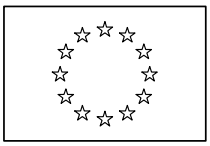

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COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

Safe, Innovative and Accessible Medicines: a Renewed Vision for the Pharmaceutical Sector

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

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Introduction

The pharmaceutical sector makes an important contribution to European and global well-being through the availability of medicines, economic growth and sustainable employment. It has been and remains a strategic sector for Europe. It employs more than 634,000 people and accounts for more than 17% of the EU Research and Development (R&D) expenditure. Most importantly, innovation in human medicines has enabled patients to benefit from treatments considered unimaginable a few decades ago. Demographic change, i.e. ageing, is a global phenomenon which will affect western societies as well as major emerging economies like China and Russia. Hence health-related services and products are growth markets worldwide and offer a potential for Europe's well- established pharmaceutical industry.

Since 1965, Community action in the field has always had the dual objective of safeguarding public health by providing Europe with safe and effective medicines, while at the same time creating a business environment that stimulates research, boosts valuable innovation and supports the competitiveness of the industry. Much has been achieved in forty years. However, at the beginning of the 21st century Europe faces major health, economic and scientific challenges[1]:

– **Europe has been losing ground in pharmaceutical innovation.** The centre of gravity for research has moved to the US and Asia. New international competitors emerge. In the 1990s pharmaceutical research and development expenditures in Europe were higher than in the U.S. (EUR 7.766 billion compared with EUR 5.342 billion). However, the picture had changed by 2006 (EUR 22.500 billion in the EU while EUR 27.053 billion in the U.S). With regard to research sites a similar trend can be identified. Between 2001 and 2006 18 research sites of 22 global pharmaceutical companies were closed in Europe (only 2 were opened) while in the same period these companies opened 14 research sites in Asia (one was closed) and six in the U.S. (five were shut down). While in general the number of new pharmaceutical substances has decreased worldwide, the decrease has been significantly sharper in the EU than in the U.S. and other parts of the world.

– **Shortcomings in the availability of medicines have been identified**. In 2008, European patients still suffer from inequalities in availability and affordability of medicines. The last legislative review[2] and the creation of the High Level Pharmaceutical Forum[3] are major steps forward, but some key issues remain open. Future proposals of the Commission will also have to take into account the findings of the ongoing pharmaceutical sector inquiry.

– **The sector is more and more globalised**. Globalisation brings new opportunities with the opening of new markets. Industry sales outside the traditional markets, i.e. industrialised regions like the U.S., Europe and Japan, are increasing significantly. At the same time, worldwide cooperation and trade lead to a global division of labour. Hence a new medicine is often the result of research and development in Europe, clinical trials in India, and active ingredients produced in China before finally produced, packaged and sold in the EU. This "global" reorganisation creates new opportunities but also new challenges, in particular counterfeit medicines are on the rise.

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1 Similar challenges exist for veterinary medicine but are not covered by this Communication.

2 OJ L 136, 30.4.2004 p. 1 – 33, OJ L 136, 30.4.2004 p. 34 – 57 and OJ L 136, 30.4.2004 p. 58 – 84.

3 http://ec.europa.eu/enterprise/phabiocom/comp_pf_en.htm

– **Scientific breakthroughs** revolutionize the way medicines are developed and prescribed. Treatments become more personalised. Linked to the ageing of the population and to a proactive involvement of patients, the demand of society is also evolving. At the same time unmet medical needs are to be met, e.g. infectious diseases (like tuberculosis and HIV/AIDS) and rare diseases whose ramifications are not limited to the EU but pose global public health challenges.

To address these challenges, this Communication outlines the Commission's vision of the future of the sector and intends to trigger a process which leads to a way forward. Based on three pillars, concrete objectives are proposed:

(1) **To make further progress towards a single and sustainable market in pharmaceuticals** and;

(2) **To take on the opportunities and challenges of globalisation;**

(3) **To make science deliver for European patients** and restore the EU's role as the natural home for pharmaceutical innovation.

