

# Pharmaceutical Forum

## Second Progress Report, 26 June 2007

### Introduction

This is the second Progress Report of the Pharmaceutical Forum. It describes the progress made so far, sets out key deliverables for the Forum and implementation plans as requested by the Pharmaceutical Forum in 2006.

Following the political directions given by the first Forum on 29 September 2006, the working groups on information to patients, relative effectiveness assessments and pricing & reimbursement have developed proposals to address the challenges facing Europe as set out in the G10 Medicines recommendations. In addition to this report, deliverables by the working groups are included in the annex to demonstrate the concrete work undertaken.

This report is divided into three sections which focus on each of the working groups providing a brief summary of the progress made so far, concrete results and implementation proposals as well as issues for the Forum to consider and discuss. The implementation of the work should be developed into concrete work packages following the political direction given by the Pharmaceutical Forum at its meeting on 26 June 2007.

The proposals and work packages which are described in this report aim to provide a framework for discussion for the 2007 Pharmaceutical Forum. Following discussions on the key issues related to the work of the working groups, the Pharmaceutical Forum process should move forward with the implementation of the work through different means and mechanisms in 2008. The implementation plans will be taken forward by all stakeholders to ensure their success in practice.

*Members of the Pharmaceutical Forum are asked to consider and adopt the draft conclusions of each of the three working groups. Collectively these conclusions will provide the mandate for implementation of proposals.*

## Relative Effectiveness

### Progress

The 2006 Pharmaceutical Forum adopted the conclusions of the relative effectiveness working group and in particular, it endorsed the draft work plan with three key objectives:

- 1.) 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 working group was also asked to consider possible ways to share information on assessments made and decisions taken following those assessments, for example by establishing a database/website.
- 2.) 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 and;
- 3.) To develop a proposal to analyse current assessment processes and to identify good practices. This work could be used to address challenges faced by both payers and industry in the assessment processes in Member States.

In addition, the Pharmaceutical Forum suggested that the working group would consider, in consultation with industry, how to test methodologies for example by choosing one or more candidate products to go through an assessment.

Concretely, the working group has prepared a working document which aims to provide an overview on the critical issues in relation to the data needed to perform a relative effectiveness assessment and methodologies used to undertake such assessments. Although it remains in draft form at this stage, the working document (titled *"Report on Data and Methodology in relation to Relative Effectiveness"*) already shows that Member States encounter similar significant difficulties when undertaking assessments, particularly at early stages such as soon after marketing authorisations are granted. In addition, the pharmaceutical industry encounters difficulties in this context.

The draft report makes clear the potential for improving both the principles and the practicality of generating, sharing and using data for relative effectiveness assessments at the national level. The working group has agreed that it will focus on relative effectiveness assessments at this stage. However, issues related to cost-effectiveness would be considered later if necessary.

The working group agreed on a set of working definitions which could be also used in the Pharmaceutical Forum meeting to ensure that the terminology is consistent among the members. These working definitions are set out below for ease of reference<sup>1</sup>.

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<sup>1</sup> **Efficacy** is the extent to which an intervention does more good than harm under strictly controlled circumstances.

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

**Relative effectiveness** can be defined as the extent to which an intervention does more good than harm compared to one or more intervention alternatives for achieving the desired results when provided under the usual circumstances of practice.

**Relative effectiveness assessments** are carried out to investigate to which extent a medicinal product does more good than harm compared to one or more other medicinal products or other alternative health interventions for achieving the desired results when provided under the usual circumstances of health care practice. The process of getting best possible information from relevant relative effectiveness data is referred to as **the assessment**. The working group has also agreed that the quality of life dimension should be part of assessments of relative effectiveness.

