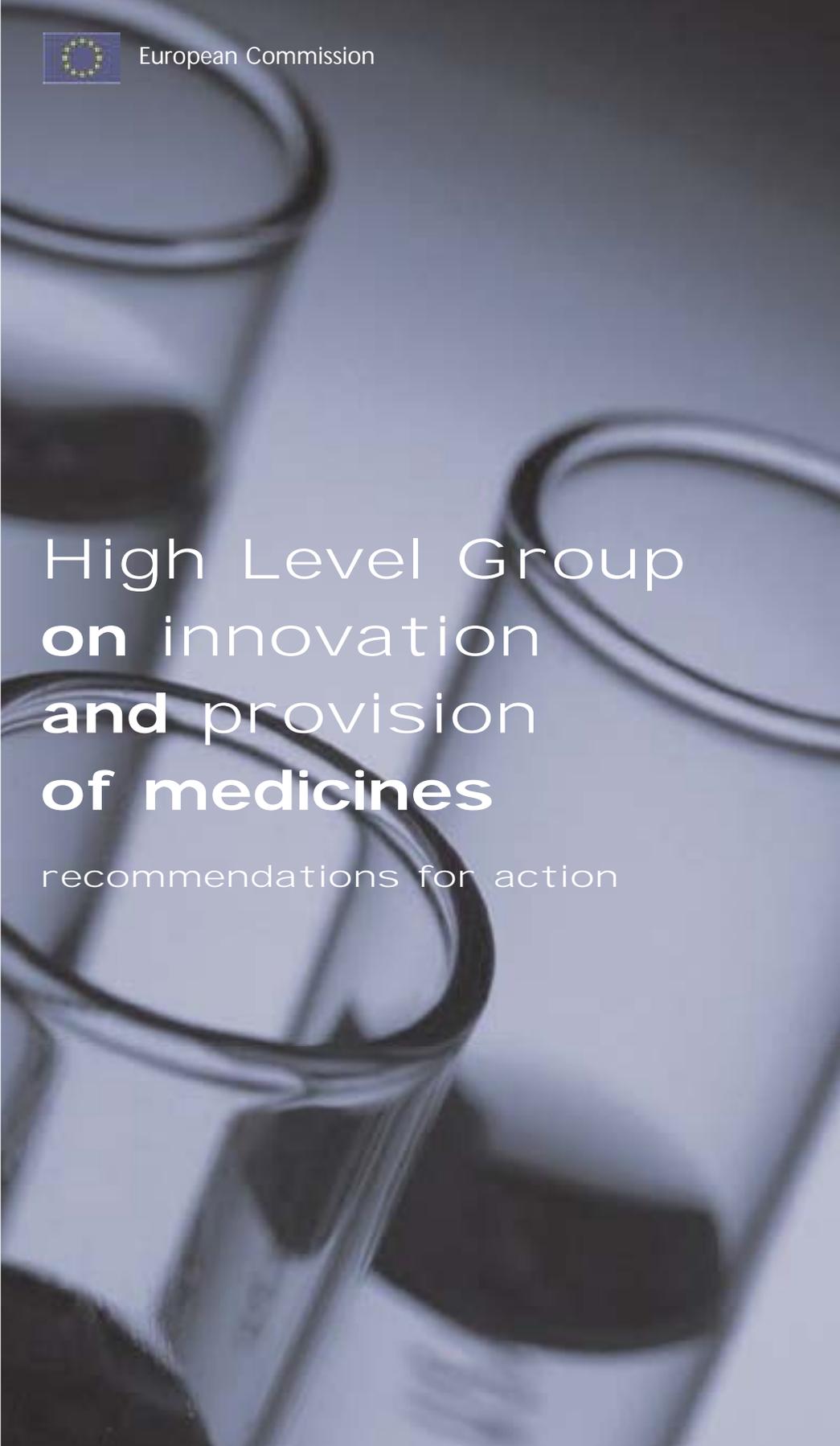




European Commission

A close-up, blue-tinted photograph of several glass beakers and test tubes in a laboratory setting, arranged in a grid-like pattern.

# High Level Group on innovation and provision of medicines

recommendations for action

A vertical strip of three images with a warm, orange-gold tint. The top image shows a doctor's hands using a stethoscope on a patient's arm. The middle image shows a silhouette of a person with arms outstretched against a bright, hazy background. The bottom image shows a doctor smiling and talking to a patient lying in a hospital bed.

07 May 2002

G10 MEDICINES - REPORT

This report was prepared by the High Level Group on Innovation and Provision of Medicines and published on their behalf by the European Commission.

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A great deal of additional information on the European Union is available on the internet. It can be accessed through the Europa server (<http://europa.eu.int>).

More information on the work of the High Level Group can be found on the G10 Medicines website (<http://pharmacos.eudra.org>).

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High Level Group  
**on** innovation  
**and** provision  
**of medicines**

recommendations for action



G10 MEDICINES REPORT

# Preface

This report represents a significant achievement. The European-based pharmaceutical industry is a key industrial sector for the European Union and makes a strong contribution to the development of the European science base and in developing and delivering high quality medicines to patients. The Report looks at ways we can build on this to improve the competitiveness of the industry while meeting important public and social objectives.

The Report recognises that progress can only be made by looking at action at both a European and a national level and by considering competitiveness issues in the light of achieving public health and social objectives. This reflects the commitment in Article 3 of the Amsterdam Treaty for European Communities to seek a high level of health protection across all Community policies. Although this approach has added to the complexity of the Group's work it was vital, for its long-term success, that they were addressed together from the beginning. Equally this is not an issue that can just be dealt with at an EU level, it must equally be addressed by member states.

The enclosed report bring to fruition a process which represents a real departure for industry and public health in the European Community. The G10 Medicines Group was convened as a practical measure, in line with the « Lisbon Method » of Open Co-ordination to bring together, under European Commission chairmanship, a variety of people who were asked to identify possible solutions on which it has proved difficult in the past to gain agreement.

The Group are to be congratulated for not avoiding difficult issues such as cost-effectiveness, information to patients etc. where, traditionally, it has been difficult for industry and social partners to establish consensus. The fact that some measure of consensus has been achieved is a tribute to the flexible way the Group has worked together.

