

# **European Generic Medicines Association**

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**Address by Mr. Philippe JEAN  
Deputy Head of Cabinet of  
Commissioner Likkänen**

**European Commission**

## **Introduction**

Ladies and Gentlemen; I am very pleased to have the opportunity to speak to you today at the Annual Meeting of the *European Generic Medicine Association*. This is my first opportunity, since the new Prodi Commission came to office, to address your companies.

I know that, within the pharmaceutical framework, there are a wide range of policy issues and challenges of considerable importance to be discussed.

But before addressing some of the issues of particular interest for you, allow me to consider - in a wider context - what the European Union has achieved so far in developing shared perspectives and approaches to the pharmaceutical market in Europe and what the future pathways might be, in particular for the forthcoming review of the pharmaceutical legislation. This is undoubtedly one of the most important pieces of business on the horizon in your field of activity.

### **1. MEDICINES LICENSING – THE GENERAL FRAMEWORK**

European pharmaceutical legislation, since its beginning in 1965, has been built on the foundation that medicinal products are not just *consumer* products but they are also *health* products and, as such, require rigorous monitoring by public authorities: it is in the interests not only of society, but also of industry, that they are regulated as such.

This principle was enshrined in the basic Directives on medicinal products in statements that the primary purpose of any rules concerning medicinal products must be to safeguard public health.

The development of the Single Market for pharmaceuticals was undertaken with both the aim and the constraint of maintaining a high level of protection of public health. Indeed this is still the “supreme proviso” and it will continue to guide our actions and proposals in the future.

But of course there are other legitimate interests involved as well. These interests are sometimes in a situation of tension - sometimes profound tension. The Commission must, therefore, take into account

the different challenges faced by the different sectors of the pharmaceutical industry, the interests of patients and of health professionals, and of course the interests of the Member States.

So far, the Pharmaceutical legislation, maybe because its development has followed a “gradualist approach”, has managed to strike a balance between all these interests reasonably and effectively. Our first concern will be not to destroy the balance achieved.

In the context of European integration, special mention needs to be made of the setting up of the European Agency for the Evaluation of Medicinal Products (EMA). This agency is increasingly considered as the model of a fruitful co-operation between national competent authorities, working together within a Community body to serve Community purposes.

35 years of developing shared approaches in the pharmaceutical sector means that we now have in place a considerable package of harmonised legislation in the form of the pharmaceutical “acquis communautaire”.

Under this legislation, the Commission will be publishing a report on the experience acquired in the marketing authorisation procedures by the beginning of next year. Although we are making no commitments at this stage, I think you can be confident that this report will be supplemented by proposals for changes to the current pharmaceutical legislation.

The report will be informed by the work of independent auditors, who have been charged by the Commission with carrying out a wide-ranging and independent assessment of the existing procedures. Their audit is in preparation, and the results are due this autumn.

## **2. THE CONDITIONS FOR A CHANGE TO THE CURRENT PHARMACEUTICAL LEGISLATION**

However, I can already say that the Commission will approach the review of the current legislation with the firm intention of ensuring that we are prepared not only for the *technical* challenges that lie ahead (new products and therapies, especially biotechnology and gene therapy) but also the political challenges (notably EU enlargement and globalisation).

Without pre-judging the outcome of the report, some observations are already clear:

Firstly: The current marketing authorisation schemes are based on the principle of co-operation and close involvement of Member States in the evaluation of medicinal products. We are not intending to touch this sound principle, it will not be wise to abandon things that work well.

Secondly: it is nevertheless evident that some issues can or need to be improved:

- We need to secure better and faster access of products to patients through and enhanced integration of the existing procedures and resources.
- We have to pay more and more attention to the transparency of the system: all interested parties have the right to know the reasons that underpin the final Decision, whatever the Decision taken, whoever these parties are.
- Finally, recent events, though not in the pharmaceutical sector, have highlighted the need for better market surveillance; you will agree me that in your sector this surveillance is of utmost importance for maintaining public confidence. The strengthening of the current structures should be one of our major goals.

Thirdly: we have to use the opportunity of this review to shape the future of the pharmaceutical sector in Europe at a time where tremendous changes are just ahead:

- changes in new technologies which will bring to society the promise of new kinds of products and therapies,
- changes in the business environment - with ever rapid trends towards market globalisation,
- changes in the ways in which business is conducted – in particular development of e-business,
- changes in Europe - particularly the creation of a "new" Europe through an unprecedented enlargement process.

Not every challenge related to these changes can be solved simply through a reform of the legislation. But in most of cases, the legislator can ease the way forward and has to provide a sustainable and predictable legal environment.

This is why the Commission is open to any suggestions about the review and we welcome for any contribution. I am aware that EGA has already contributed – in a very proactive manner.

### **3. INTELLECTUAL PROPERTY AND MARKET ISSUES**

Important though the forthcoming review of pharmaceutical legislation undoubtedly is to your industry, I think it would be remiss of me *not* to mention the other aspects of European policy, particularly the economic aspects, that are of also of particular interest to you.

For the shared approaches to developing intellectual property are ones that have responded to many of the concerns that you have raised with us in the past. It is particularly pleasing that, by developing shared approaches in the European Union, Europe has a package of intellectual property provisions - some of them specific to your sector - that put Europe in the forefront of this debate. I am sure you will agree that the forthcoming Community Patent will be a valuable addition to this solid package of measures.

Looking wider than the intellectual property issues, I am aware of the views that further work is needed on the tensions inherent in the broader economic issues raised by the Community Single Market. The issue is challenging not only because legal responsibilities are shared between the Member States and the Community but also because of the specificity of the pharmaceutical market itself: health systems in Europe respond to deeply-rooted European values about health care and about social solidarity which mean you have to do business with customers that find themselves in a complex triangular relationship between the payers, the prescribers and the patients with significant implications arising from the reality that the patient rarely chooses the product, nor (generally) do they pay for it. Specific markets need specific solutions.

No sustainable solution will ever be found without taking into account the interests of all tranches of the industry, the legitimate concerns of the Member States, the needs of the patients and the general Community legal context. The Commission has tried in the past to open new approaches: indeed, some progress has been made over the years towards more market-based approaches in the non-prescription sector, where, as in normal markets, individual consumers pay for products that *they* choose. The situation is clearly

more complex in other parts of the market and there are a number of important issues - both in terms of industrial and health objectives - that European society will require us all to meet in thinking about developments in this sensitive area. I do believe that the discussion should continue - but leave with you the thought that history tells us that - in your sector - progress is best made when there is **common** cause to address the challenges that all parties face in ways that look to build genuine European solutions.

#### **4. BIOTECHNOLOGIES – NEW CHALLENGE**

Before concluding, let me return to the importance of new technologies. New technologies and biotechnology look set to drive a tremendous evolution in your sector. Maybe even a revolution. Maybe biotechnology will have a greater effect for you than Internet has had in for information technologies. A new legal framework could be required; new regulatory concepts could be also needed. The industry needs legal certainty and flexibility. Europe needs new approaches to foster the development of these new products - perhaps an enhanced system of early scientific advice to be able to provide, in particular for small and medium biotech companies, a technical help.

#### **Conclusion**

In conclusion: I hope that what I have outlined has met my aim of responding actively to some (doubtless not all!) of the issues – and concerns – that you would like to be raised for the future. A crucial element in making this happen, of course, will depend on you. Working together, with a common concern to find responsible and sustainable solutions to the challenges ahead, I am sure that there is much that we can achieve. I would like to wish you all very fruitful days of conferencing with hopefully the opportunity to exchange views and opinions and to establish new contacts.

Thank you very much.