The working group has proposed ways forward in the following areas:

- Working towards a European consensus on general principles and good practices for relative effectiveness assessment, with a toolbox providing support on areas such as methodologies or mechanisms to interpret data, coordination of requests to companies for further work, and exchanging experience and skills;
- Improving the data available (including appropriate comparators where available) and their accessibility during product development, at the time of marketing authorisation and afterwards. Recommendations include early dialogue during product development between national authorities and companies to improve the generation of appropriate data so far as possible; agreement on sharing all relevant data with relative effectiveness assessment authorities; ways of generating additional data to assist in relative effectiveness assessment; and exploring the possibility of collaboration among Member States as well as stakeholders for studies or trials of products<sup>2</sup>;
- Strengthening networks among relative effectiveness assessment authorities and relevant stakeholders across Europe and considering mechanisms to help share data, provide support and develop common principles at European level<sup>3</sup>.

## Conclusions

1. *The Pharmaceutical Forum welcomes the progress made in the working group and its overall approach, and agrees with developing ways to support Member States on relative effectiveness by improving consensus on general principles and good practices when performing relative effectiveness assessments. This will also contribute to strengthening of the competitiveness of the European based pharmaceutical industry.*
2. *Any relative effectiveness assessment will only be as good as the data on which it is based and its methodology. Relative effectiveness assessments and consequent reimbursement decisions should thus be updated as new data becomes available. The Pharmaceutical Forum agrees that in principle all data that are available at the time of the marketing authorisation should be made available to the agencies in Member States responsible for relative effectiveness assessments in as transparent and complete manner as possible. The Pharmaceutical Forum encourages the relevant authorities and companies to explore ways to communicate and collaborate prior to the market authorisation decision as well as after it in maximising availability and best use of data relevant to relative effectiveness assessment.*

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Cost effectiveness measures the effect of an intervention in relation to the resources it consumes ("Is it worth it?").

Relative efficacy is when an intervention (a product) is compared to other existing interventions in a strictly controlled setting of a clinical trial

Reimbursement in the context of this report includes all mechanisms used at national level to apply the principle of solidarity to pharmaceutical products, as for example, pricing decisions, purchasing decisions by authorities, or any other mechanisms used by Member States.

<sup>2</sup> ESIP has expressed a reserve.

<sup>3</sup> AIM and ESIP have expressed a reserve.

3. *The Pharmaceutical Forum requests that further consensus on principles for relative effectiveness assessment be developed by exploring good practices in the Member States and by developing a toolbox and principles to provide support on areas such as robust methodologies or mechanisms to best use data, coordination of requests to industry, establishing training or other measures<sup>4</sup>.*
4. *The Pharmaceutical Forum welcomes the proposals for identifying specific products or groups of products to provide real-life examples against which these principles, methodologies or mechanisms can be tested without aiming to centralise relative effectiveness assessment at the EU level.*
5. *The Pharmaceutical Forum requests the working group also to explore different ways of encouraging the production of additional relevant data, such as:*
  - *Identifying data sets (including the possibility to have appropriate comparators) that can be helpful for relative effectiveness assessments;*
  - *Working towards consensus on good practices for concept design and analysis on what kind of new study types/study designs would be needed to improve the information available about products in real-life use;*
  - *Elaborating on methods for the transferability of data on relative effectiveness assessments between Member States*
  - *Providing Member States with options for encouraging the production of more relevant data or alternative routes for producing additional data;*
  - *Considering (with the involvement of the European Medicines Agency) how EPARs and NPARs could make a better contribution to relative effectiveness assessments;*
  - *Recognising the value of innovation building on the work of the working group on pricing.*
6. *The Pharmaceutical Forum supports the aim of sharing data on relative effectiveness assessment at European level and developing sustainable collaboration and networks between the competent authorities of the Member States and other stakeholders, and requests specific proposals for ways of achieving this.*

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<sup>4</sup> ESIP has expressed a reserve.

## Pricing and Reimbursement

### Progress

The working group on pricing has met four times since the first meeting of the Pharmaceutical Forum. These sessions involved all stakeholders and Member States. Additional debates took place within smaller groups and within the Transparency Committee (Member States only) and within a taskforce on innovation.