The report provides a signpost to a sensible and practical way forward.



A handwritten signature in black ink, appearing to read 'Erkki Liikanen'.

**Erkki Liikanen,**  
Member of the European  
Commission responsible for  
Enterprise and Information Society



A handwritten signature in black ink, appearing to read 'David Byrne'.

**David Byrne**  
Member of the European  
Commission responsible for Health  
and Consumer Protection

G10 MEDICINES REPORT

# Membership



**Bernard Kouchner**  
Minister for Health, France



**Ulla Schmidt**  
Federal Minister for Health, Germany



**Lars Rekke,**  
Secretary of State for Industry, Employment  
and Communications, Sweden



**Erkki Liikanen,**  
Commissioner for Enterprise and  
Information Society



**Francisco Ramos,**  
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**Angela Coulter,**  
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**Chris Viehbacher**  
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**Alessandro Banchi,**  
President of the Association of the  
European Self-Medication Industry



**David Byrne,**  
Commissioner for Health and  
Consumer Protection



**Philip Hunt,**  
Parliamentary Under Secretary of State  
for Health, United Kingdom



**Jean-François Dehecq,**  
President of the European Federation of  
Pharmaceutical Industry Associations



**Andrew Kay,**  
Chairman of the European Generic  
medicines Association



G10 MEDICINES REPORT

# Content

<b>Introduction</b>	<b>8</b>
<b>Report</b>	<b>10</b>
1 – Benchmarking: Competitiveness and Performance Indicators	11
2 – Competition, Regulation, Access and Availability in Markets	12
3 – Stimulating Innovation and Improving the EU Science Base	18
4 – Patients	20
5 – Enlargement	23
<b>Next Steps</b>	<b>24</b>
<b>Annexes</b>	<b>25</b>
Annex A – Terms of Reference	25
Annex B – G10 Medicines Member CVs	28

G10 MEDICINES REPORT

# Introduction

The High Level Group on Innovation and Provision of Medicines – The G10 Medicines Group - was set up following a symposium on Pharmaceutical Industry Competitiveness held in December 2000.

The Symposium considered a report on “Global Competitiveness in Pharmaceuticals – A European Perspective”<sup>(1)</sup> by Professors Gambardella, Orsenigo and Pammolli. This Report concluded that “Europe as a whole is lagging behind in its ability to generate, organise, and sustain innovation processes that are increasingly expensive and organisationally complex”.

Commissioners Liikanen and Byrne created the G10 Medicines Group to explore ways of improving industry competitiveness in Europe while encouraging high levels of health protection.

## Objective

The objective of the Group is to review the extent to which current pharmaceutical, health and enterprise policies can achieve the twin goals of both encouraging innovation and competitiveness and ensuring satisfactory delivery of public health and social imperatives. The full Terms of Reference for the Group are attached at Annex A.

## Membership

The membership of the G10 Medicines Group was limited in order to ensure that all were able to fully contribute and play an equal role in discussions. The membership of the Group consisted of representation at the highest level from different administrations and organisations. The overall aim was to ensure that as broad a range of interests as possible was covered while keeping numbers manageable.

The full list of members is attached at Annex B. The membership consisted of Health and Industry Ministers from five Member States, representation from different sectors of the industry, mutual health funds and a specialist in patient issues. The Group was chaired jointly by the Commissioners for the Directorate-General for Enterprise and the Directorate-General for Health and Consumer Protection.

## Timetable

The Group set itself a target of one year within which to prepare a report for Commissioner President Prodi. The first meeting of G10 Medicines was on 26 March 2001 followed by meetings in September 2001 and February 2002.

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<sup>(1)</sup> Published as an Enterprise Paper No 1 – 2001.  
Available from the European Commission's Information and Communication Unit, Rue de la Loi 200 (fax: +32-2-296 99 30 / e-mail: [entr-information-communication@cec.eu.int](mailto:entr-information-communication@cec.eu.int))

## Methodology

It was agreed that the Group should operate using the "Lisbon Method" in which the Commission provides a facilitating role to help the members develop practical recommendations.

The Group decided to approach its work by dividing it into the following three broad agenda areas, as set out in the terms of reference:

- Group 1 - Provision of Medicines to patients;
- Group 2 - Single Market, Competition and Regulation; and
- Group 3 - Innovation.

Three working groups were created to take work forward in each area. Key issues raised in these working groups and broad conclusions reached were combined into a consultation document which was issued for public consultation on 27 September. The primary purpose of the consultation exercise was to seek the views of other stakeholders not directly represented on the G10 Medicines Group.

In addition to launching the consultation exercise, the G10 Medicines Group also took two other measures to increase the transparency of the G10 Medicines process – the creation of a G10 Medicines website and a programme of workshops to examine specific issues in more detail.



G10 MEDICINES REPORT

# Report

The G10 Medicines process, through its working groups, consultation and workshops has generated a wealth of ideas and possible ways forward. However, in order to agree on some practical actions to be pursued, the Group decided to focus on a small core of recommendations.

The following criteria were used as a basis for agreeing the final set of recommendations:

- Recommendations were to be practical and realistic;
- The entire package of recommendations should be agreed by all G10 Members;
- The package of recommendations must find the right balance between health objectives and industry competitiveness.

The G10 Medicines Group reached a consensus on the recommendations set out in this report. This has been achieved through a common commitment to co-operative working relationships and the fact that the following recommendations should be agreed as a package. Each member of the group may have some reservations about one or more of the recommendations but believes that, as a package, they represent an acceptable balance between competing interests and a practical framework for future action.

The Group's recommendations are set out in the next section.



1

# Benchmarking: Competitiveness and Performance Indicators

At the heart of the G10 Medicines process was the examination of the individual factors affecting the competitiveness of the EU-based pharmaceutical industry alongside its ability to contribute to the delivery of European health objectives. There is no shortage of data and performance indicators on the pharmaceutical industry, much of it highlighted in the “Global Competitiveness in Pharmaceuticals” Report. However, what is missing is a benchmarking exercise to establish an agreed set of EU indicators on which to make comparisons between the EU and its major competitors as a basis for establishing best practice within the EU.

