Keynote Lecture 1

Changing role of biomedical professionals in medicines development*1

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1. Introducing World Medical Association (WMA)

I would like to use this precious opportunity to briefly introduce the World Medical Association (WMA) to you at this meeting of International Conference in Pharmaceutical Medicine (ICPM), here in Tokyo. I will speak about current matters we are dealing with and then go into some of the aspects of change and movement that we are seeing about global inequity, the changing of professions as such, and changing paradigms that we are experiencing in our professions and professional understanding. Then, I would like to ask the question, what does it mean for you as a group of professionals, especially physicians in pharmaceutical medicine. Why do we think you are important and what does this whole development mean for you? I will also give you some reasons for a very strong optimism.

The World Medical Association is a relatively new organization among the global professional organizations in health. The organization was founded after World War II (Fig. 1) as a re-foundation of a previously existing organization. Certainly under the impression of what became knowledge, especially, over the abuse of medicine in my country, Germany, during the Third Reich. This gave enough reasons to stop the old professional organization. Since that time, looking into the rules of medicine, the professional ethics, and professional code constitutes the most important part of work for the World Medical Association.

This does not mean that we are not looking at our socio-medical environment. Everything that relates to medicine, that comes from outside and determines our work is important: How we work, what we can do, and how this is being paid for, but also questions of medical education. These are the things which we are dealing with since 1947, since the organization has been re-founded in Paris on September 18th, exactly one month after the verdicts in the Doctors' Trial in Nuremberg had been

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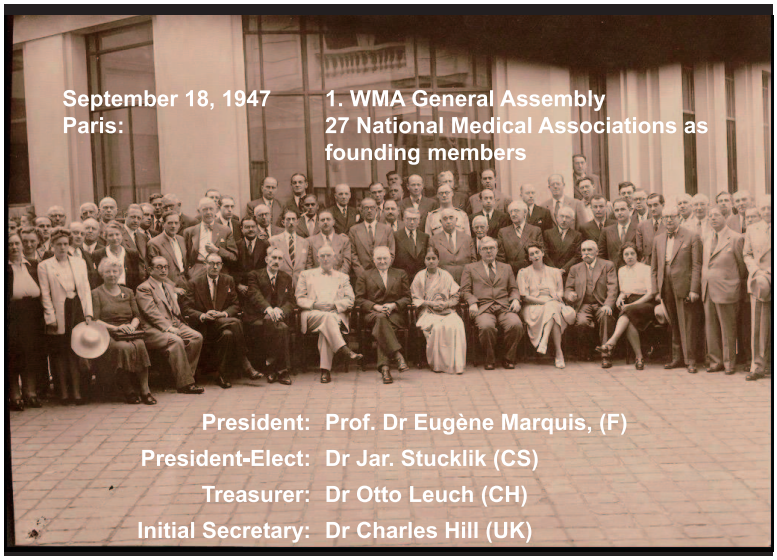
handed down. Those were the trials about the abuse of medicine in concentration camps and prisons at that time. It has a lot to do with human experimentation, which since then is one of the most important topics for especially when it comes to ethical rules of experimentation.

We are currently 112 National Medical Associations and territorial organizations from around the world. We represent close to 10 million physicians globally, and we also offer an individual membership. Individual physicians can join as associate members, to which I cordially invite you.

As I said, we are looking for a global consensus on what the rules of the profession are (Table 1).

