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

THIS ISSUE:

KIDS Madrid – Empowering Children in Health and Research

In 2018, the Spanish Association of Pharmaceutical Medicine (AMIFE), together with the Children´s Hospital Nino Jesus in Madrid, initiated a project aimed at training children and young adolescents in basics in clinical research. This project followed the developments of ICAN “The International Children´s Advisory Network” (www.icanresearch.org). It took one year to select appropriate candidates (children between 9 and 16 years old with a good command of English and interested in the project), look for lecturers among the Hospital´s physicians and professionals from the pharmaceutical industry, obtain all the authorisations, etc. We started the first three sessions – and had to stop due to pandemics.

This is the Children´s Hospital Nino Jesus in Madrid. It has over 140 years of history and is a true “hospital for children”, with great prestige on the national level. It runs over 100 clinical trials/year and publishes more than 200 scientific/medical articles.

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The activities were reactivated in 2022, with the help of an experienced Project Manager, Ana Minguez, and financially supported by the Hospital Foundation (FIB) who prepared the following objectives of the project:

OBJECTIVE OF KIDS MADRID

1. Teach and defend medicine, research and innovation that improve the health and care of children, placing the child at the centre of our field of work.
2. Promote a consultation process in the hospital, through the voice and opinion of young people in all those research projects that affect them.
3. Involve young people in detecting unmet paediatric needs.
4. Support the design of new drugs, introduce diagnostic-therapeutic improvements and innovate in the treatment of paediatric diseases.
5. Value the role of clinical research in paediatrics.
6. Communicate to the society what clinical research consists of.
7. Involve the protagonists of the research: participation of "the voice of children" in the care and research work of the Children´s Hospital Nino Jesus.

The training programme includes:

TOPICS
INTRODUCTION
FUNDAMENTALS OF CLINICAL RESEARCH
WHY CHILDREN GET SICK?
PRACTICE IN CLINICAL RESEARCH: VISIT TO ICON (CRO)
ETHICS IN RESEARCH
MEDICINE RESEARCH (VISIT TO PHARMACY OFFICE)
NURSE IN RESEARCH
ADVANCED THERAPIES (MANUFACTURE OF MEDICINES)
ADVANCED THERAPIES (CLINICAL RESEARCH)
CLINICAL RESEARCH LAB
CARDIOPULMONARY RESUSCITATION SIMULATION
SIMULATION DIGESTIVE DEPARTMENT
VISIT TO PHARMA COMPANY
PAEDIATRIC SURGERY
CHILDREN ORTHOPEDICS
INNOVATION (MEDICINES DEVELOPMENT)
BIG DATA AND NEW TECHNOLOGIES
VISION OF THE PARENTS

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The new team of enthusiastic participants and some of their professors:

In the current cohort we have 21 children/adolescents with an age range between 10 and 21 years, some of them had already participated in the first project – and want to continue!

After an exhaustive and detailed training, the participants will be able to promote clinical research as an important part of medicines development at school level and among their friends and colleagues.

The main objective of this project, once the participants finalise their training, is to add more value to clinical research in paediatrics, to become true consultants for the investigators of the Hospital achieving real improvements in the set-up and development of clinical research and to participate in collaborative activities with other Young Persons Advisory Groups (YPAGs), both in Spain and at the international level.

Anna Jurczynska, PhD, MBA
IFAPP Board of Officer Secretary and AMIFE Delegate

The Vaccine Access System in Brazil Seems like "the Perfect World". But why is the Level of Adherence Below Expectations?

When I was a medical student, I had the opportunity to actively participate in a National Polio Vaccination Day. Just like my classmates we were assigned in the region of Mogi das Cruzes to be a vaccinator in a health post. We were given a packed lunch and we were proud. So were the parents who took their children to be vaccinated. It was the early 80s.

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What has changed in 40 years that the population does not have the same culture as then?

During the pandemic, the word vaccine was mentioned dozens of times a day by each one of us and most of us saw it as the hope to survive in the midst of so much tragedy. However, we lived through curious moments in which social opinion leaders mentioned unexpected absurdities such as "chip from China", "alligator", "vaccine extracted from abortions", among others. But fortunately, common sense won out and Brazil had a relatively good level of adhesion compared to other countries.

The organisational structure of the universal vaccine access system in Brazil managed by the National Immunisation Programme (PNI) was in evidence.

