effectiveness and issues mandatory" guidelines to the NHS. The Health Care Commission evaluates the performance of purchasers (Primary Care Trusts) and providers (GPs and hospitals) against 9 key targets and over three dozen other targets on a balanced scorecard. Performance is graded with star ratings. Good performers get kudos and additional cash and poor performers get sacked (the average survival time of a NHS hospital chief executive is three years!) Pursuit of targets has led to radical changes in skill mix and tasks of providers e.g. nurse prescribers can now give patients any drug on the formulary and nurse endoscopy is quite common.

> The Government have raised public expectations about processes and quality ruthlessly to remedy the many deficiencies that characterised elective, chronic and emergency care. Demand for resources has been inflated by NICE (which tends to have too liberal a "cut off" for its guidance) and National Service Frameworks whose purpose is to raise standards of care in cancer, heart disease, diabetes, renal medicine and for the elderly and children. Because of the rent seeking behaviours of provider groups and

the great ambition of the Government, many purchasers and providers are facing financial deficits despite annual real increase in budgets of 8 per cent for 5 years. Rather than fund these expenditure increases out of progressive taxation, which might be expected from a quasi-Socialist government, increased funds are being raised from proportional taxes, social insurance.

> There is continuing debate about central control and local autonomy. Central targets and their policing have led to significant improvements in the local provision of care. Government rhetoric favours autonomous Foundation Trust hospitals. As structural change or NHS "redisorganisation" is rarely evaluated scientifically in the UK the evidence base for competing policy is very small. This does not prevent Ministers (including Prime Ministers!) from expressing loudly their evidence free beliefs!

The bold decision to increase NHS funding has led to improvements in process measures of performance in England. Like all other countries there is little effort to measure how these changes improve the health, particularly the patient reported quality of life (e.g. by using systematically in the health care system generic health related quality of life instruments such as SF36 or EQ5D (Euroqol)).

In Wales and Scotland, there is less evidence of success than in England and emerging queries about what they have done with the Blair bonanza!

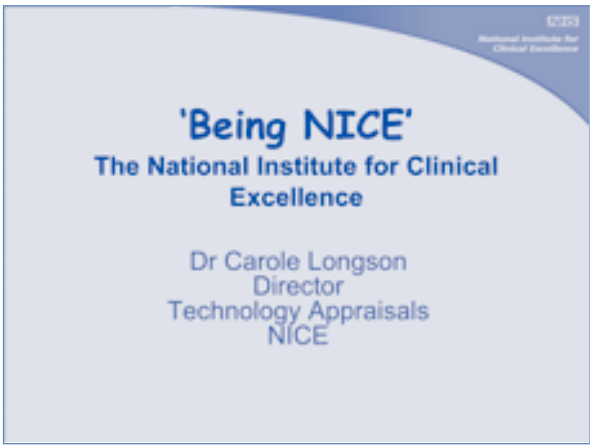
Notes

Discussant

Dr. Carole LONGSON

Appraisal Programme Director, National Institute for Clinical Excellence

Carole Longson graduated with a degree and PhD in Pharmacology from the University of Aston. She then spent 8 years at Glaxo Wellcome Research and Development, working on the development of novel pharmaceuticals for hypertension, migraine, and schizophrenia. She has also undertaken a number of academic secondments including research at The Institute of Molecular Biology in Geneva, and the University of California in Irvine, USA. Carole has previously been involved in health technology assessment as Director of the Evidence Research Unit, CMC. Her research interests lie in the methodology of systematic reviews and health technology assessment.



Why NICE was created

- To provide clear standards based on clinical and cost effectiveness
- To resolve uncertainty
- To minimise inappropriate variation in clinical practice

Main Programme Areas

Clinical and cost effectiveness

- Technology specific guidelines
- Diseases and condition-based clinical practice guidelines