Progress was made in three work streams that were called for by the Pharmaceutical Forum:

- 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.”*

The taskforce on innovation has developed an exhaustive list of valuable benefits than can be expected from innovative new medicines. This list was incorporated in a questionnaire to the relevant authorities in all Member States. Fourteen have replied on how they value these different benefits. This has allowed identification of a broad commonality in views as well as some differences between the different authorities. Additional perspectives were provided by the patient’s representatives.

- 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.”*

Contracted experts have built an overview of the application of different pricing and reimbursement practices in the individual EU Member States. In addition, they have collected detailed information on the concrete application of 6 selected practices (reference pricing, cost-sharing, payback, price-control, prescription information and generic substitution). 24 Member States (+ Norway), industry and several stakeholders have provided inputs and the results have been discussed repeatedly in the working group.

In parallel, a so-called “toolbox” was developed with guiding principles, which aim to balance the overall impact of national pricing and reimbursement policies between (1) accessibility of patients to medicines, (2) containment of the healthcare budget and (3) reward for industry and incentives to come up with further innovations. This effort was built on the collection and exchange of knowledge and experiences of individual pricing and reimbursement practices. A paper with the developed principles is attached at Annex A.

- c. *“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.”*

This work stream has been taken forward within the Transparency Committee (with the Member States only). Experts have developed and managed a pilot project on price transparency. 21 countries provided price levels of 15 best-selling and/or recent medicines in a standard format. A first discussion on the preliminary results has revealed initial findings e.g., in terms of price-differences of a similar product between Member States, in terms of availability of medicines on individual EU markets and in terms of costs of distributing medicines to the market. The findings led to interest in organizing a more regular price comparison exercise, focusing on the medicines of interest to Member

States. In addition, information has been exchanged between 17 Member States on their public websites with national price information.

The Pharmaceutical Forum 2006 had also called for progress in three other work streams. The topics on access to medicines and on implementation of the G-10 Recommendations have been discussed occasionally. These two work streams, and a potential third work stream on trade, need to be elaborated further after June 2007.

## Conclusions

1. *The Pharmaceutical Forum endorses the progress made in the Working Group on Pricing to find common ground between participants. It welcomes the shared understanding of the need to ensure (1) timely and equitable access to pharmaceuticals for patients all over Europe, (2) control of pharmaceutical expenditure for Member States, and (3) reward for valuable innovation within a competitive and dynamic market that also encourages Research & Development.*
2. *The Pharmaceutical Forum welcomes the constructive participation of all key stakeholders, patients, competent authorities, industry, physicians, pharmacists, wholesalers and social insurers. The Forum acknowledges that progress will require further involvement and commitment of all participants.*
3. *The Pharmaceutical Forum welcomes the key findings of the work within or through the Working Group on Pricing, in particular:*
  - a. *The report “Guiding principles for good practices implementing a pricing and reimbursement policy”, a first outline on how to ensure a positive and balanced impact of pricing practices in terms of (1) access to medicines, (2) reward for innovation and (3) containment of costs .*
  - b. *A toolbox with, the first draft of templates summarizing experiences of 6 selected pricing and reimbursement practices, including a description, a listing of potential benefits and risks and references to sources of evidence.*
  - c. *The report “Characterisation of the value of innovative medicines”, a survey of Member States' competent authorities on what they consider to be valuable dimensions of innovation and indicating significant commonalities in their views.*
4. *The Pharmaceutical Forum also notes the work in the Transparency Committee on (1) a pilot exercise on exchange of price information between Member States, including the collection and comparison of levels of prices and price-components for 15 best-selling and/or recent medicines and on (2) the exchange of public websites with national price information between Member State authorities.*
5. *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 make further progress by:*
  - a. *Fine-tuning and developing more convergence on the principles in the report “Guiding principles for good practices implementing a pricing and reimbursement policy”. In particular, developing solutions for the access-problems and trade-problems described, in collaboration with the concerned Member States and stakeholders.*

