IFAPP TODAY

The Global Newsletter on Pharmaceutical Medicine

INTERNATIONAL FEDERATION OF ASSOCIATIONS OF PHARMACEUTICAL PHYSICIANS AND PHARMACEUTICAL MEDICINE

The only international organisation for everyone involved in Pharmaceutical Medicine

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President's Message

The end of the 20th International Congress on Pharmaceutical Medicine (ICPM 2022) which took place from 19 to 21 October 2022 in Athens, Greece, marked the beginning of my presidential term at the International Federation of Pharmaceutical Physicians and Pharmaceutical Medicine.

As incoming President, I am honoured to take this role and I wish to elaborate with the Executive Board on our vision and mission to increase global impact, by pursuing excellence in Pharmaceutical Medicine with regard to education and promoting ethics and optimal outcomes for our members for the next years ahead.

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I would also like to extend my sincere thanks to my predecessor, Dr Marco Romano, for his great commitment and continuing support as Past President.

Moreover, I would like to express my gratitude to Professor Kyoko Imamura for her encouragement to become an active IFAPP member during her presidency at IFAPP, and I thank her for her excellent work and dedication during her tenure.

I wish to declare my huge appreciation to our Working Group Leaders for driving the "emerging science opportunities and challenges" of Pharmaceutical Medicine in their respective domains.

The first ever hybrid ICPM 2022 in Athens was a massive undertaking that injected more dynamics into our IFAPP community despite mitigating circumstances of the continuing pandemic, escalating geopolitical tensions and a worsening energy crisis. Nevertheless, we persisted and celebrated the remarkable contributions of the chairs, speakers and participants from 27 countries and 5 continents that infused us with inspiration and renewed energy.

Going forward IFAPP has a crucial role in advancing future Pharmaceutical Medicine education, and supporting National Members Associations (NMAs) as well as Individual Affiliates (IAs) in the uncertainties of exponential scientific biomedical and technological evolution in our discipline.

During my term I will prioritise:

- to increase our collaboration with our members and offer tangible benefits to our NMAs/IAs addressing their needs,
- collaborative advocacy with our external stakeholders on emerging trends,
- awarding young, mid-career and senior professionals in Pharmaceutical Medicine,
- developing a next generation of IFAPP leaders.

It is my pleasure to lead IFAPP for the next 24 months and I wish to invite all of you to become involved in our activities, working groups and to provide suggestions about how we can improve our effectiveness, quality and value in our learning environment.

I look forward to working with you all along the course of the two years ahead.

Varvara (Barbara) Baroutsou
MD, PhD, GFMD, EMAUD
IFAPP President

New IFAPP President-elect: Marlene Teresa Llópiz Avilés, Mexico

Dr Marlene Teresa Llópiz Avilés holds a Bachelor of Arts Degree from Austin College in Texas, a Medical Doctor degree with honors from the Universidad Anáhuac in Mexico City, and a Master Degree in Public Health from the Harvard School of Public Health (Harvard University).

Dr. Llópiz-Avilés is currently Global Oversight Director at PPD and, prior to this function, was CEO at Clínica Responsible Operativa, S.C. and MLL Traducciones. She previously worked at the Instituto Médico de Capacitación, Quintiles México as General Manager, Director at ICON México and General Manager at Venn Life Sciences. She has been working in clinical research for over 30 years.

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Marlene is currently part of the Commission of International Affairs and Relations at the Association of Medical Specialists and Professionals in the Pharmaceutical Industry (Asociación de Médicos Especialistas en la Industria Farmacéutica – AMEIFAC). For over 25 years she has occupied diverse positions, both as a volunteer at first and then as Secretary, Vice President (twice) and President (twice), as well as on several of its committees (Regulatory Affairs, International Affairs, Academic Affairs, etc.).

Marlene also served on IFAPP's House of Delegates in the past and, in addition, well represented Latin America in several national and international organisations, and companies in outstanding industry in development and clinical trials. She is currently also the Mexican member of the IFAPP House of Delegates and a member of the IFAPP External Affairs Working Group and the Education and Certification Working Group.

