

**PHARMACEUTICALS AND PUBLIC HEALTH IN THE EU:  
PROPOSALS TO THE HIGH LEVEL COMMITTEE ON HEALTH  
FOR POLICIES AND ACTIONS IN THE FRAMEWORK OF THE  
TREATY OF AMSTERDAM<sup>a)</sup>**

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<sup>a)</sup> Report of the Working Group on “Pharmaceuticals and Public Health” of the High Level Committee on Health.

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## EXECUTIVE SUMMARY

The Working Group on “Pharmaceuticals and Public Health” was established by the High Level Committee on Health (HLCH) which gives advice to the Commission services on matters relating to health policy. Its task is to consider issues in relation to developing Community policy and actions in the area of pharmaceuticals and public health, a central concern being with matters relating to use and cost-effectiveness, information and information systems, including the aspects of relative therapeutic value of pharmaceutical products and consumption and prescribing patterns. In light of the new legal basis for health in the Amsterdam Treaty, the Group decided to focus on considering new policy areas.

From a public health perspective, the main goal in the pharmaceutical sector is that of making readily accessible efficacious, high quality and safe medicines, including the more recent and innovative ones, to all those who need them, regardless of their income or social status. The achievement of this overall goal in the E.U. Member States implies:

- availability of resources (mostly public) needed to cover the costs of medicines, which implies that the E.U. Member States have to ensure that resources available for pharmaceutical and other health cares are prioritised to best effects;
- ability to develop new medicines for the many diseases which cannot be satisfactorily treated at the present, which depends mainly on the ability of a market-based multinational manufacturing industry to invest in research and development and, therefore, on sound industrial and public health policies from both the public and private sectors.

In this context, the main objectives to be pursued include, in addition to securing the most efficient and cost-effective distribution arrangements given the organisation of health care in Member States, the promotion of:

- innovative medicines with added therapeutic value and/or higher cost-effectiveness in relation to other pharmaceuticals and to non-pharmaceutical interventions;
- clinical and cost effectiveness of prescribing of medicines and a more effective involvement of patients;
- larger use, where appropriate, of generic drugs.

Several specific objectives and related actions have been considered by the Working Group for innovation, rational use, generics, distribution systems, information systems and other issues. The Working Group acknowledged the large body of regulations already existing in Community in the pharmaceuticals sector and has worked toward identifying those specific and practical measures that could be taken over the next few years by the Community, acting primarily as a facilitator, to assist Member States in maximising the effectiveness of their pharmaceutical programmes and policy measures. The report of the working group has been presented to the HLCH for its consideration in order to advice the Commission’s services on the future activities.

## **A. FOREWORD**

This is the report of the Working Group on “Pharmaceuticals and Public Health”. The group was established by the High Level Committee on Health (HLCH) which gives advice to the Commission services on matters relating to health policy. Its remit is to consider issues in relation to developing Community policy and actions in the area of pharmaceuticals and public health. The mandate from the HLCH was to explore “issues related to the costs, use and cost-effectiveness of pharmaceuticals and on pharmaceutical programmes and policy measures”, a central concern being with matters relating to information and information systems, including the aspects of relative therapeutic value of pharmaceutical products and consumption and prescribing patterns. In light of the new legal basis for health in the Amsterdam Treaty, the Group decided to focus on considering new policy areas rather than on reviewing in details the very large body of existing Community regulation on quality, safety and effectiveness of pharmaceuticals. The intention was for the Group to produce a document with recommendations for consideration by the HLCH on proposals for specific, practical measures that could be taken by the Community over the next few years which would assist Member States in maximising the effectiveness of their pharmaceutical programmes and policy measures. The focus was on those action areas in which the Community’s role was primarily as a facilitator.

The group met three times between September 1999 and February 2000. Nearly all the Member States have participated actively in the meetings and in providing the relevant information sought, together with representatives of the Commission services concerned and EMEA. Names of the various participants in the meetings are annexed.

## **B. INTRODUCTION**

1. From a public health perspective, the main goal in the pharmaceutical sector is that of making readily accessible efficacious, high quality and safe medicines, including the more recent and innovative ones, to all those who need them, regardless of their income or social status. The achievement of this overall goal in the E.U. Member States implies:
  - availability of resources (mostly public) needed to cover the costs of medicines and accurate prioritisation of resources to best effect;
  - ability to develop new medicines for the many diseases which cannot be satisfactorily treated at the present.

