Pharmaceutical Forum

First Progress Report, 29th of September 2006

Introduction

This is the first progress report for the Pharmaceutical Forum. The Pharmaceutical Forum was established by Vice President Verheugen and Commissioner Kyprianou in June 2005 to examine the competitiveness of the European-based pharmaceutical industry and related public health issues. The Pharmaceutical Forum will take forward some of the most crucial issues outstanding from the G10 Medicines process, in particular Information to Patients, Relative Effectiveness and Pricing/Reimbursement. This report sets out the key areas where progress is being made and the directions for future work in the form of Conclusions for the Forum to adopt.

Background

The European pharmaceutical industry is making a major contribution to achieving the renewed Lisbon objectives and in fulfilling the growing needs in public health. It is a major contributor to Europe's science base and employment. However, it is facing a number of serious challenges and is losing ground vis-à-vis its global competitors.

In parallel, the ageing of the European population, the increasing health demands of the European patients and the high level of expenditure for innovative products are putting significant pressure on the social systems and public health budgets of Member States.

Pharmaceuticals are subject to European as well as to national regulations. Fully in line with the responsibilities of Member States and the Community, the Pharmaceutical Forum will provide a platform to discuss and examine major concerns in relation to EU pharmaceutical policy.

The importance of this sector for economic growth and public health and the need for action was stressed by the conclusions of the Competitiveness and Health Councils on 22nd September and 3rd December 2003 respectively in which ministers responded and welcomed the recommendations of the G10 Medicines Group.

Some of the most crucial and outstanding issues of the G10 process, namely Information to Patients, Relative Effectiveness and Pricing/Reimbursement, have been selected as topics to be addressed in the Forum. Three technical Working Groups, supported by a Steering Committee, have been established on each of these three subjects in order to prepare the ground for the Forum discussions, share experiences and explore possible concrete and practical ways forward.

Pharmaceutical Forum members are asked to consider and adopt the first draft conclusions of each of the three working groups. Collectively these conclusions will provide the mandate for the future work programme.

Information to patients

Mission Statement

The aim of the working group is 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.

Progress

The Forum's Working Group on Information to Patients was established in January 2006. It has developed the following three work streams to:

a) develop a model package of information on diseases (using diabetes as a first example);

b) consider areas for more harmonised action on information on medicines at an EU level; and

c) improve patient access to good quality health information in healthcare environments (pharmacies and hospitals and ways to enhance access more generally).

Underpinning the work is a questionnaire that has been issued to all participants (Member States and stakeholders) seeking details of the main mechanisms for distributing information on medicines and related health issues in each Member State.

Conclusions

1. *The Pharmaceutical Forum welcomes the proposal for developing guidance in Europe on the production of high quality and easily understandable and accessible information on diseases and medicines (including prevention where appropriate) for people in Europe. Such information should also take into account other relevant treatment options.*

   <u>New patient information guidance</u>

   a. *According to a set of core principles/criteria and appropriate assessment and validation procedures to be agreed, on the production of high quality health-related information for patients and citizens as a framework for information on diseases and medicines;*

   b. *In liaison with authorised databases on diseases and/or medicines, such as the planned European EudraPharm database;*

c. *Information creation and exchange based on partnerships to be defined according to different situations (e.g. differences between national health systems) – possible partners include Member States, patient/consumer organisations, physicians, pharmacists, other health care professionals, industry, social insurers and the wider stakeholder community including learned societies and academia;*

d. *Develop an example on diabetes, based on the above mentioned criteria and principles, to demonstrate what might be possible; and*

e. *Given the importance of the availability of information to patients in their language it must be capable of translation into all the official EU languages, and take into account different capabilities/competencies of patients and citizens to understand and use such information.*

Improving access to information

2. *The Pharmaceutical Forum also welcomes the work being carried out to examine ways of improving patient access to high quality information on diseases and medicines (including prevention, where appropriate). Such information should also take into account other relevant treatment options.*

    a. *Through all healthcare environments, with work initially focusing on hospitals and pharmacies.*

    b. *By identifying tools that can help people in Europe to access and distinguish between good/objective and poor quality information on diseases and medicines and through all modern communication formats (including electronic and non-electronic means).*

    c. *By identifying valid national sources of information.*

    d. *By exploring methods to support National Competent Authorities to disseminate and manage information on diseases and medicines.*