Fig. 1　Foundation



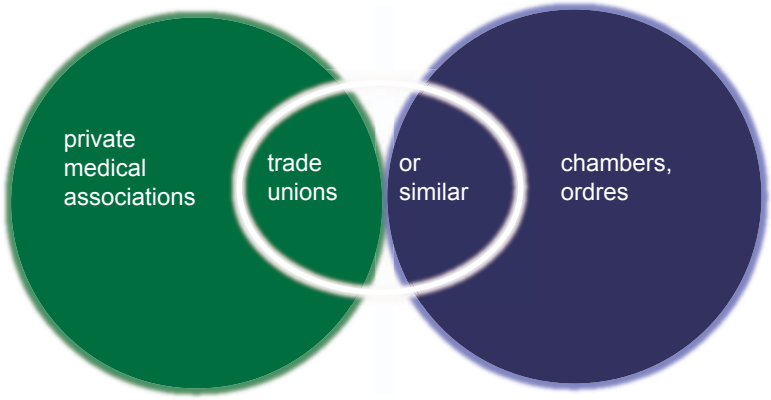
We are not looking into specialized guidelines for specific diseases, but for general rules of the profession, especially guidance on medical ethical questions and socio-medical affairs. We are looking very much at the questions of social determinants of health. We represent physician community to the global organizations, many of which are located close to our office in Geneva: The United Nations, their Economic and Social Council (ECOSOC), the World Health Organizations (WHO), but also many others like the International Labour Organization (ILO), the World Trade Organization (WTO), and many private organizations like the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA). Those are partners for us in our discussion about the work and role of physicians and the development of healthcare and medicine. We give support to national medical associations, if they ask us to do so, e.g. if they have problems with their governments. From time to time there are questions that seem to be irresolvable. Not that we are cleverer than our colleagues nationally, but sometimes it is helpful to have somebody coming from the outside in order to be heard. This is something we can do to help our national medical associations to make their voice heard and to resolve tense situations in their countries. We are very much interested in the development of self-governance of physicians in different countries and building such structures is a process we support. Again, we do this on request only. We develop projects along this line including a number of educational projects that we have developed over the past years.

Table 1 Fields of activities

- reaching global consensus on medical ethics
- guidance on problems of medical ethics
- socio-medical affaires
- representation to international Organizations e.g. UN, WHO, UNDP, UNESCO, UNICEF, ILO, IOM, IFPMA
- support for the regional and national physicians associations (on request)
- support for the development of physicians' self-government
- projects along this line

To understand the heterogeneity of the WMA, it is important to have a look on the membership of the national medical associations, because they are very different from country to country (Fig. 2). Some of the national medical associations are private organizations like the Japan Medical Association or the British Medical Association or the American Medical Association, which are founded by members out of their own. Others are

Fig. 2 Members



statutory bodies which are founded or institutionalized under a specific law like chambers, orders, or colleges in many countries of the world. This is about a 50:50 split in our organization. About half of the organizations are madated by law, and the others are private organizations. Within both, there is a subgroup that has a role as a trade union or as a similar organization. They negotiate about tariffs and payments of physicians. The classical example for being a private organization and a physician trade union is the British Medical Association which is registered as a charity and a trade union. In contrast the American Medical Association is completely barred from any trade union activity. On the other side, most of the chambers are not trade unions like the German Chambers of Physicians while at the same time the Austrian or the Romanian organisation have such functions. In summary: this is a very heterogeneous group of associations working together on the global scheme, but what they all have in common is being the most representative physician societies in their countries and as such gathering in the World Medical Association.

2. Historical policies, new policies, and policy projects

Overtime, the World Medical Association has developed some of the policies which are now historical policies. They have become cornerstones for the rules of practice of physicians (Fig. 3). In 1948-49, the World Medical Association started with creating a new version of the Hippocratic Oath, which is called the “Declaration of Geneva”, It has been revised very recently in 2017. Yet it is still very classical and traditional on one side, but now with a strong focus on patient autonomy and our role and obligations towards patient, and that differentiates it somewhat from the classical Hippocratic Oath. Nevertheless, we see the physician pledge, the Declaration of Geneva, as a direct successor of the Hippocratic Oath. And we request for instance medical schools when they are asking young physicians to take an oath to use the Declaration of Geneva.

In 1964, we developed the Declaration of Helsinki. Some people say that the Nuremberg Code, which was a result of the court procedure