ICPM 2022: Scientists Call for Cooperative Participation of All Partners & Patients in R&D of New Drugs

The scientists of the 20th International Congress of Pharmaceutical Medicine – ICPM 2022 called for cooperative participation of all partners with equal contribution of patients in the research and development of new drugs.

The **20th International Conference of Pharmaceutical Medicine** (20th ICPM 2022), a leading international scientific conference of biomedicine, pharmaceutical research and technology took place in Athens, at the Stavros Niarchos Foundation Cultural Center from October 19th to 21st. The 20th ICPM was co-organised by the Hellenic Society of Pharmaceutical Medicine - EL.E.F.I. and the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine IFAPP.

The conference successfully met its goal of highlighting the exponentially beneficial accomplishments of biomedical research and development of advanced medical treatments and technologies, as well as a view to a near future horizon.

In the realisation of this goal, 104 distinguished scientists, high ranking academic researchers, prestigious experts from regulatory authorities, and leaders of the international biopharmaceutical community, who participated as speakers and chairs, contributed significantly on what lies ahead in pharmaceutical medicine.

In parallel, young and rising biomedical researchers were given the opportunity to present ongoing research activities, with major announcements, on modern genomic tools, newer pharmacological models and medical devices.

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The hybrid ICPM 2022 was actively attended by 207 pharmaceutical medicine specialists of the international R&D research ecosystem, either in person or online.

State-of-the-art research methodologies, new clinical trial designs, as well as therapeutic innovations that will improve clinical practice through Real World Data – Real World Evidence (RWD-RWE) were presented, in connection with evolving topics in Data Science and Research Governance. The rich and diverse programme of the Conference (www.icpm2022.gr) included lectures, round tables, dialogues, and workshops, with an emphasis on biomedical R&D for public health and cutting-edge issues in paediatric research and pharmaceutical medicine education.

[Click here to read the full Closing Report]

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Future Revision of the Declaration of Helsinki: Dialogue with WMA in Athens

One highlight of the ICPM 2022 in Athens, Greece (1), came on the last day in the session "IFAPP Workshop on the future revision of the Declaration of Helsinki: Dialogue with the WMA". The key speaker was Dr. Jack Resneck, Jr., President of the American Medical Association (AMA), who also serves as the workgroup chair for the next revision of the Declaration of Helsinki (DoH) (2). The lead commentator was Dr. Otmar Kloiber, Secretary General of the World Medical Association (WMA).

Other panelists were Professor Dominique Sprumont, University of Neuchatel, Switzerland, invited because of his extensive involvement in the discussions on the WMA's Declaration of Taipei (DoT) for Health Databases and Biobanks adopted in 2016 (3) as well as in the previous revision of the DoH in 2013, and Francis P. Crawley, a member of the IFAPP Ethics Working Group (EWG). They were also speakers at other sessions of the ICPM that addressed good governance practice of research institutions (Sprumont) as well as data-driven research and the clinical trial crisis in Ukraine (Crawley).

The session was organised and chaired by Chieko Kurihara (engaged also in the above sessions with Sprumont and Crawley), a member of the IFAPP EWG. Because the WMA workgroup on the next revision of the DoH was established in April 2022 and the revision process has yet to get fully underway, the session was designed as an open discussion without prepared presentations, with the exception of Kurihara whose task was to introduce the session and set the context how IFAPP has been engaged in this issue. In 2018, IFAPP officially submitted a proposal to the WMA for areas to be considered in a future revision of the DoH by way of a Memorandum of Understanding (MoU) between IFAPP and the WMA.

Chair : **Chieko Kurihara**, BSocSc., IFAPP EWG; Specially-appointed Professor, Kanagawa Dental University, Japan
Speaker: **Jack Resneck Jr**, M.D., President of the American Medical Association (AMA)
Commentator: **Otmar Kloiber**, M.D., Ph.D., Secretary General of the World Medical Association (WMA)
Panelists: **Dominique Sprumont**, Professor, Dr iur, University of Neuchatel, Chairman of the Research Ethics Committee of the Canton of Vaud, Switzerland
Francis P. Crawley, MA., IFAPP EWG; Executive Director, Good Clinical Practice Alliance – Europe (GCPA) & Strategic Initiative for Developing Capacity in Ethical Review (SIDCER), Belgium

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IFAPP suggested in 2018 that there are three key areas for consideration in the revision of the DoH (4):

- Linking of DoH and DoT should be clarified considering the emerging role of data-driven research (5).
- the DoH paragraphs on placebo-controlled trials and post-trial access need to be revisited; and
- a future-oriented framework for the DoH revision process (e.g., the shared responsibility of a multi-disciplinary research team as well as patient and community involvement).