Safety and efficacy

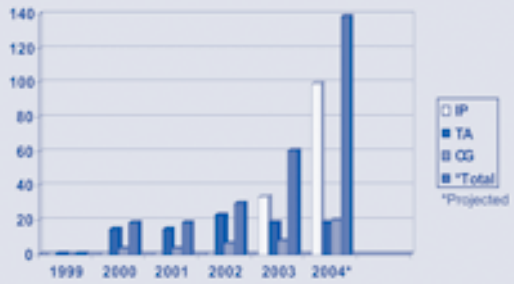
- Interventional procedures

Research and Development

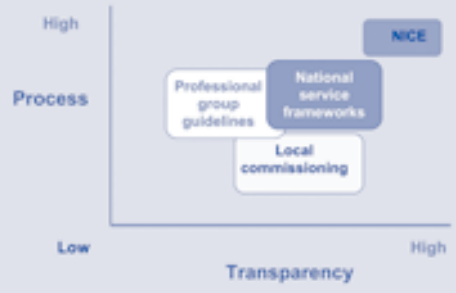
NICE Style

- Inclusive
- Transparent
- Consultative
- Accessible
- Learning

Guidance – all programmes



UK Health Policy Decisions

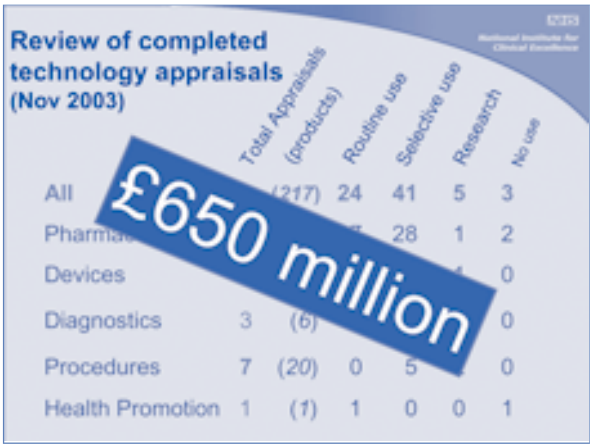


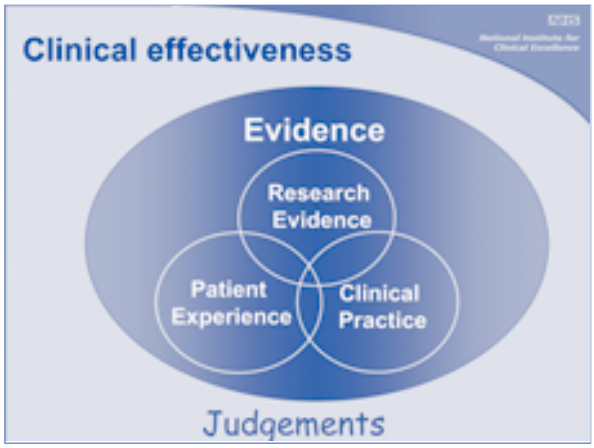
Developing NICE guidance

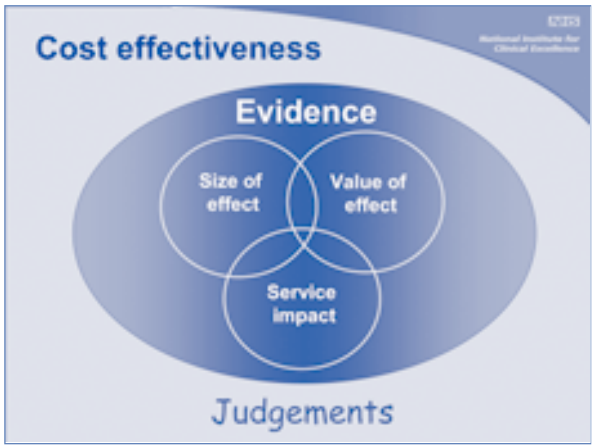
- Independent advisory committees
- Expert contributions
- Inclusive evidence base
- Transparent process & decision making
- Multiple perspectives
- Genuine & public consultation
- Regular review

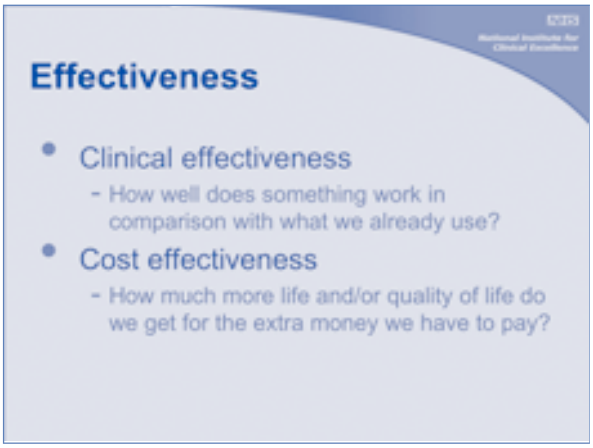
The Multiple Faces of Reform in the Europe of 25
Une mosaïque de réformes dans l'Europe des 25

Dr. Carole LONGSON, suite





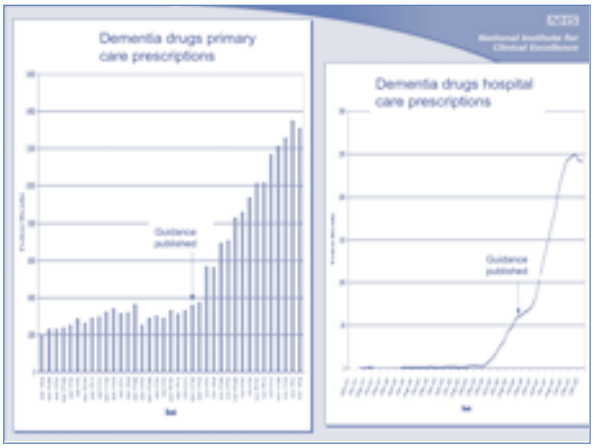




NICE is not responsible for implementation – or funding

However

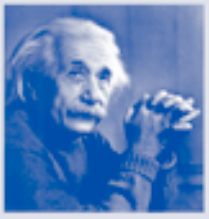
- Guidance is not an end in itself
- Guidance does not implement itself
- Implementation remains a challenge
- Competing demands are a problem
- NICE needs to consider how it can help



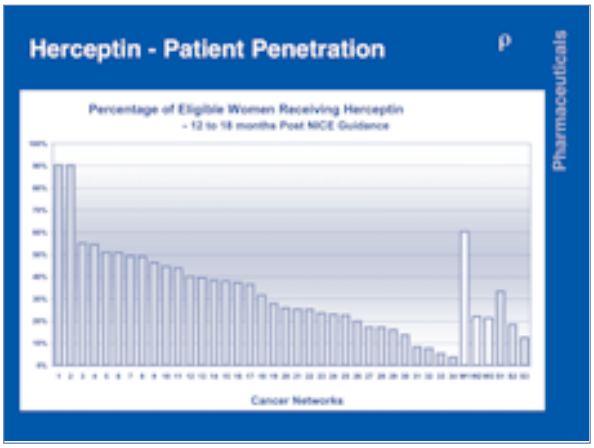
Challenges for NICE – Some solutions ?

- Improving topic selection process
  - Ensure the topics are priorities
- Rigorous development process
  - Build confidence in the recommendations
- Joined up thinking
  - Between national policy and our work
- Dissemination strategy
  - Target information appropriately
  - Influencing change

What have we learnt so far?



Things should be made as simple as possible, but not simpler.
Albert Einstein



Ass. Prof. Karel NEMECEK

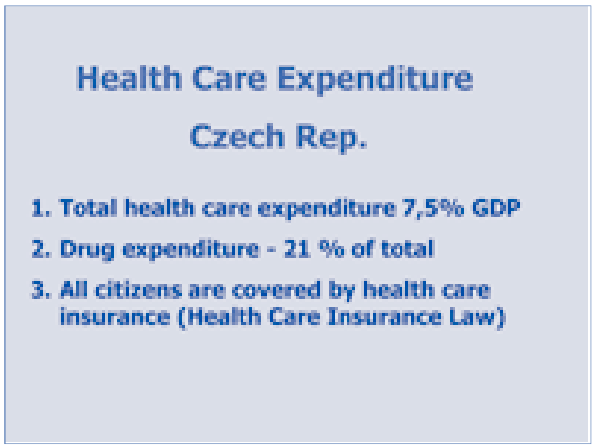
Department of Drugs and Medical Devices, General Health Insurance Company of the Czech Rep.

