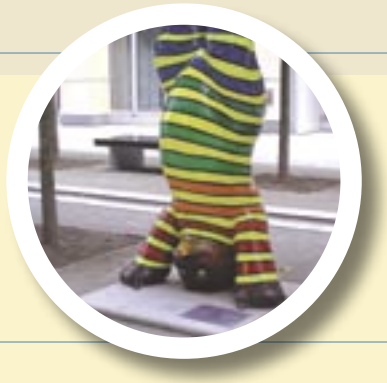

Focus on The Second Annual TOPRA Symposium

New Legislation – the future starts now – are you ready?

Berlin, October 5-7, 2005

Reviewed by Dave Gilbert, NDA Regulatory Science

This second TOPRA annual symposium was perfectly timed to discuss the subject of New Medicines Legislation, taking place as it did just weeks before the deadline for implementation of the Directive and the Regulation. Proceedings got off to a flying start with introductions from **Craig McCarthy and Margaret Jorvid, Chair of TOPRA Symposium Working Party and President of TOPRA respectively** and with keynote addresses from **Brian Ager, Director General of the European Federation of Pharmaceutical Industry Associations (EFPIA)** and from **Martin Terberger, the new Head of Unit Pharmaceuticals in DG Enterprise and Industry at the European Commission.**

Brian Ager reminded delegates that the 21.5 billion euros invested in Research and Development (R&D) by the European Union (EU) pharma industry generates a trade surplus of 38.5 billion euros and is the highest contributor among high-tech sectors to Europe's trade balance. But year-on-year the European R&D-based pharmaceutical industry is losing competitiveness to the United States of America (USA) and the EU environment has lost its attractiveness as a home for future technologies. This increasing gap is recognised at the political level and the Lisbon Agenda, Barcelona Target and G10 have identified possible solutions.

In some areas important progress has been made – for example in harmonising data protection and improving medicines legislation. But in other areas – eg, the restructuring of Frameworks VI & VII to drive R&D by providing improved co-ordination of EU research projects to reach critical mass and in the critical area of market reward – there is recognition that there is a problem to be solved but so far implementing a solution has been less satisfactory. But EFPIA fully supports the EU Commission's stated principle objectives and this led very nicely to the next speaker, Dr Martin Terberger (Head of Unit Pharmaceuticals, DG Enterprise)..

Dr Terberger was particularly welcome to the TOPRA annual symposium because while it is always interesting and important to hear the views of the Head of Unit Pharmaceuticals, in this case Dr Terberger was only in his third day in his new position as Head of Unit and this was his first public engagement! It was a perfect opportunity to meet in a regulatory professionals setting and to exchange views. The presentation from Dr Terberger was very reassuring – no radical changes but business as usual. He stated that it was not the intention of the "new" Commission to revisit the changes in the legislation but simply to implement them. It was interesting to go back to "grass roots" and to be reminded about the principle objectives of the Commission and the initiatives supporting those principles.

The three principle objectives underpinning the Commission vision are:

- To protect a high level of public health
- To complete the internal market in the pharmaceutical sector
- To ensure competitiveness of the European-based industry

and the three initiatives supporting the objectives are:

- The review of the pharmaceutical legislation
- Further Community measures to trigger innovation and
- Follow-up of the G10 Pharmaceutical Forum.

Dr Terberger dealt with each of these points in turn. Medicines legislation was the major focus of this conference report so the detail will be reported later, but at a high level Dr Terberger stated that what was critical was proper implementation of the key elements of the medicines review that will stimulate innovation. These key elements are: widened scope of the Centralised Procedure, more flexibility in the Centralised Procedure, a streamlined Mutual Recognition Procedure and improved data protection. Turning to other Community measures to trigger innovation, Dr Terberger referred to the European Technology Platform from DG Research; the Regulation on medicines for children (addressing a public health challenge while rewarding new research into paediatric medicines) and the proposal for a Regulation on advanced therapies (providing legal certainty in new areas of medical treatment). Finally, he returned to the G10 recommendations and the newly announced Pharmaceutical Forum to promote competitiveness of the European industry by taking key issues and recommendations forward. The forum will be jointly chaired by Vice-President Verheugen and Commissioner Kyprianou, will have representation from all stakeholders and will be established in first half of 2006. Their priorities will be pricing and reimbursement, clinical and cost effectiveness of medicines and information to patients. It is to be hoped and expected that these initiatives will address the "unfinished business" referred to by Dr Ager earlier in the Symposium.

Are you ready for…Implementation of the New Medicines Legislation?