The discussion during the workshop gradually focused on several areas and issues:

- **Data-driven research**

Clarifying the relationship between the DoH and DoT would be of value. The DoH was originally designed as ethical principles for medical research addressed primarily to physicians, but the recent research landscape has started to focus on data-driven research, such as the use of real-world data, the employment of artificial intelligence (AI) into data analysis and decisions, as well as analysis of previously acquired data instead of inclusion of a control arm in comparative studies.

- **Informed consent issues**

With an increased use of data technologies in health-related research, the role of informed consent is expanding. In particular, the use of "broad consent" for data and biological materials is becoming more popular, yet also more controversial. DoT would play an important role to solve this issue, proposing the idea of "valid" consent to multiple uses of data or biological materials. The idea of "dynamic consent" (iterations of re-consenting as research progresses) should be also explored. These topics of consent are intimately tied to questions of the institutional governance of health-related databases or biobanks, managing incidental findings, data and biological material ownership, and material transfer agreements (MTAs), assuring the protection of privacy rights, while avoiding discrimination and stigmatisation.

- **The placebo debate**

There was an extensive discussion about the ethics of placebo-controlled studies when there is a proven intervention. The 1996 and 2000 versions (6) of the DoH appears to permit placebo-controlled studies only when there is no proven intervention. The 2002 note of clarification permitted them only for scientifically compelling reasons. In the 2008 and 2013 versions a risk threshold was set with no "additional risks of serious or irreversible harm".

The workshop also considered the importance and role the DoH plays in the international research community in the context of an organisation's practices and governmental regulations. One example was the United States' removal of the reference to the DoH for the studies conducted abroad in the Code of Federal Regulations (7), largely motivated by the US FDA's views on DoH's paragraph on placebos in the 2000 revision. Later revisions in 2008 and 2013 were inconsistent with ICH E10 (8), with which the US FDA agreed. On the other hand, some Latin American countries incorporated the 2000 version into their legal instruments, and then later disagreed with the revisions in 2008 and 2013 (9). Kurihara suggested that this may be because it was necessary to protect their nations' populations from placebo studies that could not be conducted in wealthier regions. This issue arose again with clinical trials on COVID-19 vaccines (10). The WMA's position is that such exploitation does not happen when all the provisions of the DoH are adhered to. The attitude of global companies has been changing through the international debate on the DoH and as a result of the COVID-19 pandemic. It may be meaningful to consider that the issue is not about the employment or not of placebos in clinical trials, but whether the clinical trials achieved and maintained scientific or clinical equipoise. More discussion on this issue appears to be needed to improve the practice of sound

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scientific and ethical studies involving placebos. It should be also noted that the CIOMS 2016 version (11) adopted the different wording of the risk threshold ("minor increase above minimal risk").

- **Research in war/conflict situation**

It was also discussed that Crawley established with Ukrainian and international colleagues the Ukrainian Clinical Research Support Initiative (UCRSI) (12) and that IFAPP and other organisations (e.g., the Drug Information Association) have been addressing the issue of clinical trials in war settings through various conferences, fora, and publications. IFAPP published two scientific papers on this issue (13, 14). The WMA position is that medical ethics in peace time and war time are identical (15), but recognise that especially the strict demand for medical neutrality poses a challenge. This may be related to how the DoH should deal with the provisions on research in vulnerable populations. It has not been clarified whether this provision of the DoH should be revised; however, research in war and/or natural disaster settings should certainly be discussed.

