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HAI AP News

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HAI AP Est. 1981

Health Action International (HAI) was formally founded in Geneva in 1981 and coordinated initially from Penang. In 1995 Health Action International Asia Pacific (HAI AP) was formed in the Asia Pacific Region as part of the international collaborative network to increase access to essential medicines and improve their rational use through research excellence and evidence-based advocacy. HAI AP is committed to strive for health for all now. *HAI AP News* is the official newsletter of Health Action International – Asia Pacific and presents the happenings in the regional campaigns for more rational and fairer health policies and carries material in support of participants' activities.

In this issue

HAIAP Forum: Health Action for All - the way Forward in collaboration with USM, TWN and IIUM.

The title of the forum reflects the slogan for World Health Day this year - Health for All - with a focus on action. The event will take place between May 27 and 29 in Penang, Malaysia. We will share current activities as well as show newcomers the breadth and depth of HAIAP partners' ongong inspiring activities that are part of 'Health for All'. Importantly we are looking to the future of HAiAP and its ensured sustainability.

In this issue:

The Olle Hansson Award 2023 goes jointly to Claudio Schuftan and Michael Lim Tan, see page 2.

April 7 - World Health Day this year marks 75 years of WHO. WHO has presented a time line for these years. You might think of different issues that could have been highlighted. The *Lancet* has published its version of WHO 75 years *

Notable achievements covered in this issue include the production of bedaquiline for TB in India and Rajasthan's new health policy.

A new *Lancet* series is flagged. The significant impact on health equity of the commercial determinants of health is the subject of a Series published in this April 2023 issue of *The Lancet*.

In this HAIAP News there are several articles that highlight the commercial priorities of companies over people's health and the resulting negative impact on global health. The tobacco industry remains a focus with the struggle to control 'vaping'.

The HAIAP anniversary book
HAIAP at 40 1981-2021

'A chronicle of health heroes, historic events, challenges and victories' is available to download at https://www.twn.my/

A limited number of hard copies are available free but postage needs to be covered. Please Contact Linda Ooi at TWN for details: linda@twnetwork.org

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* https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(23)00677-3/fulltext

HAIAP Forum 'Health Action for All - the way forward' May 27-29 in Penang

World Health Day - April 7 - 2023 focusses on Health for All. The title for our HAIAP forum in Penang puts some action into the slogan.

In collaboration with long time partners at the Universiti Sains Malaysia, Third World Network (TWN) and the International Islamic University Malaysia (IIUM) we have put together an exciting program that will be wonderful to share and to inspire newcomers.

Long time partners have continued to expand their activities and will share their challenges and achievements. On the third day we will look to the future of HAIAP and plan our 'way ahead'.

We look forward to seeing many of you in Penang.

As you all are aware, HAIAP like other civil society groups globally has had to deal with funding constraints and withdrawals in recent years. In view of this issue, interested potential participants are self-funding their travel to Penang for the occasion. TWN has very generously agreed to cover accommodation and USM will provide the meeting venues.

Olle Hansson Award 2023

This year, 2023, the Olle Hansson Award will be shared by Claudio Schuftan and Michael Tan.

These two awardees will receive a tribute and their Award during the HAIAP Forum in Penang between May 27 and 29, 2023.

Claudio Schuftan grew up in Chile, got his medical degree there, began an academic career in 1970, and left for the USA due to the military coup in early 1974.

He started to travel to Africa in 1975, and worked a year in Cameroon in 1980 helping to prepare their five-year nutrition plan. He then moved to New Orleans, to Tulane University's School of Public Health, and taught in the department of nutrition for ten years, before moving to Nairobi where he was an advisor in the Ministry of Health. Seven years there led to extensive consulting in Africa, often on nutritional issues. In 1995, he moved to Vietnam where he worked for two and a half years in the Ministry of Health as a senior Primary Health Care advisor.

Claudio Schuftan's expertise is not so much centred around the access to and safety of medicines issues as such, but rather as a part of a wider issue of human rights of which he has been a pioneer. His contribution has been on supporting and promoting health for all and addressing the structural and human rights issues relating to health. For the last 12 years he has been the author of *The Human Rights Reader*, a weekly blog centred on overall human rights issues, but importantly on the right to health and the right to food. (www.claudioschuftan.com).

Claudio was a co-founder of the Peoples Health Movement (PHM) and a member of its steering council until 2018; he now is an active member of its advisory council as well as the moderator of the PHM-exchange, the movement's list server since 2002. Claudio has been representing PHM and the World Public Health Nutrition Association in the Civil Society and Indigenous People Mechanism of the Committee on Food Security in FAO and in the ongoing negotiations for a Binding Treaty on the Human Rights Responsibilities of Trans National Corporations.

Claudio has been a valued member of HAIAP for more than 20 years.

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Michael Lim Tan was born in 1952 and grew up in Metro Manila, Philippines graduating from secondary school in 1969. He majored in Biology at the Ateneo de Manila University, then transferred to the University of San Francisco, taking up the same degree. He achieved a degree in veterinary medicine from the University of the Philippines Diliman in 1977, and from there he pursued a career as a veterinarian, which included a brief teaching stint at the veterinary school of Araneta University (now De La Salle Araneta University), before moving on to human public health and pharmacology, and eventually, medical anthropology.

From 1979 to 1985, he worked with the Alay Kapwa Kilusang Pangkalusugan (AKAP), which used a primary health care approach for tuberculosis prevention and control. His work in health resulted in an interest in anthropology and he received an MA in Anthropology with the Texas Agricultural and Mechanical (A&M) University (1982) and a PhD with the Medical Anthropology Unit of the University of Amsterdam (1996).

He earned a Master of Arts in Anthropology from the Texas A&M University in 1982, and then obtained his PhD in social and political science from the Medical Anthropology Unit of the University of Amsterdam in 1996.

He worked from 1977 to 1981 in community-based health programs in Mindanao and in Luzon, and with a community-based tuberculosis control program. In the early 80s he founded a health NGO, Health Action Information Network (HAIN), among the first HAIAP

partners, concentrating on research and information for community-based health programs, government and non-government health agencies, mass media and legislators. HAIN played a major role in pushing for health reforms in the Philippines around providing safe and affordable pharmaceuticals, responding to HIV and AIDS and reproductive health needs. Michael Tan and HAIN have made major contributions to HAIAP resources.

Michael began teaching in the University of the Philippines (UP) in 1985 and in 1997 he became Anthropology Field School Director, then Chair of the Anthropology Department, Dean of the College of Social Sciences and Philosophy and, from 2014 to 2020, Chancellor of University of the Philippines Diliman. During his term, he has encouraged faculty, students and staff to engage the world outside, including speaking out on national issues.

In 2012, he was appointed a National Academician and a member of the National Academy of Science and Technology, which is the highest advisory body to the government on science and technology. His appointment as National Academician includes a citation that summarizes his commitments: 'His scholarly work provides the foundation for his social development advocacy and policy development work, which he sustains by ensuring that scientific knowledge is effectively communicated to various stakeholders including policy makers, community development workers, health professionals, and the general public.'

His talks also bring in the personal dimension where academic theories are explained as tools for facing the challenges of daily living across human life cycles, from raising children to caring for the elderly. Dr Michael Tan has published extensively. Focussing on advocacy around peace and justice issues his numerous books and articles engage with indigenous medical beliefs, reproductive and sexual health (particularly HIV and AIDS) pharmaceuticals, and health policy issues.

Claudio Schuftan explores the need for UN reform

Claudio Schuftan April 2023

The Security Council

Established in October 1945, it includes five permanent members (USA, Russia, UK, France and China) and ten temporary members, elected on a rotating basis every two years (in a staggered manner, five per year).

Problems:

Representativity – The world no longer looks like it did 80 years ago, when the winners of WWII could dictate all decisions. The most populous, powerful countries are excluded from a permanent seat, eg India, Brazil, Germany, Japan, South Africa, Nigeria, Thailand and those in the Global South.

Member selection to the UN Security Council

The ten rotating nations selected must receive two thirds of the vote from the General Assembly, which occasionally results in stalemates, favouritism and exclusions.

Veto power

The veto poses an obstacle to meaningful resolutions - so many of them human rights-related! The veto is used too often and in a self-interested manner. It has literally and historically paralysed action on sensitive issues, eg Vietnam, Palestine, Hungary, Cuba, Panama, Korea, Ukraine.

Nuclear power club

The five permanent members are considered ‘legitimate’ nuclear powers despite evidence that nearly a dozen other countries have also developed nuclear capabilities.

Peace-keeping role

The Security Council’s action on international conflicts is frequently a function of strategic political interests of permanent members.

Human rights-defending role

Because of all of the above, you can conclude yourself whether HR play an important role in Security Council affairs.

Suggestions:

- Expand the number of permanent members or create a ‘semi-permanent’ category for certain states. Alternatively:
- Abolish permanent membership altogether and make all UNSC posts rotational, establishing appropriate geographic and demographic criteria.
- Regularise the rotation of members according to a fixed schedule, without election by the General Assembly.
- Restrict/abolish the Security Council’s veto power. Allow UNSC members to register objections that are sent for resolution at the General Assembly by vote.
- Declare all nuclear weapons illegitimate. Establish a schedule for the progressive decommissioning of nuclear arms. Monitor, inspect, and publicly name and shame violators.
- Put more teeth into peace-establishing and peace-keeping missions by clarifying their mandate, terms of engagement, specific objectives, resources and exit strategy -- not missing the opportunity to put HR and humanitarian principles centre-stage.

