

December 2022

HAI AP News

Penang, Malaysia

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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.

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In this issue: We welcome Dr Pem Chuki from Bhutan to our HAIAP family. She is the Deputy Medical Superintendent of Jigne Dorji Wangchuck National Referral Hospital. Pem was the visiting editor with Therapeutic Guidelines (TG) in Melbourne in October under the TG Partnership Program, as described in *HAIAP* at 40, page 149.

During her time with TG she shared insights about her own country's health system with the group. See <https://www.haiasiapacific.org/wp-content/uploads/2022/12/Dr.-Pem-Chuki-Bhutan-Reduced.pdf>



We remember Dr Prem Chandran John who had been with us almost from the beginning. After a long illness he passed away on November 4, 2022. Our sincere condolences are with his wife Dr Hari and his three children.

In December, 2022, we see two notable anniversaries: the 200th anniversary of the birth of Louis Pasteur and the third anniversary of China's announcement of the outbreak that led to the COVID-19 pandemic. *Lancet* December 17 2022 devoted much space to the legacy of Louis Pasteur. It is worth exploring the complete issue. Here in HAIAP News we feature some of the content including the complete article setting Pasteur's legacy in the context of the COVID-19 pandemic, page 6.

Unfortunately we say goodbye to Australia's National Prescribing Service that has provided independent information and guidance for 24 years.

Richard Laing analyses articles about the understanding of selection of cancer drugs for inclusion in the WHO EML.

The Olle Hansson Award 2023: Nominations for this award close on January 31 2023.

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

Remembering Dr Prem Chandran John



The Future of our Health Services was the theme of the 2006 HAIAP Regional Consultation held at Gonoshasthaya Kendra in Bangladesh.

On the first day of the consultation Dr Prem, who was Chair of the HAIAP Governing Council at that time, raised a number of questions relevant to the theme and suggested directions to follow to achieve health for all.

Dr Prem Chandran John presentation at GK 2006:

- Whose Health Services are we talking about?
- What do we mean by 'our health service'?
- Who is 'served' by our health services?

Health Services alone can improve health **only to a certain extent**. Beyond that, other determinants need to be addressed.

Does the existence of good health services mean good health or equity in health?

Looking at the USA it is clearly not so.

So what determines access to good health services?

First of all - who you are:

Caste, class, gender, ethnicity, religion etc., all determine who you are as well as where you are from and where you live (rural-urban, ghetto-slum) - and how much you earn!

Ultimately, it is a Question of Power.

Ruling classes everywhere rule primarily for their own benefit and only incidentally for the benefit of others. There is no such thing as a free lunch.

We ask - does increasing GDP growth or an 8% economic growth rate mean better health?

Looking at the example of India - clearly the answer is No.

Conversely, is a per capita GDP of \$ 2,000 necessary to have good health services?

Looking at South Korea - good health and good services preceded their economic boom.

When socio-economic disparities are exacerbated, even existing 'good' health services deteriorate - as illustrated by the examples of South Africa and Sri Lanka. There is no evidence that in those settings more medical schools, more schools of public health, or more hospitals resulted in better health services or better health.

Factors that have an impact on health services:

Looking at the example of India - Reduction/removal of subsidies on public services such as in health, education, food and privatisation of such services; inappropriate

national priorities – developing or importing missiles; importing WTO inspired luxury imports; engaging in Trade and other treaties such as GATS, TRIPS etc. and changing cropping patterns all have an enormous impact as do inappropriate pricing policies.

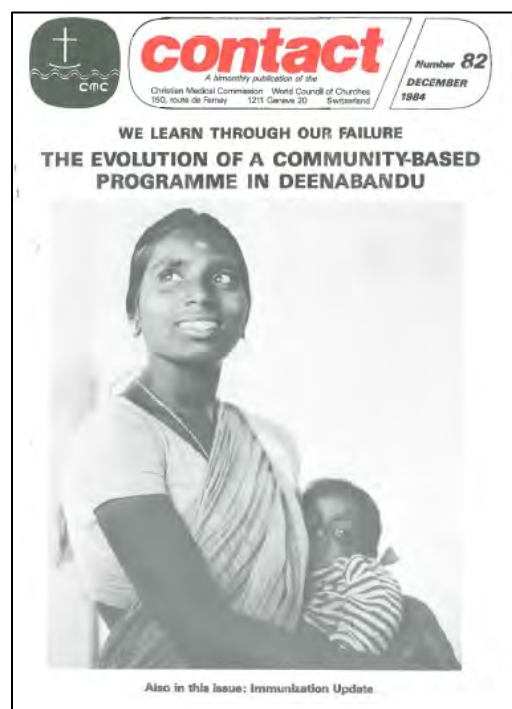
So what can we do?

Information: We must generate, collate and propagate accurate and trustworthy and information.

Other initiatives include:

- Sensitisation of decision makers like politicians and civil servants who exert pressure from above
- Addressing Social Determinants
- Ensuring equal opportunities, level playing fields
- Always engaging in participatory, grassroots democratic approaches to activities
- Solidarity building at local, national and international levels.

In 1984 Dr Prem and his wife Dr Hari wrote an important article for **CONTACT** - a publication of the Christian Medical Commission of the World Council of Churches.



The program described in the article 'We Learn Through Our failures: the evolution of a community based program in Deennabandu' relates the experiences of Drs Hari and Prem Chandran John in moving towards community based health care in a program started by Prem's father in a remote area of southern India on the border of Tamil Nadu and Andra Pradesh.

The article begins: *It was 1946. the British star in India was waning. Successful negotiations for transfer of power were going on. Ghandi was marching triumphantly all over India and*

had just delivered an impassioned plea for peace, communal harmony and development of villages.

The complete issue of CONTACT Number 82, December 1984 can be downloaded here:

<https://www.haiasiapacific.org/wp-content/uploads/2022/12/CONTACT82-Dec-1984-The-evolution-of-a-community-based-programme-in-Deenabandu.pdf>

Read the whole important story by Dr Prem and Dr Hari from the early pioneering days to achievement of a sustained comprehensive health program that is truly community based.