Within a general theme of "the devil is in the detail", **Greg Perry, Director General of the European Generics Association (EGA)**, was cautiously optimistic. For the first time the generics industry has a scientific definition of a generic, the concept of a European Reference Product, the EU equivalent of the Bolar provision in the USA, the concept of a global Marketing Authorisation ensuring no additional

data exclusivity on line extensions, variations etc, a legal basis for Summary of Product Characteristics (SmPC) harmonisation, the option to use the Centralised Procedure or the new Decentralised Procedure (DCP) and last but not least, an legal framework for biosimilars where the EU is pioneer.

But as mentioned by Dr Terberger, it is the implementation that is important and it is necessary to be vigilant to ensure that the legislation is implemented in the spirit that was intended, ie, as a tool to facilitate the introduction of generics and not to raise unnecessary hurdles. He gave specific examples including these that follow. The additional year of data protection (10 + 1) offered for significant clinical benefit must not go beyond the intention of the law and should only be given for new indications of significant clinical benefit and not to new categories of patients or improvements to therapeutic use in existing categories of patients. The Centralised Procedure will not be accessible to generics if the single name requirement is maintained. A single name is inconsistent with national requirements concerning generic naming and substitution. The theme of proper implementation became something of a sub-plot of this symposium and one was left – certainly not for the last time – that the answer to the question "The Future Starts Now – Are You Ready?", at least in some rather key areas, was a resounding No!

A perfect example was the question of the relevant data protection period when a generic sponsor refers to a reference product in another Member State (with six years protection) as the basis for approval in a recipient Member State with 10 years protection. Dr Perry argued logically enough that the six-year period was the only relevant period because it was to those data that the generic referred. But it is clear that the research-based industry would be likely to take another stance on this and with only weeks to go before implementation there is no clear direction or guidance. No doubt it will be forthcoming in the nick of time!

Dr Hubertus Cranz, Director General of the Association of the European Self-Medication Industry (AESGP), also welcomed the legislative changes with the caveat that implementation should follow the spirit of "better legislation". The procedural opportunities include the extension of the Centralised Procedure to innovative non-prescription medicines and improvements to Mutual Recognition and to the Decentralised Procedure for example by better definition of "serious risk to public health". Important incentives for research are the one-year data exclusivity offered for switches from prescription to non-prescription status. Dr Cranz expected switches for simvastatin (Zocor™), orlistat (Xenical™) and oseltamivir (Tamiflu™) among others. Also important as an incentive is the one-year data exclusivity offered for new indications for well-established substances which should encourage the continued development of new uses for old drugs. Of course, there are also some challenges, and the EMEA guideline on invented names was referred to again as an issue for this industry.

Dr Thomas Lönngren recently re-appointed for a second five-year term as **Executive Director of the European Medicines Agency (EMEA),** also made a key presentation which focussed on two issues. The first was the EMEA roadmap to 2010. The roadmap, which is underpinned by the EU network of regulatory agencies, was achieved after much discussion and involvement of all stakeholders and represents a clear route ahead ensuring that the steps made each year are part of a consistent plan with strategic direction. The second issue was the implementation of the new legislation with emphasis on:

- Safety of medicinal products
- Access to medicinal products
- Supporting innovation and R&D
- Transparency and communication and information.

The EU network was a common theme from many speakers and Dr Lönngren said that it was a main objective of the EMEA to strengthen the network to make it a **network of excellence** with the EMEA managing and co-ordinating part of the network supported by the Heads of Agencies informal management group. In order to make this "network of excellence" other steps will need to be implemented. These will include defining individual national agencies' roles in the network, the development of the role of EMEA and the identification of the best expertise together with a mechanism for training competence development and for a quality assurance system. The EU network will continue to develop a common approach to transparency and communication, risk management and telematics.

The priority for the EMEA in 2006 is to ensure the safety of medicines especially after marketing. The public expects zero risk, which is not achievable and a good balance needs to be found between rapid access to medicines, and safety. The EU risk management plan with its increased emphasis on proactive pharmacovigilance together with the provision of better and more accessible information to the public will have important contributions in this regard. Improved access to market is offered by new procedures such as conditional approval, approval under exceptional circumstances, accelerated approval and compassionate use. The need for openness, communication and provision of information has resulted in the creation of a new EMEA Sector for Medical Information headed by Dr Isabelle Moulon. And similarly the need to provide support for small and medium sized enterprises (SMEs) has resulted in the creation of another new unit specifically for this purpose headed by Dr Melanie Carr.