- **The DoH as "the physicians' ethical principles"**

All the discussants agreed the DoH is highly valued and should seek to retain this value in the next revision as a global standard for research ethics. This important high-level position of the DoH should be maintained in the form it currently is in, and should not be revised to become a detailed regulatory instrument. The DoH should remain a living document (16), to be revisited following the progress of science and medicine. Its value also lies in WMA's fundamental medical ethics as set forth consistent with the Declaration of Geneva (17) and the International Code of Medical Ethics (18). At the same time, medical research is not limited to work carried out exclusively by physicians. Thus, as a document on research ethics for physicians and promulgated by physicians, it remains important that the drafting of the DoH is enriched by experts in other fields of medicine, science, and ethics, as well as patients and the public. In this way, the DoH also achieves and maintains its broad appeal beyond physicians.

- **Proposed revision process**

The WMA will hold a regional meeting in Tel Aviv from 9 to 11 December 2022, and then in Brazil in February 2023 to consider possible revisions. Their goal is for adoption of a new revision in 2024. IFAPP is looking forward to opportunities of listening to the voices of our National Member Associations and to those of patients and the public, who are the most affected stakeholders, as we continue to seek improvement and refinement of the international research ethics framework.

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References:
1. International Conference on Pharmaceutical Medicine, organised by IFAPP and EL.E.F.I.
2. The World Medical Association. The declaration of Helsinki. Ethical principles for medical research involving human subjects. First adopted in 1964, last amended 2013. https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/
3. The World Medical Association. The Declaration of Taipei on ethical considerations regarding Health Databases and Biobanks. 2002, last revised 2016. https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/
4. Kurihara C. IFAPP TODAY. IFAPP Recommendations for the Revision of the Declaration of Helsinki, Version 2013. IFAPP TODAY. 2022; Jan (20): 3-7. https://ifapp.org/static/uploads/2022/01/IFAPP-TODAY-20-2022.pdf
5. Kurihara C, Baroutsou V, Becker S, Brun J, Franke-Bray B, Carlesi R, Chan A, Collia LF, Kleist P, Laranjeira LF, Matsuyama K, Naseem S, Schenk J, Silva H and Kerpel-Fronius S. Linking the Declarations of Helsinki and of Taipei: Critical Challenges of Future- Oriented Research Ethics. Front. Pharmacol. 2020; 11: 579714. doi: 10.3389/fphar.2020.579714
6. Previous revisions of the DoH at: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/
7. Food and Drug Administration. Human subject protection; foreign clinical studies not conducted under an investigational new drug application. Fed Reg. 2004; 69; June 10, 2004: 32467-75. http://edocket.access.gpo.gov/2004/04–13063.htm
8. International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. ICH Harmonised tripartite guideline: Choice of control group and related issues in clinical trials (ICH E10).
9. Homedes N, Ugalde A, editors. Clinical trials in Latin America: where ethics and business clash. Springer International Publishing Switzerland. 2014.
10. COVID-19 and bioethics Part 3: Pandemic and research ethics—Democracy, placebo and post-trial access. Clin Eval. 2021; 49: Suppl 38. http://cont.o.oo7.jp/49sup38/49sup38contents_e.html
11. Council for International Organizations of Medical Sciences. International Ethical Guidelines for Health-related Research Involving Humans. 2016. https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf
12. Crawley FP, Aurich B, Kurihara C, Matsuyama K. Perspectives on Clinical Trials During Times of War, The Situation of Ukraine. IFAPP TODAY. 2022; Number 24 (May): 1-4. https://ifapp.org/static/uploads/2022/05/IFAPP-TODAY-24-2022.pdf
13. Kerpel-Fronius S, Kurihara C, Crawley FP, Baroutsou V, Becker S, Franke-Bray B, Matsuyama K, Naseem S and Schenk J. The ethical responsibility to continue investigational treatments of research participants in situation of armed conflicts, economic sanctions or natural catastrophes. Front. Med. 2022; 9:950409. Doi: 10.3389/fmed.2022.950409.
14. Kurihara C, Crawley FP, Baroutsou V, Becker S, Franke-Bray B, Granville CA, Matsuyama K, Naseem S, Schenk J and Kerpel-Fronius S. The continuation of clinical trials in times of war: A need to develop ethics and situationally adaptive clinical research guidelines. Front. Med. 2022; 9.966220. doi: 10.3389/fmed.2002.966220.
15. World Medical Association. Regulations in times of armed conflict and other situations of violence. 2012. https://www.wma.net/policies-post/wma-regulations-in-times-of-armed-conflict-and-other-situations-of-violence/
16. Parsa-Parsi R, Blackmer J, Ehni HJ, Janbu T, Kloiber O, Wiesing U. Reconsidering the Declaration of Helsinki. Lancet. 2013 Oct 12; 382(9900): 1246-7.
17. The World Medical Association. The Declaration of Geneva. 1948, last amended 2017. https://www.wma.net/policies-post/wma-declaration-of-geneva/
18. The World Medical Association. The International Code of Medical Ethics. 1949, last amended 2022. Available at: https://www.wma.net/policies-post/wma-international-code-of-medical-ethics/

