Public Conference on Clinical Drug Trials, Geneva, 30 September 2016

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Welcoming remarks

Good morning, ladies and gentlemen. We're ready to get started. Could you please take your seats?

Dear guests, dear speakers, dear friends,

It is my great pleasure and a real honour to welcome you all to this public conference dedicated to clinical drug trials.

This event is co-hosted by Public Eye and Health Action International, two non-governmental organisations that have long been actively engaged in the field of medicines policy.

Public Eye, until recently known as the Berne Declaration, is an almost 50 years-old independent Swiss NGO, supported by close to 25,000 members, that strives for global justice. Public Eye provides a critical analysis across many sectors (including the pharmaceutical one) of the impact that Switzerland, and its companies, has on low and middle-income countries. It fights against injustice that is linked to Switzerland and demands the respect of human rights around the world. Public Eye is a long-standing member of Health Action International.

Health Action International is the only non-governmental organisation that is entirely dedicated to strengthening medicines policy to improve public health. Its staff and global network of independent experts in 70 countries share information and expertise to solve medicines access and use problems around the world. HAI wants all people to receive the right medicine, in the right dose, for the right amount of time, at a price they can afford.

But let's go back to the topic of the day: why clinical drug trials? Despite them representing a cornerstone and an obligatory step in the pharmaceutical research & development (R&D) process before marketing approval can occur, clinical trials are rarely debated in public (apart from specialised scientific fora). This is why we chose to dedicate the whole day to this important, albeit relatively complex topic.

The other reason is that randomised clinical trials are ultimately considered to be the most reliable, evidence-based way for evaluating treatments (actually not only medicines, but we will only focus on them today). They are thus at the core of fundamental decisions that are taken on a regular basis in the field

of public health by regulatory authorities – such as the marketing approval of medicines – and that have repercussions on treatment protocols, hence on patients.

But clinical trials are also simultaneously at the heart of fierce commercial interests, as a marketing approval for a specific medicine can represent huge money for its producer. They are therefore also subject to manipulation and biases – as published literature extensively shows – putting at risk not only the participants of the trials but also the population at large if the efficacy of the product is being overplayed and/or side-effects downsized. If results get at all reported. Unethical clinical drug trials are a major problem that must be vigorously and urgently addressed by all stakeholders involved. By unethical trials, we mean not only potentially exploitative medicines tests in low and middle income countries, but also useless, badly-designed trials with no real added medical value. We believe this conference should contribute to a wake-up call towards more stringent regulations of clinical trials – stringent meaning not necessarily more but better regulation as well as independent oversight to make sure that clinical drug trials remain a scientific endeavour. In this respect, regulatory authorities have a particularly crucial role to play. And full transparency over the whole process should be the rule, not the exception.

A commercial sponsor can ultimately plan which product, under what design and conditions, where, on which population and for how long it should be tested. They are also the ones analysing the data, writing the report about the trials and submitting the marketing approval application. The risks of commercial distortion and conflicts of interests throughout the whole chain are huge. Although they won't be addressed as such today, patents are omnipresent in this debate. As they are filed early in the R&D process, the 20-years clock is already ticking when drugs are being tested in clinical trials. And they seriously orient the R&D priorities, not necessarily according to public health priorities.

Respected authors – some of which are here with us today – estimate that one in five new drugs are likely to produce serious adverse reactions in the years after a full-length review (as it should be made today). Accelerated reviews may seem appealing at first sight, but they also increase the risks of harm – one in three new drugs according to a recent publication. This bears serious stakes, and will also be discussed today.

We have the chance and honour to have very high-profile experts present today that have kindly accepted our invitation to speak on this important topic of clinical drug trials. I would like to warmly thank them on behalf of the organisers for their presence. Representatives of NGOs, academia, international organisations, public institutions, product development

partnerships, regulatory authorities as well as independent researchers will express their views and, we hope, spark an interesting debate with all of you. We were keen to have also the point of view of the pharmaceutical industry represented, and invited the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) to speak in one of the panels – unfortunately they haven't been able to participate.

I want to welcome each of you here again on behalf of Public Eye and Health Action International. We hope you will enjoy the day and encourage you to contribute questions and comments throughout the day.

Thank you

…And now, I'd like to hand things over to the moderator for today's event, Clare O'Dea. As a former journalist and online editor with SWI swissinfo.ch—the international news service of the Swiss Broadcasting Corporation—Clare has covered a wide range of political, financial and healthcare stories. Today, she works as an author, writer and translator and, next month, will publish her debut non-fiction book, *The Naked Swiss: A Nation Behind 10 Myths*.

Ladies and gentlemen, please join me in welcoming Clare O'Dea.