Fig. 3　Historical policies

1948/2017	**Declaration of Geneva** (Physicians‘ Oath and 1. international code of ethics)
1964/2013	**Declaration of Helsinki** Ethical Principles for Medical Research Involving Human Subjects
1975/2016	**Declaration of Tokyo** Guidelines for Medical Doctors concerning Torture and other Cruel, Inhuman or Degrading Treatment or Punishment in relation to Detention and Imprisonment
1981/2015	**Declaration of Lisbon** The Rights of the Patient
1991/2017	**Declaration of Malta** Hunger Strikers

against the German physicians, was the first international code of medical ethics for research, but that is not correct. First, the Nuremberg Trials were an American Military court. It was not an international procedure. Second, it got forgotten for a long time. The revival of it came in the 70s when historians rediscovered the "Nuremberg Code". But in the meantime, there was there development of the Declaration of Helsinki. Some historians claim that the Declaration of Helsinki is a consequence to the Nuremberg Code from 1947. However, in our records, we do not find any proof for such a statement. There is probably connection through the persons, because the medical expert witness who co-drafted the Code used probably ethics guidance from the American Medical Association and the American Medical Association has been a very strong partner in developing the Declaration of Helsinki in the 60s. However, since the 60s, the Declaration of Helsinki is a cornerstone document for medical research involving human subjects. I am sure all of you have heard about the Declaration of Helsinki and many of you know it quite well.

In 1975, we produced the Declaration of Tokyo, the guidelines forbidding medical doctors participation in torture and other cruel, inhuman, or degrading treatment. When I came to a WMA meeting for the first time in 1991, I thought this was history, but then I had to learn it was not: Doctors were and are still involved in torture in one way or another: Either being themselves victims of torture or treating torture victims or, unfortunately, being part of the process of torture in some countries. And it is still something that we are dealing with in our human rights activities. This is also true for the Declaration of Malta essentially telling that it is not permissible for doctors to

Table 2 New policy 2017

WMA Declaration of Geneva (revised)
WMA Declaration of Chicago on Quality Assurance in Medical Education
WMA Declaration of Malta on Hunger Strikers (revised)
WMA Declaration on Alcohol (revised)
WMA Declaration on Health and Climate Change (revised)
WMA Statement on Access to Health Care (revised)
WMA Statement on Armed Conflict
WMA Statement on Boxing (revision)
WMA Statement on Bullying and Harassment
WMA Statement on Child Abuse (revision)
WMA Statement on the Cooperation of National Medical Associations during or in the Aftermath of Conflicts
WMA Statement on Epidemics and Pandemics
WMA Statement on Fair Medical Trade
WMA Statement on HIV/AIDS and the Medical Profession (revised)
WMA Statement on Medical Cannabis
WMA Statement on Medical Education (revised)
WMA Statement on Medical Ethics in the Event of Disasters (revised)
WMA Statement on Organ and Tissue Donation (revised)
WMA Statement on the Role of Physicians in Preventing Exploitation in Adoption Practices
WMA Statement on Water and Health (revised)
WMA Resolution on Medical Assistance in Air Travel (revised)
WMA Resolution on Poland
WMA Resolution on Prohibition of Forced Anal Examinations to Substantiate Same-Sex Sexual Activity
WMA Resolution on Tuberculosis (revised)
All policies are reviewed at least every 10 years

take part in force-feeding prisoners.

Finally, I would like to mention the Declaration of Lisbon, on the rights of the patient. We started already in 1981 with wording of the document. Many of the patient rights activists nowadays think that they have invented this idea, but indeed we have been there a little bit earlier than most of them.

In 2017, a year ago, we had our General Assembly in Chicago. The most important outcome is the revised Declaration of Geneva which I mentioned, but as you can see we are dealing with every aspect of medicine that has an importance for us as physicians, whether that is the physician pledge or fair medical trade or the use of medical cannabis, now being discussed in many countries (Table 2). Those are some of the issues where we try to find the position of the physicians as a whole. Most importantly, we did a global series of discussion about end of life issues (Table 3). You probably know that there is a strong discussion, especially in some parts of Europe, in North America, about euthanasia and physician-assisted suicide. Some countries - Netherlands, Belgium, Luxembourg, and Canada - have legalized euthanasia. We as physicians have had a very reluctant position on that, and the question was, or is, do we have to change? We tried to find out in series of discussions with our medical associations from around the world including Africa, Asia, and Latin America where until recently the medical associations have been very silent about this. This discussion will continue next week in Reykjavik at our General Assembly ("WMA Declaration on Euthanasia and Physician Assisted Suicide" was adopted at the General Assembly, October 2019).

