HAI Intervention at the United Nations High-Level Panel on Access to Medicines

London (10 March 2016)—Health Action International is an independent global network of over 2,000 pharmaceutical policy experts. Together, we have advocated for improved access to quality-assured essential medicines—and their rational use—for over 30 years in low-, middle- and high-income countries.

Essential medicines are a human right, and essential medicines policies rely on guaranteed and predictable access to safe, affordable and effective generic medicines. Without this, governments, particularly in the global south, will quickly go bankrupt. Or patients will forego treatment. It's as simple as that.

But the globalisation of western medicines patent systems in low- and middle-income countries, as a result of the TRIPS Agreement, have severely restricted governments' ability to implement national essential medicines policies and take measures to ensure new medicines are affordable.

At the same time, the much-needed innovations that were promised would result from broader IP protection—innovation that would tackle the world's worst disease burdens—have singularly failed to materialise.

Health Action International therefore encourages the High-Level Panel to focus on practical, achievable pathways that support the implementation of essential medicines policies that "promote access to medicines for all".

1. **Increase generic competition**
   For most patients in the world, this means driving prices down through generic competition. This includes starting negotiations for an essential medical R&D agreement that addresses priority setting, financing, sharing of research results, and resolving regulatory issues around market entry. This will require political buy-in and will take time, but we see the work of this panel as preparation to the achievement of the sustainable development goals related to health and access to medicines.
2. **Increase transparency**
   There is very little transparency in the current system. We don't know what it costs to research and develop new medicines. We don't know what prices are being charged given the opacity of negotiated discounts and rebates. And we don't know how many patients are excluded from access due to the price of new medicines. We also don't know enough about how much the companies spend to promote drugs, and we don't have unbiased information about the

true efficacy and safety of products. Pharmaceutical companies do have information about all of these things, so we are facing asymmetries in knowledge, where knowledge is connected to global power. Calls for evidence-based submissions and evidence-based policy need to also include calls for giving the public access to the evidence that does exist, to information has been collected,but to which access is denied, and information that should be collected, but is not.

3. **Commit to Voluntary Licensing**
   We recommend a tangible commitment to voluntary licensing for essential medicines. This can be facilitated through the Medicines Patent Pool which has a successful track record of negotiating licences that protect and promote public health. And where voluntary measures do not exist, we should have default automatic compulsory licensing of identified essential medicines, which, in addition to the benefits that Surie, mentioned, will protect countries from the threat of sanctions in response to compulsory licence requests.
4. **Delink the cost of R&D**
   Finally and crucially, we recommend delinking the cost of R&D from the price of the product. As many in the room have acknowledged, delinkage is the key. Increased public spending on R&D and, at the same time, increased public spending accountability—what do we get for our money—do we pay twice, or even thrice. All the above suggestions will help get rid of a model dependent on high prices.

We are serious about human rights, serious about access to affordable essential medicines and serious about real therapeutic innovation; at the same time, on the same day, in the same place. And this panel process is where it starts …