

**High Level Pharmaceutical Forum
2005 - 2008**

Final Conclusions and Recommendations of the High Level Pharmaceutical Forum

On 2nd October 2008, the High Level Pharmaceutical Forum agreed on the following final Conclusions¹ and Recommendations².

The High Level Pharmaceutical Forum:

1. Was launched with the overall aim of exchanging best practice and examining efficiency gains within a European high level platform, as a way of contributing to ensuring patient access to medicines within a sustainable healthcare budget, and recalls its **initial mandate** to discuss the competitiveness of the European pharmaceutical industry and related public health considerations, with a specific focus on information to patients on disease and treatment options, relative effectiveness assessments and pricing and reimbursement of medicinal products.
2. Acknowledges that the three-year process has strengthened the understanding of the positions and concerns of all parties and demonstrated the added value of **working together** in a **consensus-based** manner, leading to the adoption of strategic **recommendations** and **priorities** for **future joint work**.
3. Welcomes the **political momentum** gained in the field of public health and competitiveness of the industry and, more precisely in **the three themes of the mandate**, which was built on **mutual understanding** among the interested parties and **common diagnosis** for the core issues. The continuous exchange of experiences established new networks among experts and enhanced the knowledge within national authorities and relevant stakeholders. The added value of this cooperation has led to the adoption of strategic **recommendations** and **priorities** for **future joint-actions** to be initiated within the three key themes.
4. Endorses the **recommendations** made in the specific themes of information to patients, relative effectiveness and pricing and reimbursement.
5. Emphasises the **fundamental role and responsibility** of each Member of the Forum in actively taking forward the agreed recommendations and reporting on their efforts.
6. Invites the Commission to facilitate the reporting from the Members and to engage in a **reflection process** in 2009 to identify the remaining challenges in these fields.

¹ In line with the competences as enshrined in the EC Treaty, the final Conclusions and Recommendations of the Pharmaceutical Forum are of a non-binding nature. Their implementations should reflect the overall objectives of the Pharmaceutical Forum and, therefore, contribute to the good usage of pharmaceuticals and efficiency of national healthcare systems.

² The recommendations provide guidance to address challenges as identified in the final Conclusions from the High Level Pharmaceutical Forum. The recommendations are the result of discussions, brainstorming and exchanges of practices in the different working groups set up under the Forum. The recommendations provide concrete implementing actions, addressed to the European Commission, interested stakeholders and the Member States themselves. All the recommendations are subject to the European and national legal provisions.

Information to Patients

The High Level Pharmaceutical Forum:

7. Is aware that patients and citizens increasingly expect quality information, particularly when related to their health, and recognises the urgent **challenge to invest** in high **quality** and **accessible** information on diseases and treatment options considering the **shared responsibility** of all engaged parties and the importance of empowered patients and citizens in general.
8. Recognises the role of **national authorities** to make the best information available and stresses the added value of **common principles, European methodologies** and **specific requirements** for information development. The Forum welcomes in this respect the recommendations put forward, notably the **quality principles** for health information, the **core elements** for information material, and the enhanced access to information in **healthcare settings** for the dissemination of information to patients.
9. Recognises the benefit of **mobilising the knowledge and resources** from different partners towards the generation of information and strongly calls **all actors** engaged in the field of information to patients **to take into** account the outcomes of the Pharmaceutical Forum for use in developing approaches and actions. Notes the role of existing partnerships and other collaborative approaches, bearing in mind that healthcare professionals and competent authorities remain primary sources of information on medicinal products and takes note of the Council Conclusion of 10 June 2008.³
10. Invites sound cooperation fostered by the wealth of national initiatives and recommends the Commission and the Members to consider all aspects related to the launch of a **European information library** of existing high quality information to patients. The Forum invites the Commission and the Member States to consider developing formal **strategies to improve health information to ensure coherent approaches both at national and at European level**.
11. Stresses the need to enhance health literacy as a policy at EU and Member State levels. Recommends that future EU policy on information to patients on diseases and treatments should move towards new approaches in a coordinated manner, built on dialogue with stakeholders, promoting health literacy and health information in the broadest sense.

