



Making Medicines Affordable

EGA Conference

highlights

EUROPEAN UNION PERSPECTIVE

Mutual Trust and Commitment: Working Together Towards Sustainable Healthcare for EU Citizens

GREG PERRY, Director General, European Generic medicines Association, welcomed participants to the 14th EGA Annual Conference in Paris entitled *"Generic Medicines: Enhancing Pharmaceutical Competition and Ensuring Healthcare Sustainability"*.

Mr Perry highlighted the DG Competition "Enquiry into the Pharmaceutical Industry" aimed at looking into alleged patent abuses and proposing remedies as necessary. Secondly, he mentioned the "Consultation on the Future of the Pharmaceutical Industry" launched by the Commission to better understand how to tackle the key challenges facing the sector. A communication resulting from this initiative will present proposals for improved pharmaceutical legislation and regulation later in the year. Meanwhile, the Commission is already working on a series of proposals for 2008, including a revision of the Variations Regulation and proposals on pharmacovigilance, counterfeit medicines, and information to patients.

Mr Perry also briefly highlighted the main challenges facing the industry. He cited the continued lack of resources for the medicines authorities and the "commercially staggering" problem of obtaining a date (or slot) to apply for marketing approval. He touched on the increasing pressures from national pricing reforms which threaten the viability of generic medicines sup-

pliers. Finally Mr Perry reiterated the EGA's long-standing concern with linking product approval and pricing & reimbursement decisions with the patent status of a product. This patent linkage, Mr Perry said, is illegal, anti-competitive, and runs counter to the concept of immediate access to generic medicines upon patent expiry.

"We have to get the environment right, to foster innovation and to promote a strong generic medicines industry."

Georgette Lalis, Director, Consumer Goods, DG Enterprise, European Commission

GEORGETTE LALIS, Director, Consumer Goods, DG Enterprise, European Commission, confirmed that health and pharmaceuticals are Commissioner Günter Verheugen's main priority this year. "We have to get the environment right", Mrs Lalis said. "On the one hand to foster innovation, and on the other hand to promote a strong generics industry in the EU."

The review of the Variations Regulations, she said, aims at a clearer, simpler, and more flexible system for industry and authorities, and ensure that medicines remain safe and effective.

Similarly, the Communication on the Future of the Pharmaceutical Industry will outline the challenges facing the sector and will propose deliverables to help meet them. "The generics industry will most certainly find its place in this Communication", she said.

Mrs Lalis described the counterfeiting of medicines as a growing concern that must be combated by tightening requirements throughout the supply chain. Possible measures include enhanced traceability, seals, stricter audits, and tighter rules on importing for re-export. She addressed the generic industry's concerns, assuring them that the Commission "will have have a risk-based approach in evaluating the necessity and scope of the different actions proposed."

Mrs Lalis said she was aware "that the EGA is sceptical" about the proposal on information to patients. While saying patients have the right to high quality, objective and reliable information, she insisted on the "need to clearly define the boundaries between information and advertising as well as enforcement measures."

With regard to the enquiry into the pharmaceutical sector, Mrs Lalis said, in cases of abuse, "the appropriate legal actions have to follow." She said it was prema-

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- ★ CEO Panel
- ★ Biosimilars

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GEORGETTE LALIS
European Commission



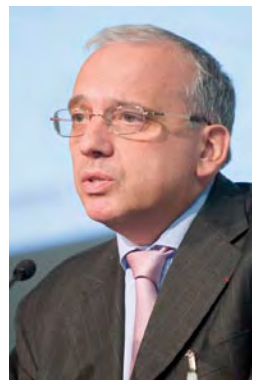
ERIC GORKA
EGA, President



GREG PERRY
EGA, Director General



PHILIPPE SAUVAGE
French Ministry of Health



JEAN MARIMBERT
Afsaps

EGA CONFERENCES 2008 | 6th EGA Biosimilars Symposium | 14th EGA Annual Conference

EU Pharmaceutical Legislative Pipeline

Enquiry into the Pharmaceutical Industry

- DG COMPETITION | aims to look into whether anti-competitive practices have slowed down innovation and blocked the entry of less expensive products onto the European market. It will examine alleged patent abuses and propose remedies as necessary. Final results are expected in the spring of 2009.