Finally in this session, the German Pharmaceutical Industry perspective on the NML was provided by **Prof Dr Barbara Sickmüller, the Deputy Director General of Bundesverband der Pharmazeutischen Industrie (BPI).** She discussed the special problems associated with implementation the NML for small and medium sized enterprises. She cited readability testing and the new renewals system as examples where implementation should be with a "sense of proportion". Dr Sickmüller also discussed a common theme which was that in the absence of timely guidance on implementation of the Regulation and

Focus on The 2nd Annual TOPRA Symposium continued…

the Directive, Member States had even more room than usual to interpret the legislation in different ways, so losing the harmonised approach intended. She cited the disharmonised introduction of the Clinical Trial Directive 2001/20/EC and the supplementary guidelines as an example of "how not to do it".

The final part of her presentation dealt with how unnecessary bureaucracy could possibly be reduced. She used the Sunset Clause as an example. An objective of the new medicines legislation is to "reduce workload with agencies" but it was difficult to see how an additional requirement – with resource implications for both regulatory authorities and industry and no obvious public health benefit – contributed to this objective. An enlightening presentation on the BPI perspective concerning the up and coming legislation!

Are you ready for…the Centralised Procedure?

Dr Daniel Brasseur, Chair of the Committee on Human Medicinal Products (CHMP), informed us that the EMEA and CHMP have been preparing since 2004. A CHMP/EMEA Implementation Task Force had (as of September 25, 2005) addressed more than 30 specific implementation topics and through 67 CHMP sponsors had published 15 guidance documents with a further nine in preparation. By the time you read this report these figures will have certainly been exceeded, providing us with further much needed guidance in diverse areas.

One important guidance document discussed in detail by Dr Brasseur (and indeed since then published on the EMEA website) relates to the hot topic which is the scope of the Centralised Procedure. For those of you who thought this topic was done and dusted, it is good to know that there is still plenty of room for debate and discussion. Dr Brasseur stressed that it was important not to go beyond the very precise scope of the Annex to Regulation (EC) N° 726/2004. It is mandatory at the moment for the following to use the Centralised route:

- Medicinal products developed by biotechnology
- Veterinary products intended as performance enhancers
- NCEs for the treatment of:
  - acquired immune deficiency syndrome
  - cancer
  - neurodegenerative disorder
  - diabetes
- Orphan drugs.

The mandatory scope is strictly limited to the above and as much as possible for the remainder the scope is left optional. The compulsory therapeutic areas are well known by now but Dr Brasseur expanded upon some of the important subtleties. The definition of "neurodegenerative diseases" for example can be open to interpretation. To aid in the recognition of disease conditions that are within the mandatory scope of the Centralised Procedure, the CHMP has used the International Classification of Diseases version 10 (ICD-10) as the basis for disease classification and, in the case of oncology, the International Classification for Diseases for Oncology (ICD-O). What is interesting is that even within these four therapeutic areas the mandatory scope is further limited to "treatments" and interventions intended for "prevention and diagnosis" are not mandatory. An intervention intended for the treatment of diabetes would be mandatory, for example, whereas an intervention intended to **prevent** diabetes in at risk patients would not. In the latter case use of the Centralised Procedure is encouraged and welcomed but it is certainly not mandatory. Similarly, a product intended for the treatment of diabetic retinopathy, a complication of diabetes, would be required to use the Centralised Procedure only if the intervention was based on treating the underlying disease. Another example of "non-compulsory" relates to treatment of side effects, for example, a new chemical entity (NCE) for the treatment of nausea and vomiting after anti-cancer therapy.

Other changes were announced. If an NCE falls within the compulsory annex, it is no longer necessary to request eligibility from the EMEA. If it is mandatory, it's mandatory, and further discussion is not required. If on the other hand you have an NCE which is not within the mandatory scope and you want to file centrally then you will still need to make that request to the EMEA/CHMP but access will be granted automatically. Compounds that are not an NCE could still be eligible if the indication is within the mandatory scope and the sponsor justifies the significant therapeutic criteria. And if neither an NCE nor with an indication within the mandatory scope, then the Centralised Procedure would still be an option in cases of significant scientific or technical innovation or if of interest to patients at the community level. This latter category seems to have defied definition so far and it will be interesting to see if this is a "catch-all" or if a narrower interpretation will be offered. In the spirit of full optionality a broad definition may be warranted.