Recommendation 1: Enhance quality of information

1.1 The Forum recognises that the mandate of the Pharmaceutical Forum is part of a broader health information context, as identified by a number of important elements which Member States and the Commission should commit themselves to taking into consideration when developing work in this field.

³ Council Conclusions on the Communication from the Commission to the European Parliament and the Council concerning the report on current practices with regard to provisions of information to patients on medicinal products, in accordance with Article 88a of Directive 2001/83, as amended by Directive 2004/27/EC on the Community code relating to medicinal products for human use.

1.2 All the relevant players, including national competent authorities, the Commission, public health stakeholders and industry⁴, should ensure high quality information and thereafter should commit themselves to implementing and using the core quality principles and their methodology of use for the development of information, and to identifying poor quality information.

1.3 The Forum recognises the added value for patients and citizens of providing information on medical conditions jointly with information on treatment options. All the relevant players should ensure that the identified key elements for information to patients on medical conditions and treatment options are taken into consideration when information to patients is produced, assessed and improved.

1.4 The Commission should consider using the EU Health Portal to raise the visibility of good information sources and ensure that all principles developed by the Forum are applied. Member States and stakeholders, with the assistance of the Commission, should commit themselves to continuing to share information about new initiatives regarding information that are in line with the principles.

1.5 The Commission together with the Member States and the relevant stakeholders should consider developing a common approach to quality assurance of information.

1.6 The ban on advertising of prescription medicines to the general public should continue.

Recommendation 2: Increase accessibility and dissemination of Information

2.1 Member States, stakeholders and the Commission should accelerate their engagement toward generation of information to citizens in effective communication formats (electronic and non-electronic means), taking account of local traditions, healthcare systems and languages. To initiate the process, Member States, stakeholders and the Commission are invited to implementing the specific recommendations identified to increase accessibility and dissemination of health information in the various healthcare settings.

2.2 The Commission should commit itself to making visible the best practices identified in the Member States and to promoting cooperation between the Member States and the relevant stakeholders to further exchange experiences.

2.3 The European Medicines Agency should continue, and be financially enabled to continue, its efforts in improving the database on medicinal products authorised in the EU as foreseen in Article 57, 1(l) of Regulation (EC) No 726/2004 and its cooperation with Member States and stakeholders with regard to information on medicinal products.

⁴ AIM expresses some reserve concerning the involvement of industry in providing information to patients

Recommendation 3: Generation of information by making the best use of all actors

3.1 Member States, the Commission and other stakeholders should take note of existing partnerships and collaborations between the various parties that mobilise knowledge and resources for producing and disseminating information to patients.

3.2 Member States, the Commission and other stakeholders should exchange information about the different approaches existing across Europe in the choice of partners, structures and responsibilities. They should also consider whether further collaborations could be created.

3.3 Where such partnerships and collaborations are set up, Member States and stakeholders should commit themselves to respecting the minimum ethical requirements of i) transparency, ii) disclosure of financial and other support and iii) definition of responsibilities as identified in the Forum process.

3.4 The Commission should raise the visibility of existing partnerships and collaborations, for instance by using the EU Health Portal⁵, which respect the ethical guidance and produce information in line with the core quality principles.

Recommendation 4: Continued momentum on Information to patients

4.1 The members of the Pharmaceutical Forum are invited to disseminate the outcomes of the Forum to all interested parties and citizens, e.g. through workshops.

4.2 Member States and the relevant stakeholders are expected to ensure that the recommendations are followed up at national level. Member States and the Commission in cooperation with the relevant stakeholders should within the next two years undertake a first review of what exists, and what has been created and/or improved following the recommendations from the Pharmaceutical Forum in the field of information to patients.

4.3 Further cooperation and sharing of experiences at EU level is needed, and thus the Commission should set up a process building on the Information to Patients working group to evaluate the direct outcomes and follow-up of the Pharmaceutical Forum.