Consultation on the Future of the Pharmaceutical Industry

- DG ENTERPRISE | launched to better understand how to tackle the key challenges facing the pharmaceutical sector. This public consultation has three major objectives:
 - To examine the Single Market for Pharmaceuticals,
 - To review implementation of the Pharmaceutical Review in the Member States,
 - To revise the Pharmaceutical Review.A communication based on the outcome of this initiative will lay out proposals for improving pharmaceutical legislation.

Revision of the Variations Regulation

- DG ENTERPRISE | aims to make the system clearer, simpler and more flexible, both for industry and the authorities, while ensuring that medicines remain safe and effective. The legislative procedure is scheduled to be completed before European elections in June 2009.

Pharmacovigilance Framework

- DG ENTERPRISE | a consultation was launched in December 2007 on proposals to modify Directive 2001/83/EC and Regulation 726/2004 with a view to revising the EU Pharmacovigilance Framework to ensure that it continues to meet today's realities and remains fit for the future. This framework was not included in the 2001 Review of Pharmaceutical Legislation.

Anti-Counterfeiting Directive

- DG ENTERPRISE | increasingly concerned at the safety risks posed by counterfeit medicines, the European Commission proposes to combat the problem by tightening requirements throughout the supply chain. Possible measures include enhanced traceability, seals, stricter controls on audits, and tighter rules on importing for re-export.

Information to Patients

- DG ENTERPRISE | aims to ensure all EU citizens have access to good-quality, objective, reliable and non-promotional information on prescription-only medicinal products. After a consultation process in spring 2008, a legislative proposal is expected by the end of 2008.

Renewing Levels of Vigilance to Meet High Expectations for Quality, Safety and Efficacy in Medicines

(continued from page 1)

ture to determine which features of the intellectual property system might need to be addressed. But Mrs Lalics did make it clear that "the conditions to grant a market authorisation are completely harmonised and do not permit patent linkage." The Commission is actively pursuing Member States that introduce patent linkage into their national legislation.

Concluding on a positive note, Mrs Lalics remarked that much has already been accomplished in the pharmaceutical sector and that many new initiatives are in the pipeline. She reminded her listeners that "our goals can only be achieved if we work together. *What we need*", she said, "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."

ERIC GORKA, President EGA, highlighted that using medicines industry generates savings of over €25 billion per year, and that generic medicines cover a wide spectrum of pharmaceutical treatment areas. Additional benefits, he said, include the drop in price of originator medicines once a generic equivalent enters the market and the subsequent increase in the affordability of medicines to patients. He said the arrival of new biosimilar medicines are presenting further opportunities to bring even greater savings to healthcare systems and patients.

And savings today are more important than ever. With Europe's ageing population and the corresponding increase in healthcare expenditure, governments are under heavy pressure to find appropriate budget solutions. Generic medicines are part of this solution.

But the sector is facing several challenges to its viability. As more patents expire, increased opportunities arise to achieve greater affordability and access to new generic medicines. But in markets such as France, Belgium, Austria, Spain or Italy, generic medicines have a largely unfulfilled potential for growth.

Citing a recommendation from the G10 High Level Group in 2004, Mr Gorka urged that "Member States—facilitated by the Commission—should explore ways of increasing generic penetration in individual markets (including generic prescribing and dispensing). Particular attention should be given to improved market mechanisms in full respect of public health considerations."

Similarly, in emphasising the importance of generic medicines to Europe's healthcare systems, Mr Gorka quoted the Pharma Forum Progress Report of June 2007, saying that "Generic medicines provide an opportunity to obtain similar treatments at lower costs for patients and payers, while liberating budgets for financing new innovative medicines."

