



Summary of position

Overall EuropaBio welcomes and supports the Pharmaceutical Package and is looking forward to working with all EU Institutions on the adoption and implementation of this package

1. European Commission's Communication on Safe, Innovative and Accessible Medicines: A Renewed Vision for the Pharmaceutical Sector

We are pleased to see the emphasis the Commission places in the Communication on restoring a strong, innovative and competitive EU pharmaceutical sector and on avoiding delays for patient access to innovative treatments. Timely access and appropriate reward to biological therapies are key components to meet those objectives, especially in times of financial and economic crisis.

However in Europe, there continues to be no consensus on how to reward and stimulate healthcare innovation and ensuring access to new treatments for patients. This coupled with inconsistent pricing and reimbursement policies and increasing safety requirements contribute to the decrease of approved new therapies within Europe and to the impediment of timely availability of innovative medicines for patients.

Therefore EuropaBio calls for the implementation of better practice principles for relative effectiveness assessments as well as pricing and reimbursement policies as defined in the Pharma Forum conclusions and recommendations; and for the EC to develop a mechanism to ensure that this new vision is implemented in a harmonised manner

2. Ensuring that EU citizens have access to reliable information

Sufficient and equal access to quality health information for patients and their families on diseases, their prevention as well as available treatment and care options is of utmost importance. This is particularly relevant for biological products as those products are far more complex than small molecule products. We are also pleased that the proposal identifies industry as a legitimate source of information.

Rightfully, the EC's proposal does not open the way for advertising on medicines; and we call Member States, the Commission and other stakeholders to take note of existing partnerships and collaborations between the various parties that mobilise knowledge and resources for producing and disseminating information to patients.

3. Strengthening the EU system for the safety monitoring of medicines (pharmacovigilance)

EuropaBio welcomes the EC proposals to strengthen and rationalise pharmacovigilance in the EU as well as the recognition by the Commission that when it comes to identification of medicines, biotech medicines face particular challenges due the nature of such products.

We support a risk-based approach to the pharmacovigilance system. Accordingly the reporting requirements and risk management plans should reflect this approach, taking account of the product types and the underlying mode of action of the medicinal product.

The additional labelling requirements as well as information presented on a new public safety web-portal will enhance transparency on safety features of our products for the patients and the public, which is in line with the needs for more and better information for EU citizens.

4. Strengthening EU legislation to better protect EU citizens from the serious threats posed by fake medicines

The ultimate goal of this EU legislation and overriding consideration must be to ensure patient safety – now, and for the future.

We are particularly concerned about the threat caused by fake medicines, because the distribution chain for biotech products is far more complex than for small-molecule drugs. Counterfeit biologics may be extremely difficult to detect in the supply chain before they reach patients and do harm.

Therefore EuropaBio calls for a ban on the manipulation of the safety features and/or packaging of the original manufacturer. Responsibilities and liability principles should be strengthened to provide adequate incentives for all stakeholders involved to check for counterfeit products. Should re-packaging occur, product liability for counterfeits or falsified products resides with the re-packager.

5. Timeline

We call the institutions should ensure that the vision of a strong, innovative and competitive EU pharmaceutical sector which provides timely and equitable access to innovative medicines to patients is swiftly approved.



EuropaBio Position on the Pharmaceutical Package

Overall EuropaBio welcomes and supports the so-called Pharmaceutical Package published by the European Commission (EC) in December 2008. The three legislative proposals 1) to ensure that EU citizens have access to reliable information, 2) to strengthen the EU system for the safety monitoring of medicines, and 3) to strengthen EU legislation to better protect EU citizens from the serious threats posed by fake medicines are essential for providing EU citizens with safe, innovative and accessible medicines.ⁱ

Europabio has actively participated in shaping the content of this package, through the EU High Level Pharmaceutical Forum (Pharma Forum) where EuropaBio has been a committed stakeholder in all three working group as well as the various EC consultations, and we are looking forward to working with all EU Institutions on the adoption and implementation of this package. EuropaBio is pleased to see that the proposals from the Commission all go in the right direction, but we strongly believe that the proposals need further improvement for the effective protection of European citizens' health.