The Commission's vision is to ensure that European citizens can increasingly benefit from a competitive industry that generates **safe, innovative and accessible medicines**. Many initiatives have been taken in this direction, most recently with the inclusion of eHealth in the Commission's lead market initiative that aims to remove barriers to the acceleration of market development[4]. The five accompanying legislative proposals (on counterfeiting, information to patients and safety monitoring[5]) are further important steps towards this vision, while other concrete objectives are listed in the Annex.

1. MAKING FURTHER PROGRESS TOWARDS A SINGLE AND SUSTAINABLE MARKET IN PHARMACEUTICALS

Major progress has been achieved over the last years. Legislative initiatives of the Commission have led to improved marketing authorisation procedures, the harmonisation of data protection in the EU, better access to medicines for children, and a new regulatory framework for advanced therapies like tissue engineering. Furthermore the Guiding Principles concerning pricing and reimbursement developed by the Pharmaceutical Forum are major steps. Nevertheless stakeholders continue to raise concerns with regard to the market fragmentation linked to disparities in national pricing and reimbursement schemes, unnecessary regulatory burdens caused by divergences in the implementation of Community legislation, and a lack of commercial interest in national markets which are economically less attractive.

This situation may create important inequalities between patients in the access to medicines while the growth potential of the EU industry is hampered.

Completing the single market in pharmaceuticals remains an important objective.

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4 Communication "A lead market initiative for Europe" - COM(2007) 860 (21.12.2007). The Communication and all relevant documents are available at the official EC LMI microsite: http://ec.europa.eu/enterprise/leadmarket/leadmarket.htm

5 COM(2008) 668, COM(2008) 662, COM(2008) 663, COM(2008) 664, COM(2008) 665.

1.1. Better Access to Medicines for European Patients

1.1.1. Ensuring Affordable Access to state-of-the-art Treatments without Delays

The lack of critical medicines in particular due to a lack of adequate financial resources is an issue that has reached the highest political level, as exemplified by the 'Bremen Declaration'[6] in the case of HIV/AIDS, where Health Ministers committed to cooperate to order to ensure access to affordable medication in view of existing problems for patients in several Member States to have access to urgently needed medication.

The lack of available of medicines has also been highlighted in a recent report of the Heads of Medicines Agencies[7] and by the Pharmaceutical Forum[8]. The problem is particularly striking in those Member States where the national market is small and the expected return on investment for companies is low.

This has important public health consequences in several Member States, despite improvements due to the last review of the EU pharmaceutical legislation. In the short term, minor changes to the regulatory framework (e.g. on linguistic regimes and labelling) can be made to improve the situation. However, a more in-depth review of the situation is required to fully address the issue. Beyond regulatory aspects the role of full-line and public wholesalers[9] in the supply of medicines in small markets needs also to be examined in more detail.

More broadly, the functioning of the network of EU medicines authorities requires re-thinking to improve its efficiency, minimise the regulatory burden it generates and thus speed up market access for medicines.

Objective #1: Options to **improve the availability of medicinal products for patients in need**, with a particular focus on smaller markets should be developed in close cooperation with Member States by 2010.

Objective #2: Based on an **evaluation of the European Medicines Agency** (EMEA) ways to optimise the functioning of the network of EU medicines authorities should be identified by 2010.

The fragmentation of the EU market primarily relates to the diversity of national pricing and reimbursement schemes. Decisions on costs of healthcare and pharmaceuticals are a national competence but must comply with Directive 89/105/EEC and the EC Treaty, requiring in particular that pricing and reimbursement decisions are made in a timely and transparent manner.