Mr Gorka concluded with a final thought on the short-term price reduction policies—such as tendering—being introduced in certain markets. While stressing that savings are important, he insisted that long-term competition and added value for patients are important, too. He urged authorities to implement policies to strengthen the sustainability of healthcare systems by reinforcing the generic medicines industry. ■

THE FRENCH POINT OF VIEW

JEAN MARIMBERT, Director General of the French medicines agency, Afsaps, pointed out that the public expects *speedy access* to therapeutic medicines that are *reliable*, *effective*, and reasonably *safe* when used properly, and *affordable*, whether reimbursed or not. Indeed, financial sustainability is an issue for all stakeholders. France started slowly with generic medicines, but their market growth has been robust over the past 5-6 years. No public health issues have been reported in relation to their use, resulting in enhanced confidence in medicines in general and in generics in particular. These safety expectations call for renewed *vigilance to avoid any possible quality issues*. His agency works to this end while striving to avoid any undue delays of generic medicines approvals. Mr Marimbert attributed the lack of agency resources partly to the success of the new decentralised procedure, with 20% more applications in 2008. Limited resources have required him to rethink operations strategies to improve efficiency and workflows. His objective is for France to increase its contribution as a Reference Member State to at least 50 dossiers this year.

PHILIPPE SAUVAGE, Deputy Chef de Cabinet to and representing Roseline Bachelot Narquin, French Minister of Health, described the evolution of the sector in France. Ten years ago there were no incentives to use, substitute or prescribe generic medicines; patients were not interested in generics; and low medicines prices characterised the French market. By 2007, however, generic medicines generated €500 million in savings each year, compared to €80 million in 2000. They now represent some 20% by volume of all pharmaceuticals prescribed. Mr Sauvage said there is strong political will to maintain low prices, and to that end the French market now has several tools to promote the use of generic medicines. These include incentives to pharmacists, including the right of substitution and equal profit margins; incentives to doctors to prescribe generic medicines; and incentives to patients to request them, including faster reimbursement for generic medicines. He said France has also accelerated access times to market for generics. In conclusion he noted that generic medicines are now a permanent part of the French healthcare scene, and that he expects a growing number of prescriptions to be subjected to generic substitution. ■

■ "Generics are a good choice!"

Kees de Joncheere, Regional Adviser Health Technology & Pharmaceuticals,
WHO Regional Office for Europe

Presentation of New EGA Report Patent-related Barriers to Market Entry for Generic Medicines in the European Union | A Review of Weaknesses in the Patent System

JULIA PIKE, Intellectual Property Director & Counsel, Hospira Global Pharma R&D, presented the EGA's latest report which details a number of hurdles resulting from weaknesses in the European patent system. It focuses on three main areas in which the patent system and surrounding legal and regulatory framework fail to ensure an appropriate balance between incentives and competition:

- Systemic failures to grant only quality patents,
- Patent thickets and follow-on patents,
- Patent litigation procedures, and
- Patent linkage.

PATENT LINKAGE

"The Single Biggest Barrier"

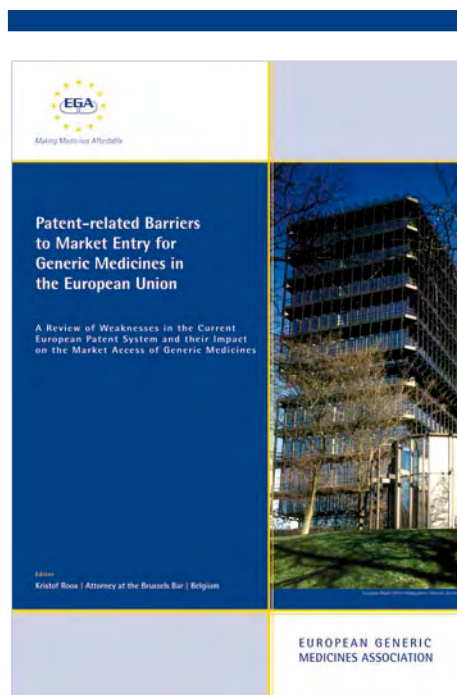
The introduction of patent linkage presents the single biggest barrier to generic competition. Patent linkage is a regulatory scheme which prohibits the granting of market authorisation or price and reimbursement status to a generic medicine until all patents have expired, or until it has been determined that no patents are being infringed, or are invalid or unenforceable.