We must not forget that the new Centralised Procedure will also be open to generics where the originator labelling is harmonised and also to innovative over-the-counter (OTC) products (still to be defined). And last – but certainly not least – all designated orphan drugs will now be mandatory for the Centralised Procedure. Because there is no transition period for implementation this has the unfortunate effect that any orphan drug application currently submitted nationally must transfer to the Centralised Procedure on the date the Regulation becomes effective.

The new legislation also allows the correct distinction between Conditional Approval and Approval under Exceptional Circumstances. In the former case, the data normally required for approval have not been provided and the sponsor will therefore need to commit to "specific obligations" to provide additional data as a condition of approval and the Marketing Authorisation (MA) will be valid for only one year and re-assessed in the light of the new data each year. It will be interesting to see what happens when the data provided later do not fully support the conditional approval. And in the latter case the data normally required never can be provided (for scientific, technical or ethical reasons) and therefore a full authorisation can still be granted without annual re-assessment.

It is also no longer necessary to make suggestions for sponsor




preference for rapporteur and co-rapporteur. The new legislation no longer allows for this possibility just as it no longer requires rapporteurs to be as far as possible distributed fairly across all Member States. The responsibility for assigning rapporteurs will lie with the EMEA and its scientific committees. Delegates heard earlier from Dr Lönngren that potential rapporteurs will be required to identify their whole assessment team at the time they propose to be rapporteur in order that the EMEA can ensure that the best scientific expertise is brought to bear on the assessment.

Dr Gonzalo Calvo Rojas and Dr Pieter Neels provided the perspective from the Member States – in this case as CHMP members for Spain and Belgium respectively. Dr Rojas spoke very well to the difficult issue of public perception when industry had the opportunity to request rapporteurs. He was reassuring that in spite of the fact that industry no longer has this opportunity, the very best expertise will be brought to bear. Dr Neels made the point, with some passion, that it is very difficult in small agencies to provide all of the resources that are required for a Centralised assessment. While on the topic of the best expertise there was general support for the increased involvement of Scientific Advisory Groups (SAGs) in the assessment process. This would certainly appear to be a way for specific expertise available throughout the community to be available to advise on specific issues without having the requirement to evaluate the whole dossier. Another interesting development is that there will be a database of scientific advice obtained at the national level. All these efforts seem to fit in with the general philosophy of increased transparency and consistency. Dr Neels also announced that the Belgian Ministry went paperless on October 1 and he urged the submission of electronic common technical documents (eCTDs).

Are you ready…for the Decentralised and Mutual Recognition Procedure?

Dr Christa Wirthumer-Hoche provided an excellent presentation from the Mutual Recognition Facilitation Group (MRFG) perspective. The presentation covered the comparison of the Mutual Recognition Procedure (MRP) and the New Decentralised Procedure (DCP). The DCP was discussed in detail with timelines for each of the 4 steps: Pre-procedural step, Assessment step I, Assessment step II and the national step. Dr Wirthumer-Hoche explained that at Day 120 of Assessment Step I, if consensus is reached – DCP is finalised, and then the national step can be progressed. However, if consensus is not reached then Assessment step II is progressed. If consensus is reached at Day 210 the national authorisation will be issued. If consensus is not reached then there will be referral to the Coordination Group for Mutual Recognition and Decentralisation Procedures (CMD) for resolution. She also expanded on the role of the CMD and the comparison with the CHMP/Committee for Veterinary Medicinal Products (CVMP), in terms of, election of the chair person and voting on procedural issues. Dr Wirthumer-Hoche emphasised the timetable for the MRP had not changed and the situation after Day 90 if agreement has not been made. Details were given on the CMD 60-day procedure. However, this has not been finalised and a proposal is to be issued.

From the Industry perspective, there was extensive discussion on these procedures and their role with generic products and non-prescription products.

Are you ready…to implement key elements of the Directive?

Patient Information

Anyone present at this TOPRA conference with any lingering doubts about the need for user testing of patient leaflets could have had no such doubts after the highly relevant presentation from **Mokrane Boussaid, Director of the European Blind Union.** Dr Boussaid provided a much-needed reminder of the very real practical difficulties that face the visually impaired when using medicines.

Jeremy Mean provided the perspective of the United Kingdom Medicine and Healthcare Products Regulatory Agency (UK MHRA) reminding us of the requirements in the new Directive 2004/24/EC. In the UK, user testing of the patient leaflet became mandatory from July 1, 2005 with a three year transition period for existing products.