Allocating healthcare funds to the most effective medicinal products as well as creating the right environment for price competition is of major importance to ensure the sustainability of healthcare systems. Different systems lead to disparities in pricing, time-to-market delays and access inequalities. Member States are entitled to make political choices on which medicines to reimburse, in line with the provisions of the Transparency Directive, and to take decisions

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6 http://www.eu2007.de/en/News/download_docs/Maerz/0312-BSGV/070Bremen.pdf

7 Availability of Medicinal Products, HMA, 5/11/2007.

8 http;//ec.europa.eu/enterprise/phabiocom/comp_pf_en.htm

9 http://ec.europa.eu/enterprise/phabiocom/comp_pf_en.htm

which take into account the effectiveness and value for money of innovative medicines as well as the budgetary constraint in Member States.

However, availability and affordability of medicines have a European dimension.Different national pricing and reimbursement schemes create a complex landscape in the EU while Member States face the common challenge of balancing three overarching objectives: optimal use of resources to ensure sustainable financing of healthcare for an ageing European population, access to medicines for EU patients and reward for valuable innovation. A common set of Guiding Principles[10] has been adopted by the Pharmaceutical Forum to support future national pricing and reimbursement policies. The positive experience of information exchange and cooperation between Member States and with stakeholders should be strengthened at EU level.

Similar price levels can lead to a different level of affordability depending on the economic situation in each Member State. More efficient market mechanisms and, in particular, price competition for non-reimbursed medicines, would provide, in this sector, more patients choice at a more affordable cost. Member States should, therefore, remove price controls on manufacturers that prevent full competition of authorized medicines that are neither purchased nor reimbursed by the State.

Further development of health technology assessments will also offer valuable support to national authorities to strike a balance between containing pharmaceutical expenditure and ensuring a fair reward for valuable innovation and access to the best available medicines. Cooperation among authorities and dialogue with stakeholders will be a prerequisite to achieve such a balance. Based on the agreement found in the Pharmaceutical Forum the exchange of data between Member States on relative effectiveness should be fostered.

Objective #3: Genuinely transparent and speedy pricing and reimbursement decisions should be made possible by **enhancing the application of the Transparency Directive**.

Objective #4: Based on the work of the Pharmaceutical Forum the **exchange of information and the cooperation among stakeholders on pricing and reimbursement** should be improved.

Objective #5: Based on the agreement found in the Pharmaceutical Forum the exchange of data between Member States on **relative effectiveness** should be fostered in order to avoid delays in the market access of innovative treatments.

1.1.2. Improving Competition and Market Access

Competition is an efficient way to stimulate valuable innovation and improve medicines' affordability. In January 2008, the Commission has launched a sector inquiry into the pharmaceutical sector on the basis of Article 17 of Regulation No 1/2003[11]. The inquiry concerns "*the introduction of innovative and generic medicines for human consumption onto the market*"[12]. The inquiry was initiated as certain circumstances in general suggest that competition may be restricted or distorted in the pharmaceutical sector in Europe, such as a decline in innovation as measured by the number of novel medicines reaching the market and

[10] http://ec.europa.eu/enterprise/pharmaforum

[11] OJ L 1, 4.1.2003, p.1

[12] For further details: http://ec.europa.eu/comm/competition/sectors/pharmaceuticals/inquiry/index.html.

instances of lacking timely entry by suppliers of generic medicines. The main focus of the inquiry is the commercial behaviour of market participants affecting market entry of competing novel or generic medicines. The preliminary results will be presented in a report scheduled for 28 November 2008. The final report is foreseen for spring 2009.

In addition, the Commission plans to launch an in-depth monitoring of the functioning of markets in the pharmaceutical sector. This action is part of the follow-up to the November 2007 Single Market Review which aimed to improve the governance of the Single Market through a systematic and integrated market monitoring of key markets.

The Commission will take into account its findings in the ongoing pharmaceutical sector inquiry and this market monitoring exercise when making future legal proposals.

Many Member States recognise that generic medicines play an important role in helping to limit their healthcare expenditure in their reimbursement and prescribing practices. Competition with off-patent products enables sustainable treatment of more patients with less financial resources. The generated savings create financial headroom for innovative medicines. All actors should therefore ensure that generics can enter the market after expiry of patent and data exclusivity protections and compete effectively.