This practice forces the scientific pharmaceutical experts at the medicines agencies and the price & reimbursement authorities to make necessarily ill-informed judgements on complex patent issues that normally can only be determined in specialised courts. Patent linkage is inconsistent with European law and must not be allowed to become ensconced in practice. ■

According to the report, the number of trivial patents could be reduced rapidly by a more stringent application of patentability requirements. More experienced patent examiners and better examiner training at the European Patent Office (EPO) would also help to improve efficiency in the European patent system. The report emphasises the need for patent offices to demand higher quality applications from patentees. In the case of pharmaceuticals, these applications should include all the relevant information about the patentability of a medicine. The use of follow-on patents in 'evergreening' practices by originator companies and the introduction of patent linkage in certain EU countries are also condemned in the report.

ALFONSO CALLES SANCHEZ, European Commission, DG Internal Market and Services, Unit D2-Industrial Property, announced the creation of a new Unit within DG Internal Market at the beginning of the year to will deal with the enforcement of IP rights. Mr Calles emphasised that strong protection of IP rights must be compatible with competition rules. He showed a high level of interest in the cases of misuse of the SPC Regulation cited in the report (such as two SPCs granted on the basis of the same marketing authorisation) and invited the EGA to send information on such cases to the European Commission.

INGWER KOCH, Director Patent Law, European Patent Office, was favourably impressed by the EGA report, and said that he and his colleagues were painfully aware of certain weaknesses raised in it. He reported that the EPO has recently undergone a strategic renewal process, and announced the implementation of a new EPO policy called "Raising the Bar". This policy, aimed at improving patent quality, involves:



- Strengthening the inventive step requirement,
- Clarifying guidelines to reflect case law,
- Increased fees for granting a patent: as of 1 April, €200 per claim and €500 from the 51st claim. The increases are expected to modify behaviour with regard to bad applications.

Mr Koch agreed that opposition proceedings are too lengthy, and insisted on the need for receiving more third parties observations. ■

"The conditions to grant a market authorisation are completely harmonised and do not permit patent linkage."

Georgette Lalis, European Commission

Forthcoming EGA Report | "Enhancing Generic Medicines Competition in the European Markets"

A new EGA report, envisaged as a "sister publication" to the EGA Report on Patent-related Barriers to Generic Medicines, will focus on the key, non-IP barriers to the entry of generic medicines onto European markets and on why generic medicines are not being taken up more rapidly. The report aims to identify the barriers that prevent an effective penetration of generic medicines and to assess how certain measures are impacting the access of generic medicines to the market, namely: governmental measures, pricing issues, market dynamics, and behavioural patterns. Mr Bongers, Chair of the EGA Health Economics Committee, highlighted some preliminary findings from the report:

- Governments that create inadequate competitive environments with overly-regulated pricing systems hinder dynamic competition and generic uptake.
- Generic medicines attain lower volume market shares in countries with high market regulation like Spain, Portugal, France and Italy.
- Affordable generic medicines prices are only possible through high volume market share.
- Price linkage mechanisms that set generic medicines prices at a

fixed percentage below the reference originator price typically exist in countries with low market share (eg, Italy, France or Spain).