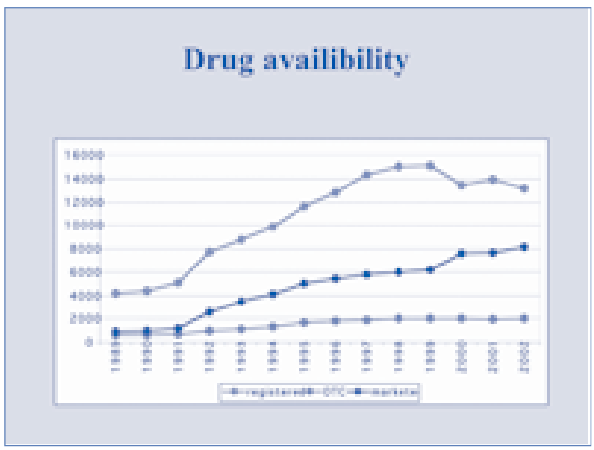
Czech Republic: Healthcare system reform and the role of the health insurance companies

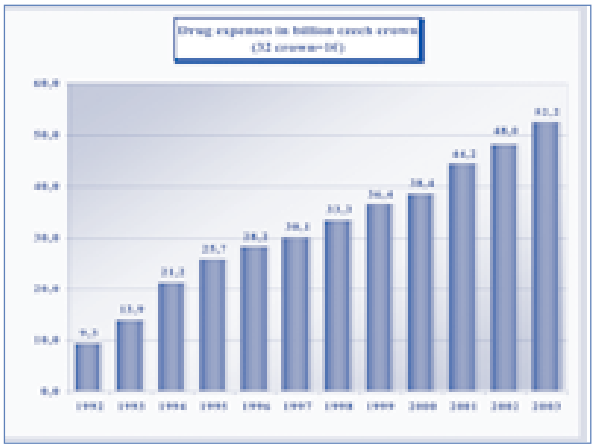
République Tchèque : Réforme du système de santé et rôle des compagnies d'assurances

Summary: Drug policy

In the last 15 years drug availability, expenses and consumption dramatically increased. Important negative issue is the common belief of all people - unfortunately based in the Czech Constitution - that every citizen is entitled to free health care at the latest level of scientific research. Health care is struggling with this situation using partial reforms. This year new legislative changes became active. These enable using more rational conditions for drug reimbursement. Without clearly defined drug and health care policy and without the change of Constitution any major changes are very problematic.

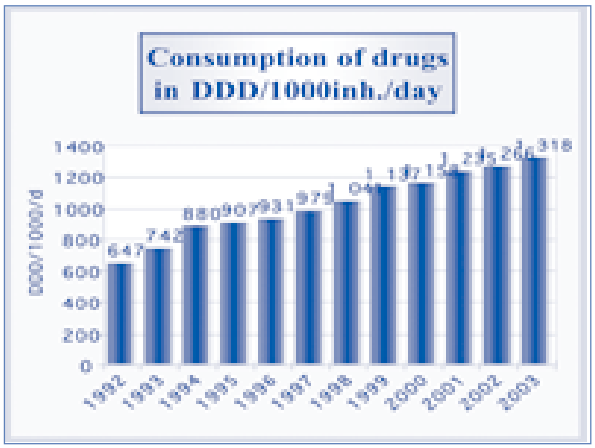






Reimbursement

- **Law (1997) -** 521 groups
- **Law (2004)** – 300 groups of reimbursable drugs
  - At least 1 drug in each group must be fully covered
- **Decree**
  - CZK/DDD chemical entity and the way of administration
  - Up-dated twice a year



Drug categorisation committee

Established by the Ministry of Health as an advisory board,

Recommending:

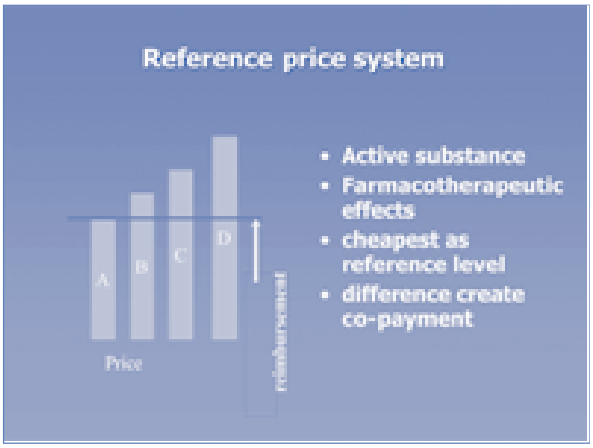
- the new **active ingredients** (chemical entities) to be covered by health insurance
- reimbursement level
- other regulating mechanisms

Categorization committee

Ministry of Health	3
Health Insurances	2
Specialists	2
Chambers	3
Patients organization	1

The Multiple Faces of Reform in the Europe of 25
Une mosaïque de réformes dans l'Europe des 25

Ass. Prof. Karel NEMECEK, next



Thank you for your attention.

Notes

Discussant

Pavel VEPREK

CEO, Tym DG Plus Insurance Company

Pavel Veprek, M.D. (1953) worked for 14 years as a paediatrician and paediatric cardiologist in Faculty Hospital Motol in Prague. After getting managerial experience (medical director and CEO in FHM Prague and contracting director of Czech National Health Insurance Fund) he focused on health care reform and related issues in Tym DG plus. He is currently promoting health care reform as a lecturer in School of public health in Prague and as a chairman of NGO Citizen.

Czech Republic: Healthcare system reform and the role of the health insurance companies

République Tchèque : Réforme du système de santé et rôle des compagnies d'assurances

Summary

The traditional systems of healthcare financing have difficulties dealing with the development of medicine and changing environment. The solution of reform puzzle is simple – create appropriate regulative framework protecting public interest and allow natural work of market forces. Main task is to turn citizens from consumers to customers. Concept of regulated competition among health insurers fulfils this assignment.

The Multiple Faces of Reform in the Europe of 25
Une mosaïque de réformes dans l'Europe des 25

Pavel VEPREK, next

Regulators

- Service organization of health insurance
  - mandatory membership of insurers
  - provision of services which cannot be effectively provided separately (risk compensation, registers of payers, providers and insured)
- Health insurance office
  - licensing, check up, ...