OLLE HANSSON AWARD 2023

Please send nominations to Haiasiapacific@gmail.com -
Subject: Olle Hansson Award



**Application
deadline
31 January 2023**

'It is time to act! It is time to act for all of us who believe in human dignity and justice'. - Olle Hansson

The Award recognises the work of an individual from a developing country who best demonstrates the qualities of Dr Olle Hansson in promoting the rational use of drugs.

Dr Olle Hansson was an icon of the activist medical profession and wrote a classic in medical investigative exposure. The book was called 'INSIDE CIBA GEIGY' and was published in Penang, Malaysia in 1989. It is an amazing piece and we quote from the Foreword written by Anwar Fazal, former President of International Organisation of Consumers Union (IOCU), cofounder of Health Action International (HAI) and the instigator for the idea of a Peoples Health Assembly. The Award was first given in 1987.

'Olle was a very special inspiration to us. His courage, his competence, his commitment were rare in a profession that is more often too comfortable or too implicated to speak out against a powerful industry.'

'His passing on 23 May 1985 was mourned not by words but by a series of actions that will continue to inspire those working to see a more responsible pharmaceutical industry worldwide.'

To mark the 40th anniversary of HAIAP, we announced the Dr Olle Hansson Award again. Nominations are invited for the Award for 2023.

This Award recognises the work of an individual from a low or middle income country according the reference list¹ who has contributed the most to:

1. Promoting the concepts of essential medicines and their rational use, and access to vaccines.
2. Increasing the awareness among consumers of the dangers of irrational and hazardous medicinal drugs and unethical marketing.
3. Supporting and promoting health for all and addressing the structural and human rights issues relating to health.

Nominations for the award, which can come from any individual or organisation, should contain:

1. A one-page biodata of the candidate (including educational background, positions held, affiliations, honours and awards).
2. A 500-word statement of the nominee's qualities and achievements in the field of medicines' safety and access to essential medicines and their rational use. Please provide:
 - a. documentation of work done.
 - b. A recent photograph of the nominee.
3. Two referee's names, affiliations and addresses.

Closing Date: Nominations will close on **January 31 2023**.

Please send nominations to: Haiasiapacific@gmail.com

The Award, which is given annually, is in the form of a commemorative certificate and a special oration and ceremony. It is managed by Health Action International Asia - Pacific (HAIAP).

About Dr Olle Hansson: The Award is named in honour of Dr Olle Hansson, a Swedish paediatric neurologist internationally known for his advocacy on behalf of SMON (subacute myelo-optic neuropathy) victims who were paralysed or blinded after using clioquinol, an antidiarrhoeal drug.

Dr Olle Hansson was a powerful campaigner against unethical promotion and marketing of medicinal drugs. In many ways, he represented the conscience of the medical profession. His influence was felt not only in Sweden, and in Japan which had thousands of SMON victims, but also in Europe and developing countries. Dr Hansson will be remembered by all who campaign for the rational use of medicinal drugs. Although he died of cancer on May 23, 1985, at the age of 49, he remains a continuing source of inspiration for public interest workers everywhere. May 23 is commemorated each year as 'Dr Olle Hansson Day'. For more information about Dr Olle Hansson, see <http://www.haiasiapacific.org/?s=Olle+Hansson>

¹ <https://wellcome.org/grant-funding/guidance/low-and-middle-income-countries>

QUALITY USE OF ANTIMICROBIALS

BHUTAN: Antimicrobial stewardship 2022

Pem Chuki, Deputy Medical Superintendent, Jigme Dorji Wangchuck National Referral Hospital.

The National Action Plan to combat AMR (2018-2022) was launched in 2017. Work on updating this plan for the future years has now begun.

The Plan for 2018-2022 was aligned with WHO Global Action Plan with the **One Health** approach covering sectors related to human health, animal health and agriculture practice.

A National AMR Technical group was formed with Terms of Reference and the following Objectives:

Objective 1: To establish a governance structure to spearhead the AMR activities.

Objective 2: To promote rational use of antimicrobial agents at all levels of health care and veterinary settings

Objective 3: To institute surveillance and monitoring system on AMR and antimicrobials use.

Objective 4: To create and promote awareness on AMR through educational and public campaigns.

Antimicrobial Stewardship (AMS)

AMS had been established in 2016 in the National hospital and then expanded to two other regional hospitals. The AMS program was led by a clinical pharmacologist (Dr Pem Chuki) supported by a multidisciplinary AMS committee including the medical superintendent, microbiology laboratory staff, pharmacist, IPC nurse, physicians and surgeons.

AMS activities

Activities include:

- Post prescription review, audit and feedback covering duplicate therapy, use of products that were broader spectrum than needed, IV to oral switching, dose optimisation and de-escalation of therapy
- Formulary restrictions for higher generation antimicrobials
- Guideline development and dissemination
- Education and training of health care workers
- Antibigram dissemination
- Development of Standard Operating Procedures for surgical prophylaxis, antibiotic skin testing, blood culture withdrawal
- Public awareness activities through media, brochures especially during annual World Antibiotic Awareness Weeks (WAAWs).

WAAW Bhutan 2022

During the recent WAAW, activities included an advocacy program on AMR for School health coordinators and high school health captains.

A similar program was conducted for the final students of Nursing College of Bhutan.

To close the WAAW we conducted a very high-level meeting called the Inter-ministerial Committee on One Health (IMCOH) chaired by Her Excellency the Health Minister. Various policy briefs and statements were developed.



Papua New Guinea Antimicrobial Guidelines

Mieke Hutchinson Kern - Therapeutic Guidelines

The National Department of Health in Papua New Guinea (PNG) has partnered with the World Health Organization, Burnet Institute and Therapeutic Guidelines to develop its first national antimicrobial guidelines.

Strengthening appropriate access to and optimising the use of antimicrobial medicines is a key objective of PNG's National Action Plan on Antimicrobial Resistance (AMR) 2019 to 2023. The aim of the guidelines is to provide practical advice to healthcare practitioners in PNG to choose the best management for their patients, aligning antimicrobial use with evidence and local epidemiology and susceptibility data. This project will also include updating the list of antimicrobials on the essential medicines list.