- Appoint a high-level HR expert to the staff of the UNSC to warn members of HR issues being overlooked in its resolutions.

Specialized Agencies, Funds and Programs under the aegis of the General Assembly

The first three agencies created in 1945 were the World Bank, the IMF and the Food and Agriculture Organization (FAO). In the intervening 75 years, scores more have cropped up. Rarely are any agencies ever phased out.

Problems:

Overlapping mandates: Some agencies are sectoral (WHO, FAO, UNIDO, UNEP, UNAIDS) while others target a specific group of beneficiaries (UNICEF, UN WOMEN, UNHCR). A dozen agencies deal with health; three handle displaced persons.

Corruption: Highly publicized allegations of organisational waste and fraud, eg Food-for-Oil, UNOPS, are difficult to identify, investigate and prosecute.

Abuse and impunity: Abuse by individuals (sexual exploitation; racial, ethnic, or gender discrimination; bullying or harassment) is rarely uncovered and even more rarely punished. There are simply colossal obstacles to bring about cultural change within UN institutions.

Biased recruiting: UN recruitment and staffing still favour candidates from industrialized nations. Donor nations have unfair advantages at all levels.

Donor driven programs: Unequal power of donor nations to define and set details of projects (where agencies will work, what sectors are a priority) and set administrative guidelines (who is hired, where equipment is purchased).

Private sector chokehold: Increasing commandeering of development efforts by private sector entities. Examples: public-private partnerships and multistakeholder platforms, not only like GAVI[1] --the Vaccine Alliance (that ostensibly works to extend immunisation to poorer developing countries) but also the Scaling Up Nutrition (SUN) Initiative, COVAX and quite a few others.

Human rights too often relegated to lip service: Every UN agency is bound by the UN Charter to put HR upfront, but too often HR are added-on as a window dressing.

Suggestions:

Re-vision and re-mission, as well as rationalisation of the coverage and efficiency of the several specialised UN agencies, emphasising sectoral distribution in a logical manner.

- Standardise administrative and contractual arrangements across all agencies, organisations and funds, so that all are governed by the same rules.
- • Consolidate and put teeth into the various legal and ethical and HR watchdog initiatives (UN Ethics Office, OIOS, UNHCHR…) to ensure institutional culture change.
- Promote multi-lateral over bi-lateral funding of agencies. Divert private sector funding/donations to a central UN Fund that will allocate the same to programs.
- End the prerogative of certain donor nations to name UN agencies' directors, eg World Bank to the USA; IMF to the EU; UNICEF to the USA.
- Provide equivalent training opportunities for potential staff from LDCs. Open JPO opportunities to citizens of the Global South keeping them funded by the Global North.[2]
- Demand that these agencies, funds and programs design and implement actions in the field around HR imperatives. Monitoring and evaluation of the same must include measuring HR impacts.

Other Miscellaneous Suggestions (in no particular order.)

- Revisit the financing of the UN System, to make the annual member states' assessments fairer, proportional and more appropriate, ensuring that the economies of the Global North pay a much greater share.
- Move the General Assembly and the Security Council out of New York City. Subsidise the relocation of headquarters with more funds for programs and agencies, to capitals in the Global South.
- Revisit the UN policy of civil-military collaboration in humanitarian contexts, taking into consideration the real impact and consequences of using military assets of donor nations that have their own geo-political strategic interests.
- Stop viewing the private sector as the panacea to all the problems of the UN!.

[1] GAVI has been criticized for giving private donors more unilateral power to decide on global health goals, prioritizing new, expensive vaccines while putting less money and effort into expanding coverage of old, cheap ones, harming local healthcare systems, spending too much on subsidies to large, profitable pharmaceutical companies without reducing the prices of some vaccines, and its conflicts of interest in having vaccine manufacturers on its governance board.' (Source: GAVI - Wikipedia)

[2] Junior Program Officer. JPO is an introductory entry level for UN officers. Typically, JPO posts are established by a UN agency (WHO, WFP, UNICEF, UNHCR...) at the request of a donor nation which, in return for funding the post, gets to place one of its up-and-coming young stars in that agency. The JPOs overwhelmingly come from the wealthy donor nations. That is why there is an abundance of sharp young professionals from the North always ready to apply for a UN post.

WHO 75 years
World health day April 7 2023

World Health Day was inaugurated April 7 1948 when the WHO Constitution was launched.

On 7 April 2023 - World Health Day - the WHO observed its 75th anniversary.

In 1948, countries of the world came together and founded WHO to promote health, keep the world safe and serve the vulnerable – so everyone, everywhere can attain the highest level of health and well-being.

WHO's 75th anniversary year is an opportunity to look back at public health successes that have improved quality of life during the last seven decades. It is also an opportunity to motivate action to tackle the health challenges of today – and tomorrow.

Join WHO on a journey to achieve Health For All.

Here are WHO's milestones

go to https://www.who.int/campaigns/75-years-of-improving-public-health for links to details and support information about each milestone

Public health milestones through the years

Since the foundation of the World Health Organization in 1948, the world has experienced public health challenges that have required us all to come together with science, solutions and solidarity. This timeline, published in 2023 on the occasion of WHO's 75th anniversary, serves as a reminder of some of the most memorable successes and how these have contributed to improved health across the world. These milestone achievements also provide inspiration for us to face the health challenges of the future.

1945 Planning for WHO

Diplomats meeting in San Francisco, California to form the United Nations agree that throughout modern history, there has been insufficient collaboration between countries to control the spread of dangerous diseases across the world. Together they decide on the need for a global organization overseeing global health. They plan for the creation of WHO.

1946 WHO Constitution approved

WHO's Constitution is drafted and then approved at the International Health Conference in New York City.

WHO/UN 1947 First-ever global disease-tracking service

WHO establishes the first-ever global disease-tracking service, with information transmitted via telex.

1948 WHO Constitution comes into force

WHO's Constitution comes into force on 7 April - a date we now celebrate every year as World Health Day. Following the mandate established by Member States, WHO begins its first two decades with a strong focus on mass campaigns against tuberculosis, malaria, yaws, syphilis, smallpox and leprosy.

1950 Discovery of antibiotics

The great era of discovery of antibiotics begins, and WHO begins advising countries on their responsible use.

1952 Inactivated polio vaccine

Jonas Salk develops the inactivated poliovirus vaccine (given by injection), paving the way for mass global campaigns facilitated by countries, WHO and other partners that have led to the near-eradication of polio.

1961 Attenuated live-virus polio vaccine

Albert Sabin develops the attenuated live-virus vaccine (given orally), paving the way for mass global campaigns facilitated by countries, WHO and other partners that have led to the near-eradication of polio.

1969 International Health Regulations

The World Health Assembly establishes the first International Health Regulations, which represent an agreement between WHO Member States to work together to prevent and respond to acute public health risks that have the potential to cross borders and threaten people worldwide.

1972 Special Programme of Research, Development and Research Training in Human Reproduction

The Special Programme of Research, Development and Research Training in Human Reproduction (HRP) is created at WHO. It is the sole body within the UN system with a global mandate to carry out research into sexual and reproductive health and rights.

1974 Expanded Programme on Immunization

WHO founds the Expanded Programme on Immunization to bring life-saving vaccines to all the world's children.

1975 Special Programme for Research and Training in Tropical Diseases

WHO establishes and begins hosting the Special Programme for Research and Training in Tropical Diseases (TDR), which is co-sponsored by UNICEF, UNDP and the World Bank. As a global programme of scientific collaboration, TDR provides tools to tackle neglected diseases and to increase the capacity for research in disease-endemic countries. TDR has made a significant contribution to elimination efforts for river blindness and leishmaniasis. By 2016, five of the eight diseases that the Programme was created to support research on are close to elimination.

1977 First Essential Medicines List

The first Essential Medicines List is published. This list outlines the medicines that a basic health system needs. Each medicine is selected based on evidence for its safety, effectiveness and value for money.

1978 "Health for All" goal set

The International Conference on Primary Health Care, in Alma-Ata, Kazakhstan, sets the aspirational goal, "Health for All", laying the groundwork for WHO's call for universal health coverage.

1978 Global diarrhoeal diseases programme

WHO launches the global diarrhoeal diseases programme with Oral rehydration salts (ORS) at its heart. By 2019, the 4·6 million annual deaths from diarrhoea in children younger than 5 years estimated in 1980 had fallen to just under 365 000 deaths, despite a 70% increase in the world's population. Although several factors contributed to this reduction, as of 2007 it was estimated that oral rehydration therapy (ORT) alone had prevented 54 million diarrhoeal deaths. In addition, ORT helped reduce the nutritional impact of diarrhoea. However, as of 2022, ORT remained underused in some critically-affected countries. Programmes to promote its use should be funded to halt deaths from cholera and other acute watery diarrhoeal diseases. ORT is also underused in high-income countries, and should be promoted to reduce costs.

