Coherence between Trade Policy and Global Health

In order to ensure that EU trade policy is coherent with health & development objectives, and does not harm access to medicines, the EU should specifically monitor and assess the likely impact of Bilateral trade agreements and the Anti-Counterfeiting Trade Agreement. The provisions in these trade agreements that pose extra obligations on trading partners that go beyond agreed provision in TRIPS should be scrutinised for it health impact.

- ➔ Establish a system with DG Trade and Global Health DGs to screen draft FTAs through independent advice and ensure compliance with Global Health and other (international) commitments.

1. Commission independent impact studies of the proposed measures for Free Trade Agreement with third countries.

The following model could be used: '*Guide to estimating the impact on access to medicines due to changes in intellectual property rights*', produced jointly by the World Health Organisation (WHO) and the Pan-American Health Organisation (PAHO). IPRIA studies were conducted in partnership with a consortium of organisations, including WHO, PAHO, the United Nations Development Programme (UNDP), the World Bank Institute (WBI) and the International Centre for Trade and Sustainable Development (ICTSD), who have been refining the methodology. EU-Colombia (2009), EU-Peru (2010), US- Colombia (2005, 2006, 2007), US-Thailand (2008)US- Guatemala (2005),US- Costa Rica (2005), US-Bolivia (2006), US- Dominican Republic (2008). The IPRIA model uses the *scenario planning method* to establish the impact. The impact itself is the difference between the *basic scenario*, which describes the current situation (no changes to the IPR system), and *alternative scenarios*, which describe potential consequences of changing the IPR context. http://ictsd.org/downloads/2010/03/guide-to-the-ipria-model.pdf

2. The EU should assess whether it should aim to export supplementary protection certificates (SPCs) or patent extension at all due to the negative effects on Access to medicines in countries with little resources.

3. The EU should assess whether it should export data exclusivity to third countries due to the negative effects on Access to medicines in countries with little resources. .

4. More attention should be given to meaningful technology transfer.

5. The EU should act with restraint in exporting enforcement measures.
   - Enforcement of Intellectual Property should be assessed on how it hampers generic competition and access to medicines before being exported to other countries through trade agreements. Enforcement of IP has proven to hamper trade in generics, the Dutch seizures just being one example. The effects of enforcement measures for health and welfare overall have not been properly studied. Enforcement measures constitute significant costs for countries to implement, which can be considered creating an imbalance between rights and obligations to be taken on under a trade agreement. The EU should have an independent research institute gather data on what the costs are to implement these stringent enforcement measures for example, customs, judges, police, and overall administration.

a. The confusion between generic medicines and counterfeit medicines should be guarded for and kept at bay as it undermines sound medicine policy.

b. The EU should withhold from demanding third countries to adhere to the Anti Counterfeiting Trade agreement. (Now referred to as the ACTA Treaty.) ACTA contains many TRIPS plus provisions that are likely to have a negative impact on generic competition and will be very costly.

c. The DG Trade Enforcement watch list should only refer to TRIPS as a standard (not for LDCs) and not higher standards like the ECs customs regulation 1383/2008.

6. Allow and assist countries to use trips flexibilities to ensure access to medicines for their populations. Take a different approach to compulsory licensing then in the past. Provide technical assistance to countries that are looking to engage in a compulsory license to address a public health emergency (!).
   - Par 6 amendment to be reviewed > position?

The challenge of knowledge: investing in research that benefits all

There is a need to explore and support both push and pull mechanisms for needs driven R&D that dissociate the cost of research and development and the price of a medical product.

Push and pull mechanism relate to grants driven research and (market) incentive driven research.
Direct grants to universities, public researchers, or firms to carry out R&D can be seen as 'push' funding: this type of funding pays directly for R&D or reduced the costs of risks to commercial product developers. Product Development Partnerships also benefit from push funding. Pull mechanisms, in contrast, seek to increase the reward to successful development of a new medicine or vaccine in the hope of motivating developers, typically private sector firms, to invest their own resources in R&D. Much has been invested by governments into push mechanisms to stimulate r&d into neglected diseases, and while more investments is needed into push mechanisms, it is crucial for the EC to also engage in funding for pull mechanisms. Push and pull mechanisms are complementary.

Examples of pull mechanism are a profitable markets, Prizes and Advanced Market Commitments (AMCs). A profitable market is absent in the areas where more medical R&D is most needed. The designs of these models is quite important and a condition and basic idea which differentiates between semi helpful and really helpful models are the ideas of de-linkage and the condition that a public good, accessible to all, is created.

Furthermore the sharing and providing access to knowledge must be encouraged. The sharing of knowledge, data and technology is essential for two main reasons:

1. Sharing of knowledge and technology will encourage and stimulate more innovation
2. This will allow more actors to engage in innovation and production of medicines, including stimulating increased participation and local production in the Global South.

➔ At the global multilateral level, particularly at the World Health Organisation the EU should

1. Take the lead in ensuring that the Expert Working Group on Alternative Financing for R&D explores truly innovative models that will structurally change the model of r&d . Engage with progressive and leading Southern governments on this.
2. The EU should give attention to models that dissociate the cost of r&d from the price of medicines, as only these models of innovation will be able to approach immediate universal access.
3. Be open to discussions about a global framework or treaty for needs driven research and development and norm setting in R&D.

➔ Within the European Union

The EU should

Explore new models of innovation that dissociate the cost of R&D from the prize of the medical product

1. Ensure access to publicly funded research: Work towards making equitable/ open licensing /non exclusive licensing and open access publication a condition for grant programs like FP 7 and FP 8,
2. Engage with pilots and feasibility studies.
   Explore innovation inducement prizes that will reward health impact. Including proposals on TB diagnostic, Cancer, Aids, Chagas.
3. Take note of the AIDS treatment bomb > second line treatment will be unaffordable for the GFTAM. Look into proposals that look to avoid this catastrophe. Unitaid Patent Pool, Donor prize fund proposal.

4. Make sustainable funding more accessible for Product Development Partnerships.

5. Take note of the 2020 Flagship Innovation Union Communication. In this communication there is a strong call and recognition of the need for the EU to engage in needs driven innovation, addressing ‘societal challenges’, and a call for the creation of platforms for open innovation and citizen engagement, including through the awarding of prizes for research.

6. Take note of and implement the Global Strategy and Action Plan for Public Health, Innovation and Intellectual Property. WHA 61.21 2008