efpia
European Federation of Pharmaceutical Industries and Associations

CETA: A Step Forward to Benefit Patients and Innovation

International trade is a key driver of growth, jobs and competitiveness for the research-based pharmaceutical sector in Europe. This underpins our industry's mission to develop life-saving innovative treatments for patients, which is why the pharmaceutical sector strongly supports the CETA agreement. Our high-technology sector is a major asset to both Canada's and the EU's economies, where it currently employs nearly 760,000 people.

The innovative pharmaceutical industry is an important player in trade between the EU and Canada and has been a strong supporter of the CETA since the negotiations began in 2009.

R&D

IN 2015, EFPIA MEMBER COMPANIES
INVESTED OVER €30 BILLION
IN R&D IN EUROPE

JOBS

EFPIA & INNOVATIVE MEDICINES CANADA (IMC)
MEMBER COMPANIES EMPLOY
760,000 PEOPLE
IN EUROPE AND CANADA

EXPORTS

€3.977 BILLION
PHARMACETUCAL EXPORTS
TO CANADA IN 2015[1]

The pharmaceutical industry on both sides of the Atlantic relies heavily on intellectual property (IP) protection as a key incentive for innovation – the life-blood of the industry. EFPIA and its Canadian sister association Innovative Medicines Canada have advocated for tangible improvements in Canada's IP regime for pharmaceuticals, bringing it closer in line with that of the European Union. With the strong support of European Commission negotiators, backed up by the Member States and the European Parliament, the final CETA text agreed between Canada and the EU has successfully delivered on many key areas.

INTRODUCTION OF AN EFFECTIVE RIGHT OF APPEAL FOR INNOVATORS IN PATENT DISPUTE PROCEEDINGS IN CANADA

Canada has committed to correct the existing imbalance in legal rights between innovators and generic manufacturers. CETA now specifically provides for equivalent and effective appeal rights in court proceedings in Canada.

ESTABLISHMENT OF A SYSTEM OF PATENT TERM RESTORATION (PTR) SIMILAR TO THE EU'S SYSTEM OF SUPPLEMENTARY PROTECTION CERTIFICATES

Canada previously did not provide for any mechanism to make up for the time it takes to obtain regulatory approval (including clinical development), which often significantly erodes effective patent life.

AFFIRMING EXISTING LEVELS OF REGULATORY DATA PROTECTION

Such protection ensures that clinical data submitted by innovative companies to regulatory agencies to demonstrate a drug is safe and effective is protected from unfair commercial use for a limited period of time.

PROTOCOL ON GOOD MANUFACTURING PRACTICES FOR PHARMACEUTICALS

The GMP Protocol builds on existing co-operation and the Mutual Recognition Agreement (MRA) signed between EMA and Health Canada in 1998 to strengthen cooperation between regulatory agencies.

We believe that, if implemented in line with the letter and the spirit of the agreement, CETA will contribute to better IP protection, enabling access to innovative medicines and vaccines, and fostering research for the cures of tomorrow. This will benefit patients in Europe, Canada, and worldwide.

While challenges remain within Canada's IP system, we believe that this agreement represents an important and positive step forward, without impacting access to medicines in low- and middle-income countries. By increasing Canada's alignment with both the EU's standards and generally with other OECD countries, we believe that European companies will enjoy a level-playing field when exporting to, investing in, or manufacturing innovative medicines in Canada.

[1] *http://trade.ec.europa.eu/doclib/docs/2006/september/tradoc_113363.pdf*