Equally, non-prescription medicines also play an important role since they offer economic as well as social benefits. Self-medication empowers patients to treat or prevent short term or chronic illnesses which they consider not requiring the consultation of a physician or which may be treated by the people after an initial medical diagnosis. Consequently, access and availability of these medicinal products require particular attention.

Objective #6: Ways to ensure **availability and market access** for generics and non-prescription medicines should be examined by 2011.

Objective #7: Launch of an **in-depth monitoring of the functioning of markets** in the pharmaceutical sector.

Patients' expectations to health systems and quality of care in relation to cross-boarder healthcare also call for a more coordinated EU action. The proposed Directive on cross-border healthcare[13] sets out common principles to ensure safety and quality of care, a specific framework on cross-border healthcare and provisions for cooperation between national systems. The proposal also provides for cross-border recognition of medical prescriptions.

1.2. Better Regulation for a More Competitive Industry

Requirements that cause a high administrative burden without providing a clear public health benefit have a strong negative impact on the competitiveness of the EU industry. Small and medium-sized enterprises (SMEs) are economically affected in particular, e.g. in the field of pharmacovigilance redundant reporting requirements in different Member States create unjustified costs. Such obstacles may be decisive for these enterprises not to apply for marketing authorisations outside their Member State of origin.

However, in view of the fact that national regulators are involved in legislation and responsible for the implementation a high level of joint commitment is required from all

[13] COM(2008) 414.

actors in order to make pharmaceutical rules clearer, simpler and more flexible without compromising public health.

1.2.1. A better Framework on 'Variations'

The Commission recognises the burden that current rules on changes to the marketing authorisations of medicines ('variations') entail. This complex framework hinders the introduction of changes that are beneficial to patients and delays access to improved treatments.

1.2.2. Improving the Framework on Clinical Trials

A number of stakeholders have raised concerns (e.g. divergence in interpreting the relevant legislation and cumbersome procedures for multi-centre clinical trails in different Member States) over the application by Member States of the Directive on Clinical Trials[14] and its impact on academic as well as non-academic research. The recent EMEA-Commission conference[15] has identified shortcomings in applying the Directive. An in-depth assessment of the matter and recommendations for improvement should now be undertaken.

Objective #8: An **assessment of the application of the Clinical Trials Directive** with a view to making, if appropriate, legislative proposals - while taking into account the global dimension of clinical trials - should be presented by the Commission by 2010.

1.3. Safer Medicines for Better Informed Citizens

1.3.1. Improving Safety

Recent events linked to adverse reactions demonstrate that the safety of medicines remains a major public health issue. To tackle it, the Commission has submitted a legislative proposal[16] to rationalise and strengthen the EU framework on safety monitoring ('pharmacovigilance').

Objective #9: The proposal to rationalise and strengthen the **EU framework on pharmacovigilance** should be adopted swiftly.

Another important health issue also follows from the increased number of medication errors which have led to severe medical conditions for patients, such as medicine name confusions, and prescription, dispensing and administrative errors. To address this, the Commission has developed new strategies to reduce the scale of medication errors in the above mentioned proposal and to specify quality criteria for Health related websites[17]. The Commission has also confirmed that patient safety will be a priority for 2008, through a proposal addressing systemic patient safety issues, which aims to reduce all adverse events in healthcare, including medication errors, as well as specific measures aimed at the prevention and control of healthcare-associated infections[18].

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14 OJ L 121, 1.5.2001, p. 34.

15 http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/archives_en.htm, 30.11.2007.

16 COM(2008) 665, COM(2008) 664

17 COM(2002) 667

18 http://ec.europa.eu/atwork/programmes/docs/clwp2008_en.pdf

1.3.2. Empowering Patients

As outlined in the Commission White paper on Health Strategy[19], patients are becoming more involved in the decision-making regarding their health. They have a right to more quality information on available medicines, the grounds on which they have been authorised and how they are monitored.