New position of insurers

- Service organization of HI, HI Office
  - public administration
- insurance funds
  - public service (regulated conditions)
  - horizontal merge of public a commercial health insurance
  - public and private money under one roof

New social insurance model

solidarity
- income-related contribution
- risk compensation
- definition of guaranteed care

→ public interest

efficiency
- competition of insurers and providers in provision of services

→ market

⇒ regulated market in health insurance (managed competition)

Thank you

pavel.veprek@dgplus.cz
www.dgplus.cz

Notes

The Multiple Faces of Reform in the Europe of 25
Une mosaïque de réformes dans l'Europe des 25

Afternoon

Chairman

Dr. Josep FIGUERAS

WHO - European Observatory on Health Systems and Policies

Josep Figueras is the Head of the European Observatory on Health Systems and Policies. and the WHO European centre on health policy. He holds a Master in Public Health and a PhD (econ) from the London School of Economics and an honorary senior lectureship at the London School of Hygiene & Tropical Medicine. He is honorary fellow of the UK faculty of public health medicine. He is the leading editor of the European Observatory series published by Open University Press and co-editor of three of its volumes Funding health care: options for Europe (2002), Purchasing to improve health systems performance (2004), Social health insurance in Western Europe (2004). He is also author of key volumes in the field of health systems analysis including Health Systems in Transition: learning from experience (2004), European Health Care Reform: An analysis of current strategies, (1997), Critical challenges for health care reforms in Europe(1998) and Choices in health policy: An agenda for the European Union, (1996).

Rapporteur

Prof. Elias MOSSIALOS

LSE Health and Social Care and WHO
European Observatory on Health Systems and Policies

Elias Mossialos is Brian Abel-Smith Professor of Health Policy in the Department of Social Policy, the London School of Economics and Political Science and Co-Director of LSE Health and Social Care. He is also one of the Research Directors of the European Observatory on Health Systems and Policies. His research interests are in health policy relating to health care systems. Currently, his particular focus is comparative health policy, addressing questions related to funding health care, pharmaceutical policies, private health insurance and the impact of EU law on health care systems.

Yves BUR

Député, Vice Président de l'Assemblée Nationale

Chirurgien dentiste de profession, Yves BUR est député depuis 1995. A l'assemblée il s'investit dans les domaines touchant à la santé et à l'action sociale. Rapporteur pour avis du projet de Loi de Financement de la Sécurité Sociale pour 2005, Yves BUR est Président du groupe d'études sur le médicament et les produits de santé, membre titulaire du Haut conseil sur l'avenir de l'assurance maladie, de la commission des comptes de la Sécurité sociale et du Conseil de surveillance du fonds de réserve pour les retraites.

France: Strategy of reform of the Healthcare System

France : Stratégie de réforme du système de santé

Discussant

Noël RENAUDIN

Président du Comité Economique des Produits de Santé

France: Strategy of reform of the Healthcare System

France : Stratégie de réforme du système de santé

The Multiple Faces of Reform in the Europe of 25
Une mosaïque de réformes dans l'Europe des 25

Andrzej RYS

- Director of the Center for Innovation, technology Transfer and University Development CITTRU - Jagiellonian University, Krakow

Andrzej Rys MD, In 1991 has established and was running till 1997 the School of Public Health of Jagiellonian University, first such institution in CEEC. In 1997-1999 he was a director of city health department. In 1995 –1999 a Polish director of "Harvard-Jagiellonian Consortium for Health" – a project focus on local government's role in health cares. In 1999 – 2002 he was a deputy ministry of health; developed: new system of emergency medicine, a reform health allied professional's education and he was a member of Polish-EU negotiation team. Currently working as: a director of the Center for Innovation, Technology Transfer and University Development at Jagiellonanian Univesity, Cracow, Poland, vice president of Diagnostic MCL Ltd. (the biggest private diagnostic laboratory group in Poland), a chief editor of the "Journal of Health and Management"

Poland: Between decentralized and centralized health systems, looking for the future of the Polish Health System ?

Pologne : Système de santé centralisé ou décentralisé : quel futur pour le système de santé en Pologne ?

Discussant

Rafal NIZANKOWSKI

- Vice Minister of Health, Poland

Poland: Between decentralized and centralized health systems, looking for the future of the Polish Health System?

Pologne : Système de santé centralisé ou décentralisé : quel futur pour le système de santé en Pologne ?

Towards a European health care « market »?
Round table. How to assure equitable access to modifications throughout Europe?

Vers un « marché » européen des soins de santé ?
Table ronde. Comment assurer un accès équitable aux soins à travers l'Europe ?

Chairman

Kees DE JONCHEERE

Regional Advisor for Pharmaceuticals and Technology, WHO
Regional Office for Europe

Kees de Joncheere (The Netherlands) is currently responsible for the area of Health Technology and Pharmaceuticals in the WHO regional office for Europe, based in Copenhagen. He coordinates the WHO country assistance in the pharmaceutical sector for Central and Eastern Europe, as well as the countries of the former Soviet Union ; and collaborates closely with western European countries and the European Commission on pharmaceutical policy issues.

He holds Master's degrees in pharmacy and business administration from the Universities of Groningen and Amsterdam in the Netherlands, and from National University, San Diego, USA / San Jose, Cost Rica.

Previously he worked for 10 years with PAHO/WHO in Latin America (Central America, Brazil and the Mercosur countries) and before that on secondment of the Dutch government in the Middle East.

Among others, his particular interests is in public policy on medicines , especially on pharmaceutical pricing and reimbursement in Europe, as well approaches to improve the use of medicines. He is co-editor of the WHO publication Drugs and Money, 7th edition, 2002, and author of several articles and book chapters on pharmaceutical issues.

Rapporteur

Prof. Reinhard BUSSE

Technische Universitaet Berlin,
Dpt Health Care Management
European Observatory on Health Systems and Policies

Professor Dr. Reinhard Busse MPH FFPH is professor and department head for health care management within the Institute of Public Health, Faculty of Economics and Management at Technische Universität Berlin. He is also associate research director of the European Observatory on Health systems and Policies. His research focuses on both the methods and the contents of comparative health system analysis (with a particular emphasis on the reforms in Germany, other social health insurance countries and central and eastern Europe, role of EU), health services research including cost-effectiveness analyses, health targets, and health technology assessment (HTA).

Jim MURRAY

Director, The European Consumer's Organisation

Jim Murray was the Director of the Office of Consumer Affairs and Fair Trade in Ireland from 1979 to 1990, responsible, inter alia, for the implementation of a wide range of consumer protection and competition laws, including laws on misleading advertising, food labelling, product safety and restrictive business practices.

