EPHA contribution – Public Health Concerns on Pharmaceuticals in TTIP

Pharmaceuticals

- **TTIP shall refrain from any provisions that would potentially increase the price of pharmaceutical treatments and medicines. In order to reduce health inequalities and ensure affordable medicines for all, TTIP shall avoid that longer patent status of medicines prevent the availability of cheaper generics**
- **Pricing and reimbursement shall be excluded any terms in all the horizontal chapters and all of the sectorial annexes of TTIP that would limit directly or indirectly the national competence of Member States to tailor their pricing and reimbursement policies to ensure sustainable access to affordable medicines.;**
- **TTIP shall ensure that clinical trials data would be available for public health research.**

The economic crisis has brought significant changes to both health system financing and regulatory framework in the pharmaceutical sector, which in turn, influences affordability and availability of medicines. Existing problems regarding the affordability of medicines in Europe and sustainability of public expenditure on medicines were heightened because of the crisis. Before health systems were on an unsustainable path due to increases in chronic illness, inefficient planning and mismanagement of health systems, the irrational use of medicines and an ageing population. The crisis can be an opportunity to make reforms that promote efficiency and reduce spending, for example the rational use of medicines, greater uptake of Health Technology Assessment (HTA), pooled procurement, and the purchase of generic medicines.[1]

The cost to Europe of pharmaceuticals was estimated by the OECD to have been €190bn in 2010, which equates to an average of 1.5% of GDP across European Member States. **There are important differences between EU and US** in how patent applications are handled.[2] The linking of marketing authorisation for a medicine to its patent status can cause delays in generics reaching the market and if TTIP included provisions relating to patent linkage then regulatory authorities would only be able to start the licensing process when the patent is terminated, a situation that is not currently legal in the EU.[3]

The harmonisation of Good Manufacturing Processes (GMP), inspection of clinical trial sites and the way that clinical trials are run have the potential to streamline drug development processes in the two trading blocs. While it is recognised that this could led to fast drug development and a decrease in prices, it remains to be seen whether drug producing companies will translate these potential efficiency savings into actual price reductions for governments and patients. The transparency gains made under the revision of the Clinical Trials Directive in 2013 and at the European Medicines Agency (EMA) as well as the EU commitment to **open access to research publications and increased access to research results** partly funded by EU biomedical R&D grants should in no way be jeopardised by the proposed changes in the TTIP.

[1] [EPHA Briefing] Access to Medicines in Europe in Times of Austerity www.epha.org/5698
[2] http://www.genengnews.com/insight-and-intelligenceand153/u-s-patent-law-retains-key-differences-with-europe-and-canada/77899549/
[3] Khan, U., Pallot, R., Taylor, D. and Kanavos, P. (2015)'The Transatlantic Trade and Investment Partnership: international trade law, health systems and public health' London School of Economics and Political Science and Modus Europe report. www.epha.org/6278