Another critical issue is to ensure that such an exercise extends to public health objectives. The assessment of competitiveness indicators alone will not allow a full assessment of the value and role of the pharmaceutical industry. The medicines developed by the pharmaceutical industry have a critical role in preventing and treating diseases and this should be reflected in the benchmarking exercise.

The Group’s Terms of Reference committed it “to arrive at a “benchmarking” exercise, which will examine the ways in which these systems operate,

and suggest best practice for the future”. This exercise should be developed by the Commission in close co-operation with Member States. The Group recognised that this would not be straightforward given the differences in regulatory structures between Member States but argued that it needed to be achieved if existing and subsequent policies in this area were to be effectively assessed. Such an exercise should also highlight where potential problems lie as regards market availability, access and uptake in each Member State.

## RECOMMENDATION 1

The development by the Commission of a comprehensive set of indicators covering:

- the performance of the pharmaceutical industry in relation to indicators of industrial competitiveness;
- and the prevention and treatment of diseases and emerging health threats with reference to data on morbidity and mortality including the performance of products;
- and the relationship between the various EU and Member State regulatory structures (licensing, pricing and reimbursement) and availability (time to licence, time to market) access and uptake of pharmaceuticals.



2

## Competition, Regulation, Access and Availability in Markets

### Access to Innovative Medicines

The EU already has in place a comprehensive system of regulation of medicines. The primary purpose of this system is to ensure that medicines are only placed on the market where they meet stringent standards of quality, safety and efficacy. These controls are supplemented by additional measures requiring the distribution and supply of medicines to be strictly controlled to ensure not only proper handling but also to facilitate the withdrawal of defective products. This is only right as medicines are not ordinary items of commerce. However, once a medicine has been assessed as meeting these standards it should be available on the market as quickly as possible for the benefit of patients and industry.

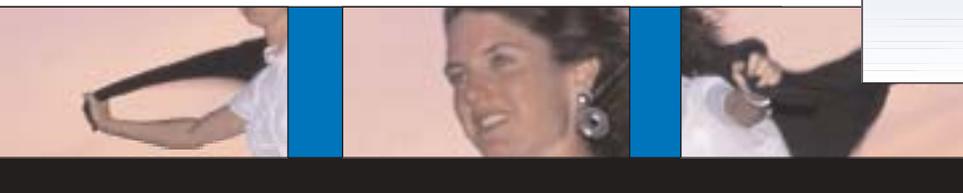
This is particularly critical where important new innovative medicines have been developed to treat serious diseases. Innovative medicines include those which are either more effective, or cause fewer or milder adverse effects, or are easier to use than existing ones used for the same purpose, although not all commercial innovations have the same therapeutic value. Not only should the assessment of these medicines be quick and robust but, once it has been made, they should reach the market as soon as possible.

In recent years significant progress has been made in speeding up the assessment of all applications, particularly with the introduction of European Centralised and Mutual Recognition licensing procedures in 1995 which contain statutory time limits. Nevertheless, the regulatory procedures must continue to give priority to ensuring that medicines reach the market as quickly as possible. The review of the pharmaceutical legislation (the "Review 2001") must have this as a priority.

#### RECOMMENDATION 2

To secure the development of a competitive innovative-based industry:

- that the European Institutions should, as part of the review of Community pharmaceutical legislation now underway, consider ways of improving the legislation or the operation of the licensing system to improve the introduction to the market in particular for innovative medicines; and
- that the European Institutions and Member States should improve the use of telematics to facilitate the operation of the Community regulatory system.



## Timing of Reimbursement and Pricing Negotiations

Improvements to the existing EU structure of regulatory controls, as recommended above, would make a substantial contribution to improving the access to market of medicines. There can often be considerable delays to medicines reaching the market once a marketing authorisation has been awarded. The price negotiating systems and reimbursement structures in a number of Member States can lead to significant delays. This is not only a problem within those Member States, but it can also result in citizens of one Member State having access to new medicines months, or even years, in advance of those in other Member States.

Pricing and reimbursement structures for medicines fall within the competence of Member States, but the Group believes that much could be done to improve the speed and transparency of national decision-making in this area. Greater transparency would allow industry and other regulators a clearer understanding of the criteria used in each Member State and lead to greater consistency of decisions. Negotiations on pricing and reimbursement should also begin quickly following the grant of a marketing authorisation.



### RECOMMENDATION 3



Respecting national competence, Member States should examine the scope for improving time taken between the granting of a marketing authorisation and pricing and reimbursement decisions in full consistency with Community legislation. To do this with a view to securing greater uniformity and transparency between markets and rapid access of patients to medicines.



## Competitive Generic Market

Patients should have access to new and innovative medicines as soon as possible. However, this must be ensured in parallel with the development of an effective generic market within the EU. The extent of generic penetration in each Member State varies enormously and is dependent on a number of factors such as market conditions for new medicines, pricing/reimbursement structures, prescribing/dispensing traditions and requirements and specific incentives in place to encourage generic use.

Although policies on the use of generic medicines fall, primarily, within the competence of Member States there is an important role for the European Institutions to ensure that there is an appropriate regulatory framework governing their use. In particular, to find an appropriate balance between encouraging and rewarding the development of innovative medicines and creating a genuine market in generic medicines. This can partly be achieved by

ensuring that the licensing procedures allow quick access to the market for generic medicines. Moreover, it is equally important to ensure an appropriate balance between providing sufficient intellectual property protection for innovative medicines and the introduction of a Bolar provision (to ease access to the market for generic medicines).

The EU Institutions could also play a role in facilitating consideration of how Member States could improve generic penetration of their markets where they choose to do so.

### RECOMMENDATION 4

To secure the development of a competitive generic market in Europe, that:

- the European Institutions agree a way forward on intellectual property rights issues (especially data exclusivity and Bolar) covered in the Commission's proposed legislation.
- Member States - facilitated by the Commission - explore ways of increasing generic penetration in individual markets (including generic prescribing and dispensing). Particular attention should be given to improved market mechanisms in full respect of public health considerations.



## Competitive Non-prescription Market

In addition to the critical innovative and generic sectors, there is the growing and important non-prescription sector. The range of medicines available for self-medication is expanding significantly in some Member States. Reclassifying medicines to non-prescription status can contribute to the empowerment of patients by allowing them to make their own treatment choices. It can have an impact on public health costs and ease the burden on busy healthcare professionals.