Prior to that he was, for seven years, the Director of the Irish National Social Service Council (now the National Social Service Board), a public organisation which pioneered the development of a network of community information centres in Ireland.
His first job was an engineer/manager in the Irish telephone administration (Department of Post and Telegraphs).
Mr Murray is a qualified lawyer (Barrister at law) and has a degree in Physics and Mathematics. He is also the holder of a Post Graduate Diploma in European Law.
In June 1990 Mr Murray took up the post of Director of BEUC, the European Consumer Organisation.
BEUC is a Brussels-based organisation representing the independent consumer associations from 25 European countries, including all the member states of the EU. The primary task of BEUC is to promote the interests of the consumer at all levels of the EU, to act as a strong consumer voice in Brussels and to try to ensure that the interests of the consumer are given their proper weight in the development of all Community policies. BEUC seeks to influence all EU policies which may affect consumers including policies relating to food, agriculture, environment, competition, single market, trade, financial services, legal interests, health, safety etc.

Jim Murray has served on many committees and advisory bodies at national, EU and international level and is currently EU Chair of the Transatlantic Consumer Dialogue (TACD). END

Greg PERRY

Director, European Generic Medicines Association

Professional

Currently: Director General of the European Generic Medicines Association (EGA) since 1993 (Brussels).
Other current professional activities: Editor of the Journal of Generic Medicines; Founding member and member of the management board of the International Generic Pharmaceutical Alliance (IGPA); Managing Director of GPA Public Affairs and Conferences.
Previously: Managing Director of Westminster-Europe Public Affairs (London-Brussels); EU Consultant to WWF-UK (Brussels); Senior EU Advisor JMD Associates (Brussels); EU Consultant to British Film Institute (Brussels); Parliamentary Advisor to Members of the European Parliament (Brussels); International Officer of the Charted Institute of Management Accountants (London); Management Trainee Leicestershire County Council (Leicester).
Other previous professional activities: Expert WHO Anti-counterfeiting Working Group (Geneva); Temporary EU officer Amnesty International (Brussels); Candidate for the European Parliament 1989 Elections (UK); Trade union representative NALGO (UK).

Academic

PSE Scholar European Parliament (Brussels)
Robert Schuman Scholar European Parliament (Luxembourg)
M.A. in European Integration University of Hull. SSRC Scholarship Award (UK)
B.Soc.Sc. (Hons) International Studies University of Birmingham (UK)

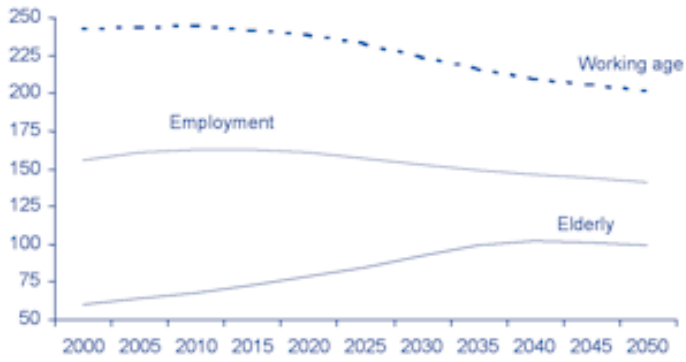
Memberships

Associate Member TOPRA; Member Friends of Europe; Member British Museum Friend; Member Friend of the Royal Academy; Supporter Fulham FC.

Abstract

Generic Medicines and Sustainable Healthcare in Europe
As a result of an ageing population in Europe, EU policy makers are faced with the alarming situation of increased pension costs and rising medicines bills. This situation calls for serious focus on accessibility, sustainability and quality of care in the new enlarged EU. A major solution to ensure equitable access to healthcare in the enlarged Europe is in increasing the use of affordable generic medicines in the off-patent pharmaceutical sector.

Europe's Ageing Population: How do we sustain affordable medicinal care?



Source: EU Economic Policy Committee
Note: Working age population refers to persons aged 15 to 64. Elderly population refers to person's aged 65 and above

The Use of Generic Medicines in Europe
Generic medicines, which sell at a 20-80% price differential to the patent expired brand, are currently creating 13 billion euros savings each year for the former EU 15 health care systems. Examples of critical illnesses treated by generic medicines include cancer, depression, hypertension, diabetes, hyperlipidaemia (cholesterol), serious bacterial infections and asthma. In CEE countries the role of generic medicines is critical to maintaining sustainable healthcare. For the region as a whole, generic medicines account for up to 70% of volume and only 30% of sales of medicines. It is clear that if generic medicines were taken out of the health economics equation the EU's health care systems would become financially unsustainable.

The Generic Medicines Market in the European Union
Over the next few years, there will be a major opportunity for increasing the availability of generic medicines both in the community prescription and hospital sectors, as 35% of top selling pharmaceuticals will be patent expired by the end of 2004. Although most EU governments have started to promote generic medicines, the potential for more cost-effective medicinal provision in the off-patent market is staggering. Many EU Members states have not yet maximised their generic medicines use potential.

Generic Availability and the New EU legislation
The new EU legislation for pharmaceuticals, expected to come into force in November 2005 will have a major impact on generic medicines since it:
> Encourages generic R&D before patent expiry

Greg PERRY, next

> Allows marketing of generics where branded pharmaceuticals have been withdrawn for commercial reasons
> Provides clear scientific and legal definitions of generic and bio-similar medicines
However, the new law will also result in delays in the availability of generic alternatives since it has increased the data exclusivity provisions which lengthens the period of time that manufacturers must wait until they can register and market their generic products.

Government Mechanisms for Promoting Generic Availability
At national level, governments will now need to give greater attention to generic policies. At the European Workshop on Generic Medicines held in Lisbon in February 2003 - jointly organised by the Portuguese medicine agency (INFARMED) and the EGA - the following 10 key measures for stimulating generic availability were recommended for implementation at national level.

