Opening remarks: Dr Ramin Parsa-Parsi

Ladies and Gentlemen, dear Colleagues,

It is a great pleasure for me to be here with you today on this historic occasion. It was here in Helsinki that, 50 years ago, the 18<sup>th</sup> General Assembly of the World Medical Association (WMA) adopted the very first Declaration of Helsinki setting out "recommendations guiding doctors in clinical research". It is therefore fitting that we should return to Helsinki five decades later to celebrate the anniversary of its adoption and to reflect on its abiding role in providing the highest ethical standards for medical research involving human subjects. My special thanks go to the Finnish Medical Association for being our hosts today.

Many changes have taken place in medical science since the promulgation of the first version of the Declaration of Helsinki in 1964, and it has been repeatedly revised to take account of these. The most recent revision lasted two years and was the most comprehensive and inclusive revision process yet undertaken. As the chair of the workgroup which oversaw it, I would like to take this opportunity to thank my colleagues for their hard work and commitment over this period. I'm very pleased to see that many of them have been able to join us here today.

During the revision process, national medical associations, international organisations and other key stakeholders were invited to provide their input at expert conferences on four continents, as well as during an international online public consultation, which attracted responses from 36 countries and regions of the world. It was the task of the workgroup members to examine all of the arguments put forward and to evaluate their merits. Our shared goal was to revise the document in such a way as to promote good quality clinical research, while at the same time ensuring the utmost protection for research subjects. The workgroup was very pleased that it could be completed in time for this anniversary year.

The current, eighth version of the Declaration of Helsinki, was adopted by a large majority at the WMA General Assembly in Fortaleza in October 2013. The result was an altogether more comprehensive, methodical and usable document. Despite the new structure of the revised Declaration, five decades after its original promulgation it still retains its unique character as a concise set of ethical principles drawn up by

physicians for physicians. This is a testimony to the strength of the Declaration and to the dedication of the World Medical Association as its guardian.

The importance of having an internationally recognised global ethical standard for physicians has again been underlined during the current Ebola crisis. For example, when concerns were raised about the ethical acceptability of using unproven interventions to treat Ebola patients, the WMA was able to react immediately by referring to Paragraph 37, which permits the use of an unproven intervention with the informed consent of the patient, where no proven intervention exists and if it offers hope of saving life. The WMA General Assembly referred to this in an emergency resolution this October.

As part of this year's anniversary celebrations, the WMA has produced a special publication summarising the history and significance of the Declaration of Helsinki and the role that it plays. Complimentary copies are available for all conference participants at the registration desk.

Many of the authors of this book are here with us today and I would like to thank them for their valuable contribution to this work. The book contains two feature articles examining the history, meaning and future of the Declaration of Helsinki from an ethical perspective, as well as the different ways that it has been implemented across the world. These are accompanied by messages of congratulation from various international stakeholders outlining how the Declaration of Helsinki has influenced their work. The 2013 revision is explained in detail and historical perspectives on previous revision processes are provided by historians and contemporaries. In addition to the current 2013 version of the Declaration of Helsinki, all previous versions are reprinted in full to show how it has evolved over the years.

Taking into consideration the nature of the Declaration as a living document, this surely won't be the last publication on this subject.

I would like to close by wishing you all an interesting and enlightening event. I am sure that these anniversary celebrations will raise further awareness of the importance of this guideline and the ethical responsibilities of physicians and researchers to promote progress in medical science without compromising the health, well-being and rights of research subjects.