Relative Effectiveness

The High Level Pharmaceutical Forum:

12. Recalls that the evaluation and the decision making process leading to decisions on the pricing and reimbursement of pharmaceutical products lie with the national competent authorities.

13. Acknowledges the **distinction between the scientific assessment** of the relative effectiveness of medicinal products and **health-economic assessments** of their costs and benefits. Endorses the aim of relative effectiveness assessment to compare

⁵ The health portal is accessible at http://ec.europa.eu/health-eu/index_en.htm

healthcare interventions in daily practice and classifying them according to their added therapeutic value.

14. Acknowledges, in this respect the **importance for Member States of exchanging information** on their respective relative effectiveness assessment criteria, systems and activities in order to i) consolidate the scientific evidence on relative effectiveness by collecting data, processes and conclusions reached at national level, for purposes of comparison, where appropriate, ii) facilitate the work of the pricing and reimbursement authorities by providing them with consolidated scientific evidence, and iii) inform health-care professionals and patients on the most effective medicines.
15. Endorses the **working definitions on efficacy, relative efficacy, effectiveness and relative effectiveness** which will serve as a common understanding for future exchange of information between all parties involved and calls on Member States to **take these definitions into account** when developing and implementing systems of relative effectiveness assessment.
16. Endorses the **good practice principles**⁶ for relative effectiveness assessment that will set the scene for the scope of future work and invites Member States to take them into account in developing and implementing systems of relative effectiveness assessment.
17. Welcomes the **check-list**⁷ **on the use of the agreed principles**, which could be used as a basis for a future toolbox for all interested parties involved.
18. Welcomes the significant added value of the **first set of information gathered in Member States on data availability and needs and on the methodologies** used to conduct relative effectiveness assessments for medicinal products sampled. Welcomes the conclusions and recommendations⁸ reached, as regards i) the need to improve data availability on relative effectiveness throughout the product life cycle⁹, notably post-market data and ii) the need to address barriers of all kinds, including legal ones, that can prevent Member States and stakeholders from exchanging data.
19. Acknowledges the fact that **more substantial work remains to be done** as regards: i) the development of methods for the transferability of such data and ii) the need to consider how information in the European Public Assessment Report and the National Public Assessment Report, as foreseen in Article 13(3) of Regulation (EC) No 726/2004 and Article 28 of Directive 2001/83/EC, can further contribute to relative effectiveness assessment.
20. Welcomes, in this respect the important added value of the mapping exercise of existing networks involved with relative effectiveness assessment at European level which could take these recommendations forward. Notes that the mapping exercise concludes that this objective would be achieved more effectively by an **existing network** rather than by setting up a new one.

⁶ See annex

⁷ See annex

⁸ See annex

⁹ AIM and ESIP recall that the major conclusion of the exercise on the availability of data was that there are not enough data to assess relative effectiveness at the time this first needs to be done and even later on. Exploring ways to generate the data needed to make relative effectiveness assessments on a sounder scientific basis should be done.

21. Considers that the Commission, in consultation with the Members of the Forum, should look together with the relevant networks at how they could take forward the work that needs doing, distinguishing as appropriate, between policy-related and scientific actions.

Recommendation 5: Implement agreed good practice principles for Relative Effectiveness assessments

5.1 Member States and stakeholders - the pharmaceutical industry, social insurers, health care professionals and patients' organisations- are encouraged to adopt the agreed working definitions¹⁰ on efficacy, relative efficacy, effectiveness and relative effectiveness and to use them in the scientific literature and reports of all kinds. The use of these common definitions will ensure a common understanding of the work done at national level and will facilitate the exchange of information between all parties involved.

5.2 Member States and stakeholders are encouraged to implement the agreed best practice principles¹¹ for relative effectiveness assessment and to regularly communicate and exchange information on their adoption, where appropriate. Such implementation should also ensure medicines receive fast access to market and appropriate reward¹².