The existing regulatory structure already sets out the safety criteria for awarding non-prescription status to medicines. Mechanisms for industry to apply for reclassifications of existing licensed medicines are well established in a number of Member States. To ensure the continuing development of the non-prescription market in the EU the existing mechanisms should be reviewed. For medicines

whose indications are currently under prescription but which are regarded as potentially suitable for self-medication, a regulatory switch mechanism should be in place encompassing appropriate safety measures (e.g. limited indications, limited package size, adapted patient leaflets). The use of the same trademarks for medicines reclassified to non-prescription status is acceptable as long as full account is taken of safety requirements to clearly distinguish between prescription and non-prescription versions of the same medicine. This should be preceded, as appropriate, by research into the suitability of these medicines for self-medication.

### RECOMMENDATION 5

To meet public health objectives in Member States and to secure the development of a competitive non-prescription medicines market in the EU (respecting that the reimbursement of medicines remains in the Member States' competence) by:

- reviewing, with full respect to health criteria, and, if appropriate, amending mechanisms and concepts for moving medicines from prescription to non-prescription status; and
- allowing the use of the same trademark for products moved to non-prescription status.



## Full Competition for Medicines neither Purchased nor Reimbursed by the State

As has been recognised earlier, there is a wide variety of pricing and reimbursement schemes practised by Member States in the EU. These schemes generally cover most if not all the medicines available in their market. The objective of these schemes is to ensure that all medicines required to maintain high levels of public health are made accessible to the public. However, there are categories of medicines that are not reimbursed, often non-prescription medicines and those supplied outside the state sector in private hospitals etc.

The Group believes that, as a matter of principle, medicines which are neither purchased nor reimbursed by the State should be open to full competition. This would not in any way undermine the existing right of Member States to establish which medicines they choose to reimburse or what pricing/reimbursement scheme they wish to operate. However, this might help to establish a viable market outside the state sector for some medicines. It could also provide an opportunity to develop a genuine EU-wide single market for non-reimbursed medicines including the possibility of a pan-European price.

### RECOMMENDATION 6



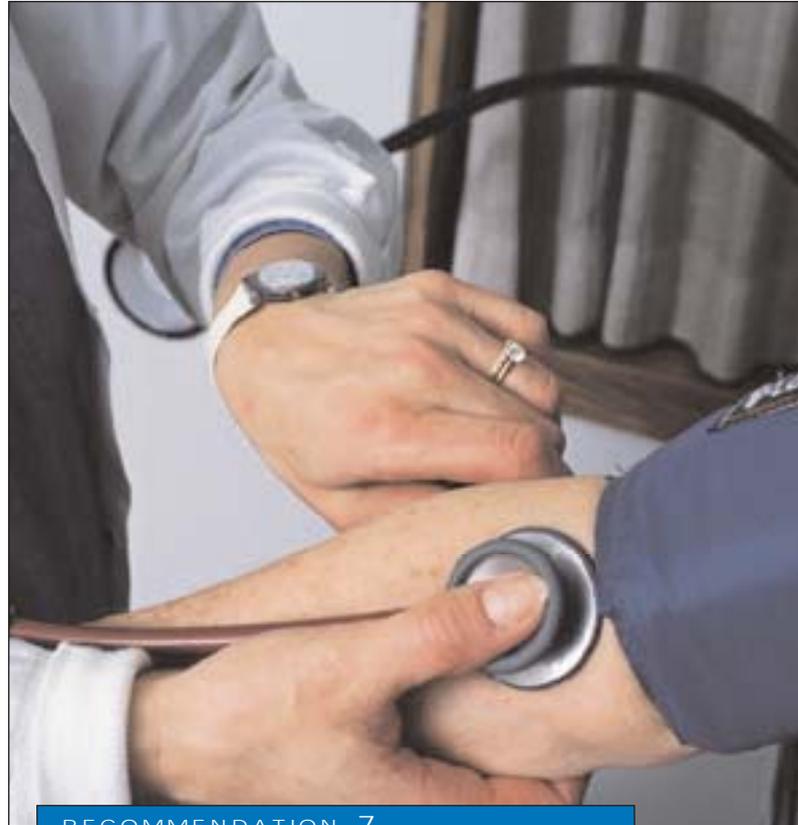
That the Commission and Member States should secure the principle that a Member State's authority to regulate prices in the EU should extend only to those medicines purchased by, or reimbursed by, the State. Full competition should be allowed for medicines not reimbursed by State systems or medicines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



## Relative Effectiveness

The existing EU regulatory structure governing the control of medicines is focused on ensuring that all medicines meet high standards of quality, safety and efficacy. Member States are increasingly supplementing this with national requirements concerning the relative clinical and cost-effectiveness of medicines to ensure the efficient use of increasingly scarce resources. Although the assessment of relative effectiveness is a matter of national competence, there could be value in facilitating the exchange of information on national practices between Member States. This should include reviewing, analysing, and supporting the exchange of experiences on, health technologies, including new information technologies.

This increased transparency should improve the quality, consistency and speed of reimbursement and pricing decisions across the EU and provide industry with a clearer understanding of the criteria used and the reasons for their use.



### RECOMMENDATION 7

- The Commission should organise a European reflection to explore how Member States can improve ways of sharing information and data requirements to achieve greater certainty and reliability for all stakeholders, even if the decisions they take may differ.
- The objective is to foster the development of health technology assessment (HTA), including clinical and cost effectiveness, in the Member States and the EU; to improve the value of HTA, to share national experiences and data while recognising that relative evaluation should remain a responsibility of Member States.



3



## Stimulating Innovation and Improving the EU Science Base

### Virtual Institutes of Health

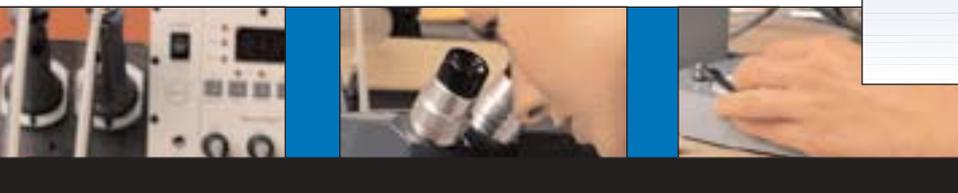
An effective dynamic science base in Europe is fundamental to ensuring the continuing development of innovation and research in the pharmaceutical industry in the EU. However, the effective exploitation of the science base in the EU is hampered by relatively weak links between research centres in different Member States. The science base is often further fragmented between Member States due to poor collaboration between public and privately funded research.