1. European Commission's Communication on Safe, Innovative and Accessible Medicines: a Renewed Vision for the Pharmaceutical Sector

An estimated 50% of all new medicines originate from biotechnology, and the proportion grows when it comes to the most innovative treatments such as growth hormones, recombinant growth factors, vaccines, monoclonal antibodies for the treatment of cancers and inflammatory and infectious diseases, cell therapy etc.

The healthcare biotechnology industry is pleased to see the emphasis the Commission places in the Communication on restoring a strong, innovative and competitive EU pharmaceutical sector and on avoiding delays for patient access to innovative treatments. Timely access and appropriate reward to biological therapies are key components to meet those objectives, especially in times of financial and economic crisis.

However in Europe, there continues to be no consensus on how to reward and stimulate healthcare innovation and ensuring access to new treatments for patients and we regret that this link was not further touched upon in the Communication.

For example, the development of a new indication for an existing product can require further significant non-clinical and clinical developments to support approval, and might only be rewarded with one single year additional data exclusivity (non cumulative).ⁱⁱ At national level, inconsistent, intransparent, different pricing and reimbursement policies create high uncertainty for developers with regard to the market future of their medicines and impede timely availability of innovative medicines.

In this respect, we call for the implementation of better practice principles for relative effectiveness assessments as well as pricing and reimbursement policies that improve access to medicines for all EU citizens as defined by the Pharma Forum. In the final report of this Forum, the EC itself clearly stated that "...pricing and reimbursement policies need to balance (1) timely and equitable access to pharmaceuticals for patients all in the EU, (2) control of pharmaceutical expenditure for Member States, and (3) reward for valuable innovation within a competitive and dynamic market that also encourages Research & Development". Yet, the Forum's conclusions and recommendations remain to be implemented and it is still unclear whether industry will even be allowed to participate in any follow up actions.

The lack of incentives and reward for innovation, inconsistent pricing and reimbursement policies and increasing safety requirements contribute to the decrease of approved new therapies within Europe.

The decrease in healthcare biotechnology innovation in Europe penalises both, patients and companies, and should not continue. The EC's call to launch a reflection on ways to improve



market access and to develop initiatives to boost EU pharmaceutical research should develop into concrete proposals for more appropriate frameworks that reward innovative efforts.

At the same time, there is an urgent need to ensure that innovative biotechnology-based therapies, also reach European patients - without delays and artificial restrictions. The great contribution of biotech in the field of rare diseases, cancer and neurodegenerative diseases should be available for patients in a fair and equitable manner and should be adequately rewarded by Member States.

Finally we would like to call the EC to develop a mechanism to ensure that this vision for safe, innovative and accessible medicines for all patients in Europe is implemented in a harmonised manner. Examples, including the implementation of the clinical trials Directive,ⁱⁱⁱ show that national supplementary or divergent ways to transpose an EU legislation can jeopardise its implementation but also its essence.



2. Ensuring that EU citizens have access to reliable information

Sufficient and equal access to quality health information for patients and their families on diseases, their prevention as well as available treatment and care options is of utmost importance. This is particularly relevant for biological products. Indeed, those products are far more complex than small molecule products - mimicking substances produced by the human body such as enzymes, insulin, and antibodies. In particular personalized medicines will crucially depend on better informed patients. Therefore, accurate and update information will enable patients to understand the principle and value of the new and innovative treatments.

Better informed patients will ultimately be more compliant users of treatments, which in turn will lead to improved health outcomes for patients and as well optimise the use of healthcare budgets. Ultimately, this will have a positive impact on the European economy.

We are very pleased that the proposal also identifies industry as a legitimate source of information. By giving pharmaceutical companies the possibility to disseminate information, under strict rules and quality criteria, about their prescription-only medicines to the general public, the proposal paves the way towards better access to information and thus to treatments. Healthcare biotechnology companies can offer a significant contribution and have an important role to play in the dissemination of information, as the application of healthcare biotech is relatively new. Most of the expertise on its production and application actually sits within the companies – including on biomarkers and rare conditions.