- b. Further developing the templates summarizing experiences with selected pricing and reimbursement practices. E.g. by updating the existing templates or by creating templates on other practices of interest to the Member States.*
  - c. Communicate and discuss the common views from Member States on what is considered valuable innovation, in particular with parties involved in Health and R&D policies and in Health Technology Assessments, including the Working Group on Relative Effectiveness.*
  - d. The Pharmaceutical Forum requests the working group to report back to its next meeting in 2008.*
- 6. The Member States in the Pharmaceutical Forum also encourage the Transparency Committee to elaborate further the exercise on exchange of price information, in order to collect and compare price levels of individual medicines in EU Member States where considered particularly useful.*

## Information to patients on diseases and treatment options<sup>5</sup>

### Progress

Following the mandate provided by the Pharmaceutical Forum in 2006, the working group focused on the following areas of work;

#### *1. Development of information to patients on diseases and treatment options*

##### Core Quality Principles

The working group developed a set of core quality principles on information to patients on diseases and treatment options. These principles were designed to provide a basis for the development of quality health information on diseases and related issues.

The working group agreed on the usefulness of establishing core quality principles which should be applied to all such information at the EU level and developed the list as set out in paragraph 6. of the Conclusions. The Steering Committee agreed that the working definitions of objective and unbiased information should be the following:

Information is:

Objective when it is based on facts and not influenced by prejudices or personal perceptions;

Unbiased when it is impartial, non-directive and balanced.

These two definitions do not relate to the source of information which is an issue set out under the transparency principle. These definitions concern the substance and the presentation of the information. The core quality principles are attached at Annex B.. Besides the core quality principles on information to patients on diseases and treatment options, the working group also put together a 'toolbox' of good practice and tools to help patients to evaluate health information.

Finally, the core quality principles were subject to an open consultation<sup>6</sup>.

##### Model information package

Related to, and in parallel with, the development of the core quality principles, the working group developed a specific example of an information package which was designed to contain the essential information on a condition and its treatment options. The objective of this exercise was to examine the value of developing health information at a European level in a partnership<sup>7</sup> with all stakeholders of the Forum.

An information package was to test how to develop an example of the key elements that could form the core of this type information and adapted as appropriate to national level. It is

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<sup>5</sup> AIM and ESIP cannot support parts of the progress report concerning information to patients on diseases and treatment options. Their concerns are set out in a joint position statement available at this website [to be added when the Progress Report is published].

<sup>6</sup> The quality principles and the diabetes information package were subject to a public consultation which ended on 4 May 2007. A summary of the results is currently being undertaken and will be circulated to the Pharmaceutical Forum members.

<sup>7</sup> France has expressed a reserve on the term "partnership".

intended to supplement, and not replace, existing authorised information and the advice of healthcare professionals.

The package was also subject to the public consultation. The responses to the consultation broadly supported this proposal but made a number of critical suggestions on the content, the methodology and the need to adapt this kind of information to national situations. All the responses to the consultation can be found at: [http://ec.europa.eu/health/ph\\_overview/other\\_policies/pharmaceutical/results\\_consultation\\_en.htm](http://ec.europa.eu/health/ph_overview/other_policies/pharmaceutical/results_consultation_en.htm)

The working group agreed that there were a number of important lessons to be learnt from this process. The most effective way for taking this model information package on diabetes forward would be to develop a more detailed core set of validated information and a comprehensive methodology for developing an appropriate collaboration involving stakeholders for the future. This could then provide the basis for such information to be adapted by national authorities and stakeholders for different uses such as information to patients, carers, health professionals etc.

The working group also agreed that it was not the appropriate platform to further develop the draft model. This would need to be done by a small working group of experts in diabetes reflecting the composition of the working group with a strong patient involvement.