Table 3　Policy projects 2018

(Non-exhaustive)
- End of Life issues
- Medically-Indicated Termination of Pregnancy
- Ethics of Telemedicine-REV2-Apr2018
- Nuclear Weapons
- Medical Tourism
- Pandemic Influenza
- Women in Medicine
- Biosimilar Medicinal product
- Professional Autonomy
- Artificial/Augmented Intelligence

3. Global inequity: A driver for change

Let me come to the changes that we are seeing. For us as physicians it is important to observe, to act on and to react to changes that we see. And this is multi-factorial. It is not only driven by technological development, most of it is driven by socio-economical development.

When we look at healthy life expectancy at birth in the different parts of the world*2 we find a big difference between some countries, especially in the south, and Sub-Saharan Africa when compared to the rich countries in the North, in Europe, Japan or America including Australia and New Zealand. Other than in the south, those rich countries have a high life expectancy and high expectancy of healthy living years. This comes together with the economic gradient between the rich north and the poor south. Unfortunately, what we also see is that the physicians are distributed unequally (Fig. 4). We see physicians move from East to West – from eastern European countries to Western European parts and over to North America, with the United States being the biggest net recipient of health pro-

*2 World Health Organization. Healthy life expectancy (HALE) at birth, both sexes, 2016. http://gamapserver.who.int/mapLibrary/Files/Maps/Global_HALE_2016.png

Fig. 5 Physician's movement (1)

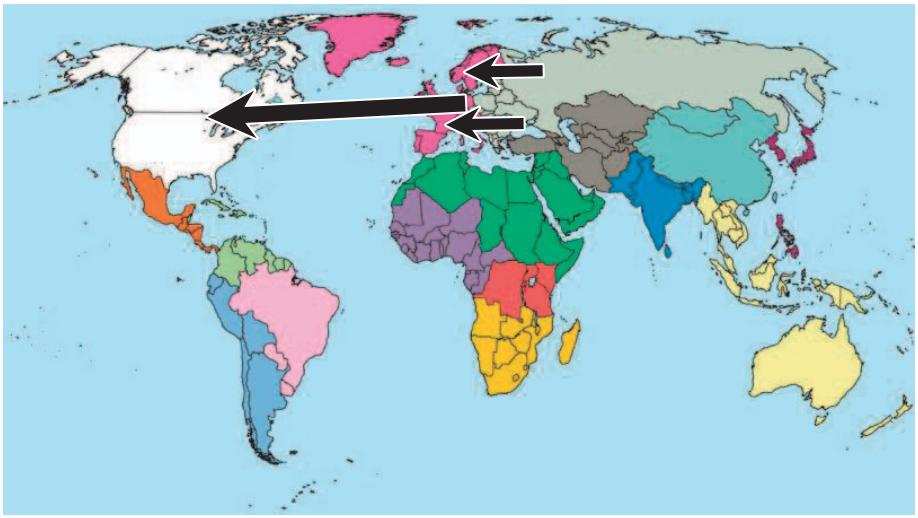
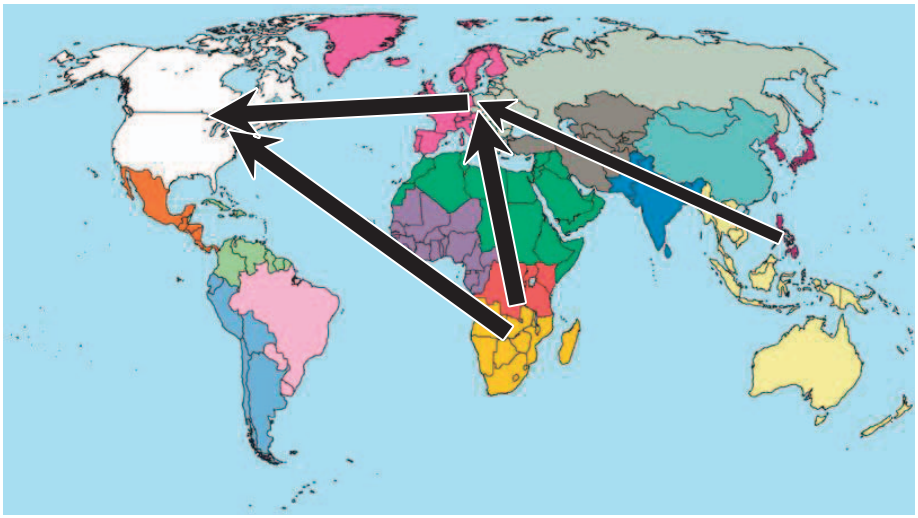


Fig. 6 Physician's movement (2)



fessionals, especially physicians. And this trend gets even stronger when it comes to the relative proportions of physicians moving from Africa to Europe or to North America (Fig. 5).