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Clinical Trials in Ukraine and Bioethics: IFAPP Collaborating with JAB

On October 10, 2022, a webinar titled "A Symposium on Clinical Trials in Ukraine and Bioethics" was held being organised by the Japan Association for Bioethics (JAB) (1) with the support of members of the IFAPP Ethics Working Group (EWG). The IFAPP EWG has been continuously engaged in discussions to support clinical trials in Ukraine, publishing articles in IFAPP TODAY (2, 3) as well as in scientific papers (4, 5). The IFAPP members have been participating in the web-based meetings organised by the Ukrainian Clinical Research Support Initiative (UCRSI) and a series of webinars produced by the Drug Information Association (DIA). As a part of these continuous efforts, the IFAPP EWG has been collaborating with JAB.

This symposium focused on listening to the voices of three Ukrainian researchers who have been engaged in the conduct of clinical trials during this extremely difficult, disruptive situation under the Russian aggression. The symposium was opened by welcome remarks by Professor Chiaki Kagawa, Representative Director of the JAB.

The first speaker, Professor Viktoriia Dobrova, reported the well-established regulatory framework for clinical trials in Ukraine, and the situation how the Ukrainian research community is responding to the current situation ensuring protection of the research participants. The second speaker, Dr. Evgeny Levenko, reported on the efforts of his laboratory conducting exploratory oncology studies. His facility has been attacked several times by Russian missiles but the research staff has been working hard to continue business and ordinary life as usual. The third speaker, Dr. Veronika Patsko, reported that just during the time of having this symposium, Russia bombed Kyiv claiming that it was in retaliation for the explosion of a bridge connecting Russia and Ukraine, killing civilians, violating international humanitarian laws. She presented the situation of continuing studies notwithstanding the necessary resources being severely curtailed. It was clarified that the preservation of the infrastructure of clinical trials is an essential part of scientific practice in a democratic regime and that the continuous support of the international community is crucially important for global peacekeeping.

We would like to express our special appreciation that Dr. Jerry Menikoff, Director of the Office for Human Research Protections (OHRP), Department of Health & Human Services (DHHS), United States, has been continuously participating in the meetings of the UCRSI, and provided extremely important messages as the closing remarks. He mentioned two publications by IFAPP (4, 5) which highlight the complex considerations, and stressed need to balance safety of patients, caregivers, other health personnel versus possible direct benefit to patient as well as benefits to the Ukraine society in general from continuation of trials, weighing of alternative options in wartime.

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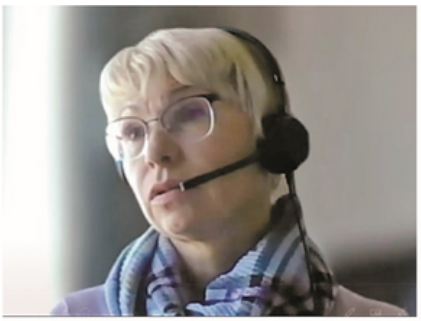
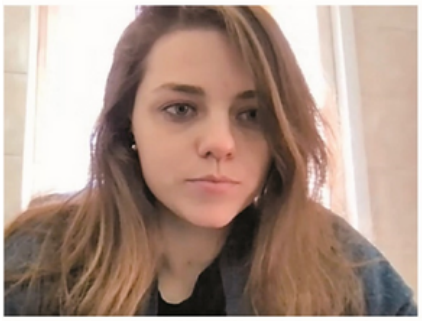
Kotone Matsuyama, chair of the IFAPP EWG, Chieko Kurihara, member of the IFAPP EWG, and Professor Kagawa, Representative Director of the JAB, will discuss these situations more in depth in the Annual Meeting of the JAB in November, from bioethical perspectives. Also, the international participants of this symposium will expand on our ongoing considerations for publication of scientific papers aiming at international guideline development and outputs based on this symposium and other for addressing research and ethics in conflict and other disruptive situations.