Instituted by Law No. 6.259/1975 and regulated by Decree No. 78.231/1976, the PNI began its first National Campaign for Vaccination against Poliomyelitis in 1980, with the goal of vaccinating all children under 5 years of age in a single day. The last case of poliomyelitis in Brazil occurred in 1989, and in 1994, Brazil received, along with other countries in the Americas region, the certificate that the disease and virus had been eliminated from the continent.

The PNI's effectiveness can be perceived through the results obtained over the years. Examples of success are the eradication of measles, the elimination of neonatal tetanus, and the control of other immuno-preventable diseases such as diphtheria, pertussis and accidental tetanus, hepatitis B, meningitis, yellow fever, tuberculosis, rubella and mumps, as well as maintaining the eradication of poliomyelitis.

In Decree No. 597 of 2004, the Ministry of Health states in Article 3, that the vaccines provided for in the PNI calendar are mandatory. Furthermore, the Statute of the Child and Adolescent (ECA) also provides that "vaccination of children in cases recommended by health authorities is mandatory" (art. 14, § 1 of ECA). Currently, 18 childhood vaccines are offered at Basic Health Units (BHUs). In the 1980s, only five vaccines were offered.

Among the largest drops in childhood vaccine coverage is the triple viral vaccine (against measles, mumps, and rubella), which, in 2015, reached 96% of children, but in 2021 had reduced to 71%. In the same period that of poliomyelitis (against infantile paralysis) was from 98% to 67%.

In Brazil, the PNI actions overcame the main challenge of the great distances, demonstrating in practice that the total capillarisation of a health action can be achieved reaching the goal of universality of the public health care system (SUS).

Measles was eradicated in 2016 in Brazil and received the eradication certificate by the Pan American Health Organization (PAHO). However, Brazil will lose the certification as new cases have been identified as of 2018. Since 2018 more than 20 deaths due to measles have been reported in Brazil.

The major concern is the growing lack of adherence to the mandatory PNI calendar. According to the DATASUS survey, the coverage for mandatory vaccines has shown a drastic drop (see Figure).

What are the reasons we can repute?

1 - Constant reduction of official investment in primary care

It was believed that by offering vaccines permanently in the BHUs, there would be an increase in vaccine adherence. We have observed a constant reduction in funds for primary care. When this happens, the more distant and poorer municipalities suffer from the quality of care. If there is no local initiative with municipal funds, the population is directly affected.

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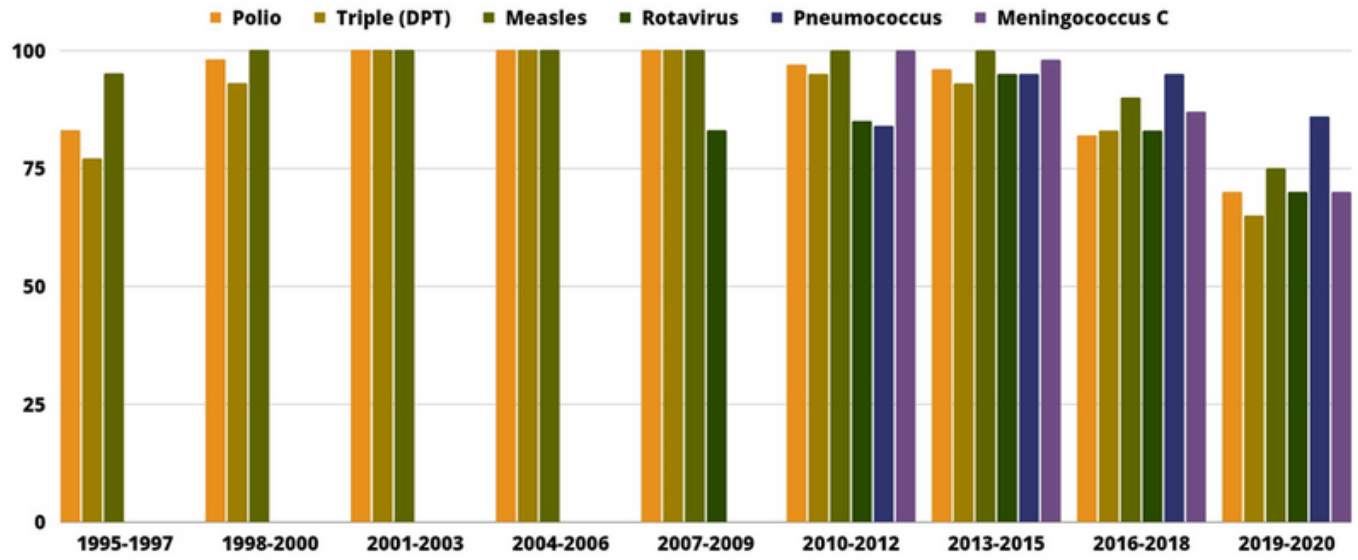
VACCINATION COVERAGE (%) AND TYPE OF VACCINE (1995-2020)