Why do I stress this? If you look into the distribution of physicians in our worlds, you will have approximately 1 physician to 500 inhabitants here in Japan. It's a little bit higher, in the United States, and in Europe, it goes up to 1:250. In a country like Malawi, this is about 1:50,000. That is a 200-fold difference between the very rich countries in the North and the resource poor countries in the South. If you consider that countries like the United States or European countries take only 1% of their physicians from those countries, and you relate this to an equal size of population e.g. in Africa, you basi-

cally are depleting the workforce in those parts of the world nearly completely. There is a joke saying that there are more Malawi physicians in Birmingham than in Malawi and probably this is closer to reality than we would like.

The shortage of physicians is one of the big drivers in changing our professions and our professional status on a global scale: A migration driven by a sharp demand of the rich countries on one hand and an inability of the poor countries to retain their physicians on the other. However, it would be simple to say: this is rich world against poor world. But it leads to have good medical conditions for healthy living and longevity in one part of the world and very poor conditions in other parts. Interestingly our past president, Sir Michael Marmot, has shown in his work on the "Social Determinants of Health" that this contradiction occurs not only between nations and between continents but also within continents and nations. He has shown this for his home town London where you find gaps of life expectancy and healthy life expectancy which are big as the gaps between the very rich and very poor countries. I give you an example from Glasgow in Scotland where the life expectancy in the richer parts of Glasgow is about 78 years for males and 83 years for females. And just a few metro stations apart from Jordan Hill to Bridgetown in the southeast of Glasgow, there is a difference of close to 15 years in life-expectancy for male in a same city where everyone has access to the same health system.

This is not a problem of England or Scotland. This is true for many of our societies and many of our cities. I am coming from Cologne, Germany, and we have a similar problem there, although everybody has access to exactly the same healthcare, the same physicians, the same hospitals, the same medicines, and the same institutions. Although the access conditions are factually the same for everybody, there are differences which we have not tackled. Michael Marmot tells us that this has to do with Social Determinants of Health. The conditions on how we live, how we work, and how we are educated determine our health.

4. Changing professions

Our professions are changing (Table 4). I spoke about the uneven distribution of professionals matching the inequalities that we have on a global scale, but we also have to notice upward aspirations of other health professionals. On the other hand those who are paying for services are trying to replace higher qualified professionals by lower qualified professionals or even non-professionals. Such aspirations and attempts are not only a problem in your field, in pharmaceutical medicine. Those aspirations have come up for instance within the nursing profession: Nurse practitioners are trying to fit in the role of general practitioners, or think of pharmacists who wish to prescribe medicines. Such development is going on in many countries. It is supported by politicians who believe that they can save money with that. Whether that is true or not is another question but the idea of saving money by using lower qualified personnel, may be other health professionals, or non-professionals, is something that we see in healthcare in general and not only in the field of the medical profession.

Table 4　Changing professions

- Global uneven distribution of professionals
- (mirrors health inequities on a global scale)
- Upward aspirations of allied health professions
- Cost containment driven by governments, payers (nurse practitioners, physician assistants)
- Control and command ambitions
- Technology replacing or facilitating human work

We have seen containment measures driven by governments and payers which lead to such development. We see very strong "control and command" ambitions; something we should not underestimate. Not all is about saving money in the first place, but it is nearly always an attempt to get a control over what we are doing as professionals by taking our professional autonomy away, an autonomy which allows us to be an advocate for our patients. Politicians and payers try to degrade our professionalism, reducing medicine from a science to a technical service. You can tell a technician what he or she has to do and you don't expect the technician to tell you what is best for a patient. This development has a very strong influence on how we work and how we can serve our patients.