Objectives of this symposium in the announcement were as described below.
A full transcription of this meeting is planned to be published by the Japanese journal Clinical Evaluation for which Chieko Kurihara is working as an editor.



Viktoriia Dobrova, Ph.D., DSci (Pharmacy); Professor of Department of Clinical Pharmacology & Clinical Pharmacy & Vice-chairperson, Research Ethics Committee of Clinical and Diagnostics Centre, National University of Pharmacy, Kharkov, Ukraine; University of Heidelberg, Germany & Ukrainian Clinical Research Support Initiative

Evgeny Levenko, M.D., Arensia Exploratory Medicine, Kyiv, Ukraine



Veronika Patsko, M.D., Clinical Oncologist, National Cancer Institute, Kyiv, Ukraine

Jerry Menikoff, M.D., J.D., Director, Office for Human Research Protections (OHRP), Department of Health & Human Services (DHHS), United States

The primary objectives of the symposium

The Japanese Constitution has a paragraph of eternal renunciation of war and many of the Japanese bioethicists recognise peace and "do no harm" (against war) to be among the core principles of bioethics.

This symposium wishes to strengthen the structure to support Ukrainian Clinical Research as this represents an integral part of the scientific and healthcare systems of the country as well as being integral to the continued development of the Ukrainian society.

Such development of the society is a right of a sovereign state and we as a national and international community of bioethicists and researchers have an obligation to strengthen solidarity to provide ongoing support to the importance of clinical research and the expansion of awareness regarding the situation of research, medicines, and health in Ukraine.

We are pleased to have the participation of Ukrainian clinical researchers and ethicists in order to gauge the real status of the effect of war on clinical research and the current situation. We wish to learn how we can support research and researchers in Ukraine while also examining how we might consider developing international guidelines for research in war/conflict and other disruptive situations.

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The secondary objectives of this symposium

The Japanese participants will take this symposium as a precious opportunity for reflection on a more in-depth analysis of the bioethical implications of the current situation, framing it in their own historical experience of (both of) aggression in other countries as well as being attacked by weapons of mass destruction during World War II.

The international participants will expand our ongoing considerations for publication of scientific papers and outputs based on this symposium and others for addressing research and ethics in conflict and other disruptive situations.

Commentators supporting Ukrainian speakers (*=IFAPP EWG)

Welcome Remarks:
Chiaki Kagawa, Professor Emeritus, Yamanashi University, Yamanashi, Japan, Representative Director of the Japan Association for Bioethics (JAB)

Moderator:
Chieko Kurihara*, BSocSc., Specially-appointed Professor, Kanagawa Dental University, Kanagawa, Japan

Commentators:
Francis P. Crawley*, MA., Ukraine Clinical Research Support Initiative (UCRSI); Executive Director, Good Clinical Practice Alliance – Europe (GCPA) & Strategic Initiative for Developing Capacity in Ethical Review (SIDCER), Leuven, Belgium
Sandor Kerpel-Fronius*, M.D., D.Sc., FFPM, Professor of Clinical Pharmacology, Semmelweis University, Department of Pharmacology and Pharmacotherapy, Budapest, Hungary
Kotone Matsuyama*, R.Ph., GFMD, Professor, Department of Health Policy and Management, Nippon Medical School, Tokyo, Japan
Courtney A. Granville, Ph.D., MSPH, Director, Scientific Affairs, Drug Information Association, Washington, DC, USA

Special guest from US DHHS OHRP
Jerry Menikoff, M.D., J.D., Director, Office for Human Research Protections (OHRP), Department of Health & Human Services (DHHS), United States

This international web-based symposium was held as a part of the 34th annual meeting of the JAB, November 19 and 20, 2022, with the presidency of Professor Kenji Doi [1] Kwansei Gakuin University). The video-recorded version is provided on demand for the participants of this annual meeting.