The Group believes that to exploit effectively the high quality research that exists in Europe there has to be much greater integration of research across national borders within the EU. This should help foster a critical mass of research in particular areas and allow much greater commercial exploitation of research.

#### RECOMMENDATION 8



The creation of the European virtual institutes of health, connecting all existing competence centres on fundamental and clinical research into a European network of excellence.



## Incentives for Research

A strong science base depends on public understanding, support and involvement. In particular, clinical trials require high participation rates if they are to be conducted efficiently and effectively. Greater transparency in the process of medicines evaluation, publicly accessible trial registers and public involvement in trial design, implementation and assessment would make an important contribution to improving public understanding of medicines R&D. The greater integration of the European science base must be actively supported at EU and Member State level. The European Commission, Member States and industry should work together to adopt and implement policies that promote disclosure and public engagement in research. These are essential to gain and retain the trust and support of patients and the public. The co-ordination of clinical trials on a European scale would help to make existing clinical trials more effective and reduce the risk of duplication. Underpinning this with a database of trials and clinical research results would provide an invaluable tool for health professionals, patients, members of the public and researchers, both public and private, throughout Europe. There should also be an examination of the new Clinical Trials Directive to ensure that its implementation does not place an excessive bureaucratic burden on both public and industry-driven clinical research.

Public health priorities should be taken into account in decisions on fundamental research into new medicinal therapies. In addition, they should be supplemented by adequate incentives to support areas that do not normally attract research funding due to the restricted size of the expected market and/or the difficulties in undertaking research e.g. orphan and paediatric medicines. A comprehensive EU biotechnology strategy should be developed to support the growth of this important sector including the completion of the implementation of Directive 98/44/EC on the Legal Protection of Biological Inventions.

### RECOMMENDATION 9

To improve the co-ordination of Community and national activities, by:

- Commission and Member States to co-ordinate and support the conduct of clinical trials on a European scale, establish a database of trials and clinical research results;
- Commission and Member States to put in place an effective policy in terms of incentives to research and support the development and marketing of orphan and paediatric medicines;
- supporting the development of a biotechnology strategy in Europe<sup>[2]</sup>.

<sup>[2]</sup> E.g. in line with the Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions on Life Sciences and Biotechnology, A Strategy for Europe. January 2002 (COM(2002)27)

4

# Patients



## Enhanced Information

Patients have a right, and an increasing expectation, to have access to good quality objective information about the medicines they take and to be actively involved in decisions about their treatment. Patients cannot express informed preferences unless they are given sufficient and appropriate information about all relevant treatment and management options and information about the potential benefits and harms of each. This will require a co-ordinated effort involving a wide range of stakeholders including national authorities, the EMEA, industry and the clinical professions. Information to patients should be objective, comprehensive, readable, accurate and up-to-date.

The provision of information on, and the advertising of, medicines to the public is a highly sensitive issue. It is currently being considered within the context of the review of European pharmaceutical legislation (Review 2001). It is made more difficult by the lack of a clear definition of the distinction between advertising and information, and the growth in the use of the Internet. Industry has a legitimate right to advertise products that are available over-the-counter to the public just as the public has a legitimate expectation to know about non-prescription medicines that are available to treat illnesses. The current regulatory structure permits the advertising of non-prescription medicines to the public, and this should remain. Equally, the existing prohibition on advertising medicines available only on prescription to the public should also remain.

However, the increasing use of the Internet has made the existing prohibition on advertising prescription-only medicines to the public more difficult for Member States to enforce. Companies and patients have to deal with a mass of unregulated and often inaccurate information on

medicines. Nevertheless, the availability of the Internet cannot be ignored. To ensure that the prohibition of advertising prescription only medicines to the public can be maintained, account needs to be taken of the public who are actively seeking information, including from industry, about medicines and alternative treatments. There needs to be an appropriate system of checks and balances. This should include:

- establishing a practical distinction between advertising and information; and
- drafting guidelines to be agreed by national authorities and the European Commission.

### RECOMMENDATION 10

- The restriction on advertising of prescription medicines to the general public should continue;
- There should be no restrictions on advertising of non-prescription medicines, which are not reimbursed, in line with existing requirements for advertising to encourage the rational use of the product and not to be misleading. There should be sharing of information and development of common approaches to regulation of such advertising;
- Consideration should be given by the European Institutions, as part of their current review of the pharmaceutical legislation, to:
  - in co-operation with all stakeholders to produce a workable distinction between advertising and information that would allow patients actively seeking information to be able to do so, and to develop standards to ensure the quality of such information; and
  - the establishment of a collaborative public-private partnership involving a range of interested parties. The information should be carefully piloted and evaluated to assess the extent to which it meets the needs of patients.

## Patient Information Leaflets

The primary source for patients of information on their medicines is, as is only appropriate, health professionals such as doctors and pharmacists. However, this source is supplemented by the information contained in the patient information leaflet that accompanies each medicine. This provides potentially invaluable information on how to use medicines safely and effectively and is usually the only source of information when the patient actually takes the medicine. This is particularly critical for over-the-counter medicines where there may be less direct involvement by a health professional.

However, these leaflets, which currently must present a set of information in a particular order, frequently do not meet the needs of patients. In particular, there needs to be greater flexibility in the way information for each medicine is presented taking account of the views of regulators, users and all stakeholders ensuring that citizens have access to harmonised, authorised and clear information which takes account of different levels of health literacy.

### RECOMMENDATION 11

→ In the context of the current review of Community legislation, the legislation relating to patient information leaflets should be reviewed taking into account views of users as well as regulators and industry.



## Pharmacovigilance

Once medicines are authorised to be placed on the market, industry and national regulatory authorities undertake regular monitoring to ensure that they continue to meet the required standards of safety, quality and efficacy. This is a vital role played by national regulatory authorities and critical to the continuing confidence EU citizens have in the medicines they are using.