We also have to deal with technology replacing or facilitating human work, and this, of course, goes on in medicine as well. Some people say radiology will vanish during the next years. I think that is nonsense. It is a misconception of what is radiology. But certainly artificial intelligence will help us to read, for instance, radiographic images and it will help to guide our work in diagnosis or treatment. Artificial intelligence, augmented reality will be instruments that certainly will help us to provide better medicines but also to provide better treatment, and better diagnostics in general. As much as I do not see this as a dramatic scenario, I am convinced that we have to engage in it. Technology will speed up change, but certainly, it is nothing that will replace the physician as such.

Yes, there have been professions in health that have gone away over the years (Table 5). This is something which I would like to stress but actually it sheds more a light on the changes and the aspirations of some other health professions trying to do the work of physicians like nurse practitioners or sometimes pharmacists. And it is nothing new. From the very beginning of the medical profession, there have been others who have done or tried to do medical work and healing. Many of those professions have disappeared. There have been the stone cutters. The original Hippocratic Oath asked physicians not to do stone cutting, and there have been professions who were doing this. Barbers, did surgery. Barbers became surgeons and later were merged into the profession. Now surgeons and physicians are one profession. There have been Bader for instance. Those were people who were running bath houses, especially in Central Europe where they have been very common. They treated people in those facilities. They did for instance, blood letting or cupping for their clients. Sometimes this was successful, very often it was just dangerous. Knowing the dangers of those manipulations, physicians would not exercise those procedures. Those manipulations were left to professions like the bader, barbers, or stone cutters.

We had coroners in many of our countries. They still existing in some; most were phased out. This work is now done by forensic pathologists or pathologists in general. We had field surgeons, which were working with the military since the end of the Middle Age. This profession was grandfathered out just quite recently in some countries. In Central Europe, there also have been vocationally, trained dentists. They learned drilling and filling holes and pulling out teeth, but they had no accadmic education. There are still some remain-

Table 5 Gone to the Oblivion

- Stone Cutters
- Bader
- Barbers
- Coroners
- Feldscher (field surgeons – vocationally trained)
- Dentists (vocationally trained; Germany, Austria)
- Apothecaries

ing in Austria working, but in most countries, they have been grandfathered out. Then there is the story of the apothecaries. I had once the pleasure to have been invited to the "Worshipful Society of Apothecaries" in London, and I was told that this is a physician's society. I always was wondering why pharmacists are called "pharmacists" and not "apothecaries" and here was the answer to that. I was told that during the Great Plague in London in the 17th Century, the physicians would ask the apothecaries to go to the patients. They would come back, get a prescription, and then would deliver the treatment to the patient. Finally, the apothecaries said we can do that ourselves. We don't need a physician for that, because a physician wouldn't take care of the patients anyway. The apothecaries became physicians, and nowadays, the "Worshipful Society of Apothecaries" in London is a physician society. Yet, this old profession grandfathered out. This changes in professional roles are nothing new. They have happened over the decades, over the centuries again and again.

5. Changing paradigms

But the changes in our professions produce also changing paradigms (Table 6). That is true for the World Medical Association likewise. In the past we have been more fraternal, inward looking, looking for our own matters and interests. Nowadays, we put the question of what is important for our patients and communities first and that has been a big change. And we are learning that what is best for our patients is probably best for us as well.

Physician are no longer lonesome fighters. The model of a single practice physician is dying out. I think that is true in most countries. Not that this

Table 6　Changing paradigms
(not always new, not always antagonistic)

• Fraternal to socially conscientious
• Lonesome fighter to team player
• Director to coach
• Service provider to partner and advocate
• Technocrat to communicator

has been a bad model in general, but the expectations to physicians have changed, and those now require teamwork, not only with other physicians, but also with nurses, with pharmacists in primary care setting and elsewhere. We are going away from the role of a patron to tell patients what to do and changing it to a partnership. Giving advice, discussing with patients, and letting patients decide. The ideal is to empower a patient to take his or her own decisions. But very often, this is not possible. You will have emergencies and you have situations where patients don't want to do that. The roles have changed, and we are in a position that we are rather coaching patients than directing them. We are reduced to being "service providers". I think we understand our role as partners and advocates for patients, and I think in our language that is important to express this. Finally, we are going away from being technocrats to be communicators – to discuss with and to explain to our patients.