The availability of innovative medicines depends mainly on the ability of a market-based multinational manufacturing industry to invest in research and development (R&D) and therefore on both sound industrial and public health policies to promote this ability, and on the negotiation of prices for medicines that should reflect R&D costs and facilitate new investment in R&D.

2. Article 152 of the Treaty of Amsterdam offers today new possibilities of Community interventions in the sector of pharmaceuticals. While Community action in the field of public health must continue to fully respect the responsibilities of the Member States for the organisation and delivery of health services including pharmaceutical and medical cares, it is clear that the provision of medicines to all those who need them

and the development of new medicines for otherwise incurable diseases, are fundamental aspects to ensure a high level of human health protection, which is a key objective for the E.U. foundation. Therefore, Community actions, intended to complement national policies and directed towards improving public health, cannot disregard pharmaceutical policies.

3. In view of the demands on health care and the constraints on funding, it is imperative that all health care expenditure be scrutinised to see if it is offering best value for money – what use of resources is most clinically-effective and cost-effective. This requirement applies as much to pharmaceutical expenditure as to other health care expenditure, especially given the fact that pharmaceutical innovation is very expensive depending on the high costs of R&D and other factors, such as distribution and marketing. The E.U. Member States have to consider how resources available for pharmaceutical and other health cares can be prioritised to best effect. In this context, the main objectives to be pursued include, in addition to securing the most efficient and cost-effective distribution arrangements for pharmaceuticals (bearing in mind the different ways in which health care is organised in Member States), the promotion of:
  - innovative medicines with added therapeutic value and/or higher cost-effectiveness in relation to other pharmaceuticals and non-pharmaceutical interventions;
  - improving the clinical and cost effectiveness of prescribing of medicines and the more effective involvement of patients in the use of medicines;
  - larger use, where appropriate, of generic drugs.
4. In this context, a particularly appropriate role for the Community is to develop facilitation tools and co-operation initiatives to assist Member States in their efforts to pursue public health and industrial policy objectives in order to overcome the existing constraints.

### **C. INNOVATION**

5. Pharmaceutical innovation is vital not only from a health-protection perspective but also from an industrial policy viewpoint. Innovation encompasses many different options going from the development of a completely new medicine for the treatment of a disease otherwise incurable to modifications of known pharmaceutical formulations to improve benefits for the patients, such as a less invasive administration route or a simpler administration schedule. It is obvious that not all the innovations have the same value. Only some can be regarded as “breakthrough” innovations representing a public good that should be supported across borders. The important contribution of the E.U. Fifth Framework Programme to pharmaceutical research is acknowledged, and should be strengthened in the future, particularly in reference to orphan drugs. Moreover, national investments in pharmaceutical research and co-operation among Member States should also be further supported in view of the important role of publicly-funded research in the discovery of new drugs. The regulation on orphan drugs recently adopted by the EU looks very promising, but careful monitoring of its implementation and its impact is needed.
6. In order to promote significant pharmaceutical innovations, ideally it would be appropriate to:

- a) Produce harmonised definitions at a European Union level of new medicines with an added therapeutic (clinical) value as compared to the existing ones;<sup>1</sup>
  - b) Develop consensus methodologies to assess such value of new medicines;
  - c) Ensure that medicines with significant added therapeutic value are easily identified;
  - d) Ensure that the above medicines with significant therapeutic benefits which meet appropriate criteria are made available to patients without any delay;
  - e) Increase national and Community public research funds devoted to pharmaceutical R&D and promote bilateral and multilateral research co- operation;
  - f) Create a positive “environment” particularly for the companies who reinvest in research and produce innovative medicines by, among other things, adopting fiscal incentives in accordance with the Treaty provisions, and simplifying the administrative procedures regulating the establishment of manufacturing plants;
  - g) Speed up the adoption of Community instruments to implement good practice in clinical trials and to simplify the administrative burden in this area;
  - h) Ensure a close integration of the different policy-making sectors (e.g. industry, commerce, research and health) competent for patients’ welfare and industrial policies both at Community and Member States levels;
  - i) Exchange of information and consensus building on sound methodologies to evaluate cost-effectiveness of medicinal products.
7. Different Member States have developed or are developing new ways of assessing the relative clinical effectiveness of new medicines. Although activities indicated under the above points a), b) and c) could be new tasks assigned to the Commission in co-operation with the Member States, as independent procedures with respect to the registration duties already entrusted to the Commission, it is arguable that – at least initially – the most helpful role the Community could undertake would be to collate Community wide decisions to identify significant differences of view where Member States might benefit from Commission facilitated discussion. In particular, case by case evaluation<sup>2</sup> under c) should be performed at launch if possible, or otherwise when required data become available and, at the latest, on the basis of post-marketing pharmacovigilance data, when the marketing authorization is renewed for the first time (i.e. after 5 years from registration), and repeated thereafter when necessary. In such a case, post-marketing surveillance of new medicines would assume a much higher importance and significance. The specific information tools necessary to support these new tasks could be an extension of the Medicines Information Network for Europe (MINE), already proposed by the EMEA, or another Community information system.

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<sup>1</sup> The difficulty of assessing “added therapeutic value” should not be underestimated. There are both intrinsic difficulties in making such assessments and the complications of the variations in medical practice and organisation in Member States that may affect the added value of a particular medicinal product. At least initially the focus would need to be on attempting to assess for each new medicine the nature of the additional therapeutic benefit (and perhaps to assign it to one of a number of categories e.g. new treatment for previously untreatable condition; significant extension in life expectancy; significant reduction in disability; significant improvement in side effect profile; significant improvement in ease of administration.).

<sup>2</sup> This could be carried out by EMEA or by another specific committee to be established.

A feasibility study could be undertaken, in consultation with Member States, industry and other groups.

8. As far as the objectives d), e), f) and g) are concerned, a Council Recommendation could be adopted to indicate which initiatives should be undertaken by the Member States and Commission. Moreover, in relation to objective d), a Community resource (e.g. an Observatory), independent of executive action, should be established to monitor price (notably ex-factory price) movements, to provide economic data and analysis of pharmaceutical pricing and to promote good practice in pharmaco-economics. This Community resource could also assist Member States to evaluate possible impacts of innovative medicines on health service organization and resources. A feasibility study should be undertaken on this subject.
9. As far as objective h) is concerned, appropriate mechanisms should be set up, e.g. ad hoc inter-sectoral committees, both at national and Community levels, to ensure proper co-ordination involving those in charge of supporting pharmaceutical innovation and those responsible for ensuring patients' welfare and rights.
10. Mechanisms to achieve the objective i) should be considered for inclusion in the Community public health action programme. A Community-wide inventory of existing good practices would be helpful in this respect.

#### **D. RATIONAL USE**

11. In order to promote the rational use of medicines, it is necessary to have:
  - j) A wide dissemination of relevant information to doctors, pharmacists and patients;
  - k) Guidelines concerning best clinical (including pharmacological) practice for treating particular conditions;
  - l) Promotion of medicines by pharmaceutical companies based on accurate information;
  - m) An effective prevention of wastage of medicines.

Appropriate incentives/disincentives could also be helpful to encourage best practice.

A significant number of activities are being carried out in these areas which fall within the competence of Member States. The added value at a Community level can be seen mainly as a sharing of experience and know how, and in the testing of different approaches to evaluate their suitability in different conditions and settings.

12. As far as the achievement of objective j) is concerned, there is a clear need to establish an effective system to make possible the access to available information on prescriptions and consumptions of medicines and, possibly, on other relevant aspects. Most countries have already developed or are developing Internet sites where information, mainly aimed at health professionals, is available on authorised products, pharmaceutical regulations and new pharmaceuticals. The EMEA's site contains details of the products that have been approved through the centralised European licensing procedure. There would be value in placing on the Internet also similar information about all medicines approved with the mutual recognition procedure; this task should be assigned to the competent authorities in the Member States in co-operation with the EMEA and the Commission.