3. *The Pharmaceutical Forum notes the contribution of the European Medicines Agency's Working Group with Patient Organisations with regard to provision of statutory information (approved information for health care professionals and patients) to the work of the Information to Patients Working Group and the forthcoming launch of the EudraPharm Database.*

4. *The Pharmaceutical Forum also notes that the Commission will take account of the output of the Information to Patients Working Group in the context of the Commission's report to the European Parliament and Council following the entry into force of Directive 2004/27/EC (amending Directive 2001/83/EC).*

5. *The Pharmaceutical Forum requests the Information to Patients Working Group to further develop its proposals, in particular in relation to implementation plans (including the important issues of user-testing and appropriate validation), and to report back to its next meeting in 2007.*

Pricing and Reimbursement

Mission Statement

To examine alternative pricing and reimbursement mechanisms to support Member States in fulfilling their commitment towards the G10 recommendations, as well as towards the public health objectives of offering an equal access to medicines at an affordable overall cost. Several factors have generated significant changes in the pricing and reimbursement mechanisms of most Member States during the last years: raising expenditure on medicines, inequity of access to medicines in Europe, the call for early access to innovative medicines. This Workgroup aims to identify, explore and exchange alternative mechanisms that can help Member States answer these different challenges. It will be up to each Member State to see how to apply these mechanisms.

Progress

This Working Group was established in February 2006. To start, participants have raised a variety of concerns and problems, related to pricing and reimbursement, to be addressed within this group. Most of these were structured within four work streams which allow a more focused approach:

- Control of expenditure, including use of price control and the variety and impact of national cost-containment strategies in line with Member State responsibilities for pricing & reimbursement decisions and ensuring the sustainability of their health systems.

- Access to medicines, for all patients within Europe, including availability and affordability issues.

- Market and trade, including organisation of distribution and cross-border trade of medicines.

- Transparency of pricing and reimbursement data, exchanged between Member States.

The participants within this Working Group started examining different national practices relating to the first three work streams, with the help of independent academic experts. The fourth work stream is more technical and will be addressed separately within the Transparency Directive Committee although with regular feedback on progress to the Working Group.

Many participants raised the relationship with the content of the Working Group on Relative Effectiveness. The chairperson of this group therefore has ensured coordination with the other Working Group from the start of the process.

Conclusions

1. *The Pharmaceutical Forum endorses the progress made in the Working Group on Pricing to find common ground between ensuring control of pharmaceutical expenditure for Member States, ensuring a timely and equitable access to pharmaceuticals for patients all over Europe and ensuring a reward for innovation within a competitive and dynamic market that also encourages Research & Development.*
2. *The Pharmaceutical Forum welcomes the active participation of all key stakeholders, patients, competent authorities, industry, physicians, pharmacists, wholesalers and social insurers. The Forum acknowledges that progress will require involvement and responsibilities of all participants.*
3. *The Pharmaceutical Forum takes note of the key findings of the first discussions within the Working Group on Pricing and Reimbursement:*
    a. *Regarding control of expenditure: Iin order to contain rapidly growing pharmaceutical expenditure, Member States make increasing use of a variety of mechanisms, aiming to control levels of price/reimbursement, to rationalise utilisation. To date there has been limited opportunity to evaluate positive and negative impacts of these different mechanisms, notably on containment of expenditure, affordability, access for patients and incentives for industry to bring further innovation.*

    b. *Regarding access to medicines: Not all patients within Europe have equal access to medicines. Different economic strengths of EU Member States may lead to different levels of affordability of medicines for both, patients and public authorities. Certain regulatory measures, market sizes and/or business considerations may lead to differences with regard to timing of availability of medicines.*