The lack of massive educational propaganda in "vaccination day" campaigns has weakened the culture of prevention. Less enlightened people think that when an eradication of a certain disease is announced, there is no longer any need for the child to be vaccinated. This is a big mistake because the maintenance of eradication depends on the continuity of vaccination. The increased access to information from social media has not resulted in benefit, on the contrary, it has favoured more "fake news" and conspiracy theories.

2 - Activism of the population, press and health professionals

The politicisation of health during the COVID-19 pandemic has shown how harmful it is to the population. The opinion of ill-informed politicians or those who have an interest in "hiding" a problem for fear of damaging the government's own image leads them to omit themselves or lie to their supporters. Opponent politicians also take advantage of the moment to criticise their political enemies. The biggest loser of this polarisation is the population itself, which unconsciously takes sides. And the worst thing is that the press and the health professionals themselves place themselves as activists. The press stopped being an informative organ and started feeding its groups of spectators or listeners with "news" that they want to hear. Health professionals use social media to increase the number of sympathisers using arguments that are scientifically questionable, but that are agreeable to those who like that information.

In this sense, silently, the so-called "anti-vax movements" usually based on theories without scientific evidence began to emerge. According to the World Health Organization (WHO), vaccines prevent 2 to 3 million deaths per year. The organisation released a list of the 10 major health threats in 2019, and among them was "vaccine fear". In 1998, the British physician Andrew Wakefield published a study in a respected scientific journal, the Lancet. In it, Wakefield linked the triple viral vaccine, which prevents against mumps, measles, and rubella, to the onset of autism. Of the 12 children with autism analysed in the article, eight would have manifested the disease two weeks after the application of the vaccine.

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The theory was that the immune system had suffered an overload with the immunisation. Sometime after the publication, the study began to be questioned. The doctor was involved with lawyers who wanted to profit from lawsuits against vaccine manufacturers. In addition, he used false data and altered information about patients. After the case was confirmed, the Lancet recanted and removed the study from its archives. For the antivax groups, the correct thing to do would be to start the vaccination when the person has a more "mature" immune system. In addition, they believe that vaccines should be given one at a time (without the application of a single dose for more than one disease) and that the time between one dose and another should be longer. The justification of the people who defend this movement is that applying combined or simultaneous doses would cause a supposed immunological overload. It is worth noting that the WHO has already declared that the administration of several vaccines at the same time does not cause immunity problems. It also defends this measure to avoid a discomfort in the child, of having to submit to several doses, and for not having to go to health centres numerous times, saving time and money and not letting the child be even more exposed to other diseases that could be transmitted in these places.

The biggest predator effect charged by a conspiracy theory happened in 2011 in Pakistan. To reach Osama Bin Laden, the CIA architected a campaign against polio. The goal: extract the DNA of children who would be relatives of the mastermind of the attack on the Twin Towers, to try to identify him. The hoax, revealed in 2011 by the British newspaper The Guardian, spurred a hunt for health workers, especially in tribal areas on the country's border with Afghanistan. The Taliban helped spread that the West was using vaccination programmes to attack Muslims. The rumour mill included vaccines containing pork (forbidden by the Islam) and causing AIDS and sterility. The balance: 22 vaccinators murdered between 2012 and 2013, according to the NGO Human Rights Watch, and a polio outbreak in the country.

Facebook in Brazil has two large movements based on conspiracy theories against vaccines with approximately 10,000 followers each: "The Dark Side of Vaccines" and "VACCINES: The Biggest CRIME in History!"

Active Search for Vaccine Coverage

The proposal currently under discussion is that an active search of the population should be carried out to encourage vaccination. But this would have to be privately funded or use municipal funds. Health agents and adequate transport would be hired to reach the population at their homes. There are already pilot experiences of this initiative, but the regions benefiting from it are still limited.

Helio Osmo, MD, MBA, Presidente SBMF,
Associação Brasileira de Medicina Farmacêutica,
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New offering of IFAPP's Continuous Professional Development Programme

INTRODUCTION TO THE NEW EU CLINICAL TRIALS REGULATION

A free virtual training workshop on 1 and 2 March 2023 moderated by Dr Birka Lehmann and Dr Ingrid Klingmann

From 31 January 2023 all clinical trials with medicines must be authorised, handled and reported according to the rules lined out in the Regulation EU No 536/2014 (Clinical Trials Regulation).