Public authorities and health care professionals have a crucial role in providing patients with relevant and impartial information. The Pharmaceutical Forum endorsed recommendations to enhance the generation, access and dissemination of good quality information on diseases and treatments. The use of quality principles and the increased cooperation among all partners for developing patient information should lead to tangible improvements for citizens.

However, information provided by public authorities currently varies considerably, and media such as the internet may not always provide reliable or understandable data. This became clear in a recent report prepared by the Commission in response to a request from the European Parliament and the Council[20]. On this basis, the Commission considers that the role of industry in this context should be clarified and presents a legislative proposal to rationalise the availability and improve the quality of information to patients within the EU[21] on prescription-only medicines. Industry should be given the opportunity to provide, under strict conditions, quality information. In that context, all actors and in particular industry and Member States should pay attention to the specific linguistic needs of patients belonging to minorities or with an immigration background.

Objective #10: The Conclusions and Recommendations of the Pharmaceutical Forum's work on **information to patients** on diseases and treatments should be taken forward.

Objective #11: Measures to ensure that the **information** provided by the industry to those who seek it is **reliable and objective** should be taken.

1.3.3. Addressing the Environmental Impact

Pollution of waters and soils with pharmaceutical residues is an emerging environmental problem and also an emerging public health concern. The Commission recognizing these concerns has funded several research projects to assess possible environmental and health impacts of pharmaceuticals. It is now necessary to focus on measures that could reduce the potentially harmful impact of pharmaceuticals on the environment and public health. Areas for further actions include evaluating environmental information on pharmaceuticals collected by the European Medicines Agency and national medicines authorities with a view to integrating this information into the current EU legislative framework.

Objective #12: Measures to reduce the potentially **harmful impacts of pharmaceuticals on the European environment and public health** should be proposed.

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19 COM(2007) 630.
20 COM(2007) 862
21 COM(2008) 662, COM(2008) 663

2. TAKING ON THE OPPORTUNITIES AND CHALLENGES OF GLOBALISATION

The EU pharmaceutical industry operates in a global economy. Globalisation brings important benefits, such as the opening of foreign markets and the rise in purchasing power, particular in emerging economies. Research-based as well as generic manufacturers see increasing market opportunities through public funding schemes as well as a growing number of patients who are able to pay for best available treatment options in emerging economies. The EU-based industry is responding to the changing environment in different ways. On the one hand innovators as wells as generic manufacturers are increasingly tapping into markets of emerging economies while outsourcing and internationalising research and development on the other hand. Furthermore, they increasingly rely on active pharmaceutical ingredients (API) imported from Asian countries as precursors for their finished products, thus maintaining their production capacity in the EU.

However, globalisation also leads to new public health challenges. Protecting European citizens by addressing these challenges is a priority of EU pharmaceutical policy. The Commission is also committed to improving medicine availability, affordability and access worldwide in the interest of global health.

2.1. Tackling Worldwide Health Challenges

2.1.1. Illegal Medicinal Products

The Commission has recently adopted a **Communication on an Industrial Property Rights Strategy for Europe** and a core element of the strategy is effective enforcement of Intellectual Property Rights. Illegal medicines exist in several forms, one of them being counterfeit medicines. Safety is a prerequisite for trade of medicines. A study launched in 2006 by the Commission on the distribution of pharmaceuticals revealed that a growing number of medicines are subject to counterfeiting in the EU.

The Commission *"Report on Community Customs Activities on Counterfeit and Piracy" for 2007*[22] also revealed that medicines seized by customs authorities increased by 628% in just two years (2005-2007). They relate not only to 'lifestyle' products, but also to treatments against life-threatening diseases. Existing contacts in regulatory cooperation with third countries should be intensified in order to combat illegal medicinal products.

On this basis, the Commission presents a legislative proposal[23] to effectively protect European citizens from this major health threat and ensure that medicines bought from the legal supply chain are fully reliable. Various means are proposed, ranging from product-related measures (such as obligatory safety features allowing traceability) to strengthened obligations for wholesale distributors. The proposal also addresses all other actors in the supply chain and clarifies their responsibilities.