Following on from Jeremy Mean's presentation on the regulatory objectives for patient information, **Dr Peter Knapp** provided a useful talk on practical issues in readability testing. Dr Knapp is the Chief Scientific Officer at "Leeds User Testing Organisation", LUTO Research Ltd, in the UK. Peter initially discussed the legislative requirements, which were introduced in July of this year. Not all of a company's products will require readability testing, the concept of grouping will be allowed. However, it was highlighted that the Medicine and Healthcare Products Regulatory Agency (MHRA) is at the moment unsure of what grouping is and means, so case law will be required.

Concerning translations of Patient Information Leaflets (PILs), "faithful translations" are acceptable, and back translation does not seem to be a requirement. Dr Knapp discussed in detail what user testing actually is and why a PIL might fail the test. Small dense text, long sentences, long or difficult words and a chaotic layout could all lead to a PIL being unreadable. In summary, this Europe-wide legislation should impact on the quality of information, and thus increase patients' knowledge of medicines and how to use them safely and effectively.

Are you ready…to implement key elements of the Directive?

Data Protection

Anthony Warnock-Smith, partner at Morgan Lewis & Bockius, introduced this important topic by gently reminding us that there is really no such thing as data exclusivity as a legal concept although it is a convenient term that we all use and understand well. In fact the legislation simply allows that under specific conditions there can be an exception to the general requirement to provide full data in support of a Marketing Authorisation Application. We are all by now familiar with the 8+2+1 concept and there is no need to go into those details here. What is important perhaps is to understand the time frame. The new harmonised data protection periods are not effective retrospectively and will only apply to new applications submitted Nationally via MRP/DCP after October 30 or Centrally via the EMEA after November 20, 2005. Also to clarify that in order to qualify for the one year extension (the +1) for a significant new indication then that new indication must be authorised (and not just submitted) within the first eight years.

Focus on The 2nd Annual TOPRA Symposium continued…

Are you ready…for future challenges?

Craig Hartford, Executive Director and Site Head, Safety and Risk Management for Pfizer Worldwide Development, discussed clinical drug safety and the fundamentals of risk management. Mr Hartford provided a very detailed presentation on the regulatory perspective of risk management. He discussed the importance of setting up a "Risk Management Committee" very early in the drug development process, and provided examples of the types of people who would be involved. The Risk Management Plan was foreseen in Directive 2001/83/EC which includes the requirement for "*a detailed description of the pharmacovigilance and, where appropriate, of the risk management system which the applicant will introduce*" and on September 6, the EMEA released a guideline on the practical implementation of a Risk Management Plan. The European Union Risk Management Plan (EU-RMP) must be submitted with the application for a new Marketing Authorisation for any product containing a new active substance, a biosimilar product, a generic product where a safety concern has been identified with the innovator product, new dosage forms, new route of administration, new manufacturing process of a biotechnologically-derived product and any significant new indication unless it has been agreed with the Competent Authority that submission is not required.

An example Risk Management Plan (RMP) was shown, and key concepts were highlighted. The plan should identify important safety risks as well as identifying any gaps in product knowledge. There should be proposals for filling the gaps in knowledge through prospective actions such as data capture aids and epidemiological studies. The Risk Management Plan and inter alia the Pharmacovigilance Plan is a living document and should be updated regularly and in the light of new knowledge. The presentation was nicely brought to a close with a summary of the current and future concepts for enhancing patient safety, which is after all the ultimate reason for risk management.

Jytte Lyngvig, CEO of the Danish Medicines Agency, and Chairman of the Heads of Medicines Agencies management group, provided a lively contribution with the overall message that transparency is here to stay and it needs to be embraced by the industry – or as she nicely put it – the wind of change is in the air so "build windmills and not shelters". The legislative framework for transparency is now in place and she said that industry should adopt a transparency strategy, which could include active dialogue with authorities and consumers for the purpose of counteracting the perception of distrust and secrecy by providing relevant information to the public (for example on clinical trials and safety issues). But, of course, transparency does not stop the questions. What the patient may actually need is tailor-made information, but that will not be possible and a balance will have to be struck between providing relevant information and the potential confusion (not to mention resource needs) of over information.

The challenge for the regulatory authorities is also there in complying with the new requirements upon the Member States to "make

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For 2006 we are delighted that with the agreement of TOPRA Advisory Council member, Dr Aginus Kalis, the Dutch Medicines Evaluation Board (MEB) will be assisting with the organisation of the programme and this meeting will be an ideal opportunity to get to know this key agency better.

Also in 2006 the programme will be expanded to include sessions covering medical technologies and veterinary matters, amongst others.