Ten Key Measures at National Level for Increasing Generic Availability
1. Educating doctors to use INN names
2. Assisting doctors in understanding the economic implications of prescription decisions
3. Increasing the use of electronic prescribing
4. Creating substitution lists
5. Increasing incentives for generic dispensing and substitution (regarded as particularly important in systems where doctors are not economically sensitive)
6. Improving consumer awareness of generic quality and availability
7. Increasing pharmaco-economic evaluation of new products in comparison with existing products
8. Establishing generic-oriented reimbursement and health insurance systems
9. Adopting reference pricing and free pricing systems instead of controlled price systems
10. Reducing the time delay between receiving market authorisation for a generic product and gaining pricing, reimbursement and/or substitution status.

Dr. Dagmar STARA

Consultant in Regulatory Affairs and Pharmacoeconomics

Work experience

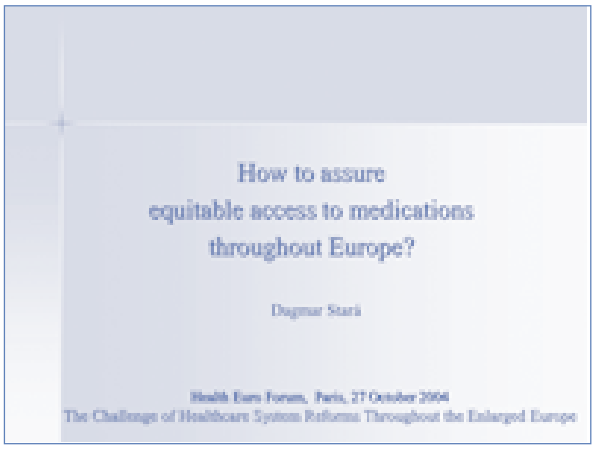
April 2004	Consultant in regulatory affairs, pricing and reimbursement of pharmaceuticals and medical devices.
1996 - March 2004	Head of the Registration and Approval Unit at the State Institute for Drug Control in Bratislava, Slovak Republic. Unit activities included marketing authorisation of medicinal products and tasks of the competent authority in the area of medical devices. My work focus was particularly on practical implementation of the EU "acquis communautaire" in both areas of responsibility as well as on activities related to the preparation of the Slovak regulatory agency/ accession countries for EU enlargement in both fields (CADREAC, PERF).
2003	6 months working as a national expert on secondment in the European Agency for Evaluation of Medicinal Products (EMEA), UK
1999	6 months working with the Medicines Evaluation Board, The Netherlands
1987 - 1995	Faculty of Pharmacy, Comenius University, Bratislava, teacher at the Department of Pharmacognosy and Botany
1983 – 1987	Drug Research Institute, Modra, SR, researcher at the Department of Clinical Pharmacology

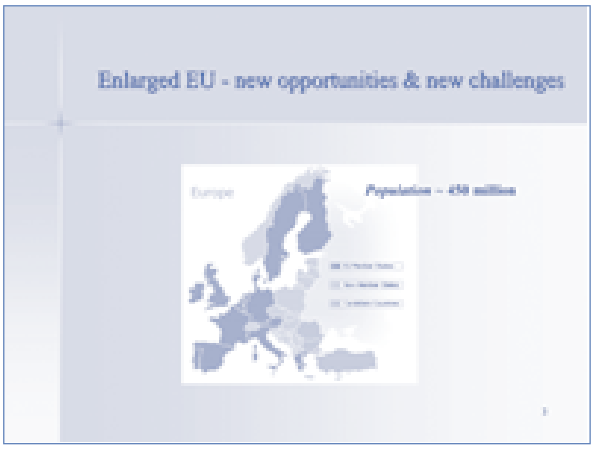
Education

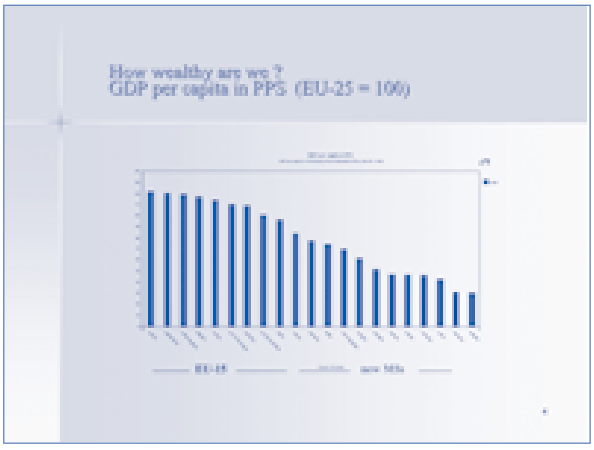
1978 -1983 Faculty of Pharmacy, Comenius University, Bratislava, clinical pharmacist
1993 PhD in Pharmacognosy
2004 Health Outcomes Research Course, Vienna School of Clinical Research

Summary

Costs for pharmaceuticals are rising. To ensure affordable, equitable and timely access to effective treatments across Europe requires pricing and reimbursement decisions based on in-deep evaluation of all data available, particularly the cost-effectiveness. CEE countries, with resources more limited than EU-15, follow the general trend and health technology asssessment bodies are set up. Pricing and reimbursement being a national responsibility rises the question of the differences and similarities across Europe and considerations about possible areas of collaboration or even harmonisation.