- Generic medicines policies lacking measures to encourage doctors to prescribe and pharmacists to dispense generic medicines foster poor uptake.
- Lengthy price & reimbursement approval periods delay market entry for generic medicines in some countries (eg, Belgium) while in the UK and Denmark a generic medicine is introduced automatically upon marketing authorisation.
- The evergreening of originator products is a deterrent to generic medicines, resulting in heavy costs to healthcare systems.

Finally, the report identifies behavioural factors amongst stakeholders as another reason for slow generic uptake. Negative perceptions of generic medicines on the part of physicians, pharmacists and patients lead to delays in generic penetration. Only a small number of countries has run information campaigns to promote generic medicines. Finally, the anti-competitive behaviour of originator companies as seen in misleading marketing campaigns is a further factor that is prejudicial to the image of generic medicines. Several such campaigns have been run in countries such as Belgium, Spain and Italy.

The report is expected for release at the beginning of 2009. ■

CEOs of European Generic Medicines Companies Share Views on Pharmaceutical Markets and the Future of European Healthcare

CEO Panel of European Generic Medicines Companies



Informal, lively and engaging: (left to right) Didier Barret, Eric Gorka, Peter Burema, Rory O'Riordan, Gerard WM van Odijk

The "European CEO Panel" was one of the most anticipated items on the programme of this year's EGA Annual Conference. The session provided industry leaders with an opportunity to share their insights into the current state of the generic medicines industry and European markets, and to expound on their personal vision for the future of the generic medicines sector.

Each of the panellists hails from a major generic medicines manufacturer in Europe, representing a broad spectrum of the industry and business strategies: **Didier Barret**, President EMEA Mylan & President Mylan France SAS; **Peter Burema**, President Global Pharmaceutical Business Ranbaxy; **Eric Gorka**, Head Commercial Operations EMEA for Sandoz International; **Rory O'Riordan**, CEO Clonmel Healthcare & Vice President Europe Stada; and **Gerard WM van Odijk**, President & CEO TEVA Pharmaceuticals Europe.

After presenting a short overview of their companies and the key aspects of their success in the sector, the panellists touched on the various aspects of developing new generic medicines from products recently coming off patent, their strategies for developing and expanding into new markets as justified by steady growth in the industry, and the delivery of new and more affordable medicines to patients. The CEOs focussed not only

on the aspects of cost, but were particularly enthusiastic about their respective companies' role in benefiting society by providing access to quality medicines to a larger segment of the population. They concurred that this vision of the industry's dual role of reducing prices and delivering added value to patients and healthcare systems has been key to the recent growth in sales and generic medicines market share in Europe.

From a different perspective, the CEOs also made reference to the difficulties generic medicines companies are facing in terms of increasing price pressures from European governments and payers. These pressures, in the form of tendering regimes and alternative pricing systems, are being applied without first implementing the adequate policies to ensure the sustainability of the generic medicines industry. Such policies would seek to encourage and facilitate generic prescribing by doctors, promote the dispensing of generic medicines by pharmacists and to increase the acceptance of generic medicines by patients.

Given the current strains on European healthcare budgets and the increasing demographic pressures of an aging population, the five CEOs on the panel insisted on the importance of the industry to work with European governments to overcome the various obstacles that generic medicines

companies come up against when attempting to introduce their products on the markets. These hurdles include: unreasonable delays in obtaining marketing authorisation from the regulatory agencies, unjustifiable delays in receiving pricing & reimbursement status, misuse of the patent system leading to time-consuming and often uncertain legal proceedings, amongst others. The CEOs said all of these issues place undue strain on the sustainability of the generic medicines industry, deprive healthcare systems of much needed savings, and deny patients faster access to more affordable medicinal treatment.