Recommendation 6: Promote the exchange of information on relative effectiveness assessments in order to improve the data availability and transferability

6.1 Member States and stakeholders are encouraged to regularly exchange information in order to achieve the objectives set out in the conclusions, namely: i) to consolidate the scientific evidence on relative effectiveness by collecting data, processes and conclusions reached at national level, for purposes of comparison, where appropriate, ii) to facilitate the work of the pricing and reimbursement authorities by providing them with this consolidated scientific evidence, focusing on their priority areas and iii) to inform health-care professionals and patients on the most effective drugs.

This exchange should also aim to identify any barriers, whether scientific, technical or legal, that prevents all the parties involved from circulating the information easily.

6.2 In particular this exchange of scientific evidence should focus on the need to:

- i) improve the understanding of the scientific evidence generated that can be used for relative effectiveness by sharing best-practice in terms of data requirements and processes;
- ii) increase the understanding among those involved in relative effectiveness assessments of the possibilities and limitations in the generation of data that can be used for relative effectiveness assessments during and after the granting of marketing authorisation;
- iii) explore better avenues for dialogue between assessing bodies and/or decision-makers and the marketing authorisation holder to address point i);

¹⁰ See annex

¹¹ See annex

¹² AIM and ESIP highlight that this last sentence was suggested by some members of the Steering Committee and not agreed upon in the working group. Further the issues of market access and reward for innovation were topics of the working group on pricing not relative effectiveness and should therefore not be included in the recommendations of the working group on relative effectiveness.

iv) strengthen the methodological quality and rigour of relative effectiveness assessments and identify any scope for common approaches in certain areas of assessment, as appropriate;
v) inform health-care professionals and patients on the most effective medicines

6.3 National authorities and companies should also consider ways of having early dialogue during product development to improve the generation of appropriate data as far as possible.

6.4 Member States, with the involvement of the European Medicines Agency, should continue their efforts to consider how European Public Assessment Report and the National Public Assessment Report can further contribute to relative effectiveness assessments.

6.5 In an effort to streamline the exchange of such information and to ensure effective EU-wide coverage of relative effectiveness assessments, Member States and the Commission should identify how existing networks could be involved and any support that might be needed. Member States and the Commission should also address the issue of the involvement of stakeholders, while observing the above agreed principles.

Pricing and Reimbursement

The High Level Pharmaceutical Forum:

22. Welcomes the development of a shared understanding that **pricing and reimbursement policies need to balance** (1) timely and equitable access to pharmaceuticals for patients all in the EU, (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.

23. Welcomes the identification, analyses and development of options addressing more specifically **access issues** like orphan medicines and small national markets. The Pharmaceutical Forum considers that patients in the EU should have equitable access to medicines. It therefore invites all Member States, all stakeholders and the European Commission to effectively ensure an equitable access by taking up the suggested options forward.

24. Recognizes the development of common knowledge on what kind of **innovation** is expected and **valued** as well as on how value assessments can translate into pricing and reimbursement decisions. The Pharmaceutical Forum considers that clear and common expectations, together with consistent pricing and reimbursement decisions, can motivate the development of highly needed medicines. It therefore invites all Member States, stakeholders and the European Commission to collaborate towards these two goals.

25. Recognizes the development of several knowledge initiatives related to pricing and reimbursement and to the **control of pharmaceutical expenditure**. The Pharmaceutical Forum considers it necessary that pricing and reimbursement policies and practices are based on good knowledge, including data, facts and experiences exchanged between different Member States and stakeholders. It therefore invites all

Member States, stakeholders and the European Commission to further develop a joint knowledge basis.

Recommendation 7: Access to medicines for EU citizens

7.1 Member State authorities and stakeholders of the Pharmaceutical Forum should strengthen their efforts in ensuring timely access to valuable innovations and in ensuring access to medicines for all citizens. Member States should do so following the requirements laid down in the Transparency Directive (89/105/EEC).

7.2 Member State authorities and stakeholders of the Pharmaceutical Forum should strengthen their efforts in ensuring sustainable availability and delivery of medicines to all EU Member States, in particular to small national markets. They are therefore called upon to take up the appropriate ideas developed in the Working Group Pricing and in other relevant fora. This should be done in parallel and in collaboration with regulatory efforts, taking into account the work of the Heads of Medicines Agencies¹³.