1980 Smallpox eradication

Following an ambitious 12-year global vaccination campaign led by WHO, smallpox is eradicated.

1981 International Code of Marketing Breastmilk Substitutes

Breastfeeding is one of the most effective ways to improve child health and survival. But it can be seriously undermined by lobbying and marketing from the formula milk industry. To address industry practices that were dissuading mothers from breastfeeding, the WHO Member States endorsed the International Code of Marketing Breastmilk Substitutes in 1981. The Code laid out rules on the marketing of baby formula - covering advertising, educational materials, store promotions, product labels, and relationships with health workers. By 2022, 75% of countries had adopted legal measures to implement at least some of the provisions in the Code. Since the Code was adopted, the percentage of babies who are exclusively breastfed has gone up by 50%.

1983 HIV discovered

The Human immunodeficiency virus (HIV), which causes AIDS, is discovered. In 1987, the first antiretroviral medication to control HIV infection and prevent it from progressing to AIDS is licensed, prompting a shift in WHO's priorities.

1988 Global Polio Eradication Initiative

Countries of the world come together to call for the eradication of polio at the World Health Assembly at a time when the disease was paralysing more than 350 000 children every year in more than 125 endemic countries. The Global Polio Eradication Initiative (GPEI), is launched. Since then, the incidence of polio has been reduced by more than 99%. In 2022 only two countries remained endemic to wild poliovirus. Twenty million cases of polio have been averted and more than 1.5 million childhood deaths prevented.

1994 Comprehensive definition of reproductive health

At the International Conference on Population and Development (ICPD) held in Cairo, Egypt, countries agree to the adoption of a comprehensive definition of reproductive health and a recognition of reproductive rights. This definition was fully supported by WHO. Also agreed at this seminal Conference was the 20-year Programme of Action which focused on individuals' needs and rights, including reproductive rights, rather than on achieving demographic targets. Advancing gender equality, eliminating violence against women and ensuring the ability of women to control their own fertility were acknowledged as cornerstones of population and development policies.

1995 Integrated Management of Childhood Illness (IMCI) strategy

The Integrated Management of Childhood Illness (IMCI) strategy was launched by WHO and UNICEF to promote health and provide preventive and curative services for children under five in countries with more than 40 deaths per 1000 live births. Over the past quarter of a century, child mortality has more than halved, dropping from 91 to 43 deaths per 1000 live births between 1990 and 2015. Yet in 2015 an estimated 5.9 million children still died before reaching their fifth birthday, most from conditions that are readily preventable or treatable with proven, cost-effective interventions. By 2016, more than 100 countries were implementing the strategy, contributing to reductions in global child mortality by an estimated 15%.

1998 Emergency contraception

WHO played a pioneering role in emergency contraception by confirming the effectiveness of levonorgestrel, which resulted in changes in regulations in countries of differing income levels and its inclusion in the list of essential medicines. Since 1998 these pills have been licensed in more than 100 countries.

1999 Global Alliance for Vaccines and Immunization

The Global Alliance for Vaccines and Immunization (now Gavi, the Vaccine Alliance) is established. The Alliance consists of major players in global immunization, including WHO, other key UN agencies, leaders of the vaccine industry, government representatives and major foundations. Its role is to overcome barriers preventing millions of children from receiving vaccines.

1999 Global strategy for noncommunicable diseases

The first global strategy for the prevention and control of noncommunicable diseases (NCDs).

2000 Millennium Development Goals

At the Millennium Summit in September 2000, the largest gathering of world leaders in history adopts the UN Millennium Declaration, committing nations to a new global partnership to reduce extreme poverty and setting out a series of time-bound targets, with a deadline of 2015. They become known as the Millennium Development Goals (MDGs) and include specific goals for health.

2000 GOARN

The WHO Global Outbreak Alert and Response Network (GOARN) is established to detect and combat the international spread of outbreaks.

2001 UN Declaration of Commitment on HIV/AIDS

The Twenty-sixth special session of the United Nations General Assembly adopts the Declaration of Commitment on HIV/AIDS as a matter of urgency to address the HIV/AIDS crisis worldwide as well as to secure a global commitment to enhancing coordination and intensification of national, regional and international efforts to combat it in a comprehensive manner.

2001 Global Fund

The Global Fund to fight AIDS, Tuberculosis and Malaria, a new partnership and funding mechanism initially hosted by WHO, is created in collaboration with other UN agencies and major donors.

2003 "3 by 5" initiative

WHO launches the "3 by 5" initiative, which aims to bring treatment to 3 million people living with HIV by 2005 and lays the groundwork for reaching 13 million people infected with HIV with antiretroviral treatment by 2013.

2003 Framework Convention on Tobacco Control

The World Health Assembly unanimously adopts WHO's first global public health treaty, the WHO Framework Convention on Tobacco Control, which aims to reduce tobacco-related deaths and disease worldwide.

2004 UN Road Safety Collaboration

The UN Road Safety Collaboration is established. WHO and the World Bank launch the first ever world report on road traffic injury prevention.

2004 New Strategic Operations Centre for emergency response

WHO's Strategic Health Operations Centre is used for the first time to coordinate emergency response support following the

Indian Ocean tsunami. The Centre is the nerve centre of global alert and response for health emergencies.

2005 International Health Regulations revised

The International Health Regulations are revised, giving countries clear and tested guidelines for reporting disease outbreaks and other public health emergencies to WHO, and triggering response systems to isolate and contain threats.

2006 Child mortality declines

The number of children who die before their fifth birthday declines below 10 million for the first time in recent history.

2006 Child Growth Standards

WHO Child Growth Standards are launched to help every child grow in an equitable way. These are unique tools that define malnutrition in children under 5 years of age. Central for monitoring child malnutrition globally, they are used by governments to establish their nutrition targets, and by data experts for calculating malnutrition estimates at national, regional and global levels. They are also used for child growth monitoring in most countries.

2008 Heart disease and stroke

Heart disease and stroke emerge as the world's number one killers – indicating a global shift from infectious diseases to noncommunicable diseases, noted the World Health Statistics report.

2009 New H1N1 virus

The world braces itself for the first influenza pandemic since 1968 with the emergence of the new H1N1 influenza virus. WHO works with collaborating centres and pharmaceutical industries to develop influenza vaccines in record time.

2010 Options for raising resources for health

WHO issues a menu of options for raising sufficient resources and removing financial barriers so that all people, especially those with limited resources to spend on health care, have access to essential health services.

2010 First rapid molecular test for detection of TB

The first rapid molecular test for the detection of TB is established after decades of using only sputum-smear microscopy. Sputum-smear microscopy had poor specificity and reliability. The new tests help diagnose TB more accurately and identify drug resistance earlier.

2011 Pandemic Influenza Preparedness Framework

The adoption of the Pandemic Influenza Preparedness Framework paves the way for equitable access to countermeasures during pandemics.

2012 NCD targets

For the first time, WHO Member States set global targets to prevent and control heart disease, diabetes, cancer, chronic lung disease and other diseases.

2012 Nutrition plan

The World Health Assembly adopts WHO's implementation plan on maternal, infant, and young child nutrition.

2013 Comprehensive Mental Health Action Plan

The first global Comprehensive Mental Health Action Plan is endorsed. More than 100 countries have used the Mental Health GAP Action Programme (mhGAP) for the integration of mental health at primary health care level since that time.

2014 Every Newborn Action Plan

The Every Newborn Action Plan is endorsed by the World Health Assembly. The Plan presents evidence-based solutions to prevent newborn deaths and stillbirths. It sets out a clear path with specific global and national milestones to achieve the SDG target of at least as low as 12 newborn deaths or less per 1000 live births.

2014 Ebola outbreak in West Africa

The Ebola outbreak in West Africa 2014-2016 was the largest since the virus was first discovered in 1976. It started in Guinea then quickly spread to neighbouring countries – Liberia and Sierra Leone. In August 2014, WHO declared the outbreak a Public Health Emergency of International Concern. Over the course of the epidemic, the disease spread to 7 additional countries – Italy, Mali, Nigeria, Senegal, Spain, the United Kingdom, and the United States of America. The WHO Secretariat activated an unprecedented response to the outbreak: deploying thousands of technical experts and support staff and medical equipment; mobilizing foreign medical teams; and coordinating the creation of mobile laboratories and treatment centres.

2015 HIV treatment coverage

HIV treatment coverage expanded rapidly with well over 17 million people living with HIV on antiretroviral therapy by the end of 2015.

2015 Elimination of mother-to-child transmission of HIV and syphilis

Cuba becomes the first country in the world to receive validation from WHO that it has eliminated mother-to-child transmission of HIV and syphilis.

2015 Interruption of indigenous malaria transmission

The WHO European Region becomes the first Region in the world to achieve the interruption of indigenous malaria transmission.

2015 Child-friendly formulations of anti-TB medicines

The first ever child-friendly formulations of anti-TB medicines, which are water-dispersible tablets, are introduced. They offer the opportunity to simplify and improve treatment for children around the world with the goals of enhancing adherence to and completion of treatment and preventing the development of drug resistance.

2015 Sustainable Development Goals

In 2015, all United Nations Member States adopt the 2030 Agenda for Sustainable Development. It sets out 17 Goals, which include 169 targets. These wide-ranging and ambitious goals interconnect. Goal 3 is to ensure healthy lives and promote well-being for all at all ages.