EuropaBio believes that European patients have a fundamental right to access the best information on the medicines which they are using and that the industry has an important role to play in providing patients with reliable and objective information. The EC's proposal rightfully does not open the way for advertising on medicines. EuropaBio welcomes the possibility for companies to give adequately monitored, neutral, factual and approved information about their medicines - such as explaining in more detail the patient leaflet for instance – through well defined communication channels. Instead of blindly authorizing the diffusion of promotional information, this proposal will likely hinder the development of an increasing number of overseas websites giving internet users a huge amount of uncontrolled information. Simple mechanisms should be installed in order to monitor and secure the quality of the information provided without hampering the use of this opportunity by increasing unnecessary bureaucratic processes. Otherwise, it would only increase the administrative burden for SMEs willing to disseminate information about their innovative products.

For this purpose and in accordance with the EU High Level Pharmaceutical Forum conclusions on information to patients, we think that “Member States, the Commission and other stakeholders should take note of existing partnerships and collaborations between the various parties that mobilise knowledge and resources for producing and disseminating information to patients”, e.g. the Swedish Medicines Information Engine (FASS).



3. Strengthening the EU system for the safety monitoring of medicines (pharmacovigilance)

EuropaBio welcomes the EC proposals to strengthen and rationalise pharmacovigilance in the EU. If realised beyond simple amendments to the existing regulatory framework, this will provide greater legal certainty to national authorities and would also avoid differences in interpretations and requirements at Member State level.

EuropaBio welcomes the strengthened role of EMEA and a single European entry for adverse reaction reporting into the EudraVigilance Database as proposed.

We support a risk-based approach to the pharmacovigilance system. Accordingly the reporting requirements and risk management plans should reflect this approach, taking account of the product types and the underlying mode of action of the medicinal product.

The additional labelling requirements as well as information presented on a new public safety web-portal will enhance transparency on safety features of our products for the patients and the public. This is in line with the needs for more and better information stated in section 2 of this paper. Careful wording of this new information and thorough education of patients and healthcare professionals is needed to improve their understanding of safety features.

A new type of regulatory Community procedure to assess the risk of medicines has been proposed including public hearings. Discussions at these hearings bear the risk of premature conclusions on the risk-benefit ratio of a medicinal product, which may have – if published in the media – an unjustified negative impact on the product and the marketing authorization holder. Therefore, assurance is needed that this type of procedure including public hearings is conducted in well defined situations.

Regarding the Pharmacovigilance and Risk Assessment Advisory Committee (PRAAC) recommendations, EuropaBio assumes that CHMP will always have the final decision power, ensuring a balanced overall benefit-risk assessment outcome.

EuropaBio welcomes the fact that the Commission has recognised that when it comes to identification of medicines, biotech medicines face particular challenges due the nature of such products (complexity, differences between the different products, etc) – hence the dedicated article 102(3) on the identification of biologics.

The unique starting material and the complex manufacturing processes of biotechnology-based products mean that it is not possible to exactly reproduce a biological molecule in the same way a chemical molecule can be reproduced. As stated by the EMEA, biosimilar versions of approved biologics cannot be regarded as generics due to this general variability of biologics. For all medicines, adverse drug reactions must be attributable to the individual product and not solely to the active substance described by the International Non-Proprietary Name (INN). Due to the described variability of biologics, proper and clear identification of all biologics including biosimilars is of special importance to these products. Therefore, especially for biologics, consistent reporting of all important product identifiers (INN, manufacturer name, brand name, batch number) should be strengthened, particularly when a physician or a pharmacist fill an adverse reaction form. EuropaBio would welcome a reinforcement of article 102(3) to ensure that these product identifiers are included.

Finally, the marketing authorization holder shall be required to perform a regular audit of his pharmacovigilance system. This shall include information on the internal pharmacovigilance audit programme within the pharmacovigilance system master file, and include a list of scheduled significant changes to the pharmacovigilance system. The Pharmacovigilance System Master File should be version controlled and have a change log.



