

EGA Annual Conference

Generic Medicines

Enhancing Pharmaceutical Competition and Enduring Healthcare Sustainability

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CHECK AGAINST DELIVERY

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Opening Address

**To get the Framework right - EU Initiatives in
Pharmaceuticals**

**Venue: Marriott Rive Gauche Hotel
Paris**

Madame le Ministre, Ladies and Gentlemen,

Let me first thank you for inviting me to the opening of EGA's annual conference. I consider it a real pleasure to be here today and to share some thoughts with you on the future of the pharmaceutical industry

There is hardly any issue that concerns people more than their own health. It is also fair to assume that health will remain one of the prime issues **on our citizens' agenda.**

Today we witness the advent of a revolution: advances in life sciences and other breakthroughs linked to biology and health are likely to trigger unimaginable changes and possibilities in healthcare.

To reap the benefits of this promising future, there are things we have to do as the rewards from these developments will not materialise automatically. We have to get the environment right

- **on the one hand to foster innovation and**
- **on the other hand to promote a strong generics industry in the EU.**

Having said this, I would like to take this opportunity to present to you today our programme and activities in 2008 and then focus on some issues that are of specific interest to you.

As you know, Vice President Verheugen has made pharmaceuticals a priority for 2008.

In this spirit, the Commission adopted a legislative proposal in March. Aiming at **simplifying the variations** regulation. It is important because today variations pose a considerable administrative burden, both to industry and to competent regulatory authorities.

The **objective** of the review of the Variations Regulation is to make the overall **system clearer, simpler and more flexible**. We pursue the final aim that all authorised medicines will be subject to the same harmonised criteria for the evaluation, approval and administrative handling of variations within the EU. It goes without saying that we will do this while we continue to ensure that medicines remain safe and effective

Furthermore, the Commission will present this autumn its "**Pharma Package**". It will consist of an overarching **Communication to the Council and the European Parliament on the future of the EU single market in pharmaceuticals** and of **three legislative proposals**.

The **Communication** will provide an opportunity to outline the challenges ahead, set out a vision for the future of the sector, and propose deliverables for the years to come. **The generics industry will most certainly find its place in this Communication.**

With regard to the **legislative proposals**, let me give you some signposts.

One proposal aims at combatting **counterfeits**, an issue of growing concern. Counterfeit medicines seized at EU borders have increased **significantly**. These findings bring a growing awareness that counterfeited medicinal products pose serious threats to the health of EU citizens.

Therefore we will **tighten the requirements** throughout the whole chain, i.e. from the import of active ingredients, through manufacturing and distribution to the patient.

We are considering requirements which clarify that **all actors**, the "traditional" wholesalers, but also brokers and traders, such as business-to-business platforms, are subject to specific distribution requirements. As such, compliance with these

requirements should be documented in an extended Community database. We are also taking into account the possibility for measures to ensure **enhanced traceability** requirements throughout the distribution chain, **including requirements to seal packs and to ensure product integrity**.

Secondly, in the light of possible risks related to **imported sub-standard and counterfeit active substances (see the latest heparin case)**, we will suggest a notification system for manufacturers and – this is new – also for distributors, brokers and traders of active substances. In addition, we are reflecting on tightening controls on **both industry’s self regulation systems** through **audits** and on **authorities’ control measures** through **inspections of manufacturing sites in third countries**.

Thirdly, as we have received indications that bonded warehouses have been misused by traders of counterfeit medicines, we are considering therefore tightening requirements for **products imported with the purpose for being re-exported**. This will be in line with the principles and elements for national legislation recently developed and published by the WHO International Medical Products Anti Counterfeiting Task Force.

I know that **EGA is concerned** about the impact of this proposal on your industry. You are afraid of **increases in costs**. We take these concerns very seriously and I can assure you that we will have a risk-based approach in evaluating the necessity and scope of the different actions proposed.

The **second legislative proposal** will concern the strengthening of the **EU pharmacovigilance system in order to improve the safety of patients**.

The current system of pharmacovigilance in the EU is complex and there is potential for duplication of effort, as well as the potential for confusion of responsibilities. A lack of harmonisation of pharmacovigilance requirements among the Member States interferes with the functioning of the single market in pharmaceuticals. These findings have been corroborated by an independent study, a public consultation, and an analysis carried out by the Commission services. The support of EGA to our proposal since the beginning is most welcome and I would like to thank the secretariat and members for their valuable contributions.

Our third legislative action aims at harmonising future EU practices on the provision of **information to patients**. It will empower EU citizens to make informed decisions when it comes to their health. This initiative is important both for patients and industry.

The proposal does neither intend to change the current ban on advertisement of prescription medicines to the general public nor the possibility to advertise over-the-counter medicines.