Antimicrobial guidelines are complex to develop. A guideline writing committee has been established with PNG clinicians from various health disciplines and specialties together with technical advisors with expertise in infectious disease and guideline writing from Australia. Writing of the content is underway with an ambitious target to complete the guidelines ready for publication by the end of August 2023

WHO fungal priority pathogens list to guide research, development and public health action

Download the whole publication from:
<https://www.who.int/publications/i/item/9789240060241>
FungalPathogensWHO2022-eng.pdf

This document proposes actions and strategies for policymakers, public health professionals and other stakeholders, targeted at improving the overall response to these priority fungal pathogens, including preventing the development of antifungal drug resistance. Three primary areas for action are proposed, focusing on:

- (1) strengthening laboratory capacity and surveillance;
- (2) sustainable investments in research, development, and innovation; and
- (3) public health interventions.

The 19 fungal pathogens included were ranked and categorized into three priority groups based on their numerical scores, and consensus discussions among the WHO AG FPP: critical, high and medium priority.

Four critical priority pathogens

Of greatest concern these are ranked highest on the list due to their high mortality, public health impact and/or risk of antifungal resistance. They are:

Aspergillus fumigatus, which mainly affects the lungs, and is becoming increasingly resistant to azole medicines. Infections caused by azole-resistant strains kill 47-88% of affected patients.

Candida albicans which can cause invasive infections, typically in vulnerable patients, and kills 20-50% of affected people. It and *A. fumigatus* are the two most common fungal pathogens globally.

Cryptococcus neoformans which has a propensity to infect the brain, especially in immunocompromised people. The main risk factor globally is HIV infection, and it is a leading killer in this population. It is more often found in Australia in transplant patients.

Candida auris - a newly emerged pathogen. Resistant to most antifungal medications, it presents a huge treatment challenge for hospitals. It is so environmentally tenacious that affected wards may have to close for prolonged periods to avoid transmission between patients.

High priority group: *Nakaseomyces glabrata* (*Candida glabrata*), *Histoplasma spp.*, *eumycetoma causative agents*, *Mucorales*, *Fusarium spp.*, *Candida tropicalis* and *Candida parapsilosis*.

Medium priority group: *Scedosporium spp.*, *Lomentospora prolificans*, *Coccidioides spp.*, *Pichia kudriavzevii* (*Candida krusei*), *Cryptococcus gattii*, *Talaromyces marneffeii*, *Pneumocystis jirovecii* and *Paracoccidioides spp.*

Executive summary

Infectious diseases are among the top causes of mortality and a leading cause of disability worldwide. Drug-resistant bacterial infections are estimated to directly cause 1.27 million deaths and to contribute to approximately 4.95 million deaths every year, with the greatest burden in resource-limited settings. Against the backdrop of this major global health threat, invasive fungal diseases (IFDs) are rising overall and particularly among immuno-compromised populations. The diagnosis and treatment of IFDs are challenged by limited access to quality diagnostics and treatment as well as emergence of antifungal resistance in many settings.

HAIAP at 40 1981-2021



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Feature: The legacy of Louis Pasteur

The Lancet Dec 17 2022

<https://www.thelancet.com/action/showPdf?pii=S0140-6736%2822%2902573-9>

Louis Pasteur 200 years

In December, 2022, we see two notable anniversaries: the 200th anniversary of the birth of Louis Pasteur and the third anniversary of China's announcement of the outbreak that led to the COVID-19 pandemic. *Lancet* December 17 2022 devoted much space to the legacy of Louis Pasteur. It is worth exploring the complete issue.



Born in France on Dec 27, 1822, Pasteur was a young polymath when he embarked on a path of discovery with profound societal relevance. By the age of 40 years, he was a national hero and an international authority on microbiology, vaccines, and immunology. His germ theory of disease laid the foundation for hygiene and sanitation within public and

global health. He developed the first vaccine against human rabies in 1885. Along with other great scientists of his time, Pasteur shaped scientific reasoning and communication for the better, creating a legacy that catalysed progress in human health that has been sustained for the past 150 years. Yet infectious diseases continue to cause millions of unnecessary deaths. Even before the COVID-19 pandemic, global burden of disease (GBD) data indicated that infections were involved in more than 20% of deaths globally. A GBD study in this special themed issue of *The Lancet* indicates that 13.6% of deaths globally are associated with just 33 bacterial pathogens.

Throughout this issue of *The Lancet*, the barriers to realising Pasteur's legacy in combatting infectious diseases become apparent.

It becomes apparent that failures in rendering equal protection to all are consequences of health inequities that are propagated by sociocultural and political environments, civil insecurity, and ineffective messaging and community engagement. The 21st century is seeing a changing landscape of infectious diseases. Old and new pathogens are emerging under growing pressure of anthropogenic forces. Climate change is affecting the distribution and transmission of pathogens. Antimicrobial resistance (AMR) and emerging zoonoses are profound threats, now and in the immediate future.

More than one million people—a number set to rise—die from bacterial AMR each year, disproportionately affecting people where health care and sanitation infrastructure are weakest. Pandemics will become more common, yet lessons from COVID-19 are being ignored.

To combat such threats, the *Lancet Commission On Lessons For The Future From The COVID-19 Pandemic* calls for prosociality, whereby governments and institutions reorient towards multilateral systems that foster international public health collaboration and solidarity.

The unstable social and political context in which we live our lives is creating new public health challenges. An infodemic has seen the rapid spread of misinformation that resonates with people in ways that expert advice does not. Vaccine hesitancy is now a major barrier to fighting infectious diseases, particularly in high-income countries. Many parents are reluctant to vaccinate their children because of concerns about vaccine safety, despite reassurances from doctors and public health authorities. This hesitancy reflects a broader breakdown of trust in the state and in scientists. As Ilana Lowy and William Bynum note, Pasteur crafted his public image to bolster support for his research. He understood the power of knowledge, know-how, and dissemination of information in his relationship with the public. Now, more than ever, the medical research community needs to hone creative and authentic science communication and public engagement skills to rebuild trust with a divided society so their work can save lives.

'In our century, science is the soul of the prosperity of nations and the living source of progress. Undoubtedly, the tiring daily discussions of politics seem to be our guide—empty appearances!—what really leads us forward are a few scientific discoveries and their applications.'