Tackling counterfeiting requires joint international efforts. Bilateral cooperation with targeted third countries must be further developed. New mechanisms of exchange of information on illegal distribution channels and counterfeiting should be established.

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22 http://ec.europa.eu/taxation_customs/resources/documents/customs/customs_controls/counterfeit_piracy/statistics2007.pd

23 COM(2008) 668

The Commission is working intensively with European and international partners on this topic. It is an active member of the World Health Organization (WHO) International Medical Products Anti-Counterfeiting Task Force (IMPACT)[24], which has delivered principles on legislation against counterfeit medical products, and furthermore the Group of Specialists on Counterfeit Pharmaceutical Products (PC-S-CP) of the Council of Europe.

Objective #13: The proposal to prevent the **entry of illegal medicinal products** into the legal supply chain should be adopted swiftly.

Objective #14: An intensified **exchange of information** on illegal distribution channels in relation to counterfeit medicinal products should be proposed by 2012.

Objective #15: **Within IMPACT, third countries** developing and enforcing legislation against counterfeit medicinal products should be assisted by the Commission.

2.1.2. Preparing to combat Pandemics

The growing number of avian flu cases has proven that a comprehensive strategy in the field of infectious diseases, notably against pandemics, is necessary.

Much has already been achieved in this field, e.g. in facilitating the marketing authorisation of vaccines against pandemics. EU preparedness planning is well established[25] and a targeted legal framework has been set up under which several products against pandemic flu have already been authorised.

However, the international dimension of the EU influenza strategy, including UN (WHO, FAO, UNICEF etc.) and OIE, needs to be strengthened so as to provide EU citizens with effective vaccines without delays after an outbreak has occurred. Regulatory cooperation between the EU and third countries should provide a platform to share information on medicines against pandemics and to benchmark pandemic preparedness plans, as well as sharing influenza strains and improving access to vaccines and other benefits.

Objective #16: To **improve international cooperation** in the field of **pandemics,** existing bilateral and multilateral relations with third countries should be strengthened and extended.

2.2. Global Cooperation and Harmonisation

2.2.1. Strengthening international cooperation

Tackling worldwide health threats is in itself a sufficient reason to strengthen international cooperation. The global burden of disease is increasing, including poverty-related and neglected diseases which disproportionately affect developing countries. Recognising this, the EU played a constructive role recently in developing the WHO's new Global Strategy on Public Health, Innovation and Intellectual Property aiming at fostering the availability of innovative products addressing the public health challenges in these countries. The Commission has already begun to promoting research with and for Africa on new treatments for neglected diseases. The EU has also taken steps to enable international companies to provide medicines at substantial discounts to developing countries while ensuring that these

[24] http://www.who.int/medicines/services/counterfeit/en/

[25] http://ec.europa.eu/health/ph_threats/com/Influenza/influenza_level_en.htm

preferential prices do not lead to negative repercussions in the EU market by reimportation. Furthermore the EU supports the Global Fund to fight against AIDS, Tuberculosis and Malaria in developing countries. The significant financial contributions from public as well as private sources like charities enable the Global Fund to boost prevention, treatment and care in order to accelerate the urgently needed response to these three diseases.

There are a number of other compelling grounds to strengthen international cooperation related to globalisation.

Firstly, a growing number of medicines are now developed in a multi-centre, international way. Clinical trials are often done outside Europe, including through the European and Developing Countries Clinical Trials Partnership (EDCTP). Ingredients and finished products are more and more sourced through international distribution channels. This makes the task of authorities (evaluation of trials, inspections of sites) more difficult and resource-intensive.

Secondly, companies increasingly operate worldwide. Side effects recorded throughout the world may be relevant to European patients as well. It is therefore essential that the EU has access to such information. Global monitoring requires global cooperation. The Commission is committed to addressing these challenges in a proactive manner. EU international cooperation has been significantly strengthened since 2005. Confidentiality arrangements with the US, Japan and Canada have been established. Yet, bilateral cooperation must still be further enhanced to better share information on the safety of medicines and coordinate actions. Mutually agreed mechanisms for inspections should also be agreed to avoid duplication of work.