The Regulation introduces an authorisation procedure based on a single submission via a single EU portal and data base, an assessment procedure leading to a single decision, rules on the protection of participants and informed consent, and transparency requirements. With this the Regulation will ensure a greater level of harmonisation of the rules for conducting clinical trials throughout the EU.

Therefore, all aspects of clinical trials are following new rules. This includes communication between sponsor, competent authorities and ethics committees. The new EU Database called CTIS (Clinical Trials Information System) is the key element. Sponsors will need to adapt their own systems and procedures to the new requirements in the European Union.

IFAPP offers you a free 2-day virtual training programme that will explain what you need to understand about the new processes, procedures and obligations of parties involved for updating your regulatory knowledge and for the preparation and conduct of your clinical trials in the EU. And the workshop will give you ample opportunities to ask your questions and discuss your concerns with experts in the fields.

Click **here** to register for the Training Workshop on **Wednesday 1 and Thursday 2 March 2023**.

Dr Birka Lehmann MD PhD is a Consultant in Pharmaceutical Medicine and a Board Member/Chair of the Education and Certification Working Group (ECWG) of IFAPP

Dr Ingrid Klingmann MD PhD is President of the PharmaTrain Federation and a member of IFAPP's ECWG

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INTRODUCTION TO THE NEW EU CLINICAL TRIALS REGULATION

Audience: People from all around the world who want to understand the principles of the new EU regulatory environment for clinical trials, e.g., sponsors of clinical trials, clinical trial experts, investigators and site staff, regulatory affairs and medical affairs professionals, competent authority and ethics committee members, patient experts.

Moderators: Ingrid Klingmann and Birka Lehmann

All session times according to CET: 10:00 – 12:30; 14:00-16:30

March 1, 2023

10:00-10:10	Welcome and introductions
10:10-11:00	Clinical trial aspects that will change under the new EU Clinical Trials Regulation *Birka Lehmann, IFAPP*
11:00-11:45	The new "Single Dossier" in clinical development Q&A *Ingrid Klingmann, PharmaTrain*
11:45-12:00	**Break**
12:00-13:00	The Coordinated Clinical Trial Authorisation procedure in theory and practice Q&A *Sean Kilbride, Regeneron*
13:00-13:45	**Lunch**
13:45-14:45	Safety data reporting and serious breaches handling under the Clinical Trials Regulation Q&A *Varvara (Barbara) Baroutsou, IFAPP*
14:45-15:05	**Break**
15:05-16:05	The Clinical Trials Information System "CTIS"–structure, functioning, requirements, training options Q&A *Nicole Waik, Biogen*
16:05-16:45	Moderated discussion: Advantages and hurdles of the new Regulation for sponsors of trials in different phases from within the EU and abroad Open Forum Discussion with Moderators and Speakers

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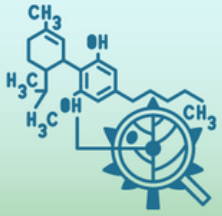
INTRODUCTION TO THE NEW EU CLINICAL TRIALS REGULATION

March 2, 2023

10:00-10:30	CTIS Access and User Management Q&A *Ana Rodriguez Sanchez Beato, EMA*
10:30-11:15	(Re?-)Organisation of responsibilities and oversight for sponsor and vendors required to achieve clinical trial authorisation in an auditable quality environment Q&A *Ingrid Klingmann, PharmaTrain*
11:15-11:35	**Break**
11:35-12:45	Reporting obligations during and after the clinical trial: study management, pharmacovigilance, technical summary and lay summary of trial results Q&A *Kerstin Breithaupt-Grögler, AGAH*
12:45-13:45	**Lunch**
13:45-14:10	IMP Management under the Clinical Trials Regulation from definitions to labelling Q&A *Antonino Severino, NextPharma*
14:10-15:00	Setting the standard for greater diversity in clinical trials Q&A *Derick Mitchell, IPPOSI*
15:00-15:15	**Break**
15:15-16:00	Challenges in the transition period between former Clinical Trials Directive and the new Clinical Trials Regulation Q&A *Ingrid Klingmann, PharmaTrain & Birka Lehmann, IFAPP*
16:00-16:30	How should I prepare for the Clinical Trials Regulation in my work environment - All I could not ask before Open Forum Discussion with Moderators and Speakers
16:30	Conclusions and Farewell



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More than 685,000 women die each year from breast cancer around the world.