The 2006 Symposium will also be the venue for the 2006 AGM and the 2006 Graduation Ceremony for the TOPRA MSc in Regulatory Affairs.

As always there will be a trade exhibition showcasing companies with products and services to assist the regulatory professional, and a social event for informal networking.

Look out for further announcements during the coming months.

In the meantime, if you would like to be part of the planning team for this or any other TOPRA meeting, please e-mail our Conference and Training Programme Manager, Christopher Bailey (christopher@topra.org)

publicly accessible" its rules of procedure, records of meetings including the explanation of votes including minority opinions and also the requirement to make available the national equivalent of the European Public Assessment Report (EPAR). It will be a challenge to respect the vision of the law makers and still make things work. There will be discussions in the co-ordination group and templates will probably come. The benefit of transparency is that it may lead to greater trust in medicinal products if it is done in a good way.

Stefan Holmstrom from NicOx returned to an issue raised by Brian Ager at the beginning of the conference – the subject of pricing and reimbursement. He graphically highlighted the complexity in Europe where national requirements vary enormously and where for many governments it is a core component of their strategy to reduce healthcare expenditure. In Europe, while there is a political consensus that healthcare costs must be reduced, he emphasised some key factors to be considered by the industry: These included to build in product differentiation early in the R&D process to allow, where appropriate, Phase III positioning to reduce the potential for clustering, to understand the needs and perspectives of each decision-maker to communicate product value and for small companies to focus on niche markets with new products emphasising differentiation in efficacy and side effects.

To be successful all companies must identify and understand the needs and priorities of the decision makers down to the lowest level in each market in order to present the appropriate data to the appropriate audience delivering a differential value argument. The impact of cost containment policies alone is forecast by EFPIA to reach almost 6.5 billion euros in 2005, or an estimated 6.4% of total market value and it is a big and costly challenge for the industry to get the price right in each individual market (the European market is not one market in this respect).

Nihls Behrntd, Deputy Head of Unit, Pharmaceuticals, presented the new initiatives of the Commission including paediatric medicines and advanced therapies. The paediatrics legislation – currently at first reading in the Council and European Parliament – is a good example of the use of "reward" to stimulate innovation and the development of drugs for children. The reward for medicines in-patent is a six month extension of the supplementary protection certificate. The reward for orphan medicines is a two year extension to the normal 10 years of market exclusivity. The reward for compounds that have no patent protection will be a new kind of stand alone Paediatric Use Marketing Authorisation (PUMA) which will benefit from 10 years data protection (but of course only for the paediatric indication which is the subject of the PUMA) and importantly the same brand name can be used. The legislation may be adopted at the end of 2006 or in early 2007 and will surely be the subject of much more discussion.

In relation to advanced therapies the Commission is working to adapt the current legislation to reflect the particularities of gene therapy, cell therapy and tissue engineered products. The legislation is foreseen to be a Regulation and that a new Committee on Advanced Therapies will be formed under the CHMP to reflect the specialist expertise required. Another important initiative is to make available information to patients on all EU medicines in a way which is accessible and which is independent from pharmaceutical companies. This EuroPharm database will make available the SmPC, leaflet and labelling in a way which is both "appropriate and comprehensible". The Pharmaceutical Forum referred to earlier will, from 2006, have a Working Group on how to improve information to patients which could result in an extension to the EuroPharm database.

Conclusion

The Future Starts Now – Are You Ready? That was the question to be addressed by the Conference. So what was the answer? From the regulatory procedure point of view probably most people felt the same as they did just before walking into final exams at University. There is always a nagging doubt that you should have done a bit more work and then maybe you would feel better prepared. But afterwards the sensation was usually that the exam was not so bad after all. And that is where we seem to be. The next weeks will see the issuing of last minute guidance documents (the equivalent of that last bit of revision late at night) and then it's exam time. There will be some unexpected questions and issues but by and large we are as ready as we ever will be…Let's take the exam!

But maybe the biggest challenge will come from a somewhat different direction which is the overwhelming mandate for increased transparency. One of the biggest challenges for EMEA, the national competent authorities and the Industry is to find an effective way to achieve the Commission's objective of transparency about the regulatory decision-making process for approval of new medicines and for better informing the patient about the benefits and the risks of medicinal products. Helping patients to find appropriate medical information which is both accessible and understandable and which they can trust is a significant challenge for the next years. It has a clear legal mandate now and is at the same time a tremendous opportunity and a significant challenge. A newly diagnosed diabetes patient using Google to search for information is likely to be confused rather than helped by 95,100,000 hits!