These words of Pasteur's could not be more poignant in a 21st century shaping up to be dominated by polarising and health-harming politics. Pasteur understood that science is fundamental for human health, and his values — scientific presence and engagement in public health crises — belong at the heart of efforts against infectious diseases.

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Louis Pasteur, COVID-19, and the social challenges of epidemics

<https://www.thelancet.com/action/showPdf?pii=S0140-6736%2822%2902488-6>

[Please access the references from the original publication]

December, 2022, sees two notable anniversaries: the 200th anniversary of the birth of Louis Pasteur and the third anniversary of China's announcement of the outbreak that would lead to the COVID-19 pandemic. These coinciding events provide an opportunity to reflect on past and current global challenges to bring epidemics under control. Pasteur himself was inextricably connected with a late 19th-century social hygienist movement to promote the health of populations and cities.¹ With other noteworthy scientists, including Robert Koch, Agostino Bassi, and Joseph Lister, Pasteur helped to generate a new field of microbiology, developing new knowledge on fermentation, biogenesis, and germ theory. He contributed substantially to the development of tools for infectious disease control in humans and animals, such as vaccines for anthrax, rabies, and poultry cholera.

The fields of microbiology and vaccinology, both legacies of Pasteur and his contemporaries, expanded globally during the late 19th and early 20th centuries via the research and initiatives of many individuals and organisations, including Oswaldo Cruz,² whose 150th birthday was also celebrated in 2022. These legacies, along with late 19th and 20th century social opposition to hygienic measures and vaccination around the world,³ have been prominent in the COVID-19 pandemic. Pandemic responses have been hindered by weak public engagement with science and public health, if we understand public engagement to be a multidirectional exchange involving an 'interchange of perspectives, opinions, and ideas'⁴ between authorities, researchers, the public, and other multisectoral interests, the inclusion of the public in pandemic response, and clear scientific and public health communications.^{4,5}

The COVID-19 pandemic and responses to it have highlighted unaddressed health and social inequities that have contributed to increased mortality and morbidity in people with chronic illnesses and reduced incomes.

Adhering to pandemic control measures, gaining access to COVID-19 vaccines, and enduring the economic and social burdens of these measures have been difficult for some populations, including those in low-income settings and in racially and ethnically minoritised, generational, and gender groups.⁵⁻⁷ Redressing these social challenges will require fundamental changes in the old Pasteur-era alliances with political and economic interests that Pasteur himself relied on to support his research and infection control interventions. A substantial integration of social sciences is needed to elucidate reasons for and potential solutions to weak public

engagement and health and social inequities. Public engagement to establish priorities for redressing these inequities and preventing their exacerbation in future pandemics is also required.⁸

Current public concerns about the quality and effectiveness of vaccines (the second legacy of Pasteur), transparency of data related to vaccine development, support for mass vaccination, and vaccine producer profits are not new.^{9,10} In many countries, including France, 19th-century vaccine sceptics, including doctors, scientists, and agriculturalists, questioned the need for vaccination, contending that it constituted an 'unnatural',¹¹ even toxic intervention. They criticised Pasteur's links to agricultural and industrial interests.¹¹ Distrust of the safety of and need for vaccination increased in the early 20th century in Rio de Janeiro, Brazil, when Oswaldo Cruz faced a so-called vaccine revolt against smallpox eradication efforts as part of an urban sanitation policy.¹²

The expansion of Rio de Janeiro had displaced the poorest inhabitants of the city to nearby hills, facilitating the construction of favelas. Cruz's policy of compulsory smallpox vaccination and authoritarian hygienic measures further increased popular distrust and opposition to his sanitation plan.¹² The effectiveness of vaccines and sanitation interventions were the priority at the time; recognising, understanding, and responding to the consequences of these sanitation policies and measures on the most marginalised in society, including popular opposition, were not.

Pasteur responded to criticisms of vaccines and other hygienic measures by arguing that the science could speak for itself; he claimed to be 'disinterested' in industrial and political interests, instead motivated by 'a real love of science'.¹¹ However, Pasteur's actions throughout his career contradicted this rhetoric. From studies of fermentation and pébrine (ie, silkworm disease) to investigations of rabies and vaccination, Pasteur and his colleagues largely depended on the patronage of political authorities and agricultural interests to fund research activities, and actively engaged with state authorities, industry, clinicians, veterinarians, and farmers to support research and vaccine production.¹³

Historical studies of science show that science as Pasteur, his colleagues, and his followers practised it was never isolated from the social, political, and economic contexts in which it took place.^{1,11} The scientific and public health institutes created in the late 19th and 20th centuries were important sites of public engagement in science. However, they simultaneously relied on and reproduced elite power and socio-political inequalities, particularly in colonial and postcolonial contexts.¹⁴ In the current COVID-19 pandemic, both public engagement in science and public health and pandemic-exacerbated social and health inequalities are crucial and intertwined weaknesses. One

indicator of weak public engagement is the so-called COVID-19 infodemic — an excess circulation of disinformation and misinformation about the COVID-19 pandemic, including its origins, treatments, and control measures.^{9,10,15} Weak public engagement has been partly supported by intense social mistrust of political and health authorities and scientists, but also by little public inclusion in the pandemic responses.^{5,9,10,16}

Investigations from social scientists between 2020 and 2022 have shown that social mistrust and distrust are 'inequality-driven'.¹⁵ Social groups and communities experiencing historical exclusions and structural inequities may be more likely to embrace this misinformation and disinformation.^{15,17,18} Therefore, weak public engagement in science and public health and serious health inequities are intertwined, and Pasteur's model of public health, supported by alliances of science, state, and economic interests, cannot respond to these social challenges.