Furthermore, there was also a preliminary discussion on the following mechanisms as possible future options for adapting and validating an agreed common core set of information for European and national level;

- 1) Ex anteriori validation mechanism which could provide a system for national authorities to assess and validate information to patients on diseases and treatment options information prior to its provision to the general public;
- 2) Co-regulation which includes a review process which would be built on a posteriori controls including sanctions. This mechanism could be based on an obligation for those providing information to allow the information to be reviewed by national authorities and relevant stakeholders; and
- 3) Self-regulation according to an agreed code of practice.

The exact scope, and any possible combination, of these mechanisms would need to be agreed by national authorities.

#### Other areas of co-operation

Furthermore, the working group addressed the issue of strengthening European co-operation on information to patients on diseases and treatment options information for example by setting up mechanisms and tools such a European network and database which would allow improved co-operation and sharing of best practices between the competent authorities and other relevant stakeholders.

### ***2. Examining ways to improve access to information to patients on diseases and treatment options in health care settings***

Two workshops on access to information in pharmacies and hospitals were organised. In addition, a summary of research was undertaken on information needs in different patient groups. Further work is needed to build upon the outcomes from the two workshops. Patients and health care professionals identified barriers such as health literacy and time constraints to accessing/providing information to meet a patient's specific needs.

These reports have been put on the Pharmaceutical Forum website of the European Commission to inform the wider public health community on the work in progress.

## Conclusions

- 1) *The Pharmaceutical Forum welcomes the work undertaken so far to develop a set of core principles on good quality information and the progress made so far on an example information package on diabetes.*
- 2) *In addition, the Pharmaceutical Forum welcomes the exploratory work undertaken by the workshops on access to information in pharmacies and hospitals and the summary of research on patient needs and existing information tools.*
- 3) *The Pharmaceutical Forum would welcome a proposal to organise a platform to bring together relevant stakeholders to explore ways to exchange good practices and on ways to overcome barriers to accessing information identified in this work and to make proposals to the European Commission.*
- 4) *The Pharmaceutical Forum particularly welcomes the fact that the results of the work described above were developed between Member States and stakeholders.*
- 5) *Moreover, the Pharmaceutical Forum notes the results of the public consultation and it considers the view of the wider public, and patients in particular, as an essential element in defining the future orientations of this work.*
- 6) *The Pharmaceutical Forum welcomes the agreement reached on the core quality principles on information to patients on diseases and treatment options;*
  - *objective and unbiased*
  - *patient-oriented*
  - *evidence-based*
  - *up to date*
  - *reliable*
  - *understandable*
  - *accessible*
  - *transparent*
  - *relevant and appropriate*
  - *consistent with statutory information*

*In addition, the Pharmaceutical Forum supports the proposal to develop a methodology for the use of the principles.*
- 7) *The Pharmaceutical Forum recommends their use by all providers in the development of all information to patients on diseases and treatment options information in the European Union.*
- 8) *The Pharmaceutical Forum requests the working group to consider further the example for an information package which should contain the key elements for a European level core information which could provide a basis for a wide range of*

*information material, and the methodology for producing it. It should be adapted to take into account national situations and specific patient needs and different mechanisms may be required to meet individual user needs<sup>8</sup>.*

9) *The Pharmaceutical Forum recognises the value of exploring the possibility for setting up, testing and evaluating a European level mechanism to validate information to patients on diseases and treatment options. For this purpose, the Pharmaceutical Forum requests the European Commission to consider a feasibility study which could look at all aspects of this proposal including<sup>9</sup>;*

- *financial and resource implications*
- *adapting existing information*
- *implications of subsidiarity*
- *the link between stakeholders involved in a process with the responsibility for its outcome*
- *the selection of stakeholders to be involved, and*
- *the supervision of the process*

10) *The Pharmaceutical Forum welcomes the publication of ‘draft report on current practice with regard to provision of information to patients on medicinal products’, as required under Article 88a of Directive 2001/83/EC to which the working group had submitted a contribution.*

11) *The Pharmaceutical Forum considers that above actions should be included in an overall strategy for information to patients on diseases and treatment options without prejudice to the outcome of the report on current practice with regard to the provision of information to patients on medicinal products, as required under Article 88a of Directive 2001/83/EC<sup>10</sup>.*

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<sup>8</sup> France has expressed a reserve.