In terms of the future, all five panellists look to the next five years as a time of potentially strong growth for the generic medicines industry. They expect a period of continuing consolidation in the sector. They look forward to further expansion into eastern European markets, and expect generic medicines companies to vigorously pursue the development of less expensive generic formulations of current "blockbuster" pharmaceuticals as their patents expire over the next few years. The CEOs agreed that these new products will provide important growth potential to the generic medicines industry, both in volume and value of the overall pharmaceutical market and in the more specialised niche markets. ■

"Generic medicines are part of the solution ...

... for solving urgent public health and healthcare challenges. Making further headway will require coordinated and converging efforts from both regulators and industry, each acting in their own fields of competence."

Jean Marimbert | Director General, Afssaps

Expert Panel Report on IP Barriers to Generic Medicines

left to right: Julia Pike | Hospira Global Pharma
Frank Bongers | Chair EGA Health Econ Cte
Ingwer Koch | European Patent Office
Imfried Schwimann | European Commission
Greg Perry | EGA Director General
Alfonso Calles Sánchez | European Commission
Laure Lechertier | Mutualité Française
Kees de Joncheere | WHO Regional Office Europe



Time for the Next Step: Developing Biosimilar Market Pathways that Benefit Patients

The first biosimilar medicines are now on the market and the EU has established itself as the world leader in the field—in both legal and regulatory terms and as the founder of the 'biosimilar philosophy'. But one key question still remains: how quickly now can these advances be passed on to patients? This central theme of how to develop market pathways formed the common thread throughout this year's 6th Symposium on Biosimilar Medicines, held in London on April 24–25. The conference attracted some 140 delegates from industry and the medicines authorities.

GREG PERRY, director-general, EGA, opened the proceedings by congratulating the industry and the EU medicines authorities for further consolidating and developing EU "biosimilar thinking" during 2007. He then stressed several key points for developing appropriate market pathways for biosimilar medicines. First, he said, it is crucial to reinforce confidence amongst patients and healthcare professionals, particularly about the quality, safety and efficacy of these products as well as about monitoring them in the market place. Then it is necessary to increase awareness about what is essentially a new class of medicines. Finally, Mr Perry emphasised the need to "stop scare tactics and the misuse of parliamentary language by certain interested parties" to frighten patients and healthcare professionals away from the new and more affordable biosimilar medicines. Referring to a recent UK publication sponsored by an originator company and presented incorrectly as a parliamentary report, he added: "This sort of activity must come to an end because it falsifies the reality of biosimilar medicines, undermines the reputation for scientific rigour of the European Medicines Agency that approved them, and gives a bad impression of the pharmaceutical industry as a whole." In conclusion, Mr Perry launched a call to discuss the "Global Biosimilar Development" concept, as well as how the Biosimilar Philosophy can be promoted and exported worldwide as a genuinely EU brand.

NICOLAS ROSSIGNOL, the European Commission administrator responsible for biosimilar medicines in the pharmaceuticals directorate of DG Enterprise and Industry, stressed in his introduction, that biosimilar products approved by the European Commission in accordance with EMEA guidelines should not be subject to unfounded questions regarding their safety and efficacy.

Rossignol praised the EU regulatory framework for biosimilar products for providing legal certainty and predictability, both key elements for attracting investment. Similarly, he cited the system's inherent ability to accommodate scientific advances. Indeed, as experience increases, scientific requirements can be adjusted which will facilitate changes to the cost structure of products in the future. Rossignol highlighted the growing importance of

"A biosimilar product is as safe and efficacious as any other product authorised by the European Commission in the EU."

Nicolas Rossignol, European Commission

the international dimension of biosimilar medicines. In this respect he referred to the strong, collaborative EU/US relationship in developing a US legal framework for biosimilars. "This will help to promote EU standards as well as EU companies by having, at least to some degree, the same type of requirements in the two biggest markets." The idea of a single registration data package for both the EU and the US—as promoted by the EGA—is acceptable in principle, he said, as there is no reason why the science should be different between Europe and the US. But Rossignol reminded his listeners that a US framework for biosimilars must first be established. He also highlighted the relationship with the WHO, where two issues are currently under discussion: the INN nomenclature for biological products, and the WHO move to establish global standards for biosimilar products. "As we are the leaders in this field, we have a key strategic interest in trying to promote our

system and the benefits of our system at the global level", Rossignol said.

