Missing Medicines campaign

Our system for developing medicines is failing; medicines are too expensive or simply missing for those who need them. We urge European Parliament to act quickly to protect our access to medicines and to support longer-term reforms of our R&D model by:

1. **Defending access to affordable medicines** by standing against any free trade agreement, including TTIP, that strengthens the patent model and hampers generic competition.

2. Urging the European Commission to **support the CEWG recommendations** and **push for global progress on creating a global R&D agreement.**

Why is our system for developing medicines failing?

Millions of people are missing the medicines they need because our current R&D system relies on the use of drug patents. This leads to:

- **High Prices:** pharmaceutical companies have a 20-year monopoly on the new drugs they produce, meaning they have no competition and can therefore charge extremely high prices. *For example, Sofosbuvir, a new drug for Hepatitis C was first marketed at US $84,000 for a 12 week treatment cost, far out of reach for people in many high income countries, not to mention low and middle income countries, even though it would cost only US $68 and $136 to produce in generic form[1]. Prices for some countries will go down due to voluntary licensing, but many countries in need find themselves outside of the scope of these deals.*

- **Skewed incentives:** medical research is driven towards the medicines likely to earn the most profit, meaning that if the development of vital medicines is not profitable they're not developed. *For example, Tuberculosis (TB) claims the lives of 1.5 million people every year and the prevalence of drug resistant strains continues to increase. Yet, biomedical research for TB has been extremely underfunded – in 2014 there was a shortfall of $1.33 billion[2]. The main reason for this is that 95% of people living with TB reside in low and middle-income countries and so the 'market' for TB does not offer pharmaceutical companies a sufficient return on investment. As a result, only 2 new drugs have come onto the market in the last 50 years. Hay fever, on the other hand has received 15 new treatments in the same period.*

- **Inefficiency:** sharing of knowledge between researchers is disincentivised, meaning the progress of scientific research is hindered and research is often duplicated. *For example the patient care group Prescrire tested the added therapeutic value of 1345 drugs between 2000 and 2013 and found that only 7% offered 'a real advantage' to drugs already on the market.[3]*

The failing R&D system is a global issue; it affects not only developing countries but also many of us in the European Union. It is widely recognised that our current R&D model has been unable to tackle our antibiotic crisis or provide affordable treatments for cancer or Hepatitis C. To ensure access to affordable and essential medicines, we must address the threats that are currently emerging in trade negotiations and support longer term reform of our R&D model:

---

[1] http://m.cid.oxfordjournals.org/content/early/2014/02/13/cid.ciu012.full

[2] http://www.treatmentactiongroup.org/sites/g/files/g450272/f/201505/TAG_2014_TB_Funding_Report_2nd_Ed.pdf

[3] Prescrire, 2014; 34 (364):132-136 'New drugs and indications in 2013: little real progress but regulatory authorities take some positive steps' available at http://www.ncbi.nlm.nih.gov/pubmed/24860905

The dangers of Free Trade Agreements

Despite the growing understanding that the patent model is failing, we continue to rely on drug patents as the main funding source for R&D. As a result, Free Trade Agreements negotiated by the EU often seek to strengthen these monopolies. The Transatlantic Trade and Investment Partnership Agreement (TTIP), now under negotiations, is a significant threat to changes towards affordability, needs-driven innovation and alternative incentive structures. European Commission position papers and pharmaceutical industry filings with the Commission and the US Trade Representative indicate threats to affordable medicines under consideration in TTIP negotiations. The Trans-Pacific Partnership (TPP) trade agreement recently negotiated by the US also contains provisions that will be devastating for people's health in countries from Chile to Vietnam.

Yet, the EU supports developing countries in implementing TRIPS and uses TRIPS flexibilities and therefore acknowledges the negative impact that Intellectual Property (IP) can have on access to medicines. The Dutch EU Presidency has questioned the excessive intellectual property (IP) rights protections that are now at the disposal of the pharmaceutical industry. The Health Minister has also clearly stated that a new balance must be found to achieve affordable and sustainable access to medicines.