2016 UN Declaration on antimicrobial resistance

The UN General Assembly adopts a political declaration on antimicrobial resistance (AMR) and calls for the establishment of an ad-hoc inter-agency coordination group on antimicrobial resistance to provide practical guidance to ensure global action against AMR.

2016 Progress towards polio-free certification in African Region

Nigeria, long considered the global epicentre of poliovirus, reports its last wild poliovirus, paving the way for certifying the African Region free of such strains. In 2023, five of the six WHO

Regions have been certified free of wild poliovirus and two of the three wild poliovirus strains have been globally eradicated.

2016 Treatment of neglected tropical diseases

The goal of one billion people treated for at least one neglected tropical disease in a single year is met for the first time.

2016 Global Strategy for Women's, Children's and Adolescents' Health

The Global Strategy for Women's, Children's and Adolescents' Health (2016-30) is launched. Coordinated by WHO and developed with partners, the Strategy provides a roadmap for action. Through its objectives of Survive, Thrive and Transform, the Strategy is a catalyst for investment to promote and protect health and support well-being.

2016 Ebola outbreak in West Africa: progress

WHO announces zero cases of Ebola in West Africa, but warns that flare-ups of the disease are likely to continue and that countries in the region need to remain vigilant and prepared.

2016 Zika association declared a Public Health Emergency of International Concern

WHO declares that the recent association of Zika infection with clusters of microcephaly and other neurological disorders constitutes a Public Health Emergency of International Concern.

2017 Antibiotic-resistant 'priority pathogens'

WHO publishes its first ever list of antibiotic-resistant "priority pathogens" – a catalogue of 12 families of bacteria that pose the greatest threat to human health. The list was drawn up in a bid to guide and promote research and development of new antibiotics, as part of WHO's efforts to address growing global resistance to antimicrobial medicines.

2017 Partnership for Healthy Cities

The Partnership for Healthy Cities is launched. It includes 70 cities of over 300 million inhabitants in total. The Partnership aims to put in place policies and programmes to prevent road traffic injuries and diseases like cancer, heart disease, diabetes and lung disease.

2019 UN Declaration on universal health coverage

World leaders adopt a high-level United Nations Political Declaration on universal health coverage, the most comprehensive set of health commitments ever adopted at this level.

2020 Global outbreak of novel coronavirus declared a Public Health Emergency of International Concern

The WHO Director-General declares the global outbreak of novel coronavirus a Public Health Emergency of International Concern (PHEIC). A PHEIC is defined in the International Health Regulations (2005) as, 'an extraordinary event which is determined to constitute a public health risk to other States through the international spread of disease and to potentially require a coordinated international response'.

2020 New SDG indicator on blood stream infections

The UN Statistical Commission approves a new SDG indicator on blood stream infections due to selected antimicrobial-resistant organisms. WHO is the custodian for this indicator, with data provided through WHO's Global Antimicrobial Resistance and Use Surveillance System.

2020 First oral regimen for treatment of multidrug-resistant tuberculosis

The first oral regimen for the treatment of multidrug-resistant tuberculosis (MDR-TB) is established. For decades, the cornerstone of treatment for TB had been the administration of painful injectable agents, which are now replaced by 2-3 times shorter, fully oral, more effective treatments with the new drugs.

2020 Access to COVID-19 Tools Accelerator

The Access to COVID-19 Tools Accelerator (ACT-Accelerator) partnership is launched by the WHO Director-General, the European Commission, the President of France and the Bill & Melinda Gates Foundation. The ACT-Accelerator is a global collaboration to accelerate the development, production, and equitable access to COVID-19 tests, treatments, and vaccines.

2021 Antiretroviral therapy

At the end of December 2021, 28.7 million people were accessing antiretroviral therapy, up from 7.8 million in 2010. This meant that 75% of all people living with HIV were accessing treatment.

2021 Malaria vaccine for children

WHO recommends a ground-breaking malaria vaccine for children living in areas of moderate to high malaria transmission. The long-awaited malaria vaccine is a breakthrough for science, child health and malaria control. It is the first vaccine against a parasite and could save tens of thousands of young lives each year.

2021 Tuberculosis prevention and care

More than 74 million lives had been saved through tuberculosis prevention, diagnosis and treatment since 2000.

2022 Agreement for cooperation on the health of humans, animals, plants and the environment

Four international agencies - the Food and Agriculture Organization, the World Organisation for Animal Health, the UN Environment Programme and WHO, sign a ground-breaking agreement to strengthen cooperation to sustainably balance and optimize the health of humans, animals, plants and the environment. The Quadripartite MoU provides a legal framework to tackle the human, animal, plant and ecosystem challenges by using a more integrated and coordinated approach. This framework reinforces national and regional health systems and services, and contributes to global health security.

2022 Updated edition of 'Family Planning: A Global Handbook for Providers'

With co-authors USAID and Johns Hopkins University, WHO releases the 4th edition of 'Family Planning: A Global Handbook for Providers'. The Handbook provides clinic-based health professionals with the latest guidance on providing contraceptive methods. Since its first edition in 2007, almost a million copies have been distributed around the world.

2023 Looking back - and forwards

WHO's 75th anniversary year is an opportunity to look back at public health successes that have improved quality of life during the last seven decades - and to look forward to motivate action to tackle the health challenges of today and tomorrow.

JSA Urges Rajasthan Government to make clarifications in Health Bill to Ensure Effective Implementation

https://www.newsclick.in/jsa-urges-raj-govt-make-clarifications-health-bill-ensure-effective-implementation

Newsclick Report [3] 03 Apr 2023

New Delhi: Jan Swasthya Abhiyan (JSA) (PHM India) released a press statement welcoming the Rajasthan Right to Health Act passed in the State Legislative Assembly on March 21, 2023, and congratulated the State government of Rajasthan for achieving an important milestone in the history of Health policy in India.

JSA is a joint platform of hundreds of grassroots organisations and state and national level networks that work for the health and related rights of the people and is affiliated with the Global People's Health Movement.

While the platform has welcomed the Act, it has also criticised the misinformation spread by certain lobbies claiming that it is an anti-private sector, linked with their politically motivated demand that the Act be withdrawn. At the same time, JSA is also concerned that despite several strengths, some provisions in this Act need clarifications or modifications to ensure optimally effective implementation.

After passing the Right to Health Act last week, an unprecedented kerfuffle followed, with doctors in the State vehemently protesting what they called a 'draconian law'.

The Right to Health is in sync with the constitutional guarantee of the right to life and other components of the Directive Principles. This means that no person seeking health care should be denied it on the grounds of access and affordability.

The Rajasthan Right to Health Act, 2022, addresses these critical issues of access and affordability. It 'seeks to provide protection and fulfilment of rights, equity in relation to health and well-being for achieving the goal of health care for all through guaranteed access to quality health care for all residents of the State, without any catastrophic out-of-pocket expenditure'. The law, which also provides for a social audit and grievance redress, gives every resident of the State the right to emergency treatment without paying a single paisa to any healthcare institution and specifies that private healthcare institutions would be compensated for the charges incurred for such treatment.

However, agitating doctors are worried about financial losses and dread humiliation at authorities' hands.

Civil society groups, including JSA Rajasthan, had a significant role in pushing for this Act. In their press release, JSA National Coordination Committee and JSA Rajasthan state unit have offered their full support and solidarity to the Government of Rajasthan towards realising health rights for all people of the state. They have also urged the government towards speedy implementation of the Act after making necessary clarifications to address the misinformation campaign against this law. They have also urged the government to 'build the trust of all constituencies and uphold Rajasthan as a model state in achieving health rights for all, which could become an example for others in India.'

The complete press statement is given below:

> Jan Swasthya Abhiyan welcomes Rajasthan Government's Right to Health Act - a landmark in ensuring people's access to healthcare
>
> Along with its overall support, JSA recommends improved drafting of certain provisions, to be clarified and strengthened during further legislative processes.
>
> JSA appeals to private medical professionals to recognise the importance of this Act, and to positively engage with streamlining of the Act and Rules, while avoiding misinformation.
>
> Jan Swasthya Abhiyan welcomes the Rajasthan Right to Health Act passed in the State Legislative Assembly on 21st March 2023, and congratulates the State government of Rajasthan for achieving an important milestone in the history of health policy in India. Rajasthan has initiated the process of making basic health services a justiciable right, based on providing legal guarantee of public health services and emergency healthcare in the state, setting a historical example for the rest of the country.
>
> JSA criticises the misinformation being spread by certain lobbies which are claiming that the act is anti-private sector, linked with their politically motivated demand that the Act should be withdrawn. At the same time, Jan Swasthya Abhiyan is also concerned that despite several strengths, some provisions in this Act need clarifications or modifications to ensure optimally effective implementation of this Act to ensure realisation of health rights for people of the state, while also being fair to healthcare providers. We recommend that the following issues should be addressed by the State government:

[3] Newsclick is the Independent News Organisation where Amit Sengupta worked. Newsclick co-organised the Delhi segment of our 2022 Olle Hansson Award ceremony (the tribute to Amit).