Social sciences research shows that social and health inequities among the most socioeconomically disadvantaged have been compounded by control measures,^{5,19} similar to the dislocations precipitated by Cruz's social hygiene measures in the early 20th century. In the COVID-19 pandemic, some social groups, including informal workers, undocumented migrants, people older than 65 years, low-income populations, and people living in collective housing, substandard housing,

or informal settlements, have found it difficult to adhere to Pasteurian hygienic measures (eg, physical distancing, mask wearing, and aeration of living and working environments) when other, more important concerns (eg, food, childcare, and income) exist and when suitable housing, clean water, sewage systems, and health care are not accessible.²⁰

Consequences of control measures have included income loss, increased domestic violence, interrupted education, social isolation, and mental illness.^{19,21}

The management of pandemics is never only about disease surveillance, diagnostics, vaccines, and treatments. Pasteur's legacies of microbiology and disease prevention through hygienic measures and vaccination have remained crucial during the COVID-19 pandemic.

However, beyond such efforts, pandemic management and preparedness should also be about recognising and addressing the global, regional, and local inequities that have prevented all populations from securing health and wellbeing. An initial advance would entail strengthened scientific and public health dialogue and consultation with local populations to account for their experiences and priorities.

The social sciences have a crucial role in identifying hidden vulnerabilities and the power relations that produce and entrench them; evaluating the social

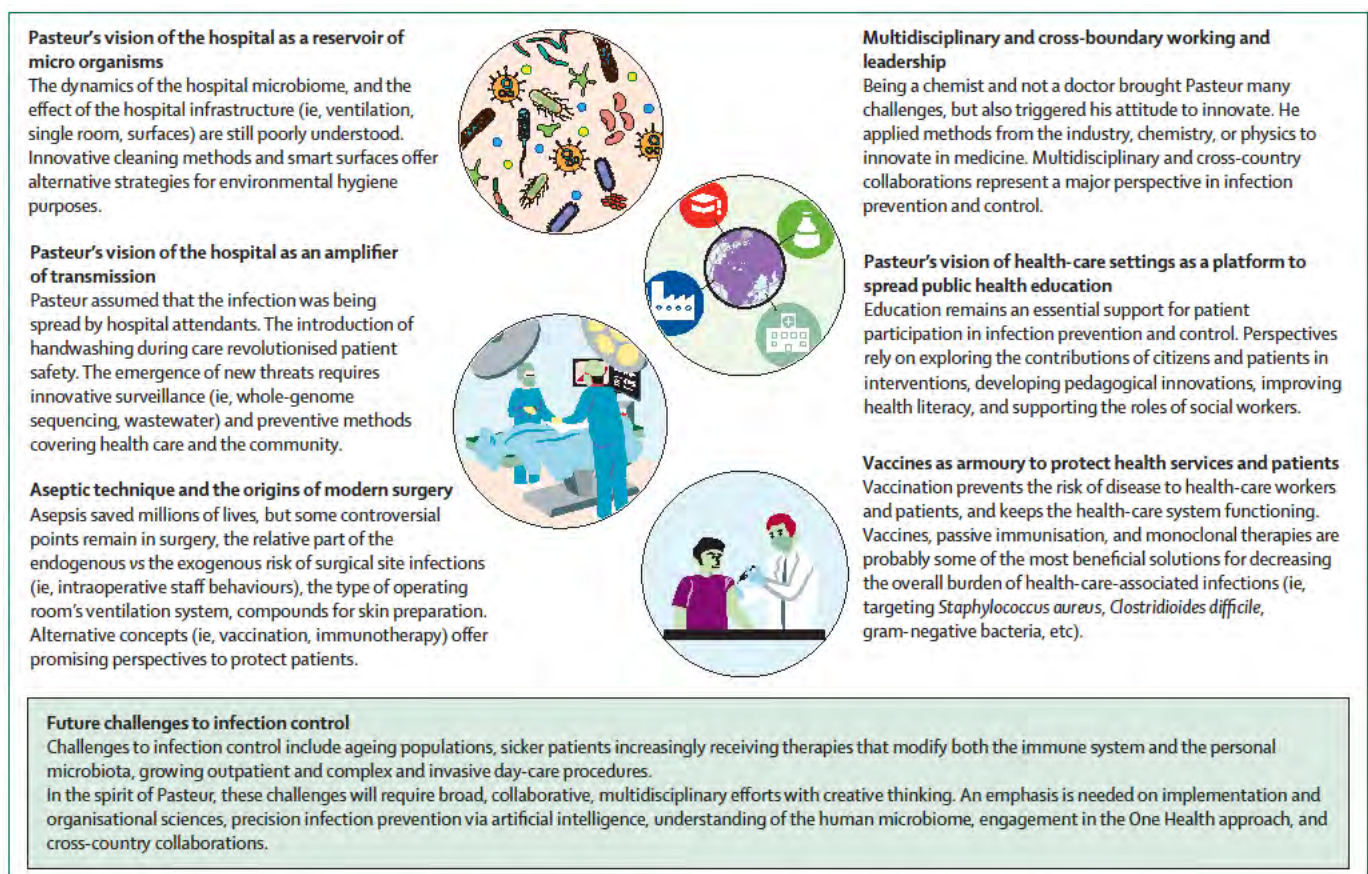


Figure 1: Louis Pasteur's vision and legacy in infection prevention and control

consequences of epidemic control measures; and co-developing specific multisectoral initiatives that redress the long-term consequences of the COVID-19 pandemic and its interventions and prepare for future outbreaks with officials, formal and informal leaders and organisations, and the public.^{22,23}

Such actions entail a reworking of pandemic preparedness, response, and recovery as consultative, open-ended, and equitable processes.

We declare no competing interests.

Tamara Giles-Vernick, Phaik Yeong Cheah, Gustavo Matta, Nisia Trindade Lima tamara.giles-vernick@pasteur.fr Anthropology and Ecology of Disease Emergence, Pasteur Institute, 75015 Paris, France (TG-V); Mahidol Oxford Tropical Medicine Research Unit, Mahidol University, Bangkok, Thailand (PYC); Nuffield Department of Medicine, University of Oxford, Oxford, UK (PYC); Oswaldo Cruz Foundation, Rio de Janeiro, Brazil (GM, NTL)

World AIDS Day 2022: WHO calls on the global community to equalize the HIV response

1 December 2022 News release

<https://www.who.int/news/item/01-12-2022-who-calls-on-the-global-community-to-equalize-the-hiv-response>

On 1 December, World AIDS Day 2022, the World Health Organization (WHO) called on global leaders and citizens to boldly recognize and address the inequalities that are holding back progress in attaining the global goal to end AIDS by 2030.

