European Medicines Agency
Celebrating ten years – 1995 – 2005

"A Scientific Perspective on the Future of Medicines"

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EMEA, 10th Anniversary
Place of CHMP in the **EU – Registration System** at the EMEA

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The Committee for Human Medicinal Products is a scientific body evaluating mainly new drugs and working fully in the sprit of a *European* registration system. Their tasks and opinions however cover larger domains of the medico-pharmaceutical science. And their current borders are expect to shift even further

The years 2000 to 2004 were characterized by a tremendous and lively discussion around Revision 2001. That perspective gave an opportunity to all partners involved in the field of registration of medicines in Europe to express themselves. The population and even patient groups remained curiously silent in this debate *but with few late exceptions.* Three main issues emerged from ongoing debates giving suddenly an unexpected flavour of how the EU-system had been perceived since its creation in 1995. Three words were mentioned repeatedly: **complexity**, **transparency**, and **rapid access to patients.**

All partners agreed that the system put in place as transient in the mid nineties had been helpful but was too complex. However Industry and Regulators were split in the way forward to a mandatory simplification. A single (centralized) system could not be agreed upon but for opposite reasons. Two optional routes would allow better competition between different registration systems increasing their efficiency and offering flexibility. Focussing on one procedure would concentrate resources and expertise warranting fairness, equity, credibility and potentially predictability. The outcome of the revision 2001 is a compromise: both systems survive and co-exist. Although the picture looks today more complex than ever, one can reasonably expect a differentiation and specialisation of each branch in terms of excellence. A clarification of the landscape will presumably follow.

Rapid access for patients to new drugs was a leitmotiv supported by all representatives except regulators. The final result offers an opportunity to shorten delays for straightforward dossiers. However some timelines are too short to assure optimal evaluation and provide safe service to the patients. Logically regulators will take their responsibilities and adapt the deadlines on a case-by-case basis.

The transparency of the EU-Registration system has improved a lot over the years. Initiatives were taken to discuss with industry their development of products (Scientific Advice), to consider together the rules and criteria to evaluate the quality/efficacy/safety of their products (Guidance), to analyse the outcome of the procedures (level of expertise). Further internal audits and external consultations were organized to appreciate the SOPs of EMEA and CHMP, particularly in the context of minimizing and managing risks of efficacious drugs but bearing safety concerns.

CHMP

As a consequence of the willingness to implement better transparency and communicate , CHMP tirelessly adapts itself by delivering a number of documents to facilitate the circulation of information, new ET-systems and rules to exchange with companies, procedures to consolidate variations, sitting and brain storming over the

Scientific Advise, Additional Clinical Advisory Groups (SAGs) and the pharmaco-vigilance forum for discussion... and the list is far longer.

The Scientific Advice Working Group is the one amongst all having changed most its working procedures. The timelines were adapted, as was the composition dictated by expertise rather than by national origin, the way tackling questions handled henceforth during face to face meetings, to find practical solutions to common research and development hurdles while respecting strict rules and convincing methodology. This group needs future reinforcement and additional experts. Their challenge is no longer the delays, but rather the scope and variety of scientific problems arisen. The protocol assistance for Orphan medications has eventually shown the way.

Lively discussions about PhVig took place witnessing the true concerns of all involved parties to improve a real complex situation. Different cultures, sensitiveness, approaches, resources, methodologies make it really a challenge to find a common pathway condensing the national and European concerns in a final strategy. Although national authorities rightly believe that most of these responsibilities remains within their obligations, the upcoming CHMP together with the EMEA will nonetheless be confronted to react, handle and communicate appropriately in case of crisis whatever its origin and cause.

More difficult issues raised by applicants and their R&D teams will increasingly touch to pharmaco-genetics (and ethics). The real sensitive issue will be to stratify the patients' population in order to screen the appropriate target population strengthening unavoidably early links between Industry and patient groups. While some fields of medicine happened to become more familiar to all partners (HIV, Biotechnology…), some others still raise questions (oncology, gene therapy) whereas older domains brought up new problems (ethics, vaccines, paediatrics…). The requests of the EU-Commission (GCP-Directive, Risks of BioTerrorism, Preparedness of Pandemics, New Medicines for Children) are assignments that CPMP/EMEA has to cope with

Expectations

In May 2004, ten new members joined the EU and concomitantly a revised regulation became applicable across the EU. Most important are the changes implemented to increase the transparency of the EMEA and its several Committees. The presence of patient representatives at several levels of decision, the access of the general public to different sources of information (databases,) and the clear recommendation of the EU-Parliament to increase and improve the level of information to the citizens are stringent duties for the CPMP to be channelled by the EMEA.

Wider than the EU-borders, the WHO expects the CPMP to answer their requests to evaluate products having public health interest globally or in non-European regions. This difficult mission (defining what is acceptable in a different health care contexts) is nonetheless an ethical duty facilitating access to drugs in good efficacy/safety conditions for those who are dramatically lacking good medicines.

The new CHMP will be confronted with the need to change some of its working habits with 25 full members having each a voting alternate, and another 5 co-opted members to assist CPMP. Establishing contacts with a wider network of experts will be a learning process..

The legal frame seems to be fixed for about a decade, but still there will be some room left for changes. These can be easily anticipated, as for instance the scope of the centralized procedures (more diseases, new technologies, medicines for children, orphan products…). Uncertainties concerning emerging therapies and related technologies will be clarified, e.g. for cell therapy and tissue engineering. Gene therapy is no longer science fiction but will fall under not yet defined remits. This will be one of the many challenges that EMEA and CHMP will have to solve in close collaboration.