Vara's mission is to find every deadly breast cancer early - because if breast cancer is detected early, (1) survival rates increase by more than 60 percentage points when diagnosed at stage I compared to later stages (2) treatment costs are lower and less invasive and (3) life quality increases significantly.

We envision a world in which cancer screening is accessible for everyone, regardless of where they are, such that the current 800 million women at risk of developing breast cancer who lack access today can be screened for breast cancer before it is too late.

To accomplish that, Vara has developed a breast cancer screening platform with Artificial Intelligence at its core. It allows local radiology clinics to make better use of their existing mammography scanners to provide high-quality and reliable breast cancer screening at much lower costs - proven by leading and globally accepted clinical evidence.

Vara is unique because we're approaching the problem holistically - which is required to establish breast cancer screening in developing markets in a cost-effective and scalable way:

- We help our partners raise awareness and education to more women and attract them to screening (via Vara's strong medical brand, its corporate partnerships and clinician network).
- Our AI decision referral pathway (published in Lancet Digital Health and developed in Germany) augments our partners' radiologists, such that they can screen more women and achieve better efficacy.
- The Vara platform navigates the entire screening workflow, from appointments to the follow up after screening (incl. real-world evidence monitoring).

Other AI companies focus exclusively on the algorithm, which is too narrow to bring screening to previously underserved populations. Vara goes much beyond the algorithm and creates an entire ecosystem around it.

Our customers are women at risk of breast cancer who require a mammogram at least once every second year but (in most parts of the world) do not have access to that opportunity yet. We reach those women via corporate partnerships (employer health benefits), medical doctor networks or directly via our own awareness campaigns.

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Our partners and users are radiology clinics with existing mammography scanners and radiologists who seek to screen more women for breast cancer to drive their revenues and create positive change in their region. In Germany, we work with 30% of all screening centers and were able to show that we can find 42% of all missed interval cancers and reduce workload by 73%.

In some markets, like Mexico, we work with a mission-driven strategic partner like Mamotest to deliver the platform faster and to more women. With Mamotest, we have already launched 5 mammography screening clinics and have been able to sign corporate partnerships with multiple employers and NGOs.

Many health systems want to implement population-based breast cancer screening programs, but implementing such programs based on European guidelines is very costly, and requires sub-specialized screening experts which are very scarce worldwide.

Radiology clinics often have mammography scanners (for women with symptoms) which aren't frequently used and thus aren't profitable. Those clinics lack the radiologists and the processes to ramp up their screening business and aren't effectively driving awareness in their communities.

Women's insurance plans often do not cover preventative mammography screening, which results in high out-of-pocket costs for screening. Also, they lack trust in the healthcare system and aren't educated enough about how important regular breast cancer screening is.

1. Ultimately, our vision is that breast cancer screening is provided to every woman at risk. For this, we'll need to bring the health systems and payers (e.g. insurance companies) on board which help us to roll-out breast cancer screening at a wide scale.

For this, we need to be able to demonstrate the health economic return on investment we're able to deliver to healthcare systems - which requires prospective, real-world evidence. For this, we need to be able to demonstrate the health economic return on investment we're able to deliver to healthcare systems - which requires prospective, real-world evidence.

Time Schedule

07:00 - 08:30 AM EST
12:00 - 01:30 AM GMT
01:00 - 02:30 PM CET
09:00 - 10:30 PM JST

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"VARA AND ARTIFICIAL INTELLIGENCE IN BREAST CANCER SCREENING"

In Germany - where we already work with 30% of the screening market - we have therefore launched the PRAIM study, a prospective, real-world observation study that aims to prove the non-inferiority of our decision referral AI pathway on a nationwide scale. The PRAIM study is the first of its kind worldwide and by far the largest ever prospective study conducted. By June 2023, we'll have included 400,000 women.

PRAIM is the foundation for future studies to evaluate health economic endpoints both in Germany and the emerging world. *The study is led by Prof. Dr. Alexander Katalinic, Director of Social Medicine and Epidemiology at the University of Lübeck and scientific advisor to the German Mammography Screening Program.*

2. The second north star right now is to continue reaching more women in Mexico, where we have launched 5 Vara-powered clinics together with Mamotest such in Monterrey and other regions in Mexico. Hundreds of women are screened every week and we are very focused on launching further clinics and growing the ecosystem in Mexico, which was joined by large corporations as well as NGOs such as ProMujer. We launched in Mexico this year but already see exciting interest and support coming from large international corporations.