WHO joined global partners and communities in commemorating World AIDS Day 2022 under the theme 'Equalize' – a message highlighting the need to ensure that essential HIV services reach those who are most at risk and in need, particularly children living with HIV, key populations to HIV and their partners.

'With global solidarity and bold leadership, we can make sure everyone receives the care they need,' said Dr Tedros Adhanom Ghebreyesus, WHO Director-General. 'World AIDS Day is an opportunity to re-affirm and refocus on our shared commitment to end AIDS as a public health threat by 2030.'

HIV remains a major public health issue that affects millions of people worldwide. But our response is at risk of falling behind.

- Of the 38 million people living with HIV, 5.9 million people who know they have HIV are not receiving treatment.
- A further 4 million people living with HIV have not yet been diagnosed.
- While 76% of adults overall were receiving antiretroviral treatment that help them lead normal and healthy lives, only 52% of children living with HIV were accessing this treatment globally in 2021.

- 70% of new HIV infections are among people who are marginalized and often criminalized.
- While transmission has declined overall in Africa, there has been no significant decline among men who have sex with men – a key population group – in the past 10 years.

Delivering for key populations of HIV

This World AIDS Day, WHO recommends a renewed focus to implement WHO's 2022 guidance to reach the HIV and related health needs of key populations and children.

'People must not be denied HIV services no matter who they are or where they live, if we are to achieve health for all,' said Dr Meg Doherty, WHO Director of the HIV, Hepatitis and STI programmes. 'In order to end AIDS, we need to end new infections among children, end lack of treatment access to them, and end structural barriers and stigma and discrimination towards key populations in every country as soon as possible.'

Australia: The end of NPS MedicineWise

Deborah Rigby Aust Prescr 2022;45:186-7

30 November 2022

<https://www.nps.org.au/assets/AP/pdf/p186-Rigby.pdf>



The National Prescribing Service was established in 1998, by the Department of Health and Family Services, to improve health outcomes by supporting the quality use of medicines (QUM).¹ The establishment of an independent, not-for-profit organisation working alongside government was considered progressive and insightful policy. Over the next 24 years the organisation, now known as NPS MedicineWise, built a trusted reputation for providing national leadership, education, behaviour change and resources to support QUM and medicines safety in Australia.

In March 2022, the Federal Government's budget included a redesign of the Quality Use of Diagnostics, Therapeutics and Pathology Program. Some functions of NPS MedicineWise would shift to the Australian Commission on Safety and Quality in Health Care, while others would be subject to new contestable funding arrangements.

These unexpected changes to the role and funding of NPS MedicineWise have led to a decision to end its operations in December 2022. It is therefore time to reflect on the impact of the organisation and its people,

celebrate the achievements and look to the future of QUM and medicines safety in Australia.

The fundamental role of NPS MedicineWise is stewardship of the QUM objectives of the National Medicines Policy.² Early evidence-based strategies embraced the ethos of QUM with clinical audit and feedback, educational visiting and newsletters. Publications grew to include NPS News, RADAR, and, from 2002, *Australian Prescriber*, possibly the most widely read medical journal in Australia. As the impact, reach and credibility of NPS MedicineWise evolved, its range of initiatives grew.

A critical strength of NPS MedicineWise programs was behavioural intervention. When NPS MedicineWise was first established, some were suspicious that it was an arm of government set up to save money. However, over time, the organisation built trust, respect and credibility through well-designed interventions, with an evidence-based approach and being mindful of the complexity of prescribing and medication management.

One of the principles of QUM is partnership. NPS MedicineWise therefore worked collaboratively with member organisations, other associations and government to ensure its programs were grounded in issues important to consumers and other stakeholders.

An example of partnership is Choosing Wisely Australia, launched in 2015. This is a key social movement involving NPS MedicineWise working with health professional colleges, societies and associations to address low-value and unnecessary healthcare practices.

With a multidisciplinary view, the Prescribing Competencies Framework was developed. This describes prescribing expectations for all prescribers and also curriculum design for medical, pharmacy and allied health courses.³

NPS MedicineWise's MedicineInsight program provides important insight into real-world prescribing practices, supporting quality improvement in primary care and postmarket surveillance of medicines. Its reach at a local level also enables evaluation of the impact of NPS MedicineWise programs. NPS MedicineWise has delivered over \$1.1 billion in direct savings for the Pharmaceutical Benefits Scheme and Medicare Benefits Schedule, representing a twofold net return on investment for the government.⁴

Consumers are at the centre of every program and resource created by NPS MedicineWise. Their voice is present across every step of program needs assessment, design, delivery and evaluation. Innovative programs including Be MedicineWise Week, Good Medicine Better Health, Medicines Line and Adverse Medicine Events Line, mass audience campaigns such as Antibiotic Resistance Fighter, and the MedicineWise app have made a substantial contribution to the health literacy of consumers to enable Australians to make better decisions about their medicines and health.

A subsidiary, VentureWise, was established in 2015, to extend QUM activities, beyond those supported by government funding, to other areas of the health system. This was a strategic decision to raise revenue to build equity and financial stability for NPS MedicineWise.

In 2018, the Department of Health undertook a review to provide clarity and guidance on NPS MedicineWise governance, performance, transparency and accountability.⁵ The review acknowledged the high quality and valued resources used in the delivery of the programs to support the Quality Use of Medicines and Diagnostics, but made recommendations for improvement. NPS MedicineWise accepted the recommendations in principle. It committed to enhancements to deliver efficient, flexible and innovative QUM programs, while VentureWise was wound up in 2020.

The policy change announced in March 2022, to cease funding for NPS MedicineWise, was met with dismay and disappointment across the health sector. A change of government led to a rapid review to assess the appropriateness of the proposed redesign of the Quality Use of Diagnostics, Therapeutics and Pathology Program. This desktop review occurred without much stakeholder consultation. When it reported in August 2022, the review identified several risks in the proposal. However, it supported moving QUM stewardship functions to a standards-based organisation, accompanied by competitive tendering for program delivery and design.⁶ As funding for NPS MedicineWise will therefore end on 31 December 2022, the board of directors had little choice but to close the organisation.⁷

The legacy of NPS MedicineWise must drive the future direction of QUM stewardship in Australia. NPS MedicineWise had a remarkable record of excellence, innovation and engagement, particularly with primary care and consumers. The imperative for an independent, evidence-based QUM voice in Australia remains more important than ever.