Looking to the future, Mr Rossignol informed conference delegates that the European Commission will propose a package of pharmaceutical initiatives toward the end of the year, which will include an overarching communication underpinned by legal initiatives related to pharmacovigilance, information to patients, and counterfeit medicines. In terms of pharmacovigilance, he said the package will aim to strengthen and streamline current rules, particularly with regard to traceability and the monitoring of adverse reactions to biological medicines. The system, he said, must be able to trace which product has been given to the patient, even in case of interchangeability or substitution.

Rossignol concluded his remarks with a specific take-home message on transparency: "We need the commitment and the transparency of industry", he said, "both the innovative and the biosimilar industry, to play by the framework which we have jointly established in Europe. If transparency is ensured, the system will evolve positively. If transparency is not ensured, then the system will be at risk." ■

Three Key Messages from the European Commission

I. On the Safety of Biosimilar Medicines

"The EU has promoted and developed a specific framework for biosimilars, recognising that biosimilars are not generics. This means we are confident that if a product goes through all the steps, and meets all the requirements, and receives in the end an approval through a Commission Decision, then that product is as safe and efficacious as any other product authorised by the European Commission in the EU."

II. On Transparency

"We need the commitment and the transparency of industry, both the innovative and the biosimilar industry, to play by the framework which we have jointly established in Europe."

III. On International Non-proprietary Names (INN)

"There may be a need to revise the [WHO INN] system and to adapt to the specificities of complex biologicals. This is key. We don't want the INN system to be used as a way to discriminate between biosimilar products on one hand, and innovative products on the other. The INN system should be the same for all types of products, whatever their legal status."



EMA Looking for Further Debate with Stakeholders on INN & Interchangeability

JOHN PURVES, head of sector, pre-authorisation evaluation of medicines for human use, EMA, opened the second day of the 6th EGA Symposium on Biosimilar Medicines.

He identified three major challenges to the further development of biosimilar regulatory guidance: communication to stakeholders—which needs to be both transparent and science-driven; technical and regulatory harmonisation to achieve a consistent approach at national level; and finally, pharmacovigilance that will strengthen product identification and traceability of adverse reactions for all biological products.

Purves also called on companies to participate in the process by "coming to us at the EMA for scientific advice, so that the debate(s) can be opened". Purves added that, "It is important to see the benefits that have arisen from the fact that all interested parties have been involved in the development of the legislation and in the development of the guidelines for biosimilar products."

The new EMA mission statement says it aims to foster scientific excellence in the evaluation and supervision of medicines for the benefit of public and animal health. "Behind all of that", Purves said, "is the fact that *we want to make medicines accessible to patients within Europe.*"

Purves noted that "Over the last 20 years there have been changes to the science, changes to the legislation, and also changes in the way in which dossiers are reviewed. We have much more sophisticated review procedures that allows us to make decisions, not only in relation to quality, safety and efficacy, but also in relation to risk management plans."

Similarly, he emphasised that "after six years we have a much clearer picture now regarding biosimilar medicines, but there are still some other things we need to deal with. We need more debate on the INN and we need to think about the issue of interchangeability—and that has to be done among the interested parties." ■

Biosimilar Medicines: Information, Traceability and Decreasing Uncertainty

ARNOLD VULTO, hospital pharmacist/pharmacologist from the Netherlands and editor-in-chief of the European Journal of Hospital Pharmacy Practice, explored the decision-making process for biopharmaceuticals by hospital pharmacists.