Cooperation must be intensified with other key third countries (*e.g.* Russia, India, and China) where more and more clinical trials are carried out and active ingredients produced. Compliance with the ethical principles of the Helsinki Declaration[26] must be a common objective for clinical trials in third countries. First steps have already been achieved, notably with India. Concrete initiatives such as training of regulators, information sharing procedures and work towards common standards should be initiated to increase mutual understanding and confidence.

Objective #17: The **regulatory cooperation with the US, Japan and Canada** within existing confidentiality arrangements, focusing on safety monitoring should be intensified.

Objective #18: **Mutually agreed mechanisms for inspections** in third countries should be proposed to these three countries by 2010.

Objective #19: **Bilateral cooperation**, including the research field, with **Russia, India and China**, focusing on clinical trials and the manufacture of active ingredients should be strengthened.

Objective #20: **Training and information sharing procedures** with these three countries should be fostered.

[26] http://www.wma.net/e/policy/b3.htm

2.2.2. Promoting Global Harmonisation

Establishing and enforcing international public health standards is essential to minimise the risk that unsafe products enter the EU market. The work carried out with the US and Japan at the International Conference on Harmonisation (ICH) is essential in this context and must be expanded. ICH standards should be promoted so that they can become worldwide standards.

International cooperation also provides opportunities to strengthen the EU position by launching initiatives that benefit European companies. The EU-US Transatlantic Economic Council (TEC)[27], in particular, provides a unique chance to bring closer the two biggest pharmaceutical markets in the world, lowering costs by reducing unjustified regulatory divergences. Important simplification initiatives such as the action plan adopted after the Transatlantic Workshop on Administrative Simplification[28] have already been initiated. Joint upstream regulatory dialogue initiatives with other third countries could prove to be successful and should be further developed.

Objective #21: **International harmonisation** at ICH and the **promotion of the use of international standards** by third countries beyond the US and Japan should be further developed.

Objective #22: **Using the TEC areas for simplification and convergence** of rules between the US and the EU and engaging in **upstream regulatory dialogue** for major legislative proposals should be pursued.

2.3. Towards Global and Fair Competition

New markets (China, India, Brazil, Russia, Indonesia, Mexico and Turkey) are expected to represent one fifth of the global sales by 2020. Globalisation and the opening of these markets therefore bring major business opportunities for EU companies. At the same time, new competition from India, China and other Asian countries is emerging. These countries have already become centres in producing Active Pharmaceutical Ingredients (APIs) and prime sources for European imports of those substances.

Europe is in a good position to compete globally, provided the competition is fair, *i.a.* based on international rules. However, it is acknowledged that non-tariff barriers often impede market access for European operators while at the same time non-EU companies enjoy full access to open European markets. Therefore, the Commission has established cooperation in various areas relevant to pharmaceuticals with emerging trading partners in order to ensure that EU companies are able to compete on a level playing field in foreign markets, in particular that their competitors abide by the World Trade Organisation (WTO) rules.

Objective #23: The EU should work towards the **implementation and enforcement of the WTO framework** in its bilateral and multilateral contacts, including bilateral Free Trade Agreements (FTAs), in particular as regards the protection of intellectual property rights.

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[27] http://ec.europa.eu/enterprise/enterprise_policy/inter_rel/tec/index_en.htm

[28] http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/archives_en.htm, 30.11.2007.

3. MAKING SCIENCE DELIVER FOR EUROPEAN PATIENTS

3.1. Supporting Pharmaceutical Research

Research and Development in life sciences is a key to pharmaceutical innovation. However, Research and Development investment has gradually been relocating from Europe to the United States and Asia. While certain factors are sector-specific others also relate to broader factors such as fiscal policy, cost of labour or education and training.