### RECOMMENDATION 1 2

- That systems for post-marketing surveillance should be optimised to ensure that co-ordinated processes are in place to gather data on adverse events and patient safety.

## Funding of Patient Groups

Patient groups have an important contribution to make to the development of health and medicines policy by articulating the needs and views of patients, scrutinising new policy proposals and calling policy makers to account. Concern has been expressed, however, about the reliance of small NGOs on external funding, and their need, from time to time, to have recourse to industry funding.

### RECOMMENDATION 1 3

- That the Commission consider providing core funding for European patient groups to enable them to participate independently in the debate and decision making on health matters in the EU.

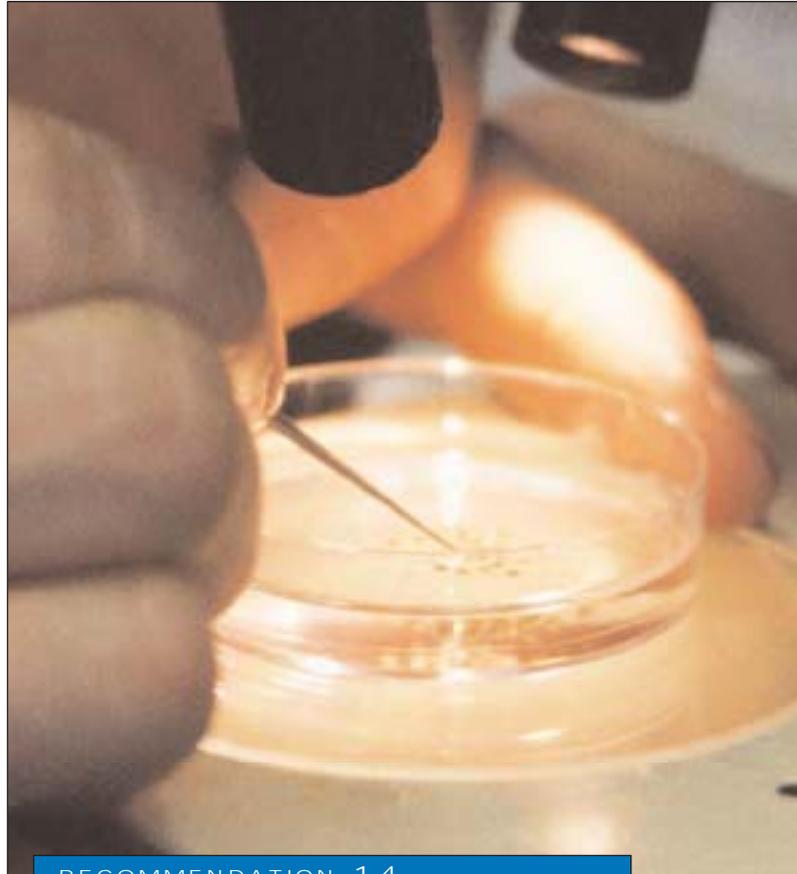


5

## Enlargement

The EU will shortly face the most significant expansion in membership in its history. This will have a massive impact across a number of areas including pharmaceuticals. Although it is difficult to predict the impact of enlargement in this area with any accuracy its impact needs to be taken into account when the Commission considers how to respond to the above recommendations.

To ensure that there is a "level playing field" for the pharmaceutical industry within the expanded EU, the differences in marketing and economic conditions between Member States and candidate countries need to be taken into account when considering rules governing parallel imports.



### RECOMMENDATION 14



That the implementation of the above recommendations should take full account of the future enlargement of the EU. In particular, rules should recognise the differences between public health, marketing and economic conditions between existing Member States and the accession countries; to that extent, a derogation governing parallel imports should be included in the accession treaties.



G10 MEDICINES REPORT

# Nextsteps

The Group recognises that these recommendations do not represent an immediate solution to the question of competitiveness and achieving certain health objectives, but we do consider that the package as a whole represents a practical and reasonable framework for further action. We also appreciate that, even if the Commission were to agree with all the recommendations, not all the action is for the Commission. A number of the issues fall to Member State competence. However, we have identified areas where we think the Commission could play a useful facilitating role. We await the Commission's response with interest.

The Group would also like to record the fact that it has found the G10 Medicines process to be a valuable method of working and expresses its wish to see it continue in an appropriate form. A monitoring mechanism should be set up to focus on the results of any agreed benchmarking exercise. The G10 should meet once a year to examine progress and results of this exercise.



## Annex A

### Terms of Reference

The Group of ten is intended to bring together the top decision-makers on medicines from the EU. The Group will discuss the major issues relevant to the right balance of health objectives and industry competitiveness in Europe.

It will, in parallel:

- Contribute during the period covered by its meetings to the ongoing policy process in the EU through better communication and a fostered sense of teamwork.
- Prepare and present, no later than April 2002, a report on its findings to the College and President of the European Commission, outlining proposals for concrete action to be taken.

The group will be time limited, meeting three times between March 2001 and February 2002, presenting its report in April. It will comprise the top team-members only, discussing short, focused agendas, and working in a transparent way. The group may issue a joint statement following each meeting, outlining decisions taken and progress made.

A secretariat service will be provided by the Commission's « Enterprise » DG in close co-operation with DG « Health and Consumer Protection ». All participants will be encouraged to maintain close communications with one another, and outside views will be sought where appropriate.

The Group will review the extent to which current pharmaceutical, health and enterprise policies achieve the twin goals of both encouraging innovation and competitiveness and ensuring satisfactory delivery of public health and social imperatives.

The group will aim to arrive at a “benchmarking” exercise, which will examine the ways in which these systems operate, and suggest best practice for the future.



## Agenda areas of the Group

The group will examine the major areas of concern to private and public policymakers in Europe, and will cover three main topic areas. It should be understood that in some cases the distinctions made below are somewhat artificial, as many of the policy areas are intricately linked.

### 1. Provision of medicines to patients

The medicines industry produces products intended to cure disease and save lives. How does Europe shape up internationally in terms of availability of new, effective products meeting Europe's real health needs? How successfully do member states' health care systems deliver cost-effective and equitable access to medicines? How could systems of post-marketing pharmaco-vigilance be improved?

