European Federation of Pharmaceutical Industries and Associations

European Commission New Trade Strategy

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EFPIA Contribution

Benefits of Trade for the Pharmaceutical industry, Patients and the Economy

EFPIA (European Federation of Pharmaceutical Industries and Associations) represents the pharmaceutical industry operating in Europe. Through its direct membership of 33 national associations and 40 leading pharmaceutical companies, EFPIA is the voice on the EU scene of 1,900 companies committed to researching, developing and bringing to patients new medicines that will improve health and the quality of life around the world.

The innovative pharmaceutical industry is a key strategic sector for the European economy, driving medical progress by researching and developing new medicines. In 2014, Europe accounted for 25,3% of world pharmaceutical sales[1] and the EU pharmaceutical sector is considered to be the high-tech sector contributing the most to the EU trade balance.

The pharmaceutical sector sustains around 800 000 jobs throughout Europe and an open trading system can protect these jobs and create new employment opportunities throughout the pharmaceutical value-chain, including jobs for scientists, regulatory experts and packaging officers, among others. New jobs in the pharmaceutical sector can provide opportunities to join the health industry and work towards better healthcare outcomes. A progressive and ambitious trade policy agenda also means a secure and predictable business environment for companies operating globally.

The pharmaceutical sector is a global industry with operations in many countries around the world. **Key strategic markets include both developing and developed markets such as the US, Canada, China, India, Russia, Japan and Turkey.** For the pharmaceutical industry, trade policy at bilateral, plurilateral and multilateral level plays a key role in opening important markets and eliminating red tape. An ambitious trade policy helps addressing trade barriers in a constructive and inclusive manner through trade agreements as well as regulatory and Intellectual Property (IP) dialogues with trading partners. Removing trade barriers and regulatory hurdles in third countries and increased market access enables the pharmaceutical industry to operate in a more transparent and predictable environment. These efficiencies reduce costs of production and generate cost savings, which can be used for increased investment in research and development, and an improved regulatory environment which is key in order to advance innovation of new medicines and accelerate patient access to new treatments.

[1] Numbers for Europe include Russia and Turkey

EFPIA is supportive of the Commissions work on the new Trade Communication, and proposes the following key issues to be addressed in the new Trade Strategy.

Strategic Partners and Emerging Markets

Estimations[2] show that up to 90% of the growth, including of the pharmaceutical industry, will be provided by emerging markets by 2020. During recent years, we have already seen this rapid growth in emerging economies such as China[3]. This has led to a migration of research and economic activities to some of these markets, a trend that will likely continue in the coming five years. In many of these markets, the pharmaceutical industry faces a number of barriers, where weak regulatory systems and limited harmonisation with international standards present distinctive and numerous challenges for multi-national companies, which effectively hinder access to innovative medicines for patients.

For example, in China, due to regulatory and bureaucratic barriers, new medicines typically take four to six years longer to reach patients than other major markets, such as the US, Japan or Europe. These challenges have been addressed by the Commission in several high-level bilateral dialogues and summits, and they have proven to be effective platforms for discussion. **EFPIA would therefore like to emphasise the importance of keeping the bilateral dialogues high on the Commission's agenda**. This includes existing dialogues such as with China and India, but we would also like to see more intensive bilateral dialogues with other countries, such as Turkey.

In Turkey, there are a number of pressing issues for the industry, including unfair pricing decisions, restrictive regulatory decisions (for example on Good Manufacturing Practices) and lack of alignment with international and European IP standards. In light of the announced upcoming modernisation of the Customs Union, EFPIA would like to stress the importance of prioritising an ambitious upgrade process, including comprehensive chapters on IP, procurement and regulatory cooperation, as well as maintaining dialogues and bilateral meetings to aiming to solve and discuss these long-standing issues.

EFPIA member companies are also experiencing increased protectionism in important international markets such as Russia, Vietnam, and in Latin America, relating to for example:

- Discrimination against foreign investors through local content and localisation requirements, compulsory licensing and in tendering procedures
- Lack of transparency in pricing and reimbursement decisions
- Lack of reward for innovation coupled with inadequate levels of protection and enforcement of IP rights, while failing to address fundamental access issues.

EFPIA would therefore like to reiterate the importance of continued bilateral discussions and finding avenues for constructive dialogue with these and other important trading partners.