1. Greater clarity and specificity are required regarding the definition of 'emergency care', keeping in view the complexities of emergency management, and the limited set of first aid measures which can be offered by most healthcare providers.

2. Larger private hospitals (those having over 50 beds) should have broader provisions for providing emergency services, while smaller health care providers and clinics should have restricted obligations in this regard, in keeping with their limited capacities.

3. Ensuring that reimbursement to private providers for providing emergency healthcare would be transparent, hassle-free, corruption free and time-bound.

4. Major increase of the state health budget, to provide the substantial additional resources which must accompany expansion and strengthening of public health services in the state, required for fulfilling all the provisions under this Act.

5. Strengthening mechanisms to ensure accountability of regulatory authorities to people as well as involved healthcare providers.

The Rajasthan Government has agreed to address many of these issues on the floor of the State Legislative Assembly, or in their other public communications. These concerns should be addressed by the Government during further deliberations involving associations of private healthcare professionals as well as civil society networks and NGOs.

However we are concerned that entities like the Indian Medical Association (IMA) have been engaging in agitations aimed at pulling down the Act itself, perhaps without realising the fact that such a stand goes against the ethos of the medical profession, and the duties of healthcare providers to fulfil people's right to health care. We urge the IMA and involved medical professionals to reconsider their position, and to positively engage with and support the further rolling out of the Act and its Rules.

JSA realises that the Government has been consultative in the process of developing this legislation and has already accommodated many suggestions from associations of private doctors. After the State Government first introduced the draft bill in the Legislative Assembly in September 2022, it was sent to a Select Committee of the Assembly, keeping in view concerns of private doctors' associations. Then there were several rounds of discussions with various groups, leading to a series of amendments to the earlier draft of the bill. Given this background of consultations, JSA strongly criticises the misleading campaign by certain lobbies which claim that doctors' concerns have not been considered. JSA hopes that such pressure will not lead to any weakening of the provisions for Right to Healthcare.

JSA strongly welcomes the current Act as a major step forward for ensuring the right to health services for people in the state. However, we urge the State Government to address the following issues in further processes, to ensure the full effectiveness of this initiative:

• The current Act mainly ensures right to healthcare; to move towards comprehensive Right to Health. Further concrete steps are needed by the state to ensure entitlements to determinants of health (such as food security and nutrition, water supply and sanitation, healthy environmental conditions etc);

• The state and district level health authorities are presently limited to government officials and doctors affiliated with the IMA, however public health experts, PRI members, and civil society representatives also need to be represented;

• Provisions for helpline and web-based grievance redressal systems for patients which were made in earlier versions of the Act need to be restored;

• The Act must ensure health rights for all persons present in the state, not only permanent residents but also migrants, nomadic persons, visitors from others states.

JSA reiterates that the Right to Healthcare can be achieved only through a strong public health system, and we hope that the Rajasthan Government will take all necessary steps to ensure public health system strengthening.

In conclusion, JSA urges the State Government of Rajasthan to take immediate measures to:

1. Consider necessary amendments to the Act as required, in order to address the gaps and concerns as mentioned above, towards strengthening health rights for all in Rajasthan;

2. Urgently prepare and introduce necessary Rules for the Act, in order to concretise various provisions and to roll out the implementation of the Act;

3. Set up strong oversight and accountability bodies so that the services to ordinary people are guaranteed to be provided with dignity, while reimbursements to the private sector providers are ensured in a transparent corruption free environment, within stipulated time frame;

4. Adopt a well-defined plan for substantially enhancing the State health budget in line with the obligations and enhanced requirements being generated through this Act, in order to ensure overall expansion and strengthening of government provided health services in the state;

5. Make necessary clarifications to address the misinformation campaign against this law, building the trust of all constituencies and upholding Rajasthan as a model state in achieving health rights for all, which could become an example for other states of India.

Jan Swasthya Abhiyan's National Coordination Committee and JSA Rajasthan state unit offer their full support and solidarity to the Government of Rajasthan towards realising health rights for all people of the state.

World TB Day March 24

Feature: A Ray of Hope for TB Patients: Indian Patent Office Rejects a Secondary Patent on TB drug Bedaquiline

Prathibha Sivasubramanian (Legal Researcher, Third World Network)

[In this article all the ploys and tricks employed by a patent applicant are examined and the rightful rejection by the Indian Patent office is clearly explained.]

On 23 March 2023, in a landmark victory to tuberculosis (TB) patients all over the developing world, the Indian Patent Office (Mumbai) rejected a patent application relating to fumarate salt of bedaquiline.

Bedaquiline is a drug used to treat drug resistant (DR) TB. It is a component of all the short, and the most long regimens to treat DR-TB in adults. Before the introduction of bedaquiline, patients diagnosed with DR-TB had long and tormenting treatment (20 months) with a combination of medicines including daily injections which had adverse side-effects such as permanent hearing loss and psychosis.

The new bedaquiline-based oral regimen has increased the cure rate of DR-TB and replaced medicines causing severe side-effects. Bedaquiline inclusive treatment regimen is a boon for DR-TB patients and is used to treat almost every person with DR-TB.

MDR-TB is related to the condition where *Mycobacterium tuberculosis* is resistant to isoniazid and rifampicin. In early 2018, the WHO published new treatment guidelines establishing a new all-oral, bedaquiline-based standard of care for MDR-TB.[1]

It is estimated that globally the incidence of DR-TB increased to 450,000 cases in 2021 as compared to 437,000 in 2020.[2] However, only 36% of patients could access treatment.[3] India has a high incidence of DR-TB. In fact, India, China and Russia combined contribute more than half of the multi-drug resistant tuberculosis (MDR-TB) cases globally.[4]

There are an estimated 130,000 cases of drug-resistant TB in India every year and currently less than 30% of these patients are diagnosed and put on appropriate treatment regimen.[5] The India TB Report 2022 estimates that in 2021, 48,232 patients were diagnosed (laboratory confirmed) with multi-drug resistant TB (MDR/RR-TB) and 43,380 patients were put on treatment.[6] However, more than 50% of the DR-TB cases go undetected and untreated in India.[7]

Currently the treatment for a six-month course of bedaquiline costs around USD 350 for the Indian Government.[8] It is expected that the cost would come down with the entry of Indian generic pharma companies.

Bedaquiline was granted accelerated approval by the United States Food and Drug Administration (FDA) in 2012 as part of a combination treatment in adults with pulmonary MDR-TB.

Conditional marketing authorisation for bedaquiline was subsequently granted by the European Medicines Agency (EMA) in 2013.[9] Bedaquiline is not available in the retail market in India. So far it has only been rolled out through the National TB Elimination Program (NTEP).

For 50 years, before the introduction of bedaquiline, there were no new medicines for TB. Around 2005, bedaquiline was identified by Janssen, a subsidiary of the pharmaceutical company Johnson and Johnson (J&J). However, the further development of bedaquiline involved a lot of public funding and contributions from philanthropic organisations. Academia, non-governmental and humanitarian organisations and governments have played a role in the development of this drug.

In 2009, Janssen entered into an agreement with the Global Alliance for TB drug Development (TB Alliance), a non-profit organisation, to share resources and expertise for the development of bedaquiline.[10] Consequently Janssen did not conduct the phase III trials of bedaquiline. Several phase I and II trials conducted prior to the drug registration were sponsored by the U.S. National Institutes of Health/National Institute of Allergy and Infectious Diseases and the TB Alliance.[11] The phase III trials to confirm the efficacy of bedaquiline and to identify potential combinations with other TB medicines are being undertaken by other non-profit organisations such as TB Alliance, the Union (previously the International Union Against Tuberculosis and Lung Disease), Médecins Sans Frontières (MSF), and Partners In Health (PIH).[12]

Apart from the clinical trial costs, other incentives such as tax rebates, orphan drug status and seven years of exclusivity were granted for bedaquiline[13] but J&J has obtained multiple patents on bedaquiline in many countries. Considering the philanthropic contributions to its development, the company should be obligated to provide access to all MDR-TB patients who need it.

Multiple secondary patents extend market monopoly

Currently J&J has a monopoly in the market due to the primary patent on bedaquiline. This patent is set to expire

in July 2023. Generics can enter the market after July 2023 and provide low-cost versions of bedaquiline. However, J&J has filed multiple secondary patent applications on various forms such as fumarate salt of bedaquiline, dispersible tablet formulation, to treat latent TB, also for a combination of bedaquiline, pretomanid and linezolid—with many of them being granted in some countries. These secondary patent applications if granted will block generic versions of the drug.

India patients opposed patent application in 2013

In India, the patent application relating to the fumarate salt of bedaquiline along with the well-known wetting agents like TWEEN20 was filed in 2009 [1220/MUMNP/2009].

In 2013, the Network of Maharashtra People Living with HIV (NMP+) filed a pre-grant opposition raising objections on novelty and inventive step under Section 3(d) and 3(e) of the Patents Act, 1970.

[A patent is granted only on the satisfaction of three criteria: novelty/new, inventive step (qualitative improvement from a previous product) and utility. These criteria differ for different countries depending on national laws and standards. Some countries lay down a higher standard, resulting in grant of patents to only genuine inventions giving more space for local industries to grow in the particular field of the art. It is set according to the needs of the country. In this regard, the Trade-related Aspects of Intellectual Property Rights Agreement (TRIPS) administered by the World Trade Organization sets only minimum standards and does not define these criteria.]

