

Pharmaceuticals – The G10 Process

a report by

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G10 Communication and G10 Process

The G10 initiative represents an innovative attempt to break through the often sterile debate on the balance between competitiveness and public health objectives. These objectives have too often been seen as mutually exclusive. It is to be hoped that a general acceptance now exists that a dynamic competitive pharmaceutical industry and high levels of public health are the two sides of the same coin. This has become apparent during the G10 discussions.

It is important not to lose sight of the fact that the key objective of improving competitiveness is to bring benefits to patients. The strength of G10 is that it has proved successful in creating a non-confrontational mechanism to encourage consensus between key stakeholders on critical issues. This is something that must be built on. The task of the G10 Communication group was to build upon the work of G10 to provide a solid platform for implementation, which must begin as soon as possible.

Competitiveness

Fears over the weakening of Europe's competitive position, particularly in comparison with the US, lie at the heart of G10 Medicines. The Communication builds on the work of the G10 Group by identifying key actions to address this issue. The central message of its work on competitiveness is that it is essential to establish the right environment to ensure that medicines become available to patients and healthcare systems as soon as possible after they have been authorised.

The European Commission (EC) believes that this is of clear benefit to patients, national healthcare systems and industry. It also believes that progress in this area is achievable, while taking full account of Member State competence and responsibility to ensure that their citizens have access to affordable medicines. The issue of access to medicines is analysed in the Communication from a number of perspectives. To make an impact, action needs to be taken in a number of areas, as follows:

- shortening the regulatory procedures;
- improving the functioning of the procedures;
- examining national pricing and reimbursement structures; and
- extending the scope of the centralised marketing authorisation procedure.

Pricing and Reimbursement

The EC supports the G10 Group's conclusion that there should be greater competition in the national pricing and reimbursement systems. The Communication calls for greater competition and, in particular, for price controls to be lifted on authorised medicines that are neither purchased nor reimbursed by the state. However, with the increasing pressures on national health budgets and the forthcoming enlargement, it is time for a wider debate on pricing and reimbursement. This should not be restricted to verifying compatibility with existing requirements, principally the Transparency Directive, but should take a fundamental look at the way in which the pricing and reimbursement systems operate.

The EC has taken the Communication as an opportunity to announce the launch of a reflection on finding alternative ways of controlling healthcare expenditures. The Communication has proposed one option, which is based on the principle that manufacturers should have the freedom to set prices while negotiating budgets by product and rebates to ensure that member states have a safeguard mechanism for controlling pharmaceutical expenditure. To facilitate its implementation, the system could be applied to new medicines authorised through the centralised procedure.

The EC believes that such an approach could ensure that patients have quicker access to medicines and, especially, to newly authorised innovative products. This is only a proposal and needs to be further developed. It also, of course, must be compatible with EU law on competition and free movement of goods. However, most



importantly of all, it is for member states to decide whether such an approach would bring benefits to their citizens.

It is to be hoped that member states, whatever their individual views are on the proposal, are generally agreed that now is the right time for such a discussion. A number are already reviewing their pricing and reimbursement decisions in response to increasing budgetary pressures on healthcare. There is also the forthcoming enlargement, which will add further complexity to the existing situation. The understandable desire for member states to ensure that they best value for their citizens should not be at the expense of access to the medicines. The EC believes that its approach could provide an answer to both problems.

Enlargement

The forthcoming enlargement will bring many new exciting opportunities, as well as challenges. The main challenge for the author in his capacity as the Commissioner for Enterprise is to ensure that every possible measure is undertaken to support the new member states in implementing and operating the European legislative framework. It is the author's belief that the EC has been able to provide significant assistance in the form of the Pan European Regulatory Forum, which provides an opportunity for informal discussions on practical problems with implementing the legislative framework. However, it is also essential ensure that there is a level playing field for industry. It is for this reason that the Accession Treaties were amended to include a transitional provision covering

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Generic and Non-prescription Sectors

The EC is also looking for competitiveness improvements across other sectors as well and the Communication puts forward key actions for the generic and non-prescription sectors. In support of the European generics industry, the EC review of the pharmaceutical legislation proposed to allow the trials required for a generic application to be submitted before expiry of a patent or other intellectual property protection.

In addition, for some products, a generic manufacturer will be entitled to apply for a marketing authorisation before the end of the data protection period of the reference product. The result will be an accelerated generic competition, once the intellectual property rights of the reference products have expired.

The EC is also proposing a further clarification to the legal framework that is applicable to the generic medicinal products, a definition generic and measures to tackle anti-competitive strategic withdrawal of reference medicines, among other improvements. In order to encourage innovation on the OTC market, the review of the pharmaceutical legislation provides for a period of one year of data protection for significant pre-clinical or clinical trials carried out, in order to propose a medicinal product for reclassification.

medicines that do not benefit from full protection of intellectual property rights across the EU.

Stimulating Innovation

Stimulating innovation is the often-forgotten third aspect of the G10 process, but the one on which competitiveness and public health depend. Without retaining and enhancing its innovative sector, Europe will run the risk of future medicines being developed primarily for markets other than its own. This will also lead to an erosion of the European science base. A great deal is already being undertaken to tackle this issue through the 6th Framework Programme and other initiatives such as the Biotechnology Strategy Action Plan, which aims at harvesting the potential of European biotechnology and ensuring responsible governance of the process. This is a vital sector for the pharmaceutical industry, as at least one-fifth of all new medicines are derived from biotechnology. This proportion is rapidly increasing. To support this vital field, it is necessary to establish a strong, harmonised and affordable intellectual property protection system, measures to support the capital base of the biotech industry and much better networking of the biotechnology regions across borders in Europe. The EC is striving to establish this through its biotechnology strategy.

This paper is based on a speech made at the G10 Medicines Conference Rome on 11 July 2003. ■