<sup>9</sup> France has expressed a reserve.

<sup>10</sup> France has expressed a reserve.

## **Guiding principles for good practices implementing a pricing and reimbursement policy**

The decisions on cost of healthcare and pharmaceuticals are a national responsibility, it has appeared in the working group that with decisions on pricing and reimbursement of pharmaceuticals, Member States aim to achieve 3 overall objectives of (1) optimal use of resources to maintain sustainable financing of healthcare, (2) access to medicines for patients and (3) reward for valuable innovation. Each Member State has its specific approach for guaranteeing these 3 overall objectives.

Member States shall ensure that any national measure to control the prices of medicinal products or to restrict the range of medicinal products covered by their national health insurance systems complies with the requirements of Directive 89/105/EEC and the Treaty. This EU legal framework requests in particular that pricing and reimbursement decisions are made in a transparent manner.

The following toolbox principles will allow good implementation of pricing and reimbursement practices and are meant to offer guidance and facilitate the sharing of information and assessments. They are not binding rules.

### **Access for patients**

Ensure timely access to valuable innovation. The Transparency Directive defines deadlines that have to be respected in taking pricing and reimbursement decisions. In standard cases, a request for a pricing and reimbursement decision should come with proof of benefit upfront, based on good clinical trials delivered by the applicant, whenever possible in a comparative set-up with a standard treatment.

In some cases, when a full assessment is to be made for a new breakthrough medicine with a value not yet certain or difficult to prove, these deadlines might be a constraint in spite of good clinical trials. In these cases more evidence needs to be gathered after a medicine has been put on the market. In such cases, and in particular where it concerns life-threatening situations for which no alternative treatment exists, national authorities and companies could take a first pricing and reimbursement decision with conditional on gathering more information in order to review this decision. Such decisions allow patients to gain early access to potentially valuable medicines and innovative companies to get an earlier reward for investment in R&D. In the meantime necessary data can be collected within well-designed outcome research studies. These pricing and reimbursement decisions should come with a mutual commitment to a risk-sharing contract between companies and authorities. This commitment has to come upfront given that it is difficult to withdraw a medicine from reimbursement. Such a contract lays out the expected benefits of a new medicine, the criteria to assess these benefits, the data needed and methods/capabilities to do these assessments as well as the overall timeframes. On the financial side, the contract can define prices, reimbursement levels and restrictions of utilisation during the temporary period, as well as the financial consequences once new proof of benefit is available (for example leading to price or reimbursement changes –upwards or downwards-, changes in utilisation, premiums or payback).

Provide affordable medicines. Medicines should be equally accessible at an affordable cost to all concerned patients. Generic medicines provide an opportunity to obtain similar treatments at lower costs for patients and payers, while liberating budgets for financing new innovative medicines. Promoting generic medicines requires a good combination of demand-side as well as supply-side mechanisms. This includes a flexible and adaptive pricing and reimbursement system, an appropriate level of price-sensitivity in patients (and payers where insurers/sickness funds are involved) and a sufficient level of competition among the different actors in the supply system (manufacturers, wholesalers and pharmacists, taking account of their public health role).

It has also become clear that affordability has a European dimension. A similar price-level leads to a different level of affordability depending on the economic situation of each Member State. Attention could be given to measures that allow companies to offer medicines at affordable prices in each EU market. Limiting price-control only to nationally used volumes, as Recommendation 6 of the G-10 Medicines report stipulates, would allow differential pricing taking account of national socio-economic indicators like GDP-levels<sup>11</sup>.

Affordability could also be ensured through upfront agreements on maximal expenditure. This could allow authorities across the EU to accept similar prices for a limited number of innovative medicines while maintaining the total expenditure at a nationally affordable level, although this cannot be seen as a large-scale solution.