In 2019, two TB patients also filed a pre-grant opposition pointing out that many parts of the patent specification have been copy-pasted from an earlier application relating to an HIV drug, rilpivirine, which the Indian Patent Office (IPO) had rejected. The second opposition also raised objections on inventive step under Section 3(d) and 3(e) of the Patents Act, 1970. The claims were amended after the oppositions were filed.

After hearing both parties, on 23 March 2023, the IPO rejected the secondary patent application relating to fumarate salt of bedaquiline on the grounds of lack of inventive step in the light of disclosures in prior published documents. The IPO referred to disclosures relating to bedaquiline and suggestions to make a fumarate salt of bedaquiline in the primary patent (220/DELNP/2005) and also the disclosures in literature about advantages of the salt form over the base compound in terms of bioavailability.

The IPO also took into consideration that the use of TWEEN20 as a wetting agent in pharmaceutical compositions in a particular range is well known in the pharmaceutical field. The IPO noted that the affidavits filed by the Applicant company in support of the patent application failed to prove that the composition of fumarate salt of bedaquiline and TWEEN20 would show surprising effect over the known composition of bedaquiline disclosed in the primary patent. Thus, combining the teachings and suggestions of the prior art, the IPO concluded that the application is obvious to a person skilled in the art.

Additionally the IPO also found that the Applicant had provided data on improved bioavailability to prove Section 3(d). Bioavailability of drugs indicates the percentage, amount or concentration of drug that reaches into the systemic circulation and is available at the site of action. However, the IPO observed that this data was insufficient to satisfy the requirement of enhanced efficacy, as bioavailability is not the same as efficacy. The IPO concluded that 'improved bioavailability would not constitute enhancement in therapeutic efficacy of the pharmaceutical composition unless it shows significant enhancement in known therapeutic efficacy in terms of efficacy results.'

The IPO also found that the Applicant has not proved any synergistic effect of the formulation and considered it as a mere admixture (fumarate salt of bedaquiline and TWEEN20) which is disallowed under Section 3(e) of the Patents Act, 1970. The Supreme Court of India in Novartis AG v Union of India (2013), had ruled that 'efficacy', a term in Section 3(d) of the Patents Act, 1970 means 'therapeutic efficacy – effect of the drug on the body'. It is not the same as bioavailability. The Applicant has to prove that increase in bioavailability should in turn increase the therapeutic efficacy of the drug.

The bedaquiline ruling is relevant not only because it disallows evergreening of patent monopoly on bedaquiline, but it also sets a good precedent for subsequent oppositions on secondary patents relating to pharmaceutical salts, compositions and tablet formulations. Further it encourages the use the public health safeguards such as pre-grant opposition by not only companies or civil society organisations or academicians or scientists, but also patients who are directly affected by the grant of patent monopoly.

This decision is in line with the current WHO guidelines, whereby pretomanid, (another new TB medicine) is to be used in combination with bedaquiline/linezolid/ moxifloxacin (BPaL or BPaLM regimens) for DR-TB and possibly depending on the outcome of clinical trial results, a combination of bedaquiline/moxifloxacin/pyrazinamide (BPaMZ regimen).

Once India adopts the new WHO guideline, the Government will have scaled up the production of bedaquiline. Hence, this order of the IPO is significant as it will reduce the current expensive cost that the Indian Government has to incur to buy bedaquiline. Rejection of the fumarate salt of bedaquiline is not only important for India but also for other developing countries as it may facilitate the export of generic bedaquiline.

However, MSF reports that J&J has licensed bedaquiline to treat drug sustainable TB (DS-TB) to the TB Alliance, who in turn sub-licensed it to two generic companies in India – Viatris (formerly Mylan) and Macleods.[14] With these sub-licenses in place these companies could only supply bedaquiline for DS-TB and not DR-TB. Since these agreements are not available in the public domain, it is not clear whether these licenses have any unbundling clause in the sub-licence. However, other companies who have not entered into licenses are now free to develop the generic bedaquiline.

All India patent offices must disallow evergreening patents.

Since this decision is given by the Mumbai Patent Office, it has only persuasive effect on the decisions of other patent offices in India. While we celebrate this order, the increased grant of patents to existing drugs by the IPO is still a huge problem.

Lack of uniformity in decisions is a crucial issue which leads to conflicting decisions in the grant of secondary patents to salts, polymorph, compositions etc. For instance, the IPO had granted a patent to the combination of tenofovir and emtricitabine in May 2022 (IN 201817001590). Both tenofovir and emtricitabine are known and their combinations were earlier rejected by the IPO.[15] Despite the glaring disclosures in the previously published documents the IPO has granted the patent without applying the inventive step or Section 3(d) appropriately.

Further a patent for a bilayer tablet[16] comprising old HIV drugs – rilpivirine and tenofovir – was granted in 2019 (4424/DELNP/2013).[17] Many of these orders granting secondary patents of the existing drugs have no reasoned decision by the IPO. It appears that the IPO has been lowering the inventive step criteria and granting more and more patents and not implementing the Supreme Court judgement on section 3(d) in their bid to compete with their counterparts in China and the United States.

Apart from the potential benefits in the context of bedaquiline, this recent ruling's significance is broader and deeper. It is an exemplar of how patient groups can effectively use legal safeguards to oppose frivolous secondary patent applications even when the generic pharmaceutical companies are not part of the process.

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[1] World Health Organization. Rapid Communication: Key changes to treatment of multidrug- and rifampicin-resistant tuberculosis (MDR/RR-TB). 2018 https://www.who.int/publications/i/item/WHO-CDS-TB-2018.18

[2] https://cdn.who.int/media/docs/default-source/hq-tuberculosis/global-tuberculosis-report-2022/global-tb-report-2022-factsheet.pdf?sfvrsn=88f8d76_3&download=true

[3] The reported number of people started on treatment for RR-TB and MDR-TB in 2021 was 161 746, covering only about one in three of those in need. https://cdn.who.int/media/docs/default-source/hq-tuberculosis/global-tuberculosis-report-2022/global-tb-report-2022-factsheet.pdf?sfvrsn=88f8d76_3&download=true

[4] World Health Organization Global tuberculosis report 2020. https://apps.who.int/iris/bitstream/handle/10665/336069/9789240013131-eng.pdf. [Ref list]

[5] https://scroll.in/article/941815/in-india-over-56-of-multidrug-resistant-tb-cases-remain-undetected-and-over-64-untreated#:~:text=In%202018%2C%20India%20diagnosed%2044%25%20%E2%80%93%20or%20around,put%20on%20treatment%2C%20the%20Global%20TB%20report%20said.

[6] https://tbcindia.gov.in/WriteReadData/IndiaTBReport2022/TBAnnaulReport2022.pdf

[7] https://scroll.in/article/941815/in-india-over-56-of-multidrug-resistant-tb-cases-remain-undetected-and-over-64-untreated#:~:text=In%202018%2C%20India%20diagnosed%2044%25%20%E2%80%93%20or%20around,put%20on%20treatment%2C%20the%20Global%20TB%20report%20said.

[8] https://www.theguardian.com/global-development/2022/aug/11/patients-are-falling-through-the-cracks-drug-costs-hinder-indias-response-to-tb

[9] https://msfaccess.org/open-letter-jj-calling-affordable-access-critical-tb-drug-bedaquiline

[10] https://www.jnj.com/media-center/press-releases/unique-collaboration-between-tb-alliance-and-tibotec-to-accelerate-tuberculosis-drug-development

[11]Evaluation of Early Bactericidal Activity in Pulmonary Tuberculosis With(J-M-Pa-Z) (NC-001) – Full Text View – ClinicalTrials.gov ; Evaluation of Early Bactericidal Activity in Pulmonary Tuberculosis (TMC207-CL001) – Full Text View – ClinicalTrials.gov; https://clinicaltrials.gov/ct2/show/NCT01341184 ; https://clinicaltrials.gov/ct2/show/NCT00992069

[12] https://msfaccess.org/open-letter-jj-calling-affordable-access-critical-tb-drug-bedaquiline

[13] Gotham, D., McKenna, L., Frick, M., & Lessem, E. (2020). Public investments in the clinical development of bedaquiline. PLoS One, 15(9), e0239118. https://doi.org/10.1371/journal.pone.0239118

[14] MSF Issue Brief, DR-TB Drugs Under the Microscope 2022, 8th Edition. https://msfaccess.org/dr-tb-drugs-under-microscope-8th-edition

[15] This combination is of tenofovir alafenamide fumarate and emtricitabine; earlier combinations of tenofovir disoproxil fumarate and emtricitabine were rejected few years ago. Patent applications relating to tenofovir alafenamide were also rejected before. Further, the combination of tenofovir alafenamide fumarate and emtricitabine was very obvious in light of the literature and disclosures in the prior art. Basically the active ingredients tenofovir and emtricitabine and their combinations are well known in the art.

[16] Bilayer tablets, sometimes called double-layer tablets, are a combination of two or more active pharmaceutical ingredients in a single dosage form. It is a technology for controlled release formulation and the use of bilayered tablets is growing in treatments.