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References:

1. Japan Association for Bioethics.
2. Kerpel-Fronius S, Baroutsou V, Franke-Bray, B Kurihara C, Mutsuyama K, Naseem S, Schenk J, Members of the IFAPP Working Group of Ethics. Investigational Drug Supply for Seriously Ill Patients in Time of War. IFAPP TODAY. 2022. Number 23 (April); 1-2.
3. Crawley FP, Aurich B, Kurihara C, Matsuyama K. Perspectives on Clinical Trials During Times of War - The Situation of Ukraine. IFAPP TODAY. 2022; Number 24 (May): 1-4.
4. Kerpel-Fronius S, Kurihara C, Crawley FP, Baroutsou V, Becker S, Franke-Bray B, Matsuyama K, Naseem S, and Schenk J. The ethical responsibility to continue investigational treatments of research participants in situation of armed conflicts, economic sanctions or natural catastrophes. Front. Med. 2022; 9:950409.
5. Kurihara C, Crawley FP, Baroutsou V, Becker S, Franke-Bray B, Granville CA, Matsuyama K, Naseem S, Schenk J and Kerpel-Fronius S. The continuation of clinical trials in times of war: A need to develop ethics and situationally adaptive clinical research guidelines. Front. Med. 2022; 9.966220.

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Evgeny Levenko, Arensia Exploratory Medicine, Kyiv, Ukraine
Veronika Patsko, Clinical Oncologist, National Cancer Institute, Kyiv, Ukraine

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Swissmedic: An Important Part of the Swiss Healthcare System for 20 Years

The Swiss therapeutic products agency Swissmedic is celebrating its 20th anniversary in 2022. This year has seen various activities to mark the occasion, the highlight of which was the anniversary event with 150 guests. This was attended by the Swiss Health Minister, Federal Councillor Alain Berset, Dame June Raine, Chief Executive of the British Medicines and Healthcare products Regulatory Agency (MHRA), and Severin Schwan, CEO of Roche, among others.

Swissmedic is the licensing, authorisation and supervisory authority for therapeutic products in Switzerland. It is managed by an eight-member Management Board headed by Raimund Bruhin as its Excutive Director. As a key part of the safety and industry monitoring authorities, the therapeutic products agency has almost 500 employees. This year it is celebrating its 20th anniversary. Since 2002 it has ensured that only high-quality, safe and effective therapeutic products are placed on the Swiss market. The agency approves and monitors clinical trials, and issues authorisations for medicinal products and establishment licences for the manufacture, import and export of medicinal and transplant products. It is also responsible for market surveillance and for enforcing the Therapeutic Products Act under criminal law.

New organisation and entry into force of the Therapeutic Products Act

The Swiss Therapeutic Products Act came into force in 2002 and established the centralised control of medicinal products and medical devices by an independent therapeutic products agency. Swissmedic was formed from the merger of the Intercantonal Office for the Control of Medicines and the Main Unit Medicines of the Swiss Federal Office of Public Health. Since then, it has played a key role in national safety and industry oversight. As the enforcement body for the Therapeutic Products Act, it contributes significantly to ensuring patient safety and public health – not only during authorisation, but throughout the life cycle of therapeutic products.

Swissmedic's considerable contribution to managing the crisis

On 27 October 2022, Executive Director of Swissmedic Raimund Bruhin welcomed 150 guests from Switzerland and abroad to the anniversary event in Bern Rathaus. In addition to the Swiss Health Minister Alain Berset, the attendees included members of parliament, cantonal representatives and industry, research and patient representatives. Mr Bruhin outlined the agency's development over the past 20 years into a dynamic, agile organisation with lean processes, motivated employees and a broad international network. Federal Councillor Berset emphasised the importance of Swissmedic during the pandemic, with a reminder that it was the first agency in the world to authorise a COVID vaccine under the regular procedure. This was crucial in leading our society and economy out of the health crisis.