Above all else, he said, they look for reliable supplies, easy-to-use products, and "decreasing uncertainty". "You have to collect information [about the product] ... to reduce uncertainties since every biopharmaceutical—innovative or biosimilar—carries some uncertainties, and we need to reduce these uncertainties." He further pointed out that "Biosimilars build on the experience of the originator product so they have intrinsically reduced uncertainties."

Vulto specifically pointed out that there is no doubt that "biosimilars fulfil, as they are licensed, basic quality requirements like every new drug".

But he stressed the importance of traceability. "You have to know and be able to find back, in case of problems, which product actually caused the problem." He also recommended therapeutic substitution, which is different than generic substitution.

In conclusion, Vulto expressed some hope "that in the end biosimilars will add to market dynamics and eventually lower prices of treatment costs so we have more money available for innovative therapies." ■

EMA Working Party Calls for Industry Briefings to Track New Developments

CHRISTIAN SCHNEIDER, acting divisional head at Germany's Paul Ehrlich institute and chairman of the CHMP Working Party on Similar Biological Medicinal Products (BMWP), highlighted that the EU has the "most balanced" approach to safety-related issues, which "reconciles science with common sense and chooses the most relevant data." This approach was marked out by the fact that, in addition to quality, safety and efficacy, it added product risk management plans as a key criterion for the evaluation of biosimilars.

Referring to the rapid pace of scientific advances in the field of biosimilar medicines, Schneider said, "We will also have to learn from you [the industry], who are developing these products, where the issues are and where we need to adapt our framework, or where we have to develop new ideas." The EMA's BMWP must track the developments of novel methodologies both for better characterisation of biosimilarity and for tackling immunogenicity. Industry is invited to contact the EMA for mutual scientific exchanges. ■

Health Canada Praises EU for its Pioneering Work on Biosimilar Medicines

ANTHONY RIDGWAY, Senior Regulatory Scientist, speaking on behalf of Health Canada, Canada's federal department of health, praised the EU for its pioneering work in establishing a regulatory framework for biosimilar medicines, and particularly for its ability to create rational approaches to difficult issues.

He also acknowledged that some attitudes towards biosimilars have changed over the last few years. "I have seen rather polarised positions towards this type of products on either side, which have now become a bit more softened. Recognising some intermediate position makes a lot of sense. I think that the formalisation of the approaches that has taken place in the European Union has done a lot to contribute to that." "There are challenges, clear challenges," he continued. "But how can one ignore the fact that a highly similar product may have been used in perhaps millions of patients over the previous 10-15 years? How do we ignore that? And our argument is that one should not, and somehow one has to figure or capture that knowledge about an active ingredient into the decision-making process for biologics and biosimilars."

In terms of regulatory pathways in Canada, Ridgway referred to the International Conference on Harmonisation (ICH) guidance. "We will use similar approaches, or perhaps adopt elements of the EMA guidance. And we seek, as we always seek, international harmonisation where possible." ■

Biosimilar Medicines are Therapeutically Interchangeable

In closing, **INGRID SCHWARZENBERGER**, Head of Regulatory Affairs (Biopharmaceuticals) at Sandoz, explained that the development of a biosimilar medicine requires a complete product and process development as well as comparative testing with the reference product at the level of quality, safety and efficacy. She stressed that the vast majority of questions routinely asked by hospital pharmacists are addressed in the European Public Assessment Report (EPAR), which becomes publicly available once the biosimilar medicine is approved by the European Commission. The EPAR provides detailed information on quality, safety and efficacy and post authorisation activities. Schwarzenberger emphasized that the the 'Quality by Design' (QbD) concept governs the entire development of a biosimilar medicine which is targeted to match the reference product. This combination of the QbD approach and systematic and thorough comparison to the reference product "qualifies a biosimilar medicine for therapeutic interchangeability." ■

Making Medicines Affordable



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The EGA is the official representative body of the European generic and biosimilar medicines industry, which is at the forefront of providing high-quality affordable medicines to millions of Europeans and stimulating competitiveness and innovation in the pharmaceutical sector.