7.3 Member State authorities, stakeholders and the Commission should strengthen their efforts to ensure access to orphan medicines in all EU Member States. They are therefore called upon to take up the appropriate ideas developed in the Working Group Pricing regarding i) early dialogue on research and development, ii) exchange of knowledge on the scientific assessment of the clinical added value, iii) specific pricing & reimbursement mechanisms and iv) increased awareness on orphan diseases.

Recommendation 8: Expect, Identify and Reward Valuable Innovation

8.1 Member States are called upon to set clear and common expectations on what innovation they consider valuable and would reward. This will give companies a clear direction on healthcare priorities and indications on the evidence needed by authorities, while bringing authorities clarity on the mid- to long-term budget needs. Companies are called upon to deliver the innovative medicines that society needs. Cooperation with patient organisations should also be encouraged.

8.2 National pricing and reimbursement policies should reflect and recognize these expectations and give a consistent reward to benefits considered valuable.

8.3 National systems on pricing and reimbursement should therefore be well aligned with systems that assess the value of medicines.

Recommendation 9: Optimal use of resources

9.1 Optimal use of national budgets should take into account patients' needs.

9.2 National pricing and reimbursement policies should ensure an efficient use of price control, a consistent package of supply- and demand-side measures and the right environment

¹³ See the Report of the task force of the Heads of Medicines Agencies MG, "Availability of Human Medicinal Products – 2007" http://www.hma.eu/uploads/media/Availability_medicines_HMAMG_TF_Report.pdf

for price competition. Member States should secure the principle that a Member State authority to regulate prices in the EU should extend only to those medicines purchased by, or reimbursed by, the State. Full competition should be allowed for medicines not reimbursed by State systems or medicines sold into private markets.

9.3 National pricing and reimbursement practices should take account of experiences in other Member States. The mutual exchange of knowledge and experiences should be continued and fostered.

9.4 Further knowledge and experience should be gathered and exchanged regarding tendering, conditional pricing / risk sharing and utilisation of generic medicines.

Recommendation 10: Continued momentum on Pricing and Reimbursement

10.1 Member States, the Commission and relevant stakeholders are called upon to take into account the above recommendations in policy developments. Member States and the Commission, in cooperation with relevant stakeholders, should within the next 2 years undertake a first review of progress following the recommendations from the Pharmaceutical Forum in the field of pricing and reimbursement.

10.2 Further cooperation and exchange of experiences at EU level is needed. The Commission, in cooperation with Member States, is called upon to build on and bridge the work of the Pricing and Reimbursement Working Group and the Relative Effectiveness Working Group in order to evaluate the direct outcomes and follow up of the Pharmaceutical Forum.

Annex:

Pharmaceutical Forum Reference Documents

The reference documents are the result of discussions, brainstorming and exchanges of practices in the different working groups set up under the Forum.

1. Information to Patients

- Overview of practices on access of health information in health care settings
- Recommendations to enhance access to information using health care settings
- Core quality criteria and a Methodology for use of the core quality criteria
- Diabetes information example package
- Summary of research: equipping patients to distinguish good quality health information
- Key elements for information to patients
- Overview and explanatory document on different partnerships providing information to patients
- Ethical guidance with regard to partnerships
- Wider Health Information – looking at the future

2. Relative Effectiveness Assessments

- Core principles on relative effectiveness assessments
- Study on the availability of data to conduct relative effectiveness assessments
- Overview of existing networks and recommendations for the development of networking and collaboration on relative effectiveness assessments

3. Pricing and Reimbursement

- Guiding principles for good practices implementing a pricing and reimbursement policy
- Ensuring access to medicines in small national markets in Europe
- Improving access to orphan medicines for all affected EU citizens
- Characterisation of the value of innovative medicines
- From assessing innovative value of pharmaceuticals to pricing and reimbursement decisions
- Risk sharing practices and conditional pricing of pharmaceutical
- The Toolbox exercise