Human Rights Council, Social Forum, 2-4 October 2017.

Speaker notes by Ellen ‘t Hoen.

The title of this Forum is Promotion and Protection of Human Rights in the context of HIV epidemic and other communicable diseases and epidemics. I want to preface my presentation with the warning that my recommendations are not limited to communicable diseases. The dichotomy communicable/non-communicable is somewhat artificial: people with HIV are at higher risk of cancer, HCV causes liver cancer, and, HPV causes cervical cancer. Many so called non-communicable diseases are caused by “commercially communicable diseases” lung cancer, certain types of diabetes, food borne diseases etc.

States as primary duty holders to ensure the right to health and this includes ensuring that essential medicines are ***available, accessible, acceptable and, of good quality*** and to prevent unreasonably high costs for medicines from undermining the right to health.[[1]](#endnote-1)

States – those that are member of the WTO – also have the obligation to be compliant with the WTO TRIPS Agreement and thus provide patents for pharmaceuticals lasting at least 20 years – with the exceptions of LDCs.

Obviously there is a huge tension between these 2 sets of duties that came to a head in the late nineties with the HIV A2M crisis.

Late nineties – 800 people day were dying of HIV/AIDS.

ARVS cost 15000 pppy – produced on a small scale and only available in wealthy nations, widely patented including in the developing world.

Massive CS mobilisation and campaigning brought the global community together – funding – WHO PQ – ARV were put on the WHO EML. First line generic ARVS became available from India. India could do that because it did not grant medicines patents at that time.

While generic first line generic ARVS were becoming available from India access to them remained a problem because they could not be made available in most countries were they were needed because of patents. Procurement agencies operating globally were reluctant to supply for fear of legal repercussions by the patent holder. And patent conflicts broke out in various countries. Growing realisation that access to new patented ARVS was a problem.

The tension between the duty to provide lifesaving medicines and the obligation under the WTO TRIPS 🡺 African nations supported by others brought this to the 2001 Doha Ministerial conference. Which adopted the Doha Declaration on TRIPS and Public Health.

We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that **the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.**

It also outlined the measures countries can take: provided a waiver for LDCs (do not provide patents) and specifically compulsory licensing – and government use. This is a measure whereby the state lifts the monopoly effect of a patent by granting others than the patent holder the right to produce and or supply generic versions of the originator product.

Doha offered much needed relieve.

It is a little known fact that it has been widely used. I have studied the use of TRIPS flexibilities over a period of 15 years and found:

176 instances of the use of or intention to use TRIPS flexibilities by 89 countries. Of the 176 instances, 100 (56.8%) concerned compulsory licences, including public non-commercial use licences, and 40 (22.7%) concerned instances of the use of the LDC waiver. [The remaining cases concerned parallel import (1), patent exception (3), and non-patent-related measures (32). Of the instances documented,] 152 (86.4%) were executed. The instances covered products to treat 14 different diseases. However, 137 (77.8%) of the instances concerned medicines for HIV/AIDS and/or related diseases.

As a result of this same policy process and IP debates - in 2010 - the MPP was established (initially HIV now also HCV and TB) – the Doha principles also played a role there. For example the MPP ensures that its licensees – the generic companies – can supply countries outside the territory when they make use of TRIPS flexibilities. MPP licences also has waivers for data exclusivity – [something even the EU medicines regulation does not have. ]

-

We do not have systematic licensing for **new essential medicines.** The WHO and the Lancet Commission recommends **MPP expand** to include all essential meds. But today this is not the case. And even if it had there would be restrictions.

Important lessons to be learnt from HIV for other diseases. We heard about Malaysia’s CL for HCV medicine SOF.

Therefor, it is important that governments take action.

The right to health, including access to essential medicines, requires that governments act in the face of patent barriers and a refusal from drug companies to lower the price or to license.

**I would like to argue that the use of TRIPS flexibilities when needed to ensure the right to access to medicines is not an option –**

**it is a duty.**

Countries that contravene the fulfilment of this duty to ensure the right to health by other states – or limit the scope of the measures at countries disposal to fulfil their HR duties - for example through trade retaliation or through TRIPS-plus demands in Trade Agreements - including accession agreements with the WTO - are therefor directly contravening Human Rights.[[2]](#endnote-2)

**And this has to stop.**

I think we need a mechanisms to systematically assess trade agreements, including accession agreements of the WTO and EPO validation agreements with a view to protecting the measures countries have under TRIPS to protect and advance HR.

The UNHLP in its report to the Secretary General highlights the importance of TRIPS flexibilities and recommend their use. But the Panel also points at the need for deeper reform.

The reason why we have problems with patents and increasingly with other market exclusivities such as data exclusivities – is because our system of innovation is based on the premise that granting monopolies is the best way to finance innovation. But these monopolies will always drive R&D efforts into most profitable areas (not areas of highest needs) and lead to high drug prices.

We need to move away from that. If you continue to rely on the system of exclusivities as a way to finance innovation you will always have high drug pricing, rationing of essential meds and growing inequalities and inequities in health.

While TRIPS flexibilities may remedy the latter it does not offer a solution to the deeper problem.

The UNHLP recommends the following:

Secretary-General should initiate a process for governments to **negotiate global agreements on the coordination, financing and development of health technologies. This includes negotiations for a binding R&D Convention that delinks the costs of research and development from end prices to promote access to good health for all**.

[It is not alone in this recommendation – WHO – Lancet Commission on Essential medicines Policies and many others have made the same recommendation.]

The UN leadership should take up this recommendation. This can happen in incremental steps. The Panel recommends to form a Working

Group to begin negotiating a Code of Principles for Biomedical

R&D. There is no reason for delaying the implementation of this recommendation.

An important prerequisite for advancing this agenda is **greater transparency of cost of production and cost of R&D** is essential and pricing and cost of production. This is an issue that will likely be debated by the WHA and something the UN should take on.

Another important step is identifying the needs – Lancet recommends a list of missing essential medicines (this should include those that are priced out of reach). WHO is the obvious the agency to lead this.

Not all countries will embrace these recommendations. But India has put these issues on the table at the WHO and asked for action towards an R&D treaty. I would recommend countries create coalition of the likeminded and get to work on it.

1. UN Committee on Economic, Social and Cultural Rights (CESCR), *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12 of the Covenant)*, 11 August 2000, E/C.12/2000/4, paragraphs 12(b) & 43(d).

   UN Committee on Economic, Social and Cultural Rights (CESCR), General Comment No. 17: The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from any Scientific, Literary or Artistic Production of Which He or She is the Author (Art. 15, Para. 1 (c) of the Covenant), 12 January 2006, E/C.12/GC/17, point 35. [↑](#endnote-ref-1)
2. The Human Rights Council has affirmed in 2016 that TRIPS-plus measures in trade agreements directly contravene General Comment No. 14. ⁠ http://www.un.org/ga/search/view\_doc.asp?symbol=A/HRC/32/L.23/Rev.1 [↑](#endnote-ref-2)