Many of the provisions foreseen for TTIP will put industry interests ahead of patients' health. If adopted, they will make it impossible for governments to make certain changes later on[4]:

- **TTIP could restrict national pricing and reimbursement decisions:** TTIP could offer the pharmaceutical industry a much bigger say in governments' decisions on pricing and reimbursement. It could weaken the negotiating power of governments to make medicines affordable for patients by imposing cumbersome procedural requirements on public authorities that attempt to enact cost-containment measures, potentially including cost-benefit analysis.

- **TTIP may expand monopolistic IP practices:** TTIP could further extend monopoly periods derived from patents and market exclusivity rules and delay price-lowering generic competition. The agreement is likely to lock into place the worst rules from each side of the Atlantic, and block the path toward future cost-cutting reforms

- **TTIP will enshrine trade secrets regulations:** The EU is about to adopt a Directive that aims to harmonise trade secrets protection rules amongst EU Member States. The Directive extensively refers to an IP framework, threatening citizens' freedom of expression and right to know. It will likely restrict access to information that is in the public interest, such as medicines safety and efficacy data, as well as technical know- how to enable generic competition. In effect, the scope of IP protection would be widened. In the US, negotiations for new rules on trade secrets are also underway. The objective down the line is to include trade secret protection in TTIP, enshrined as an international benchmark.

- **TTIP regulatory cooperation mechanism could pave the way for more corporate influence:** EU–US working groups for ongoing bilateral coordination on IP and pricing and reimbursement decisions established under TTIP would have the ability to influence domestic medicines policy. A complex institutional infrastructure for regulatory cooperation in the context of an agreement meant to reduce barriers to trade will, in practice, inevitably lead to more possibilities for industry to influence national pharmaceutical policies.

- **The inclusion of any investor-state dispute settlement mechanism in TTIP could jeopardise public health:** The inclusion of investor-state dispute settlement in any form—whether it is based on the US Model Bilateral

[4] http://commonsnetwork.eu/wp-content/uploads/2016/02/Position-Statement-TTIP-and-Access-to-Medicines.pdf

Investment Treaty or the European Commission's "Investment Court System" proposal—in TTIP would allow foreign companies to extra-judicially challenge legislative, administrative measures, and even judicial decisions taken by a government to safeguard public health and other public interest concerns

- **TTIP may set global standards that would harm public health in lower- and middle-income countries:** TTIP could harm patients in low- and middle-income countries (LMICs) where resources are more constrained. TTIP may include EU–US cooperation agreements against policies that developing countries use to access affordable generics. Many LMICs have fewer institutions to balance IP monopolies and rally against high prices. This could lead to health systems being even less able to provide care and treatments to patients due to a lack of funds

With this in mind, **we urge MEPs to stand against TTIP**. In addition, on March 30th the European Council and Commission are organising the first EU-India Summit in 4 years. Prime Minister Modi will be in Brussels and it is expected that the EU-India Free Trade Agreement (FTA)negotiations will be restarted in the wake of this summit. These have previously threatened to put pressure on India's IP laws. **Therefore we ask that MEPs defend our access to medicines by refusing any trade agreement that strengthens intellectual property law and hampers generic competition.**

Whilst these measures will defend our access to medicines in the short-term, longer term R&D reform is both essential and possible.

An historical opportunity to reform our biomedical R&D system

As you may know, the World Health Organisation (WHO) created the Consultative Expert Working Group (CEWG) to seek solutions. They recommended a package of reforms that would seek:

- **Introduce alternative incentives** to producing new medicines, such as cash prizes, to replace patent monopolies and ensure affordability while still providing the innovator companies with an ample return on investment.

- **Prioritise health research** according to need rather than profit by supporting the development of a global R&D Observatory at the WHO.

- **Establish a pooled fund for R&D** financed by all countries contributing 0.01% of GDP to ensure the R&D burden is shared.

These reforms should be realised through a new, legally-binding global framework - similar to the convention on Human Rights - called The R&D Agreement. By 'de-linking' the profit incentive from the cost of R&D, it has the potential to unlock access to affordable and appropriate treatment globally. A global agreement appears to be imperative – a point reflected by the UN Secretary General's High Level Panel on Access to Medicines, convened in November 2015

In light of these high-level discussions, **we kindly ask MEPs to urge the European Commission to support the CEWG recommendations and push for global progress on creating a global R&D agreement.**

To discuss the above or find out more, please contact the Youth Stop AIDS Coordinator, Tabby (tabby@restlessdevelopment.org)