Towards a European health care « market »?
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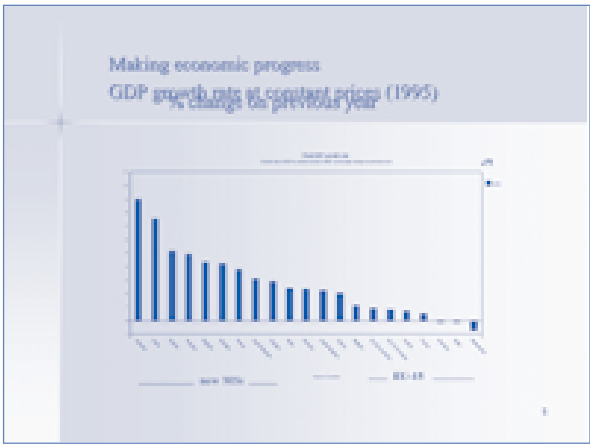
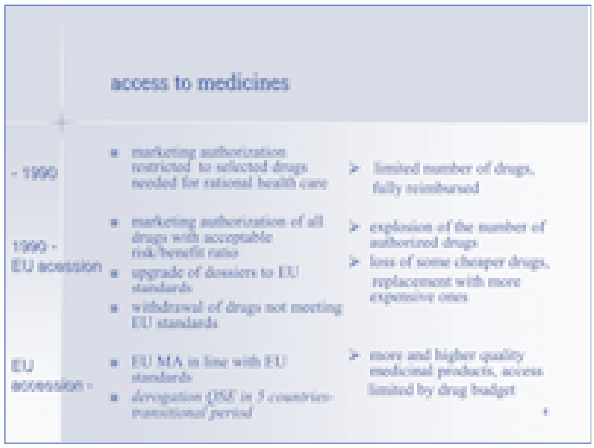
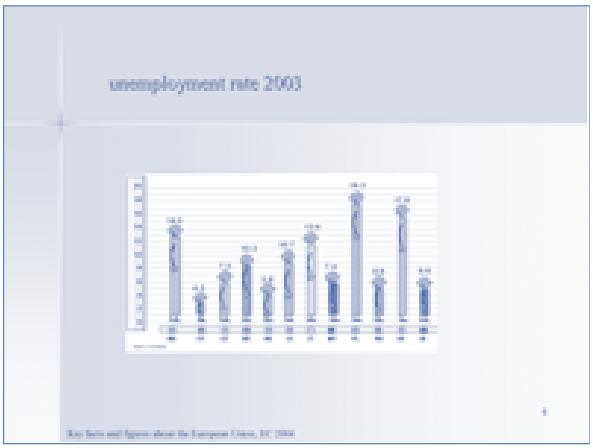
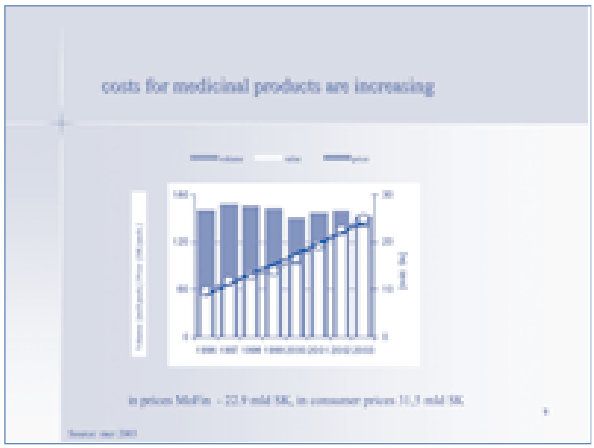
Dagmar STARA, next





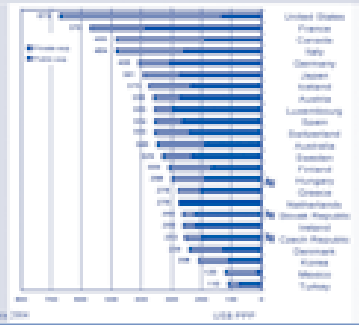




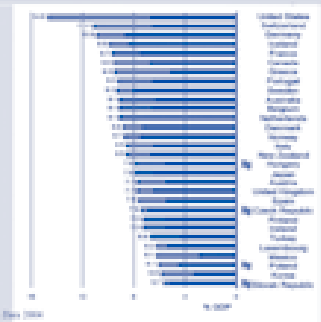
costs for medicinal products are increasing (cont.)

- payers to control the trend
- available finance
  - pressure to stay within budget
  - ability to increase funding from taxes or insurance premiums is limited
  - employers concern about cost of health care as a component in their cost of doing business
  - performance measures linked to budgetary criteria as well as meeting disease targets, maintaining quality and access

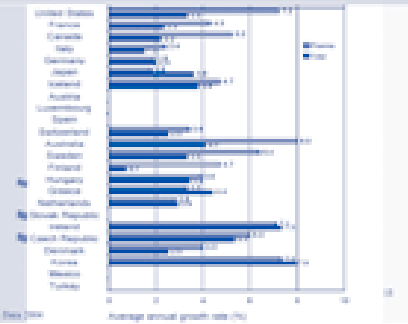
pharmaceutical expenditure per capita, US$PPP, 2002



health expenditure as % of GDP, 2002



annual average growth rate in pharmaceutical and total health spending,1992-2002



health expenditure per capita, US$PPP, 2002

access to medicines (cont.)

- marketing authorization is EU driven (~ 1998 ... 2004 ....)
- national responsibility for pricing and reimbursement
- EU Transparency directive (acquis communautaire)
  - criteria (objective and verifiable)
  - timeframe
  - appeal (EE to court)
  - transparency, publication of price
- *parallel trade/ specific mechanism: IPP / patent protection / SPC*
- *reviewed legislation : data exclusivity, EU reference product*

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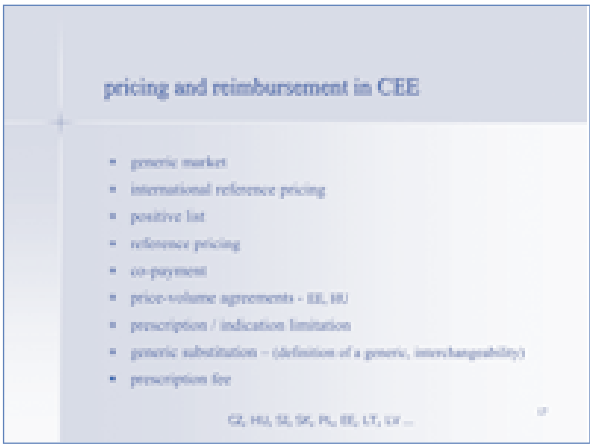

