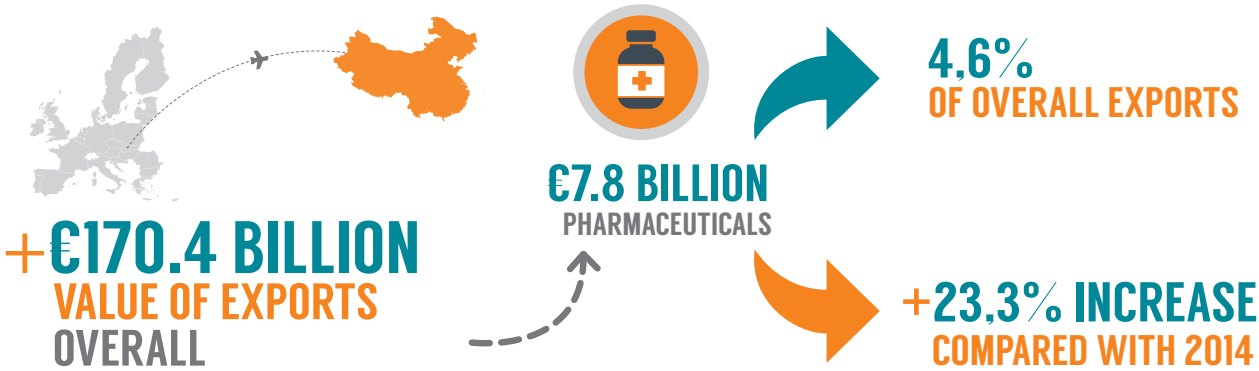
efpia
European Federation of Pharmaceutical Industries and Associations

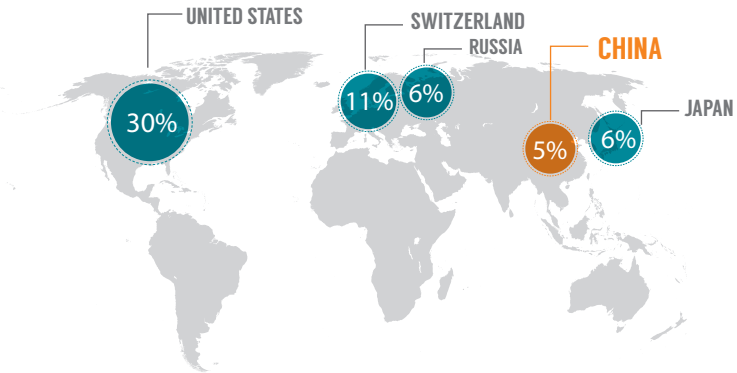
EFPIA Key priorities in China

The Chinese market continues to represent one of the most relevant growing markets for pharmaceutical companies operating in Europe, with significant growth potential reliant on modernization and reform. Over the past years, we have seen continued growth of bilateral trade between the EU and China, which is projected to be maintained during the coming years. In 2015, EU exports to China amounted to €170,376 million, with pharmaceuticals making up 4.6% of these exports, representing €7,801 million and registering a 23.3% increase when compared 2014 figures[1].

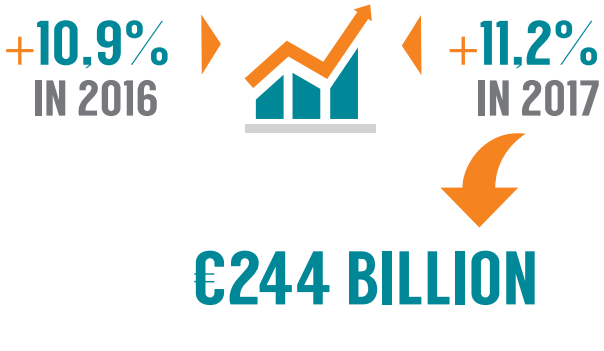


China is currently the second-largest pharmaceutical market in the world, and set to surpass the United States. According to forecasts, pharmaceutical sales in China will grow by 10.9% in 2016 and by 11.2% in 2017 to reach € 244 billion in 2017[2]. EFPIA member companies are determined to continue investing in R&D to bring new and innovative medicines to Chinese patients.

MAIN MARKETS FOR EU EXPORTS



PHARMACEUTICAL SALES IN CHINA



China has been going through significant healthcare reforms in the past few years and a good number of comprehensive reforms are planned or underway in key policy areas relevant to pharmaceuticals, such as the revision of the Drug Administration Law, the Drug Registration Regulation and the Pricing and Reimbursement system, including the update of the National Reimbursement Drug List, amongst others. While the overall objectives of the announced reforms are broadly far-reaching and generally aim to establish closer alignment with international standards, Industry remarks that their actual implementation falls short of genuine ambition.

[1] http://trade.ec.europa.eu/doclib/docs/2006/september/tradoc_113366.pdf
[2] IHS Markit Healthcare Forecasts Q4 update, October 2016, (CNY1,786.4 billion= €244 billion)

MARKET ACCESS

Price commitment policy proposal

Chinese Food and Drug Administration (CFDA) informally shared the draft "Announcement Concerning the Undertaking on the Sales Price of Newly Marketed Drugs" with foreign-based industry in April 2016. This draft policy aims to make regulatory approval conditional to price commitments, whereby a company should commit that the price of drugs in China would not be higher than the average retail price in the country of origin or in "comparable", neighbouring markets. This proposed policy runs counter to global practice of regulatory agencies, whose decisions are based solely on science-based criteria, such as safety, efficacy and quality, and not on price considerations. China's State Council released Opinions on "Further Reforming and Improving the Policies of Using, Production and Circulation of Drugs" in February 2017, which also refers to the implementation of the policy proposal. CFDA is expected to publish implementing guidelines, which should outline the details of the proposal. Overall, there is a lack of clarity regarding the status of the proposed policy, however global industry has joined forces to construct a dialogue with Chinese authorities towards a sustainable pricing policy framework, while acknowledging and respecting the China's efforts to reform its pricing and reimbursement system.

Government pricing and reimbursement

The Chinese Ministry of Human Resources and Social Security (MoHRSS) released the update of the National Reimbursement Drug List (NRDL), which represents the first modification of the list since 2009. The industry welcomes this long-awaited update to the reimbursement list and the inclusion of 339 new medicines. While this is a positive step, we urge that forthcoming updates will follow key principles of transparency and predictability, and will allow for a reasonable consultation process with relevant stakeholders.

REGULATORY ISSUES

Drug Lag

The industry faces long approval process timelines in China; new medicines typically take four to six years longer to reach patients than other major markets. These delay stem from approval procedure changes implemented by the CFDA in 2014, which were introduced without any consultation with industry. Lack of clarity and predictability regarding changes concerning multi-regional clinical trials also remain an issue. This further contributes to the extension of the drug lag by approximately two years. The recent review of the Drug Registration Regulation (DRR) allowed for some progress in this sense, however it failed to address the core of the problem and did not resolve the issue.

INTELLECTUAL PROPERTY

Regulatory data protection (RDP)

As part of its WTO accession in 2001, China has committed to introduce RDP protection of at least 6 years to pharmaceutical products against unfair commercial use for clinical test and other data submitted to secure approval of products containing a new chemical ingredient[3]. China has not yet taken steps to effectively implement this protection despite ongoing legislative reforms that could fix the issue, such as the DRR.

Weak Patent Enforcement

The provisions for drug registration do not currently provide for an effective and transparent mechanism to ensure that patent issues can be resolved before potentially infringing generic substitutes or biosimilars products are launched on the market. The review of the DRR addressed, but failed to solve the issue.

[3] In accordance with Article 39.3 of the WTO TRIPS Agreement.