13. Moreover, in order to improve prescribing, some recent experiences, particularly in the U.K. indicate the significant potential for interactive computerised systems (“Prodigy”) which support doctors in general practice in making decisions about the management of patients, including advice on prescribing options. Computerised systems also provide UK general practitioners with detailed information about their prescribing practice, including comparative performance. More traditional methods which can also be used to assist physicians’ prescribing behaviour include use of printed material and targeted lectures, combined with discussion in a peer group. The cost-effectiveness of prescribing can also be improved with patient participation and consensus; this requires, however, provision of more high-quality information to patients to enable them to make well-informed choices. In order to exploit the possibilities offered by the use of computerised prescribing management systems and other methods available in this area the Commission should evaluate the potential transferability of such systems between Member States (see also point 17).
14. In relation to objective k), it is known that a number of Member States are active in producing guidelines in relation to pharmaceuticals to improve quality and performance in health care and to avoid unnecessary and costly hospitalisation. This is, obviously, an area where there are many opportunities for co-operation at bi- and multi-lateral levels as well as at a Community level. It is recommended that this activity is pursued by joint efforts by the Commission and Member States as one of the components of the "Programme of action in the field of public health" to improve information for the development of public health and the strengthening and maintenance of effective health interventions and efficient health systems. It is also essential that such activities include possibilities to follow up the outcome of the guidelines among prescribers, notably by professional groups.
15. The diffusion of innovation through information and advertising is an important feature of the pharmaceutical industry. An important contribution to the rational use of medicines may also derive from a closer co-operation of public competent authorities and pharmaceutical companies to improve the nature and quality of the information on medicines provided by the companies through a number of channels. Compliance with existing legal requirements must be assured in all cases; therefore, the information must reflect officially-approved documents. To this end, the Commission, in co-operation with Member States, should aim at developing ad hoc agreements with the associations of pharmaceutical companies. Such agreements should cover all the types of activities, including the information provided through the Internet. In principle, the Internet represents a useful tool for providing high-quality information both to health professionals and to the general public. However, there is already a very large and growing number of web sites providing information of all types and it is clear that quality of available information is not always satisfactory. To improve the situation, it could be useful also to verify the possibility of the supervision of the web sites by accredited scientific societies. One approach covered by the proposed agreements could, therefore, be to offer the high-quality information in such a way that the information can be regarded as objective, reliable and easily understandable by those for whom it is intended. This issue should be also brought to the attention of the Pharmaceutical Committee for consideration when discussing electronic commerce.
16. To prevent wastage of medicines, that is an important issue in all Member States; the Commission should facilitate discussion and exchange of information and experience of measures being pursued in Member States.

## **E. USE OF GENERIC DRUGS**

17. Prescribing available generic medicinal products, both those branded and using the international non-proprietary name (INN), rather than equivalent more expensive in-patent products, should be seen by doctors as a matter of good professional practice and a deontological issue. To this end, doctors would benefit from the availability of easily retrievable comparative (electronic) databases and of information benchmarking their comparative prescription behaviour with respect to their colleagues (see also point 13).
18. Different policies are at the present adopted by the E.U. Member States with respect to generic substitution (i.e. the replacement by the pharmacist of the prescribed branded drug by a generic with the same active ingredient). Moreover, in view of the many terminological differences and public health implications, an activity to exchange information and to analyse the implications of present national policies should be undertaken.
19. Another important aspect enabling generic entry on the market is related to the conditions surrounding the judicial enforcement of patent rights since clear procedures are likely to improve the ability of generic companies to organise their products launch. Such an approach could also lessen existing tensions between the interests of research –based pharmaceutical companies in the E.U. to assure maximum data protection for their products and those of generic producers which want access to the market for their products as soon as possible. Issues about the extent of access to trials data are also relevant in this context. These are complex issues and the attention of the HLCH is drawn to the large amount of work required to explore fully this subject in order to decide whether further activities should be carried out by the Working Group.

## **F. DISTRIBUTION SYSTEMS**

20. Distribution costs form a significant part of overall pharmaceutical costs and need to be scrutinised in the same way as other costs in order to ensure that value for money is obtained and resources can be redeployed in particular to ensure access to innovative medicinal products. Distribution margins are often established as a fixed quota of selling prices. Therefore, they tend to be more onerous for innovative medicine which are, in general, characterized by a higher price per package unit as compared to less innovative medicines and not enough incentive for generics which have lower price per package unit. The issue of distribution margins is a matter for national authorities to consider. However, given the trend, particularly in the wholesale sector, towards the development of European markets, there is a strong case for work at Community level to look at trends and costs in the market as a whole.