4. Strengthening EU legislation to better protect EU citizens from the serious threats posed by fake medicines

Healthcare biotechnologies treat debilitating and life-threatening disease. Because they are so complex, the manufacturing of biotechnology-based products requires a high level of monitoring and quality testing - typically, around 250 in-process tests are conducted for a biological medicine. If administered to a patient, counterfeit biological products could have devastating and irreversible consequences on patients' health and safety. The ultimate goal of this EU legislation and overriding consideration must be to ensure patient safety – now, and for the future.

According to the Commission, “the risk profile of counterfeited medicines is changing to cover not just life-style products, but more and more innovative and life-saving medicines”. As representatives of healthcare biotechnology, we are particularly concerned about the threat caused by fake medicines, because the distribution chain for biotech products is far more complex than for small-molecule drugs. Counterfeit biologics may be extremely difficult to detect in the supply chain before they reach patients and do harm.

In general, we fully support the principles of the proposed amendments to the Directive 2001/83/EC.

The use of legally protected tamper-evident security seals on the outer packaging of medicines and the serialization of seal packs of biological medicines according to harmonized international standards are necessary. Therefore, any efforts to set up a harmonized EU-wide identification system should be supported and encouraged.

Furthermore, this means that it is of very high importance to the biotech sector to ensure that the integrity of the original package throughout the entire supply chain is not jeopardized. Consequently, EuropaBio calls for a ban on the manipulation of the safety features and/or packaging of the original manufacturer. Responsibilities and liability principles should be strengthened to provide adequate incentives for all stakeholders involved to check for counterfeit products.

Should re-packaging occur, product liability for counterfeits or falsified products resides with the re-packager.

We also urge for a Pan European Certification scheme for Internet Pharmacies. If Internet Pharmacies are a part of the Legal Distribution Chain in Europe, they should be covered by a set of legal requirements similar to High Street Pharmacies. Given the rapid increase in trade via Internet Pharmacies, this issue grows in importance. Together with information on the potentials and dangers of using Internet Pharmacies, this could help prevent the spread of illegal pharmaceuticals via the Internet

Biotech medicines treat serious, often life threatening diseases, therefore the consequences of patients taking fake medicine may result in fatal consequences for the patients in question. In light of this, EuropaBio would like to assure that all biotech medicines, whether original or biosimilar versions are subject to the same stringent anti-counterfeiting measures, in order to protect patient safety.

Finally we would recommend not to extend the dissemination of the information on covert and forensic devices with third parties (e.g. wholesale distributors or pharmacists) as suggested by the EC's proposal. These devices are already widely known by the original manufacturer, law enforcement bodies and the regulatory authorities and could, from a security perspective, become worthless if they are publicly known. Indeed this would increase their likelihood of being copied, irrespective of their level of sophistication.



5. Timeline

The proposals are now been discussed by the Council of the European Union and at the European Parliament. The institutions should ensure that the vision of a strong, innovative and competitive EU pharmaceutical sector which provides timely and equitable access to innovative medicines to patients is swiftly approved. However, because of European elections and the uncertainty around the composition of the new EC, there are concerns about the timing for approval and implementation might be unduly delayed.

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About EuropaBio

EuropaBio's mission is to promote an innovative and dynamic biotechnology-based industry in Europe. EuropaBio, (the European Association for Bioindustries), has 68 corporate and 5 associate members operating worldwide, 4 Bioregions and 25 national biotechnology associations representing some 1800 small and medium sized enterprises.

Members of EuropaBio are involved in research, development, testing, manufacturing and commercialisation of biotechnology products and processes. Our corporate members have a wide range of activities: human and animal health care, diagnostics, bio-informatics, chemicals, crop protection, agriculture, food and environmental products and services. www.europabio.org

ⁱ See the European Commission's website to download the proposal:
http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/pharmpack_en.htm (as consulted in March 2009)

ⁱⁱ Directive 2004/27/EC Article 10(5) amending Directive 2001/83/EC

ⁱⁱⁱ Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use



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