    c. *Regarding market and trade: Systems for distributing medicines are organised differently by each of the Member States, in function of local needs and environment. However, in order to ensure access of patients and citizens to all medicines there are specific public service obligations for the supply chain. Parallel imports are not part of organised systems of distribution but they can increase price competition and can offer an opportunity for cost-containment in several EU Member States. In other EU Member States, export of these medicines leads to pressure to accept higher prices and possible stock-ruptures. Such parallel trade might shift reward for innovation from industry towards trading parties.*

    d. *Regarding transparency of data: There is a concern on transparency, consistency and interchangeability of information and data, regarding pricing, price components and related issues, exchanged between different Member States and stakeholders. Although several good initiatives are ongoing in this field, there is need to further coordinate development and exchange of this type of information.*
4. *According to the mandate of this Working Group, and in line with national competencies of the Member States, the Pharmaceutical Forum encourages the Working Group on Pricing to further progress by:*

a. *Clarifying views on the value of innovation, taking account of national health systems in order to establish a sound basis for further discussion between different stakeholders.*

b. *Increasing mutual knowledge on pricing and reimbursement systems and on different cost containment mechanisms by further exchanging experiences between Member States and stakeholders. While doing this, taking into account work already undertaken in different other initiatives.*

c. *Identifying, assessing and recommending ways to ensure incentives for competition (including on price) and valuable innovation, in particular in line with the relevant G-10 recommendations on pricing (Recommendations 3, 4, 5 & 6).*

d. *Identifying, assessing and recommending ways to ensure a timely, equitable and affordable access to medicines for all patients in Europe both within industry business strategies and within the various cost-containment mechanisms applied within Member States.*

e. *Identifying, assessing and recommending ways to minimize risks and adverse consequences for patients, Member States and industry as a result of trade between Member States.*

f. *Following up on different projects and initiatives within Europe, aiming to increase transparency, consistency and interchangeability of information regarding prices, price components and related issues, e.g. within the Transparency Directive Committee. Where appropriate, giving inputs to increase coordination between these efforts.*

g. *The Pharmaceutical Forum requests the working group to report back to its next meeting in 2007.*

Relative Effectiveness

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.

Progress

This Working Group was established in February 2006. As a consequence of the wide variety of national relative effectiveness schemes, it was decided to circulate a questionnaire to all participants to get an overview of different relative effectiveness practices in Member States. This served as basis for discussions on definitions and further objectives. This was supplemented by a further questionnaire focusing on the availability and use of different sources for information and data.

The chairpersons of this group ensure coordination with the Working Group on Pricing and Reimbursement on the related issues.

Conclusions

1. *The Pharmaceutical Forum welcomes the work carried out by the Relative Effectiveness Working Group towards facilitating exchange of information among Member States to improve the quality of relative effectiveness assessments for all stakeholders and to improve the cooperation between Member States.*
2. *It particularly welcomes the report produced by the Working Group on Relative Effectiveness Assessments in the EU which gives more insight into the goals and timing of the assessments in the different Member States as well as the organisation, the transparency, the data used and other methodological aspects of the assessment.*
3. *It also endorses the proposal for the future work plan which has three objectives:*

   - to develop mechanisms in order to increase the quality and quantity of the available data to carry out an assessment and to consider ways to manage uncertainty. The lack of reliable data (notably to support the initial pricing and/or reimbursement decision) is one of the key challenges to be addressed, and EU cooperation in this field will help to improve the quality of data for Member States and to achieve efficient use of limited resources. The Working Group will also consider possible ways to share information on assessments made and decisions taken following those assessments, for example by establishing a database/website. In doing so, the different national legislative backgrounds for these assessments and decisions must be taken into account.

   - to improve the degree of consensus at European level between Member States on the nature of the data required to carry out cost-effectiveness, relative effectiveness and relative efficacy assessments and on the procedure and the time schedule to provide these data.

- to develop a proposal to analyse current assessment processes and to identify good practices. This work could be used to address challenges in the assessment processes in Member States.

The Pharmaceutical Forum requests the Working Group to report back on the implementation of this work plan prior to its next meeting in 2007.