EFPIA would also support a **revised and more ambitious strategy on Asia-Pacific**, **engaging and re-engaging with key countries in the region,** such as India, Thailand, Malaysia and the Philippines. In light of the rapid development and integration of China and other Asian countries into the international market and global value chains, **a comprehensive Asia-Pacific strategy should be of high priority**.

[2] COM 2013 Investment R&D scoreboard

[3] In 2014, the Chinese market grew by 11,6% compared to an average market growth of 2,4% for the total European market (Source: IMS Health, April 2015)

Taking into account the expected rapid economic and societal changes in the coming years, it is crucial that the Commission continue, and intensify, constructive engagement with Europe's strategic partners, setting out clear action plans for improved market access conditions, as well as increased alignment of regulatory and IP standards with international best practices.

Free Trade Agreements

EFPIA member companies are committed to a comprehensive and ambitious FTA agenda, including engagement with emerging markets. Over the past years, changes in both the scope and content of FTA negotiations have taken place and as emerging economies evolve, FTAs are becoming more complex, and business is also operating in an increasingly global context. Therefore, the way FTAs are negotiated with partners of both developed and developing economies will require changes and new ways of thinking.

EFPIA views the increased comprehensiveness and complexity of FTAs in a number of areas as a positive trend. To this end, **the scope of on-going and new FTAs should focus on a variety of issues included in recent FTAs, such as increased regulatory convergence.** Trade agreements fit for the 21st century require strong chapters on regulatory cooperation, including elements such as Good Regulatory Practices, transparency as well as sector-specific regulatory provisions. Such chapters help avoiding duplicative processes and create synergies and efficiencies between competent regulatory authorities that have equal standards in place. Enhanced regulatory cooperation and the removal of Non Tariff Barriers (NTBs) in the pharmaceutical sector, as well as the removal of barriers to public procurement, will open up markets and create new opportunities for business, new employment possibilities and increased access to medicines for patients worldwide. The inclusion of IP provisions aligned with international standards will also provide a crucial platform to foster innovation and incentives which are essential for the development of new medicines. In addition, ambitious investment provisions are an essential part of modern FTAs, where the EU has a chance to set global standards and aspire to reform current systems, in order to ensure European investments are protected and enforcement is guaranteed.

Ambitious provisions on regulatory cooperation and IP in FTAs will improve the overall operating environment for pharmaceutical manufacturers in international markets and facilitate increased cooperation and investment in research and innovation. This will enable the pharmaceutical industry to develop new treatments and tomorrow's cures for patients all over the world, reflecting the true value that trade agreements can bring to patients, health systems and society.

EFPIA would also like to emphasize the importance of key developed markets where the EU has on-going FTAs, such as the US and Japan, where we would like to see ambitious results, including comprehensive provisions on regulatory cooperation, IP and the inclusion of a pharmaceutical annex. EFPIA believes that it is fundamental to **finalise and implement the on-going trade agreements** with these important trading partners in the next five years. EFPIA would also like to see the successful ratification of the CETA and Singapore FTAs, and welcomes the possible modernisation of current agreements with Latin America (Mexico, Chile) as well as the revival of on-going FTAs in Asian markets.

Lastly, EFPIA welcomes and supports the Commissions enhanced work on transparency in trade negotiations and engagement with the full range of stakeholders, and would urge the Commission to continue this initiative with on-going and forthcoming trade agreements.

Implementation

EFPIA would like to underscore **the importance of an increased focus on the effective implementation of finalised FTAs, with increased resources devoted towards monitoring the implementation of FTA commitments in order to fully utilise the trade agreements full capacity**. With the completion of many of the key on-going FTAs, it is likely that the trade landscape will look different in the next five years. Within this context, the Trade Strategy should entail a clear and concise focus on implementation of trade agreements, in order to ensure that the EU FTAs deliver clear results for the economy, citizens, industry and society. In the area of pharmaceuticals, proper implementation and enforcement of commitments is of great importance, in order to improve overall market conditions and provide faster patient access to innovative medicines.

In this context, we would also like to stress the need for DG Trade and other Commission services to secure the appropriate resources to deliver on the ambitious EU Trade Policy agenda set out for the coming five years.


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