How to identify the value of innovative medicines in relation to other pharmaceuticals (where appropriate, generic drugs) and to non-pharmaceutical interventions, ensuring appropriate and effective involvement of patients?

Are European medicines systems ready for enlargement? What might be the effects of adding additional lower-income populations to the equation?

Central and Eastern European systems, often with lower incomes and very different healthcare provision, are likely to have a very strong impact on future policies. They bring with them traditions of social solidarity and government provision which are even stronger than those in most of Western Europe – as well as fundamentally different market structures.

#### Information and Technology

What information can patients obtain? How is this managed? In what ways do developments in ICT affect both information and provision of medicines? What are the issues of competence, and of equity and regulation?

### 2. Single Market, Competition and Regulation

#### Market structure in Europe

Pharmaceuticals can not be exempted from the Single Market because they are used in health care systems. The existence of price controls is not in itself contrary to the principle of free movement of goods. To what extent is there scope for development of a single market in healthcare?

What scope is there for improved competition – between sectors, between products, on price, on other criteria? What is the real impact of fragmentation, and how can it be addressed? How can the dynamism of the market be improved?

What about the role of funding systems in promoting efficient consumption of medicines? For example, through improved comparative analysis of member states' reimbursement decisions and drug consumption patterns? Through analysis of fiscal and other regulatory mechanisms for influencing prescribing practices? By means of improved information to patients, and to purchasers of over-the-counter (OTC) medicines on the efficacy of products? By attention to the appropriate role of generic products? Can we foresee the likely impacts on EU policy in the future? How can we assure healthcare provision in a changed Union?

#### Regulation

In the past two decades European legislation has been introduced across the spectrum; it is now being reviewed. Is the balance right? Does it achieve the right objectives? Can we take an overview of these issues and build a coherent picture?

### 3. Innovation

#### Identification of and reward for innovation

How can purchasers identify innovation? What is the best way of rewarding it?

Current European systems use different ways of rewarding innovation. EU IPR is recognised as being the best single method of rewarding innovation – giving, as it does, innovative companies considerable market power. Several issues related to the period of time taken between regulatory authorisation and actual market access remain to be resolved, and it is clear that at this stage we have not arrived at a point where products are “European – marketable” at the same time, or in the same ways.

Related to this issue, is the question of which innovations to reward the most. The key to this is whether or not a new product is effective relative to the treatments that are already available, when and how this could be proved, and how such information might be made use of.

#### The Science Base in Europe

Looking at ways in which the US system has encouraged basic research; making comparisons with EU systems; looking for « best practice » in Europe.

There are several key areas of interest here, related to the ways in which basic science in Europe is managed. Links between industry and academia have traditionally been tenuous at best. Questions remain over the attractiveness of public fundamental research and personnel mobility between public and private organisations. Ways of remedying these problems have been attempted at member State level, but there is scope for examining ways in which leadership and cooperation might be provided at European level.

#### Biotechnology

How can we encourage better uptake and commercialisation of biotechnology in Europe? What synergies exist between businesses and academia already, and how might these best be exploited?

However, there remain issues around public perceptions and intellectual property where there is scope for improvement. How may these be addressed?

#### Ways of working

The group will work in accordance with the “Lisbon method”, examining and analysing areas of interest, and seeking where possible to propose ways forward that might not necessarily require legislation.

The group will be supported by appropriate expertise to provide an informed backdrop.



## Annex B

G10 MEDICINES REPORT

# Members CVs

### Erkki Liikanen,

Member of the European Commission responsible for Enterprise and Information Society

Mr Liikanen has a master's degree in Political Science with a specialisation in economics from the University of Helsinki, Finland. He was elected to the Finnish Parliament in 1972 at the age of 21. He was Finland's Minister of Finance from 1987 to 1990 and Ambassador Extraordinary and Plenipotentiary from Finland to the European Union from 1990 to 1994. During that period Finland negotiated its accession to the European Union. Mr Liikanen served from 1995 to 1999 as Member of the European Commission, responsible for budget issues, personnel and internal administration. In September 1999 he was appointed as Member of the European Commission responsible for enterprise policy and information society. Mr Liikanen has also served on the boards of various corporations, as a Parliamentary Trustee of the Bank of Finland and as a Member of the Science and Technology Policy Council of Finland.

### David Byrne

Member of the European Commission responsible for Health and Consumer Protection

David Byrne was educated at University College, Dublin, where he earned a Bachelor of Arts in Economics, Ethics and Politics, and at King's Inns, Dublin, after which he was called to the Bar. Mr Byrne was Attorney General in the Irish Government from June 1997 to July 1999, responsible for legal advice to the Government and for all litigation involving the State before the Irish and European Courts. His principal political contribution was as one of the negotiators of the Good Friday Agreement in April 1998. Subsequently he oversaw the major constitutional amendments required by that agreement, which were approved by Referendum in May 1998. Mr Byrne also advised on the Constitutional Amendments necessary for Ireland's ratification of the Amsterdam Treaty. In September 1999 he was appointed European Commissioner for Health and Consumer Protection, with particular responsibility for Food Safety, Public Health and Consumer Protection.

### Ulla Schmidt

Federal Minister for Health, Germany

Ulla Schmidt was a member of the teaching profession from 1976 to 1990. In 1983, she joined the SPD (Social Democratic Party) and took up political duties in her hometown of Aachen, at the local party level and further afield. Since 1990 she has been a Member of the German Bundestag, serving, among other things, as Deputy Chair of the SPD parliamentary group for Labour and Social Affairs and Women, the Family and Older Persons. She was named Federal Minister for Health on 18 January 2001.

### Bernard Kouchner

Minister for Health, France

A Doctor of Medicine specialised in gastroenterology, Bernard Kouchner is the founder of Médecins sans frontières (Doctors without Borders) and Médecins du monde, of which he was President from 1971 to 1979 and 1980 to 1988 respectively. From 1988 to 1992, he served as State Secretary, first for Social Integration and later for Humanitarian Action, prior to being appointed Minister for Health and Humanitarian Action, a position he held from 1992 to March 1993. In 1994, he was elected to the European Parliament and became the Chair of the Committee on Cooperation and Development. In June 1997, he returned to the French Government as State Secretary for Health. In July 1999, he was appointed as the Special Representative of the Secretary General and head of the United Nations Interim Administration Mission in Kosovo (UNMIK), a position he held until January 2001. He has been the Minister for Health in France since February 2001.