[17] Rilpirivirine combination with tenofovir was rejected by IPO(IN687/DELNP/2006).

Unravelling the commercial determinants of health

Lancet Editorial April 8 2023

www.thelancet.com Vol 401 April 8, 2023

In early March, in the wake of the COVID-19 pandemic, nearly 200 people—including former UN Secretary-General Ban Ki-moon—signed a letter strongly criticising pharmaceutical companies for putting a desire to make extraordinary profits before the needs of humanity. Selling publicly funded vaccines, treatments, and tests to the highest bidder resulted in inequities that cost more than a million lives, while private companies made billions of dollars. The signatories called on world leaders to ensure that such an injustice is never repeated.

The conflict between profits and health equity is not new. The global health community fought for decades to provide access to antiretrovirals for patients with HIV and AIDS in less-resourced settings. Many commercial actors attempt to negatively influence national and international policies, undermine science, or to directly attack individuals calling out their actions. The recent *Lancet* Series on breastfeeding showed how an extensive network of lobbying by formula milk companies has derailed progress on breastfeeding education.

This history speaks to the central importance to health equity of the commercial determinants of health, the subject of a Series published in this April 8 2023 issue of *The Lancet*, led by Rob Moodie of the University of Melbourne, along with authors spanning 15 countries and six continents, with the support of the Victorian Health Promotion Foundation of Australia. The headline findings are startling: four industries (tobacco, unhealthy food, fossil fuel, and alcohol) are responsible for at least a third of global deaths per year. Yet much of the work to understand the harmful (or beneficial) impact of commercial actors has to date been done in health research silos. Each field faces many of the same tactical battles and strategies without a unified agenda to protect health. There is a lack of consensus across fields of health to define and understand the commercial determinants of health. The *Lancet* Series seeks to remedy this long-standing and complex situation with a consensus definition of the commercial determinants of health ('systems, practices, and pathways through which commercial actors drive health and equity'), a framing to understand commercial entities' impact on health, and a commitment to address its challenges in a holistic way.

The Series authors set out a bold vision in which governments, commercial actors, and civil society contribute first and foremost to improving health and societal wellbeing. Such a vision is needed urgently. As the second paper in the Series outlines, commercial actors are diverse and many play a vital role in society, but the products and practices of many are having increasingly negative impacts on human and planetary health and equity. The Series provides a comprehensive agenda for action, recognising the need for regenerative business models and accountable transparent policies (including an end to commercial actors opposition to health regulation and policies).

Moodie emphasises that the Series is not anti-business; it is pro-health. There are some notable good models of pro-health-acting businesses. For example, nearly 200 leading financial institutions (which together manage more than US 16 trillion) have signed a pledge to support tobacco-free policies across lending, investment, and insurance. However, although Environmental, Social and Governance frameworks are increasingly used to guide more responsible investment, they still lack specific health indicators. Health needs to become a crucial consideration of investor frameworks and global capital markets. Doing so will require the adoption of different economic models, new legislative and regulatory measures, civil society advocacy and accountability, and better corporate social responsibility. Governments must be empowered to encourage businesses to prioritise positive health impacts. As Tedros Adhanom Ghebreyesus, WHO Director- General, writes in an accompanying Comment, public health cannot progress without action on the commercial determinants of health. *The Lancet* welcomes the upcoming WHO Congress and first Annual Report on the commercial determinants of health, especially in helping to address non-communicable diseases. Given their huge unresolved impacts, the commercial determinants of health must be recognised—and funded—as a crucial field of research.

Commercial actors and government leaders have a vital opportunity to protect and improve health and advance health equity. The findings of this Series should embolden young researchers, communities, and new government and business leadership to imagine, co-design, and—importantly—invest in a world where human and planetary health is always prioritised over profit.

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See **Series** pages 1194, 1214, and 1229
in *The Lancet*

Vape Products: The Next 'Rahmah-Like' incentive in Malaysia

Dzulkifli Abdul Razak

The Malaysian Poisons Board has (re)discussed the proposed exemption of liquid or gel nicotine used in e-cigarettes and vape products from control under the Poisons Act 1952, so that nicotine e-liquids will be exempted from Poisons List of controlled substances April 1 in an order gazetted by Finance Minister. In other words, there was a big U-turn! If it is meant to an April Fool's joke, it is a deadly one.

The move has just switched the toxic item to junk food item, similar to chewing gum, readily available to all!

Instead of bringing mercy to all, many more will be exposed to a highly addictive poison in stark contradiction to safeguarding the sanctity and sacredness of life. There are almost 30,000 tobacco-related deaths in Malaysia annually.

The issue of tobacco control is a vital one, especially involving young adults, not only to prevent avoidable loss of life, but also tobacco addiction. The success rate for elimination of the tobacco menace seems a dismal one after spending billions of ringgit, and after so many decades. In short, we are losing the war!

Hence, the enthusiasm to support the recent actions aimed at elimination of 'vaping' is overwhelming given well-documented evidence in many neighbouring countries, and internationally particularly in the more health-enlightened ones.

Muslim countries and communities are generally laggards in this endeavour. In Malaysia, for instance, the decline in smoking prevalence has been slow.

Male smoking prevalence has remained persistently high, with only a slight decline from 49.5 percent in 2003 to 40.5 percent in 2019. The rate of adolescents who smoke is about 13.8 percent putting Malaysia among the poorly ranked even among ASEAN countries.

Therefore, when the Poisons Board, an independent national body formed under the Poisons Act to advise the health minister, wholly objected to the government's proposal and moved 'to exclude liquid nicotine from the Poisons List on the basis that the harm of allowing e-cigarettes and vape to be sold to anyone, including children.' It was another impetus for a battle to strengthen tobacco control. The unanimously rejection of the government's proposal came ahead of the April 1 planned taxation of e-cigarettes and vape products.

The Health Minister however, can reverse the decision as she holds the ultimate power to amend the Poisons List. Arguably, rejection is 'outweighed by the benefit of tax revenue' from such products containing nicotine, a highly addictive substance.'

The 'vaping epidemics' especially among youth have now been a global concern, leading to some firm policy decisions taken to prevent the 'poison' ingredient from being accessible by making it a controlled substance.

The United Kingdom reportedly prohibits the sale of e-cigarettes and vaping products to anyone below 18 years of age. Among ASEAN nations, Brunei, Cambodia, Laos, Singapore and Thailand have already banned vape and 'health tobacco' products.

Malaysia has been mulling the issue since 2015 as if the high annual death toll of its citizens due to tobacco (mis)used is not impactful enough.

This Malaysian move is despite the World Health Organisation Framework Convention on Tobacco Control Article 16 calling for a ban on sales to and by minors, consistent with the Convention on the Rights of the Child, which Malaysia is a party to and thereby obligated to - to protect children from harm.

The fact remains that vaping among Malaysian school children is already problematic, with more girls starting to vape and about 10 percent of adolescents — 17 percent of teenage boys and 3 percent of teenage girls — vape.

Their numbers are expected to increase in coming years with easy online access to the products through (bad) influencers on social media.

Having said that, hopes were raised when the new Minister of Health issued a long-awaited statement in January 2023, to express her concern about the promotion, advertising, and sale of e-cigarettes and vape products that resembled children's toys.

She had also duly noted then that the sale of liquid nicotine was controlled under the Poisons Act. This provision resonates well with the earlier statements made by professional bodies like the Malaysian Medical Association, the Malaysian Pharmacists Society, and the Galen Centre for Health and Social Policy denouncing the exclusion of nicotine from control under the Poisons Act.

These bodies categorically highlighted that the Malaysian plan ran contrary to public health and would lead to 'cheap vape disposables containing high concentrations of liquid nicotine flooding the market.' Unfortunately, their efforts to convince the Poisons Board have been unsuccessful.

The toxic products have been switched to the category of junk food items, similar to chewing gum, readily available to all! - much to the delight of the B40 vape-users and the ardent supporters. Instead of bringing mercy to all, many more will be exposed to highly addictive poison in stark contradiction to the essence of 'Rahmah' [4] in safeguarding the sanctity and sacredness of life!

[4] According to Imam Ibn al Jawzi, rahmah means loving and caring. Love and care are basic to the wellbeing as well as happiness and survival of human beings. Without these attributes in existence, there would be no life, no respect, and no collaboration among human beings.

How lies help to sell 'Vapes'

The Conversation 6 March 2023

Anna Evangeli Deputy Health editor

https://theconversation.cmail19.com/t/r-e-tjukihil-ojddhdjilu-r/

It is so easy to buy vapes or e-cigarettes online. Usually, buyers just have to check a box to say they're aged 18 or over. They rarely have to show ID.

If buyers are new to vaping, there are products bundled together as 'starter packs'. There are deals and discounts, loyalty schemes and free delivery.

Then there are the health claims – false or misleading claims about how vapes contain 'zero' carcinogens, are an effective aid for quitting smoking, and lead to improved breathing 'in a matter of days'.

Vapes are marketed as sexy, sleek and environmentally friendly.