Ensure equal availability of medicines. Several medicines are not available in some markets, in particular small or low-price markets where the potential profits may not seem to justify the investment to organise local supply. Manufacturers should commit to register and supply all EU markets at reasonable prices, including the small and low-price markets. Wholesalers should commit to supply all these EU markets at reasonable prices. Where this is not possible, purchasing and supply managed (partially or totally) by national authorities, potentially in collaboration with other Member States, are to be fully accepted as an alternative.

Overall, sufficient attention should be given to patient's concerns in the development of a pricing and reimbursement policy, in particular to the existing inequities among Member States in availability and affordability.

### **Optimal use of resources**

Limit price control to where it is needed to contain the public budget. Member State authorities usually fix prices and reimbursement levels to ensure access to medicines at affordable cost for utilisation within their territory.

Member States are not interested in fixing prices of products that are only transiting through their territory to be utilised within other Member States. They should, therefore, abstain from fixing prices for products that will not be used within their territory and that will not impact on their national budgets (as outlined by Recommendation 6 of the G-10 Medicines report)<sup>12</sup>. Control of supply and utilisation, including a system of traceability, might be helpful.

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<sup>11</sup> France has expressed a reserve on reference to G10.

<sup>12</sup> France has expressed a reserve on reference to G10.

Price control is not necessary for non-reimbursed medicines. For these products, price-competition can steer the price-evolution sufficiently well. Therefore, Member States should abstain from price-control. Monitoring systems might be helpful to get an overview of market- and price-evolutions and to mitigate any potential risk of significant price increases.

Set-up a consistent package of supply and demand-side measures. To manage expenditure on pharmaceuticals, authorities need to manage prices, reimbursement levels and proper use. Supply side measures, addressing prices and reimbursement levels, are, therefore, to be managed in coordination and alignment with demand side measures, determining the volume. On the demand side, the individual behaviour of doctors, pharmacists and patients will determine the total use of and expenditure on medicines. Interests of all these actors, therefore, need to be aligned with the national objectives. One or several of these actors should be motivated to push forward utilisation of medicine in a cost effective way, either through a (financial) incentive, or through a controlled obligation. Practices (1) on prescription guidance for doctors, (2) on substitution by pharmacists and (3) on cost-sharing and price-sensitivity of patients, should therefore be aligned.

In addition, upfront agreements on overall maximal expenditure, in the form of payback or price-volume agreements, allow effectively increased predictability of overall expenditure.

Create the right environment for price competition. Direct or indirect control of prices, reimbursement and expenditure are clearly relevant in a market with low price-sensitivity and high market power of manufacturers, in particular for medicines under patent protection. In situations where competition between different products is possible, e.g. when generics enter the market, open price competition may lead to good containment and significant reduction in prices and costs for patients and payers in a less cumbersome way. On the other hand, maintaining fixed pricing or reimbursement levels, in a situation where competition is possible, could prevent price-reductions. To ensure savings, authorities need to provide for a flexible, adaptive pricing system, an appropriate level of price-sensitivity in patients (and/or payers) and a sufficient level of competition among the different actors in the supply system (manufacturers, wholesalers and pharmacists, taking account of their public health role). Particular attention is to be paid where generic prices are always defined as a fixed percentage of the originator price, regardless of the number of price-decreases of this originator. Such systems may lead generics being out-competed through consecutive price-reductions of the originator.

Cost containment mechanisms can create sufficient headroom that is needed for rewarding valuable innovation. This could also benefit from a holistic and long-term perspective, aiming for sustainable financing of healthcare, beyond pharmaceuticals.