3. We are launching this year in Egypt and India too and are excited to announce very soon what we have been working on in the past months!

4. We're also working on expanding our AI technology to other modalities, starting with 3D mammography (tomosynthesis) to be able to provide the best possible screening quality to women with dense breast tissue.

REGISTRATION

- This webinar is free to everybody
- Click **here** for registration

After registering, you will receive a confirmation email containing information about joining the webinar.

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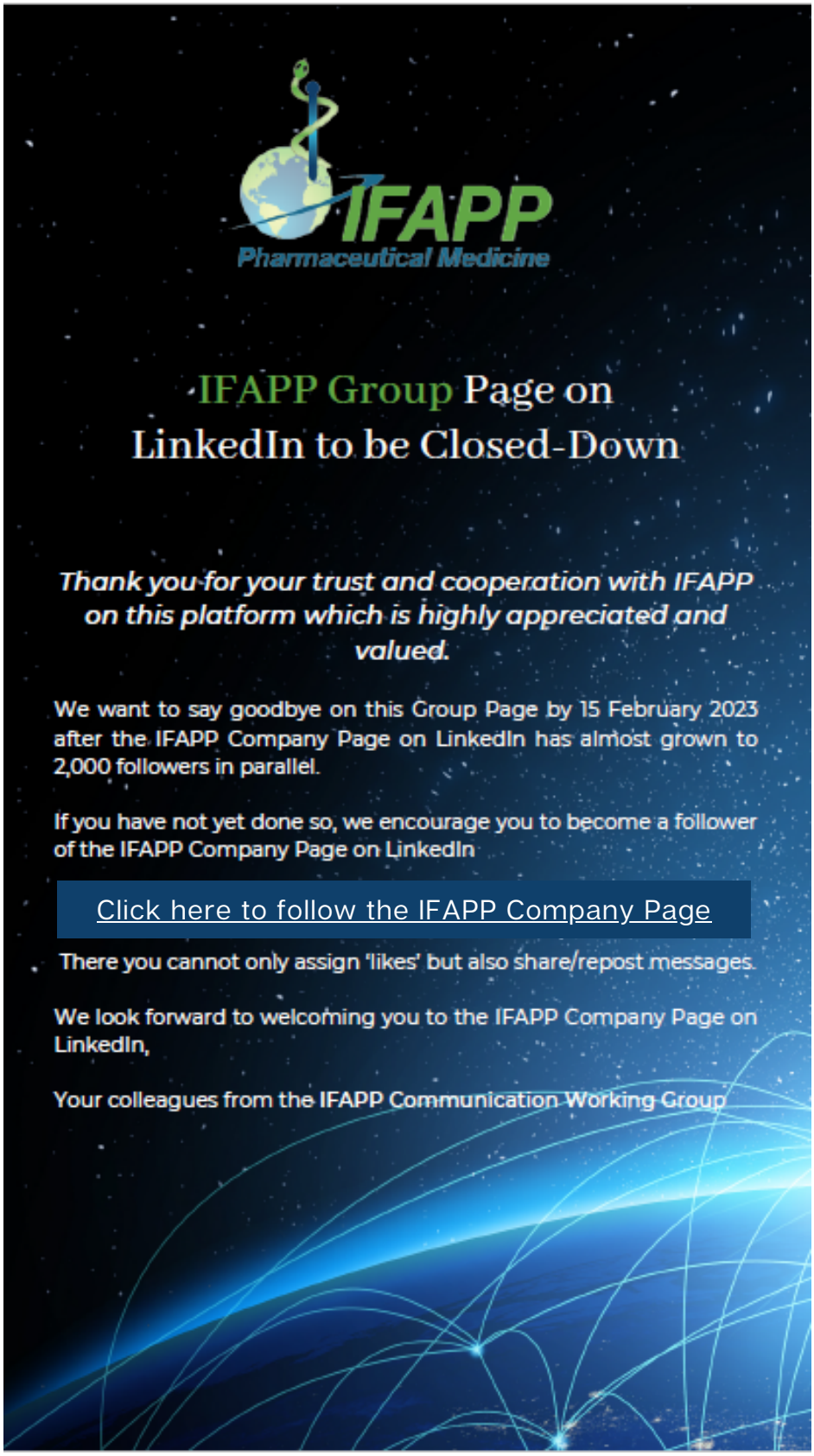

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THE FLAG

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