Civil society appeal to medicines regulators and governments on the occasion of the 17th International Conference of Drug Regulatory Authorities

We are a coalition of five patient groups and non-government organisations. We are concerned with the regulation of medicines in the public interest, both in our various countries and globally.

As delegates gather this month in Cape Town, South Africa for the 17th International Conference of Drug Regulatory Authorities (ICDRA), we wish to raise the following three urgent concerns with recent developments regarding medicines regulation and the current state of medicines regulation globally and in our various countries.

1. **The lowering of regulatory standards must be stopped**

The public interest requires that medicines must be proven to be safe, effective and of high quality before allowed onto the market. This well-established standard requires compelling evidence from large phase III trials.

In certain very limited cases where patients have no other options it is in the public interest to allow access to new medicines prior to the availability of phase III trial data. Two well-established mechanisms have been developed to meet this need: Compassionate use and conditional approval. We consider these two mechanisms to sufficiently meet the need for early access in life-threatening cases.

These two mechanisms must be distinguished from efforts to lower regulatory standards.

We are deeply concerned by two parallel efforts to lower standards. First, in the United States, the 21st Century Cures Act will lower standards by allowing biomarkers and expert opinion to determine whether medicines should be registered. Second, in Europe, so-called 'adaptive pathways' will allow medicines onto the market at a stage when much fewer people have taken that medicine.

Both 21st Century Cures and the European Medicines Agency's (EMA) Adaptive Pathways will put patients at unnecessary risk by allowing potentially unsafe and ineffective medicines onto the market. We urge governments and law-makers to reject these attempts at deregulation.

- For more on 21st Century Cures we recommend this article from the New England Journal of Medicine http://www.nejm.org/doi/full/10.1056/NEJMp1506964#t=article
- For more on the EMA's Addaptive Pathways pilots we recommend this article from the British Medical Journal http://www.bmj.com/content/354/bmj.i4437.full?ijkey=u9prq012WyEvAfa&keytype=ref

2. Governments and regulators must demand publication of all past and future trial data

For regulators, health professionals and the public to make informed decisions about the safety and efficacy of medicines it is essential that all clinical trial data pertaining to medicines is publicly available. This must include data from trials with negative and inconclusive findings. The public interest demands that both regulatory and clinical decisions are based on all the available evidence and not on just a biased sample of the evidence.

We agree with the recent report of the United Nations Secretary General's High Level Panel (UN HLP) on Access to Medicines that recommended: "Governments should require that study designs and protocols, data sets, test results and anonymity-protected patient data be available to the public in a timely and accessible fashion."

We urge governments, working with regulatory authorities, to take the necessary legislative and other measures to implement this recommendation.

- Read the UN HLP report here http://www.unsgaccessmeds.org/final-report
- Learn more about the need for all trials to be registered and all trials to be reported from the AllTrials campaign http://www.alltrials.net/find-out-more/all-trials/

3. Governments must accelerate regional regulatory harmonisation

We are concerned by the fact that some drugs are never registered in some countries and by the fact that registration sometimes takes too long – especially in smaller and poorer countries. This limits access to important new drugs. We stress that lowering regulatory standards is not an appropriate response to these problems.

We urge especially smaller countries in Africa, Eastern Europe, Asia and Latin America to accelerate efforts at regional regulatory harmonisation. This should include harmonising specifications and procedures for regulatory submissions, harmonising compassionate use procedures, and sharing data and expertise. We also urge countries to participate in the World Health Organization's Collaborative Registration Program.

Given the risk that regulatory standards may become less stringent in the United States and Europe, we caution other countries against implementing arrangements where registration by the US FDA and/or EMA would lead to automatic registration in their countries – although countries may wish to consider presumptive reliance rather than automatic reliance. (Presumptive reliance means that countries can rely on the FDA or EMA for registration, but that that reliance can be overridden if

certain conditions are not met.) The guiding principle must be that any harmonisation or reliance that leads to lower regulatory standards is not in the public interest.

Governments and regulators must also compel pharmaceutical companies to register medicines in the countries where the clinical trials on the medicines in question were conducted. It is unacceptable that medicines are not registered in the communities where they were studied.

Signed by the following organisations:

- Global TB Community Advisory Board
- Health GAP
- SECTION27
- Treatment Action Campaign
- Treatment Action Group