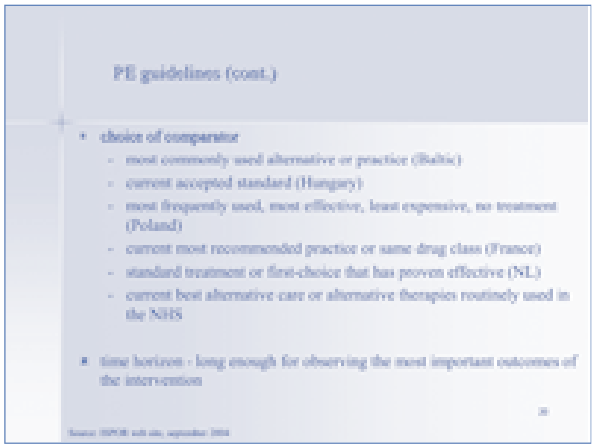

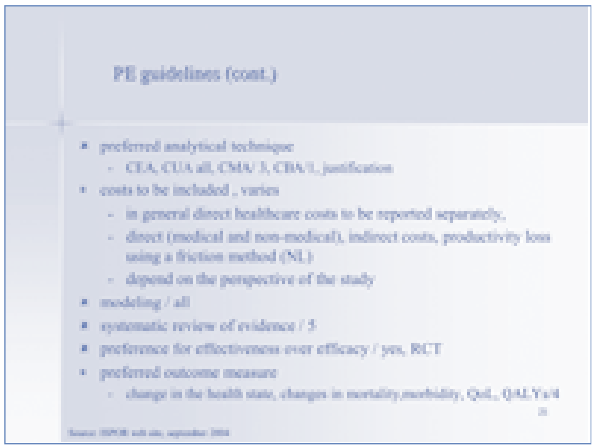

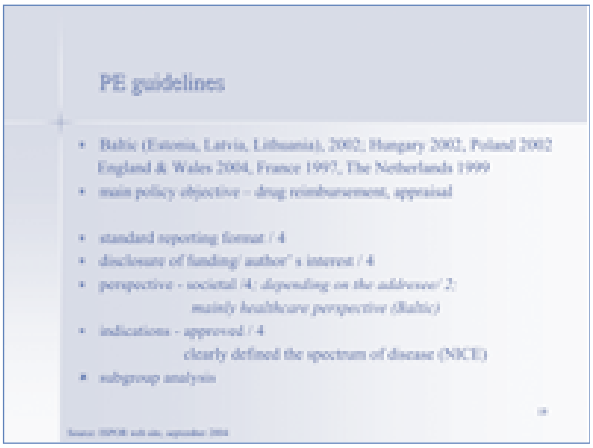

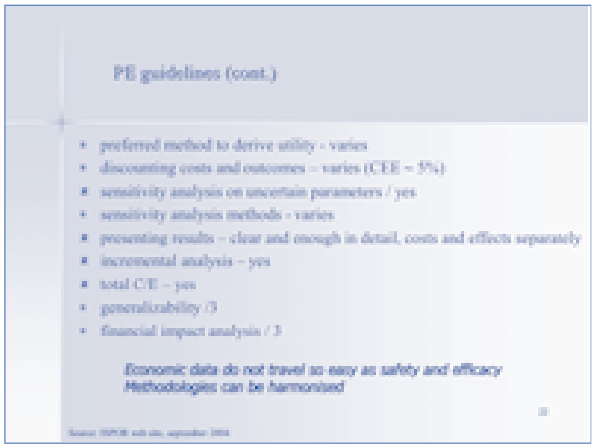

ethical issues

- equitable access to effective, safe and good quality medicines
- ***equity*** - each group of patients, irrespective of their social status, should receive all drugs essential for their treatment with appropriate level of reimbursement
- ***solidarity*** - very expensive treatments are fully reimbursed, co-payments for cheaper and/or not essential drugs are fixed at relatively higher level to equilibrate drug budget
- co-payment (SK may 2004)

< € 1,25	42 %	(1320)	< € 4,00	17 %	(525)
< € 2,50	22 %	(680)	> € 4,00	19 %	(592)

prescriber and patient

- influencing physician's prescribing …
  - clinical practice guidelines …
- easily accessible, simple, unbiased source of information for patients
- patients' representatives in the reimbursement decision making

➢ ensuring affordable, equitable and timely access to effective treatments across Europe

Thank you

Notes

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Albert VAN DER ZEIJDEN

Chair, The International Alliance of Patients' Organisations

Albert van der Zeijden studied psychology and pedagogy. His last permanent appointment was that of chairman of the board of a teachers college. Since he was diagnosed in 1980 for Crohn" disease and ankylosing spondylitis. Sinse that time he is involved in patients organisations on a national and an international level. At present he is chairman of the International Alliance of Patients' Organizations (IAPO). As such he represents IAPO in and to numerous organisations, including: The European Health Forum gastein and the European Health Policy Forum of DG SANCO, the international associations of doctors (WMA), nurses (ICN) and pharmacists (FIP) and the World Health Organization.

Abstract

European health care systems are build on the assumption that all citizens have the same indefeasible right to health care arrangements. Access to the systems is therefore a matter of national policies. With regard to this there is no difference between systems financed by state taxes, like the National Health System in the United Kingdom or financed by compulsorily and voluntarily contributions to the national health insurance, like in the Netherlands.

Equitable access to the systems is under constant pressure the last decades and will be in the future, due to the progressively rising expenditures for the system. The answers are the same throughout Europe:

Rationalisation: more interventions for the same money

Claim-reduction: a shift from public funding towards private funding, which includes co- and self-payment

The system itself is discussed for its lack of efficiency. The important question, whether the design of the system is the right one to answer the problems of our time is hardly discussed. This discussion is much needed by the growing costs of our health care systems, caused by the introduction of new innovative medications, the ageing population and the growing non acceptation of ailments and health related complaints.

The design of the current systems is based on the successes in the battle against transferable diseases and on a division of roles between professionals and consumers, which denies the changes since that golden age of health care: 1850 – 1950.

At present the majority of costs is related to long term care arrangements and not to occasional interventions. The citizens are much better educated and in principle in the position to take more responsibility than a century ago. So, first of all the systems should be redesigned to meet the needs of people with a long term medical condition. Secondly we need a shift from health care, controlled by professionals to supported self-medication, wherever possible.

This changes will not be achieved overnight, so we have to start now. One condition for this changes is heavy investment of society in improvement of the health literacy of the population as a whole.

Contacts
Contacts

Steering Committee/*Comité de pilotage*
Anne Bardot, Ph D., Chair of the Steering Committee
H. Lundbeck A/S
Ottiliavej 9 DK - 2500 Valby
COPENHAGEN Denmark
e-mail: adot@lundbeck.com

Scientific Coordinator/*Coordinateur scientifique*
Professeur Robert Launois
REES France - 28, rue d'Assas 75006 PARIS France
e-mail: launois.rees@wanadoo.fr
Tél: 01 44 39 16 90

SFES - Société Française d'Economie de la Santé
51-53, rue Saint-Denis
75001 Paris

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The Challenge of Healthcare Systems Reforms Throughout the Enlarged Europe

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