

Annual Conference of the European Generic medicines Association (EGA) Opening session

Paris, 2nd-3rd June 2008

*Agence française
de sécurité sanitaire
des produits de santé*



**Keynote speech of Jean MARIMBERT, Director
General the French agency for the safety of
health products (Afssaps)**

High expectations of society as a whole



- Easy and speedy access to innovative products to meet therapeutic needs;
- Reliable products, really efficacious and reasonably safe, when properly used;
- Affordable products, whether reimbursed or not.

- European / international price for true innovation;
- Increased selectivity of healthcare systems for reimbursement, based on therapeutic added value and cost-efficiency;
- Steady decrease in the price of existing products thanks to sound competition between generic and branded products;
- Substantial level of healthcare coverage for patients.

What has already been accomplished to date ?



- Robust increase in the share of generic products on the market, with significant differences between countries in terms of starting points and pace;
- Without significant safety and public health issues;
- All that resulting in an enhanced confidence of the public in medicines as a whole and generics in particular.

Need to remain vigilant to safeguard the results and achieve further progress



- Globalisation of production/distribution implies renewed challenges for securing quality of starting materials, reliability of bioequivalence studies, tracking counterfeit products;
- High safety expectations require pro-active post-marketing monitoring by regulators and by the firms themselves (whether originator or generic);
- Fierce competition is overall beneficial to the public and healthcare systems, but may sometimes lead to bad choices in terms of safety (lack of investment in GMP, QA, PHV) or unprofessional behaviour of suppliers.

Need to address safety controversies from a sound and evidence based point of view



- In times of sharp competition and termination of patents, controversies on the reliability of generics are sometimes raised ;
- Put in perspective afterwards, their relevance may seem uneven;
- But medicines regulators must seriously handle every seemingly substantiated assumption on safety, lest it should be accused of overlooking a public health issue.

Need to cope with the resources strains in the field of medicines regulation



- Intensification of established tasks : example of pharmaceutical quality assesment, due to the increasing number of generic submissions and variations;
- Additional assignments deriving from legislation for NCA at national level, as contributors to centralised tasks (widening of CP scope) or at both levels (pediatrics);
- Some of the new missions are not matched by corresponding resources (either for lack of financing at European level - pediatrics, herbal - or due to budgetary and public workforce restrictions at national level).

Enhancing efficiency is a must for each NCA to cope with the scarcity of resources



- Organisations reengineering : adapting organisational design; revisiting work methods;
- Revamping information systems : workflow, common data bases, full digitalisation of some procedures (possibility to accept purely electronic submissions in Afssaps by next summer)
- Developing operational cooperation between different areas of regulation : evaluation, inspection, laboratory control...
- Rethinking operational strategies with a view to prioritising actions on the basis of risk based and public-health-added-value concepts.

The European regulatory network endeavours to effectively tackle the issue of resources



- Specific working group on resources set up in 2007 (chair : Steve Dean);
- First HMA strategic debate on resources scheduled for the July HMA meeting in France (preparatory group chaired by Jean Marimbert);
- Main topics : availability of resources, development of resources, efficient use of resources, relevant use of resources.

- EGA letters of 30th October and subsequent messages between EGA and HMA-MG;
- The problem partly stems from the impressive quantitative success of the decentralized procedure (1034 new procedures in 2007, 300 during the first three months of 2008 !),
- Creation of a HMA/CMD (h) taskforce (chair : Gunnar Alvan) to analyse the problem and identify ways to achieve progress;
- Need of converging efforts from the regulatory network and from industry.

A coordinated effort of the European regulatory network



- Raise the number of agencies acting as reference members states : positive prospects are emerging , and could be sustained by cooperation with new RMS (training, workshops...);
- Increase in the number of submissions assessed by some countries as RMS : as an example, France intends to initiate about 50 procedures during the full 2008 year (32 in 2007, 29 in 2006) without registering any significant decrease in national applications;
- Reduce parallel full assessment in MRP/DCP and rely more on the work of RMS;
- Questionnaire currently circulated in the network to feed future recommendations to HMA.

A necessary contribution from industry itself



- Accept to try new member States as RMS;
- Be realistic about time slots that are booked, and avoid double booking for the same dossier;
- Refrain from submitting premature applications with insufficient quality dossier, that will require many long clockstops;
- Notify to the RMS when submitting duplicates (copies of a dossier).

- Generic medicines are part of the solution for solving urging public-health and healthcare challenges;
- Making further headway will require coordinated and converging efforts from the regulators and industry, both acting in their own field of competence.