## **Reward for Innovation**

Set expectations. Limited resources force authorities to make choices on what new products to reward and pay for. Through its pricing and reimbursement decisions, each Member States tends to grant incentives (e.g. a high price and reimbursement level, or good access to the market) for those new products that it really appreciates as bringing valuable improvements compared to the standard therapy. In this way, Member States indicate what they expect from pharmaceutical R&D to deliver. It is, therefore, important to reflect what are and will be the desired additional benefits and to allocate resources accordingly. (A separate paper has been prepared by the Working Group. This paper reflects the outcome of a survey of Member States on what they consider to be valuable innovation.

Recognise innovation. The degree of added value delivered by new medicines is often incremental and, therefore, harder to recognise. Companies should, therefore, be prepared to clearly prove this added value versus existing therapies and authorities should be prepared to recognise proven incremental benefits that are estimated valuable and reward them appropriately (i.e. with incremental price-premiums or with measures allowing a higher utilisation). Pricing and reimbursement mechanisms, as well as utilisation guidelines, should be in line with this and ensure a scaled recognition and reward. It should thus not be expected that incremental benefits would be rewarded with break-through premiums.

Where added value versus existing therapies cannot be proven and recognised, timing of market entry of a new medicine should be taken into account as well as its effects on competition. Products coming to market soon after the first-in-class originator are the result of a parallel R&D process and should be rewarded in parallel to the first-in-class originator. Products entering the market significantly later should not get a similar reward.

Be consistent when giving reward. Criteria for pricing and reimbursement need to be transparent, as requested by the Transparency Directive, and consistent over time. This gives the right signals to companies on what innovations are expected and valued. Research and development of a medicine is a risky and multi-year process, in particular for small and mid-size biopharmaceutical companies. The national pricing and reimbursement decisions and related decisions on the timing and utilisation are the only indicators that show whether it will be worthwhile starting this risky process.

In addition, overall cost-containment mechanisms, like price-cuts or payback, could be aligned with these initial decisions; they could, for example, foresee exemptions for those innovations that are considered very valuable and have been granted a consequent price and reimbursement level.

Working Group on Pricing, 14/05/2007

## **Core quality principles for patient information on diseases and treatment options**

High quality information must meet the criteria set out in these principles and should also have a clear process for compliance/certification. Information provided by a Member State and/or the European Commission should be done without restricting or replacing other sources.

### **Objective and unbiased**

Information is objective when it is based on facts and not influenced by prejudices or personal perceptions. Information is unbiased when it is impartial, non-directive and balanced.

These two definitions do not relate to the source of information which is a separate issue (see the 'Transparent' principle).

### **Patient oriented**

Information provided should be patient-centred taking into account patients' needs and expectations in order to empower patients. Patients should be involved in the production and dissemination of information on diseases and treatment options wherever possible.

### **Evidence-based**

The evidence base for any information resource needs to be clearly stated, including making clear the level of evidence. Information should be verifiable, based on comparisons and backed up by scientific peer review where possible.

### **Up-to-date**

Information should be kept up-to-date and the date of publication should be included.

### **Reliable**

Information needs to be factually correct and not misleading. Information should be scientifically valid and reflect latest knowledge.

## **Understandable**

Information provided should be comprehensible for a patient/citizen.

## **Accessible**

Information should be easily accessible via different mechanisms for example, through written documents, websites of certified official bodies etc. Information should also be accessible to people with disabilities.

## **Transparent**

Informed choice requires transparency. That entails transparency of what is known as well as what is not known. Funding, sources of information, evidence for that source and transparency when there is known controversy about a particular treatment, for example, all need to be made clear.

## **Relevant**

Information should include issues of relevance and importance to patients' decision-making e.g. including adverse effects. Impact on quality of life and the consequences of the disease on contribution of the patient to society/the work place are important elements of information on disease.

## **Consistent with Statutory Information**

Information not regulated by statute should, nevertheless, be consistent with the legal requirements of European law (e.g. must not be designed to promote a prescription only medicine, reflecting the prohibition of direct to consumer advertising of prescription only medicines, must not be misleading etc.) and should refer, where appropriate, to statutory information approved through the process of regulation.