Conflicts of interest: Deborah Rigby was a Director of NPS MedicineWise from 2008 to 2020.

This article is peer-reviewed.

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Curriculum for Pharmacists' training on substandard and falsified medicines in Africa

Download the publication here: <https://www.fip.org/file/4917>

This curriculum is directed primarily towards African countries where there is evidence of greatest need for such an initiative. However the problem is global and the program could be used or adapted for use in many other settings.

Substandard and falsified (SF) medical products are a major public health threat jeopardising access to safe, quality, efficacious and affordable medical products. SF medical products can contain no active ingredient or an inappropriate level of active ingredient, making them incapable of curing the disease or causing misleading therapeutic results. In addition, falsified products can contain toxic substances that can lead to disability or death. The consequence is a lack of confidence in healthcare. In particular, falsification of antibiotics is expected to be a major contributor to antimicrobial drug resistance. All medicines and medical devices are in danger, both the lifesaving and lifestyle ones, generic and branded medicines, and increasingly also biologic medicines.

Introduction

Recognising that substandard and falsified (SF) medical products are an unacceptable public health threat, the WHO and its member states have developed a holistic prevention-detection-response strategy to address the issue. Within the prevention pillar, quality ought to be demanded at all levels to guarantee supply chain integrity and product quality. This requires full involvement of those healthcare professionals who work closest to medical products and patients, namely, pharmacists.

Currently, in sub-Saharan Africa, there is no standardised, formal or harmonised university training for pharmacists dedicated to SF medical products. This region, which is most vulnerable to these products, is also that in which the WHO technical unit dealing with the issue has conducted most activities in close collaboration with national regulatory authorities, making it the most logical location to pilot this project.

There is a clear need for comprehensive and multidisciplinary training in SF medicines for pharmacists. Therefore, the International Pharmaceutical Federation together with the WHO developed this compulsory education component on SF medicines in four African countries as part of a pilot project.

This curriculum guide is to be used as training material on the issue of SF medical products that will be incorporated into the pharmaceutical university curriculum in the African region.



It is designed to increase and improve the education and awareness levels of pharmacists in order to better prevent SF medical products reaching patients.

This guide contains the Global Competency Framework for Pharmacists' Education and Training on Substandard and Falsified (SF) Medical Products based on learning objectives for attainment of knowledge, skills and attitudes and the comprehensive curriculum training materials.

This curriculum is designed to teach pharmacy students how to avoid, detect and report SF medicines, and how to advise affected patients and consumers. Pharmacy students at five pilot universities in sub-Saharan Africa were chosen as the target for the curriculum. Ideally, the curriculum will be expanded to other schools of pharmacy and other regions across the globe.

Understanding selection of cancer medicines for inclusion on WHO EML

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Richard Laing analyses the interpretation of selection of cancer medicines for the WHO EML as demonstrated in two recent articles.

<http://lists.healthnet.org/archive/html/e-drug/2022-11/msg00014.html>

There have been two recent articles about cancer medicines and the WHO Model List of Essential Medicines: In *JAMA* and *Lancet Global Health*.

The first in the *Journal of the American Medical Association* is a short Viewpoint article by three authors from Harvard Medical School.

Reforming the World Health Organization's Essential Medicines List Essential but Unaffordable.

Authors: Thomas J. Hwang, MD, Aaron S. Kesselheim, MD, JD, MPH. Kerstin N. Vokinger, MD, JD, PhD

Reference: *JAMA*. 2022;328(18):1807-1808.

doi:10.1001/jama.2022.19459 October 24, 2022

available at

<https://jamanetwork.com/journals/jama/fullarticle/2797965>

It is available free but you have to register.

There is no abstract for the article so I will summarise it briefly.

The authors briefly introduce the history of the WHO Model List of Essential Medicines (WHO MEML) and state that the selection of medicines for the list has been increasingly complicated by the escalating cost of new drugs entering the market.

The authors make a proposal to remove cost and cost effectiveness from consideration by the WHO Expert Committee. They provide information about two categories of cancer medicines: Programmed cell death 1 (PD-1) and programmed cell death ligand 1 (PD-L1) immune checkpoint inhibitors that were considered at the 2021 Expert Committee meeting but were rejected.

They suggest that because one of these products, pembrolizumab, is recommended by both the US National Comprehensive Cancer Network and European Society for Medical Oncology (ESMO) clinical practice guidelines; that these products should have been included without considering the cost.

They also discuss the rejection of pertuzumab in combination with trastuzumab and taxane chemotherapy for first-line treatment of ERBB2 (formerly HER2)-positive unresectable or metastatic breast cancer.

They summarise their proposal as follows:

'For future iterations of the Essential Medicines List, WHO should formally separate its expert committee reviews of comparative effectiveness, safety, and public health priority from consideration of the price of medicines and their cost-effectiveness.'

Later they justify this suggestion by stating:

'...having a 2-stage, independent approach that separates clinical and economic reviews, as is currently done by health technology assessment agencies in France, Germany, and several other countries, could provide a more robust and reproducible basis for establishing the list.'

These are the key points that I got from the opinion piece. But I disagree with their proposal. I looked at the application for the 2021 meeting and it is deficient in many areas.

Their application is available at

https://cdn.who.int/media/docs/default-source/essential-medicines/2021-eml-expert-committee/applications-for-addition-of-new-medicines/a.1_anti-pd1-ici.pdf?sfvrsn=8b1482fc_8

The application was submitted by a representative from the European Society for Medical Oncology (ESMO). The application failed to respond to a number of the sections in the application form. For example the section 5 on International availability - sources, if possible, manufacturers and trade names - the applicants respond by saying:

'In this submission, we will consider the indications for ICIs in NSCLC scored as European Society for Medical Oncology-Magnitude of Clinical Benefit Scale (ESMO-MCBS) grade 4 or 5 in Non-Curative settings and for which no controversies exist.'