6. Why do you matter to the WMA?

What does that all mean for you as physicians in pharmaceutical development? Does it need physicians in medicines development (Table 7)? My conclusion is, yes, it clearly needs physicians. It needs physicians when it comes to research, development, clinical testing, clinical trials and evaluation. It needs consulting services because physicians in research need medical education and not only a "training". Physicians are educated professionals and not only trained people, and I think that is important to stress. You are a part and should be a part of physician policy development, and you should make yourselves heard in this process. You do government relations for your companies. Very often, those are physicians, because you can speak best when it comes to medical questions. Vice-versa we hold you as physicians, as our colleagues, socially accountable. This sometimes may be a very difficult role in organisms, in organizations, in companies which are profit-driven, but nevertheless, that is an expectations that societies and that we as colleagues have to you as well.

The most important responsibility is probably in clinical testing or human experimentation. You are bound to the same ethical code as any other physician (Table 8). As physicians, you are bound by the Declaration of Helsinki which gives you very strict principles on how to prepare and perform experimentation. Some people have said this is limiting the work of physicians in research. I actually think and we can show this quite well after 1964, the rules of the Declaration of Helsinki have facilitated research not hindered it. The Declaration has built trust in research, because it produced safety and assurance in research, and those are factors facilitating the research by protecting the subjects putting the care for the patients first. We have last revised the Declaration of Helsinki with input from

Table 7 Pharmaceutical medicine: Does it need physicians? (1)

- Research
- Development
- Clinical testing
- Clinical evaluation
- Consulting services
- Policy development
- Government relations
- Social accountability

Table 8 Pharmaceutical medicine: Does it need physicians? (2)

WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects

- **Protecting subjects**
- **Facilitating research**

IFAPP (International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine) in 2013. We inserted a principle demand for those doing clinical trials to have a specific qualification for that (Table 9). Now, the Declaration of Helsinki is a document of principles. We don't talk about accreditation, certification, and so on. We just state principles, and this principle came in on specific request of IFAPP into the Declaration of Helsinki. I personally would have liked the Declaration to focus a little bit more on physicians, but we have to acknowledge that there are other health professionals who are also working and having important roles in clinical research and clinical trials.

We are now in a position that we are thinking about the next revision. We are collecting ideas and asking you as physicians who are involved in clinical trials, to help us. You should tell us what we have to look at, where we may have to change the Declaration of Helsinki, or where we just have to keep and strengthen it.

7. Reasons for optimism

Finally, let me give you a positive outlook for healthcare. You hear our politicians lamenting about the cost of healthcare and that everything is too expensive. Having seen the financial crisis 2008 and the money our governments spend for improperly working banks, I think healthcare is actually pretty cheap. We have seen two major financial crises in 2000 and 2008, which led to depressions in employment. Some sectors lost a lot of employment, in agriculture, but also industry in general. At the same time, services have been growing strongly, and within that, the health sector has been producing more jobs than ever*3. During the financial crisis in many countries, especially those who did not suffer from austerity measures on health, healthcare was producing jobs and still is. Why is that? Because we are shifting away from primary economies and secondary economies into service-based economies. In service-based economies, healthcare is simply the biggest part. We are delivering not only a very important service by helping people to stay healthy and to get healthy again or at least to alleviate symptoms, which is likewise important, but we are also a very strong driver for the development of our economies and stabilizing them. Let me conclude with that. The investment in our profession, in healthcare and in medical care is by no means a cost. It is an investment for the health and the economy of our societies. Thank you very much.

Table 9　Declaration of Helsinki
Ethical Principles for Medical Research Involving Human Subjects

Paragraph 12: Medical research involving human subjects must be conducted only by individuals with the appropriate ethics and scientific education, training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional.

*3 World Health Organization. Working for health and growth: Investing in the health workforce. Report of the High Level Commission on Health Employment and Economic Growth. 2016.
https://apps.who.int/iris/bitstream/handle/10665/250047/9789241511308-eng.pdf;jsessionid=97143E54893B1423219F7759B2151F68?sequence=1