However, patients have the right to high quality, objective and reliable information. In doing this, we need to clearly define the **boundaries between information and advertising** as well as adequate enforcement measures. Specific quality criteria would have to be respected with regard to the information disseminated. I know that EGA is sceptical about this proposal and would like to see a status quo. We have however the obligation to present a proposal to EP.

We will therefore not long-overdue as much as possible the outcome of the Pharmaceutical Forum.

This brings me to the ongoing activities of the **Pharmaceutical Forum**. The last meeting will be in October 2008. As most of you know the Forum was created in 2005 by the Commission to address some of the most pressing issues that are at the

basis of the relative decline in competitiveness of the EU pharmaceutical sector and for which no solution was found in the G10 process. It's time limit was of 3 years. The Forum covers **three sensitive and important issues: information to patients, relative effectiveness of medicines and pricing and reimbursement.** The **objective has been to find a way forward** which will ensure patients' access to new medicines at affordable prices and create a predictable environment for businesses with economic rewards for innovators. Pricing and reimbursement are Member States' competences. It has never been our intention to change this. But one thing which should not be underestimated is the **Commission's role as an honest broker** who can try to bridge seemingly irreconcilable differences between Member States. This has been our role in the process. And we have made significant progress. I'm sure that this platform has improved the understanding of the issues at stake and their often interwoven nature.

But let me turn now to three other issues we at the Commission are currently dealing with and which are definitely of great concern to you.

The first one relates to the **ongoing inquiry launched** by our colleagues in DG COMP. Some of you may have received the questionnaires. I know that filling them out is quite time consuming. The objective is to look into practices from the originators in exercising their IP rights (and other commercial practices) which may not serve to protect innovation but to block innovative and/or generic competition.

Our position is very clear. If there are individual cases of abuse, the appropriate legal actions have to follow.

With regard to the more general issue as to whether there are features in of IPR systems which need to be addressed, I consider it premature to draw any conclusions at this stage.

Let's get the facts right first. Let's talk about the assessment of the situation in a few months' time, in the autumn when the Commission will present its report. From a

regulator's side I need once again to say that the conditions to grant a market authorisation are completely harmonised and do not permit patent linkage. We are actively pursuing Member States that introduce it in their laws. We are however aware of practices in some Member States that have the same effect. We have to see how we address these cases. In our legislation we have always guaranteed **an IP regime for pharmaceuticals which takes into account the specifics of this sector and strikes a balance between rewarding innovation and creating competition after the expiry of IPRs.**

In the meantime we will launch a **"market monitoring"** exercise the pharmaceutical sector to accompany the sectoral enquiry. We will do this, in close cooperation with the other Commission services concerned. The objective of this exercise is to provide an assessment of the nature and the causes of the shortcomings in performance of this industry (when compared with their international competitors), notably to **determine the underperformance and - this is most important - the extent to which it is related to market malfunctioning.** The **pharmaceutical industry** seems to be a **very interesting case** since one can hardly argue that it is subject to **"normal market forces"** given Member States' involvement in pricing/reimbursement.

The second issue is in a way linked to the previous one as your industry faces delays in getting marketing authorisations in Member States because of lack of capacities in Medicine Agencies. We at the Commission are concerned about this and will seek to address it in the future by working with regulatory authorities in **optimising the procedures** (Why not a form of **Mutual Recognition** of authorisations for generics?) and the burden sharing of the work within the EU architecture. We will launch this debate in our Pharma Communication.

My final point touches upon **biosimilars**. To address the issue of **traceability of biologicals**, we initiated a **revision of the Eudralex Volume 9A** guidance on

"Pharmacovigilance for Medicinal Products for Human Use" already last year. A public consultation on a first draft proposal was done on that topic in March-May 2008.

Furthermore we **have written to Member States'** regulatory authorities to take necessary measures to ensure

- a method to link suspected adverse reaction reports to specific products (such as a unique product identifier) and
- to ensure that prescribing doctors know which glycoprotein has been given to their patient.

The topic of improving and strengthening the Community pharmacovigilance system for biologicals was also taken up in the **public consultation** on our legal proposal to strengthen pharmacovigilance.

With regard to the nomenclature of biosimilars, **we do not endorse the idea that** any difference in glycosylation automatically leads to a different INN. We have serious doubts that this stance could be scientifically justified. We are also concerned that the WHO is promoting a double-standard policy on biosimilars.

Let me conclude on a very positive note. A lot has been done in the past years in the pharmaceutical sector and new initiatives are in the pipeline or already on their way. In any case, **our goals can only be achieved if we work together.** What we need is mutual trust and commitment in order to achieve our shared objectives: the highest possible level of public health and patient confidence in safe, effective and high-quality medicinal products as well as a strong European pharmaceutical industry. I want to thank EGA for its constructive contribution to our work and thank you all for your attention.

Thank you very much for your patience.