These are just some of the research findings Jonine Jancey from Curtin University shares today.[5]

And many of these tactics – marketing to young people, positioning vaping as 'cool', and saying it has health benefits – are taken from the same playbook as those used for smoking decades ago. Which is no surprise, explains Simon Chapman,[6] as all the major tobacco companies are now manufacturing vapes as well.

It took decades for the disease burden of smoking to appear, and even longer for successful tobacco control, thanks to the stymying efforts of Big Tobacco. It's often said that if cigarettes were invented tomorrow, and we knew of their health harms, they would be banned outright. So, he asks, why are we letting history repeat itself with vaping?

[5] https://tinyurl.com/3x3udum8

Australia: 'Indigenous health renaissance': new journal and new graduates

MJA Insight Issue 9 / 20 March 2023

Becca Whitehead

[Becca Whitehead has written for The Age and The Sydney Morning Herald newspapers, Women's Health Magazine Australia, Wellbeing magazine, and many others. Rebecca writes about health, science, and is an excellent interviewer (live on radio, as well as for articles and profiles).

She said First Nations health is urgent and important. 'A couple of cool things happened this month and I've been lucky to get to write about them for the Medical Journal of Australia mag, InSight+.']

MJA Insight Issue 9 / 20 March 2023

Indigenous health advocates hope that the launch of a new, dedicated First Nations health journal will help Close the Gap, while in a small town in the Northern Territory, six students have made local history by graduating with qualifications in Aboriginal Primary Health Care.

Six students have graduated from the Mala'la Health Service Aboriginal Corporation, in a town in Arnhem Land, with a Certificate II in Aboriginal Primary Health Care.

They become the first graduates to achieve nationally recognised health qualifications on-country in Maningrida.

The Maningrida Health Service, formerly under Northern Territory Government control, transitioned to Aboriginal community control in 2021.

Seide Ramadani, Training Coordinator at Mala'la Health, is overjoyed at what the graduates have achieved, after identifying they had a shortage of qualified Aboriginal health workers.

'Mala'la looked at local workforce development and professional learning pathways,' Ms Ramadani said.

[6] https://tinyurl.com/2p99utnw

'We created a place-based training model to support adult learner engagement and retention, and increase likelihood of course completion,' she said.

Mala'la Health partnered with the Northern Territory Primary Health Network and Ninti Training to tailor and deliver the course.

Among the six students to graduate earlier this month were Natasha Bond and Jermaine Namanurki, who both received Student-of-the-Year awards.

'I've got so many choices of pathways to choose from, and I'm just so excited about it,' Ms Bond said.

'It was important to show that it doesn't matter who you are, where you're from, anything is possible.'

One significant benefit of training on-country was real-time translation, both literally (the graduates speak seven languages between them) and culturally.

'It's important to know about this stuff so that we can encourage our families and friends to not be afraid about coming into the clinic,' Mr Namanurki said. 'That's the reason that we went forward for this course,' he said. Mr Namanurki plans to continue studies and become a fully qualified health care professional.

Aboriginal Workforce Coordinator at Mala'la Health, James Woods, has been a part of the generational chain of mentors leading to these promising changes in Indigenous-led health.

'This was the model – breaking the gap in communication,' Mr Woods said. 'Getting back to that on-the-job training that was gone over the decades. The [graduates] understand the Western medical terminology and they take it to the community.'

According to a national health profile study[7], although there has been growth in the number of Indigenous health workers, the growth is not commensurate with Aboriginal and Torres Strait Islander population growth. 'It's a journey, and our graduates have paved for others to follow as well, now,' Ms Ramadani said.

Indigenous health 'renaissance'

Meanwhile, half a country away in Melbourne, the Lowitja Institute, Australia's first community-controlled Indigenous research institute, has created a new, international, inter- and multidisciplinary peer-reviewed, open-access journal dedicated to collecting and expanding access to First Nations research.

First Nations Health and Wellbeing — The *Lowitja* Journal will focus on primary research articles, systematic reviews and informed short reports on all aspects of science, culture, philosophy and practice surrounding health and wellbeing for First Nation people and communities. Professor Catherine Chamberlain is the editor-in-chief of the journal, which is based in Melbourne.[8]

She told *InSight+* that the journal's goal is to provide good quality evidence that can inform effective policies and programs to improve health outcomes for First Nations people. 'That is how we improve health outcomes,' Professor Chamberlain said. 'The journal is going to provide authentic Indigenous evidence – about us, and for us.' All articles published in the journal must contain substantive contributions from First Nations authors.

Chamberlain said that while the journal's key focus was aligned with Closing the Gap,[9] it would also collect crucial and overlooked cultural knowledge underpinning generations of Indigenous good health and wellbeing.

'Prior to colonisation, Aboriginal Torres Strait Islander people were healthier than non-Indigenous people,' Professor Chamberlain said. '[We had] a thriving spiritual culture for over 2000 generations. With colonisation, everything changed.

'But that state of wellbeing wasn't achieved by accident. We've had sophisticated understandings of what it takes to achieve social and emotional wellbeing. 'We've dealt with devastation before. We've lived through ice ages. The purpose of the journal is to support an Indigenous [health] renaissance.

'All the 'knowledge' about indigenous people was generated by non-Indigenous researchers, and it's underpinned by assumptions, superiority and racism that has informed our health programs and policies. So, this journal is really important.'

Medical Journal of Australia editor-in-chief, Professor Virginia Barbour, has warmly welcomed the new journal.

'First Nations Health and Wellbeing is an important initiative to address and highlight the specific health issues that Indigenous Australians face,' Professor Barbour said. 'At the Medical Journal of Australia, we are committed to publishing on indigenous health issues. 'I very much welcome this journal and its First Nations leadership and would be keen to collaborate with Professor Chamberlain and her colleagues as the journal develops.'

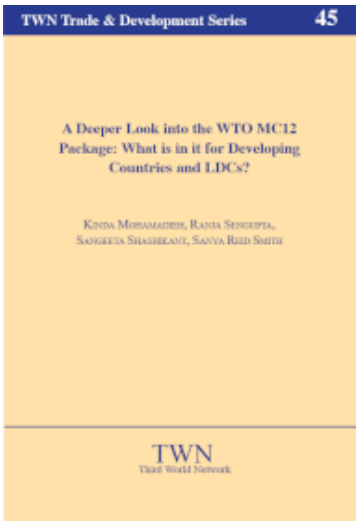
The *Lowitja* Journal was developed in partnership with Elsevier and the Coalition of the Peaks, and will consider research articles on any topics relating to First Nations health and wellbeing. Submissions are currently open and free until December 2023. The journal will officially launch at the 3rd International Indigenous Health and Wellbeing Conference, being held from 14 to 16 June 2023, in Cairns, Queensland.

[7] https://drive.google.com/file/d/1XThllalTVyQbu6l--UivNSLyPm5owsaY/view

[8] https://www.closingthegap.gov.au/

[9] https://www.closingthegap.gov.au/

New books from TWN



TWN Trade & Development series no. 45

A Deeper Look into the WTO MC12 Package: What is in it for Developing Countries and LDCs?

By *Kinda Mohamadieh, Ranja Sengupta, Sangeeta Shashikant and Sanya Reid Smith*

Publisher: TWN Year: 2022 No. of pages: 58

Download the book
https://www.twn.my/title/tnd/td45.htm

About the Book

The World Trade Organization (WTO) has been lauded for overcoming longstanding negotiating deadlock to adopt a set of substantive decisions and agreements at its 12th Ministerial Conference (MC12) in June 2022. However, when viewed from the standpoint of the WTO's developing and least-developed member states, these outcomes deliver disappointingly little, this report maintains/argues. The authors examine the main elements of the MC12 package – encompassing such issues as WTO reform, a TRIPS decision, pandemic response, agriculture, fisheries subsidies and electronic commerce – and find that they largely fail to address core concerns of the developing and least-developed countries.

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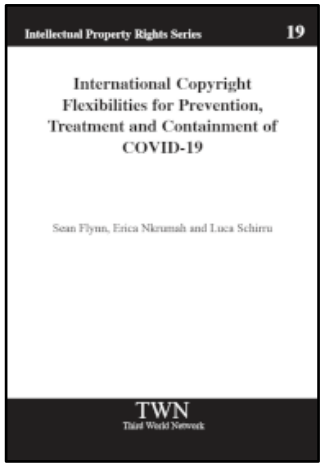

Intellectual Property Rights Series no. 19

International Copyright Flexibilities for Prevention, Treatment and Containment of COVID-19

By *Sean Flynn, Erica Nkrumah and Luca Schirru*
Publisher: TWN Year: 2022 No. of pages: 28

Download the book

About the Book

Most policymaking attention with respect to intellectual property barriers to COVID-19 prevention, treatment and containment has been focused on patents. This focus is reflected in the World Trade Organisation (WTO) Ministerial Decision on the TRIPS Agreement, adopted on 17 June 2022, which provides a limited waiver of TRIPS rules on compulsory licences for production of COVID-19 vaccines. The original WTO proposal for a TRIPS waiver, however, explicitly applied to all forms of intellectual property, including copyright. This paper outlines the numerous ways in which copyright can create barriers to addressing COVID-19. It also provides a description of international copyright treaty provisions that permit uses of copyright materials in response to the barriers identified, despite the exclusion of copyright from the final TRIPS waiver.

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