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Swissmedic's independence is vital

Health Minister Alain Berset also stated that an impartial and scientifically independent therapeutic products agency guarantees a safe therapeutic products market. Swissmedic thus stands for the rapid availability of innovative therapeutic products, as demonstrated during the pandemic. "Independence creates trust. And this is crucial in Swissmedic's decisions", Mr Berset said. Despite a great amount of pressure, the therapeutic products agency took the time to carefully review the authorisation applications from the vaccine manufacturers – and did not approve all of them. This was necessary in order to protect the health of the public. Mr Berset stressed the importance of Swissmedic for the Swiss pharmaceutical industry, with 200,000 jobs and exports worth more than CHF 100 billion a year. He concluded his speech by thanking Swissmedic's employees and giving them a symbolic cake with 20 candles.

Congratulations from the industry and the British therapeutic products agency

For the CEO of Roche, Severin Schwan, it is crucial to minimise the time from the research idea to the market launch of medicinal products. His interest lies in making medical innovations available to patients as quickly as possible. He explained which steps in this process could still be accelerated in Switzerland, congratulated Swissmedic on its major milestone, and thanked it for their good cooperation. Dame June Raine, Chief Executive of the British Medicines and Healthcare products Regulatory Agency (MHRA), emphasised the importance of global cooperation between therapeutic products agencies. This is a success factor given patients' growing expectations of fast access to innovative medicinal products. As a partner in Project Orbis and the Access Consortium, the MHRA enjoys a very good working relationship with Swissmedic. She congratulated Swissmedic and praised its high quality standards, which benefit the Swiss population.

At the drinks reception to round off the event, the guests enjoyed a relaxed setting in which they discussed the challenges facing healthcare and expressed their good wishes for Swissmedic and its employees.

IFAPP TODAY

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Executive Director **Raimund Bruhin** invited around 150 guests from Switzerland and abroad to Swissmedic's anniversary event.

The Swiss Health Minister, Federal Councillor **Alain Berset**, emphasised Swissmedic's important role during the pandemic.

Dame **June Raine**, CEO of the British Medicines and Healthcare products Regulatory Agency (MHRA), praised Swissmedic's high quality standards.

Severin Schwan, CEO of Roche, called for short time periods between the development of medicines and their market launch.

Author:
***Alex Josty**, Media Spokesperson, Swissmedic*

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Swiss Society of Pharmaceutical Medicine (SSPM; Schweizerische Gesellschaft für Pharmazeutische Medizin, SGPM)

The Swiss Society of Pharmaceutical Medicine (SSPM) was founded in 1997 with the aim of advancing the science and practice of Pharmaceutical Medicine, by developing and maintaining competencies, ethics, and integrity in order to provide the highest professional standards for the benefit of patients and the public.

In Switzerland, Pharmaceutical Medicine is one of 45 Swiss Medical Board physician specialties currently accredited by the Federal Office of Public Health. On January 1, 1999, the Swiss Department of Health officially recognised Pharmaceutical Medicine as a fully board-certified physician specialty in Switzerland. Over the past 20 years, more than 120 physicians have been board-certified as specialists in Pharmaceutical Medicine.

The post-graduate practical training consists of 2 years of patient-related clinical work, followed by 3 years of vocational training at certified training centres in Pharmaceutical Medicine. The theoretical training includes the completion of an academic post-graduate diploma in Pharmaceutical Medicine: 30 ECTS - European Credit Transfer and Accumulation System, European Credit Transfer and Accumulation System (ECTS) | European Education Area (europa.eu). As a result of the last accreditation of the specialist title in 2018, the post-graduate training programme has been adapted to a fully competency-based curriculum. To this end, the Swiss Catalogue of Core Competencies in Pharmaceutical Medicine (SC3-PM) has been created, which adopts the concept of the IFAPP core competency description based on applied knowledge, skills and behaviours.

As a medical-scientific discipline, our goal is to enable best possible therapeutic coverage for the benefit of patients and society through a medical need-based development and optimal use of medicinal products. The role of the specialist in Pharmaceutical Medicine is to closely collaborate with various stakeholders of the healthcare system in the context of the discovery, research, development and approval of new medicinal products, as well as safe and effective use of new and established medicinal products in daily clinical practice.

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Main author: **Dr Martin Traber** MD PhD, President of the Swiss Society of Pharmaceutical Medicine (SGPM)

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Birka Lehmann (Germany)
Chair/Moderator

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Ingrid Klingmann
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CVs to be found:
https://ifapp.org/working-groups/education-and-competencies

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IFAPP is the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine.

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