The Commission recognises the crucial role pharmaceutical research and development plays. It is currently implementing various sector-specific initiatives to foster innovation in this field. In 2006, the 7th Research and Development Framework Programme (FP7[29]) and the Competitiveness and Innovation Programme (CIP[30]) were adopted to support not only the development of new technologies, but also to ensure the early commercialisation of scientific findings.

The Commission will also in its planned Communication on rare diseases for the end of 2008 look into how it could strengthen its research and development efforts in relation to rare diseases.

The Innovative Medicines Initiative (IMI[31]) is a key measure to strengthen Europe's competitiveness in biopharmaceutical research and development. The objective of this new instrument, an industry-Commission public-private partnership, is to enhance and accelerate medicine development so as to make new treatment options available to patients earlier.

3.2. Keeping the Pace: New Horizons in Medicine

New technologies and therapies such as tissue engineering or nanomedicines and innovative information and communication technology (ICT or eHealth) tools for healthcare are emerging. They often lie at the borderline between various fields (medicines, medical devices, transplantation, ICT). Their emergence emphasises the importance of the proportionality and flexibility of the regulatory framework.

The Commission is committed to incorporating scientific breakthroughs into the EU pharmaceutical framework of the 21st century like tissue engineering and gene therapy and its translation into marketable products, in particular in areas with unmet medical needs, e.g. infectious diseases (like tuberculosis, HIV/AIDS) and rare diseases which do not only pose public health challenges for Europe but also for developing countries, particular in sub-Saharan Africa. All new technologies must however be evaluated properly. It is particularly important that the ethical pluralism and the principle of subsidiarity are fully respected.

3.2.1. Realising the promises of regenerative medicine

Regenerative medicine, i.e. the use of genes, cells and tissues to treat dysfunctions or regenerate parts of the human body, offers a huge potential, notably against diseases like Alzheimer or Parkinson which are of high prevalence in an ageing population. The new EU

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29 http://cordis.europa.eu/fp7/home_en.html
30 http://ec.europa.eu/cip/index_en.htm
31 http://www.imi-europe.org

Regulation on Advanced Therapies[32] should speed-up the development of these products and foster industry's competitiveness, while respecting national prerogatives on ethics.

Objective #24: **The effects of the implementation of the Regulation on Advanced Therapies should be assessed and reviewed** by 2012.

3.2.2. Towards more personalised medicines

With the emergence of new technologies like pharmacogenomics and patient-specific modelling and disease simulators, personalised medicine is now on the horizon. In the long term, doctors may be able to use genetic information to determine the right medicines, at the right dose and time. This field is already affecting companies' business strategies, the design of clinical trials and the way medicines are prescribed. Although it is too early to say whether '-omics' technologies will indeed revolutionize the sector, the Commission closely monitors the area and will reflect on how it can support its development.

In addition, it has to be assumed that the high costs of these new treatment options are likely to put strains on public healthcare budgets. The deliberations in the Pharmaceutical Forum on matters related to pricing and reimbursement have set the ground to address these issues.

Objective #25: A **report on the use of '-omics' technologies** in pharmaceutical research and development **should be submitted** by 2010 and the subject as to whether **new Community instruments** are needed to support their development should **be explored with stakeholders**.

4. CONCLUSION

The Commission firmly believes that in today's globalised world and security environment, Europe needs a dynamic and competitive pharmaceutical sector. The EU has major assets to meet this objective: a strong research base, a renowned education system and skilled workforce, a well-established and innovative EU-based industry.

The future of the sector will be shaped by structural factors, some of which go beyond the sole pharmaceutical area. Nevertheless, the Commission underlines the major role that EU policy can play in this sector. Community action is most appropriate to tackle the challenges that Member States have in common. The commitment of all actors involved in the implementation of this Communication will be essential to achieve the intended vision: a competitive industry that generates safe, innovative and accessible medicines.

Based on the objectives outlined in the Communication, the Commission, therefore, invites the other institutions to engage in a constructive dialogue on the way forward.

[32] OJ L 324, 10.12.2007, p. 121.