## **G. INFORMATION SYSTEMS**

21. The working group welcomed the information on the Commission President's initiative, "e-Europe: An Information Society For All". It was noted that this initiative is likely to provide a very positive environment for the development of a number of priority initiatives needed in the field of pharmaceuticals.

22. The survey carried out by the working group has shown that a number of information systems being operated and/or developed in the EU both at Community level (e.g. EMEA's information system and MINE; Commission's EUDRA system) and at Member State levels, contain much valuable information. However, for many of these systems there are also a number of limitations and problems in relation to their comprehensiveness and accessibility; moreover, national systems are very different one from the other and in no way can they easily interact among themselves or with the Community ones (the summary of the responses was attached to the minutes of the November Meeting, sent to the HLCH). Moreover work should be continued in order to get a clear and concise account of what information is collected, by whom and for what purpose. Such a "map" is needed if effort is not to be wasted by either failure to use/exploit existing information or to develop new systems without a clear understanding of their relationship to what already exists."
23. Quite apart from the specific weaknesses of the existing information systems, a problem of a different order is that they are not able to provide all the information necessary on medicines from a public health point of view. Information is needed particularly in the additional areas, already identified in this paper under the above paragraphs:
- n.7 (Development of data base(s) to support the identification of medicines with an added therapeutic value);
  - n.8 (A common resource to support good practice in pharmaco-economics and price evaluation);
  - n.12 (Extension of the EMEA's information system in cooperation with the Commission and the Member States, to include medicines approved with the mutual recognition procedure);
  - n.13 (Pilot project on interactive medicine prescription information)
  - n.15 (Improvement of information on medicines provided by companies through internet);
  - n.17 (Providing information to medical doctors on generic drugs)
24. As far as the national pharmaceutical information systems are concerned, it would be helpful to develop "core information packages" common to all the systems which could be made available to all Member States. This issue should be considered in the framework of the EU information system on pharmaceuticals with a view to agree on tasks and responsibilities.

## **H. ENLARGEMENT OF THE EU**

25. The recommendations put forward in this report should also be considered in the perspective of the enlargement of the EU to central and eastern European countries. Most of the problems which have been identified are likely to increase as a result of accession in view of the reasons set out in the Commission Report on Health and Enlargement (SEC (1999) 713). In order to minimise the problems of the transitional period, it is recommended that the candidate countries be invited to participate in the EC actions and programmes identified in this report.

## **I. OTHER MATTERS**

26. In the light of Article 152 of the Treaty of the European Union, the working group also recommended that the 2001 review of the European marketing system should offer an opportunity to overcome, from a public health perspective, significant deficits in the current regulatory framework. Two major areas for consideration were identified as follows:

- Safety of blood donations: Medicinal products derived from human blood and plasma, and blood components for transfusion medicine, require special attention because of their inherent potential to transmit infective agents. This is a dynamic area where changes in disease epidemiology and advances in technology and scientific understanding have to be evaluated for their impact on safety. Since medicinal products derived from human blood and plasma, and blood components, share a common starting material, harmonisation of the screening of donated blood throughout the European Union should be considered.
- Vaccination schedules: Comparison of the European vaccination schedules shows that EU countries have different administration time schedules; the differences are wider for children over one year of age and in booster schedules. Immunisation schedules and policies, however, depend more on national healthcare systems and established immunisation practices than on the scientific basis for granting marketing authorisation of vaccines. As there was no consensus that this policy matter should be taken up at Community level, the HLCH is asked to give its view as to whether work should be pursued in this area.

27. An assessment on the implementation of the Commission guideline for switching the legal status from prescription to non-prescription medical products, now in the process of being published, should be performed in order to assess the level of consistency in the European market of OTCs.

## **J. CONCLUSION**

28. The present paper offers a number of proposals for public health policies and actions in the area of pharmaceuticals. According to the spirit of the Community Treaty, the focus of these proposals is on exploiting collective experience and know how of the E.U. Member States and on promoting their future co-operation to help each country to find its own individual optimal manner to delivery pharmaceutical and medical cares.