**Philip Hunt**

Health Minister, United Kingdom

Lord Hunt has long experience of health administration. He was the first Chief Executive of the NHS Confederation, and previously Director of the National Association of Health Authorities and Trusts (NAHAT).

He was appointed a life peer in July 1997 and in 1998 became a Government Whip and spokesperson in the House of Lords on Education, Employment and Health. He was joint chair of the All Party Primary Care and Public Health Group from 1997 to 1998 and Vice-Chair of the All Party Group on AIDS from 1997 to 1998.

Lord Hunt was appointed Parliamentary Under Secretary of State for Health (Lords) on 29 July 1999. His ministerial responsibilities include NHS Performance Management, Information Technology, Research & Development, the Modernisation Agency, clinical quality with National Institute for Clinical Excellence (NICE) and Commission for Health Improvement (CHI), Counter Fraud and Executive Agency Management. He is responsible for medicines and medical devices, genetics and biotechnology and shared the chairmanship of the Prime Minister's Pharmaceutical Industry Competitiveness Task Force.

**Lars Rekke**

Secretary of State for Industry, Employment and Communications, Sweden

Lars Rekke held various positions in the oil industry from 1992 to 1994. He then went on to pursue a career in government, serving from 1994 to 2001 as State Secretary at the Ministry of Industry, Employment and Communications; the Ministry of Industry and Commerce; the Ministry of Defence; and the Ministry of Health and Social Affairs. In 2001, he was appointed Director General and Member of the Board of the Swedish Civil Aviation Administration, Member of the Board of A-Banan Projekt AB and Member of the Board of the National Agency for Government Employers.

**Francisco Ventura Ramos**

Secretary of State for Health, Portugal

Francisco Ventura Ramos is an economist. He also holds a master's degree in Hospital Administration, with a specialisation in Health Economics. He is Professor of Health Economics at the National School of Public Health, New University of Lisbon, and a consultant to the World Health Organisation, the World Bank and the European Union on health matters.

**Angela Coulter**

Chief Executive of the Picker Institute Europe

UK-registered charity with branch offices in Germany, Sweden and Switzerland, the Picker Institute works with European health care providers to obtain feedback from patients and promote patient-centred care. Angela Coulter is Visiting Professor in Health Services Research at the University of Oxford, Visiting Fellow at Nuffield College, Oxford, a Governor of Oxford Brookes University and an Honorary Fellow of the UK Faculty of Public Health Medicine. She is also the founding editor of Health Expectations, an international peer-reviewed journal of public participation in health care and health policy.

**Jean-François Dehecq**

President of the European Federation of Pharmaceutical Industry Associations

Jean François Dehecq earned a degree at the Ecole Nationale des Arts et Métiers, a national engineering college. In May 1999, he was appointed President and Chief Executive Officer of Sanofi-Synthelabo. He is currently the President of the Conservatoire National des Arts et Métiers (C.N.A.M) and the President of the European Federation of Pharmaceutical Industries and Associations, the representative voice of the pharmaceutical industry in Europe.

**Andrew Kay**

Chairman of the European Generic Medicines Association

Mr Kay earned a bachelor's degree in Pharmacy in 1974. He is a registered UK Pharmacist. From 1977 to 1990 he held sales and marketing positions in various generic manufacturing companies, and worked for a time in pharmaceutical distribution. He was Commercial Director of APS/Berk from 1990 to 1994, at which time he was named Chief Executive Officer of the firm, a post he still holds. In January 2000 he was appointed Vice-President of TEVA Pharmaceuticals Europe. Andrew Kay was Chairman of the British Generic Manufacturers Association from 1996 to 1998 and in 2000. He is also President of the European Generic Medicines Association (EGA).

**Alessandro Banchi**

President of the Association of the European Self-Medication Industry

Dr Alessandro Banchi has worked for Boehringer Ingelheim since 1973 and was the CEO of BI Italy during the 1990s. On 1 January 2000, he was named a Member of the Board of Directors of Boehringer Ingelheim, and he is currently President of the Association of the European Self Medication Industry (AESGP).

**Chris Viehbacher**

President of GlaxoSmithKline Pharmaceuticals Europe

Chris Viehbacher, who holds dual German-Canadian citizenship, graduated from Queen's University, Ontario, in Commerce and completed his training as a Chartered Accountant in Canada. He was President and Chief Executive Officer of Burroughs Wellcome Inc., Canada from 1993 to 1995. He joined Wellcome GmbH, Germany in 1988 as Chief Financial Accountant and was promoted to Finance Director in 1989. Mr Viehbacher joined Glaxo Wellcome France in August 1995 as Vice President for Strategy and Integration, following a period based in London as a member of the Co-ordination Team. He became General Manager of Glaxo Wellcome France in 1996 and was promoted to Chairman and Managing Director the following year. He was appointed Director for Continental Europe in January 1999 in addition to his role as Chief Executive Officer of Glaxo Wellcome France. Mr Viehbacher was named to the GlaxoWellcome Executive Committee in January 2000 as Regional Director for Europe. He is a member of the Corporate Executive Team.

**Ueli Müller**

President of the Association Internationale de la Mutualité (AIM, or International Association of Mutual Health Funds)

Ueli Müller studied economics at the University of Bern. He began his career as an economist in the engineering industry (1968-1971) and went on to become technical assistant for the umbrella group of Swiss Health Insurers, from 1972 to 1975. He was appointed Secretary-General of the same group in Solothurn, Switzerland, serving from 1976 to 1984, at which time he was named President, a post he held until 2000. Mr Müller has been a member of the Swiss Medicines Commission for 19 years (1981-2000) and President of the Association Internationale de la Mutualité (AIM) since January 2000.







A great deal of additional information on the European Union is available on the internet. It can be accessed through the Europa server (<http://europa.eu.int>).

More information on the work of the High Level Group can be found on the G10 Medicines website (<http://pharmacos.eudra.org>).