They then provided details of how the different products are recommended for use.

In response to the question about Information supporting the public health relevance of the application, they point out that lung cancer is common. They then state that targeted therapies have redefined the therapeutic landscape for a particular subtype of these molecularly druggable cancers.

What does this mean?

An example they give is 'epidermal growth factor receptor [EGFR] mutations, anaplastic lymphoma kinase [ALK] rearrangements, ROS1 rearrangements, BRAF mutations, HER2 mutations or amplifications, NTRK1-3 fusions' and they then say 'these therapies are ineffective in those tumours lacking such genetic alterations - the majority of NSCLC patients.'

What they do not say is how many countries could detect those lung cancers that could be treated.

In their response to the question concerning *Summary of available data on comparative cost and cost-effectiveness within the pharmacological class or therapeutic group* they state:

'The cost-effectiveness (CE) studies published exhibit some aspects that are worth being recognised: Often, health technology assessment, governmental, and independent CE analysis in the literature were not updated according to the recent and mature overall survival (OS) benefit data. For

instance, NICE² analysis and decisions commonly reflected the uncertainty of OS immature data from interim analysis, where the CE threshold was not favourable to the medicine adoption considering the price negotiations.

'Some of those analyses occurred before the updated OS mature data, and further analysis will be required for the appraisal committee decision. Far beyond a comprehensive CE analysis, finance as one of the pillars for UHC³ goal also requires budget impact analysis, and the costs related to the investment for maintenance, and improvement to offer quality and timely diagnosis, the most appropriate treatment, and the expected follow up in terms. To deliver such tasks, workforce, capacity building, are also components to guarantee a feasible and universal access to medicines.'

But no data from non OECD countries is provided. So I believe that the 2021 Expert Committee was correct to reject this application.

I believe that the Hwang JAMA viewpoint article fundamentally misunderstands the role of the Expert Committee in recommending which products should be included in the WHO MEML. The expert Committee is not asked to evaluate which medicines are efficacious for common conditions of public health concern. That is a **prerequisite** for consideration. The committee is asked to prepare a model list to guide decision makers in Low and Middle Income countries as to which medicines that they should try to make available to their populations. The criteria used includes public health need taking into account the availability and costs of diagnosing these conditions, clinical effectiveness under real world conditions not clinical trial efficacy studies alone, safety, comparative cost and cost effectiveness within the therapeutic class, regulatory status, availability of Pharmacopeial standards and the proposed text for the WHO Model Formulary. The committee is tasked with reviewing all aspects of an application and then balancing all the factors to make a judgement that is then published to advise individual authorities. Governments are not bound to follow the WHO Model List. Every country makes its own decisions! Cost and comparative cost effectiveness are just another set of considerations for the committee to consider. Separating the functions of the committee into two streams will complicate and delay decision making by the WHO.

The second article is in *Lancet Global Health* 2022; 10: e1860-66 Published Online September 29, 2022

[https://doi.org/10.1016/S2214-109X\(22\)00376-X](https://doi.org/10.1016/S2214-109X(22)00376-X)

Here is the title, authors and abstract

Cancer medicines on the WHO Model List of Essential Medicines: processes, challenges, and a way forward by Kristina Jenei, Zeba Aziz, Christopher Booth, Bernadette Cappello, Francesco Ceppi, Elisabeth

G E de Vries, Antonio Fojo, Bishal Gyawali, Andre Ilbawi, Dorothy Lombe, Manju Sengar, Richard Sullivan, Dario Trapani, Benedikt D Huttner, Lorenzo Moja

Abstract: The selection of cancer medicines for national procurement requires deliberate evaluation of population benefit, budget impact, sustainability, and health system capacity. However, this process is complicated by numerous challenges, including the large volume and rapid pace of newly developed therapies offering marginal gains at prohibitively high prices. The WHO Model List of Essential Medicines (EML) and Model List of Essential Medicines for Children (EMLc) have undergone a series of evidence-based updates to ensure recommended cancer medicines offer meaningful clinical benefit.

This Health Policy paper describes how cancer medicines are listed on the EML and EMLc, including two updated WHO processes

(1) the formation of the Cancer Medicines Working Group, and (2) additional selection principles for recommending cancer medicines, including a minimum overall survival benefit of 4-6 months with improvement to quality of life compared with standard treatment. These updates, along with proposals to include formal price considerations, additional selection criteria, and multisectoral collaboration (eg, voluntary licensing) promote procurement of high-value essential cancer medicines on national formularies in the context of supporting sustainable health systems to achieve universal health coverage. [End abstract]

Available at
<https://www.thelancet.com/action/showPdf?pii=S2214-109X%2822%2900376-X>

This is a very different paper. It is much longer and is written by WHO staff members and a number of cancer experts from around the world though there is only one author from a Low or Middle Income country.

The authors describe the history of how WHO has attempted to address the inclusion of cancer medicines on the WHO-MEML. The authors describe how the WHO Expert Committee on selection and use of Essential medicines established a Cancer Medicines Working Group in 2017 to advise the Expert committee.

This led to the Expert Committee accepting the recommendation of the Working Group to use the ESMO Magnitude of Clinical Benefit Scale to identify high value cancer medicines worth considering for addition to the WHO Model List.

They also adopted a survival benefit threshold of 4-6 months as a pre requisite for inclusion. Other criteria for consideration for inclusion of cancer medicines are also discussed in the article.

² National Institute for Health and Care Excellence

³ Universal Health Coverage

These include disease stage and line of therapy, health system feasibility, and prices. They end the article by suggesting a way forward. Their final sentence reads

'The endorsements of a minimum threshold for overall survival gain, use of the ESMO-MCBS tool, and concurrent proposals to include formal price considerations and additional selection principles, ensure cancer medicines recommended for inclusion on the WHO EMLs offer maximum overall survival benefit and are sensitive to associated health system impacts.'

This is an important paper that lays out how WHO is attempting to address this challenging issue. This is an issue that LMICs have to struggle with and taking this article as a starting point countries may wish to discuss this topic and develop criteria and processes for how they will make these difficult decisions.

For me personally, when I worked on the Zimbabwe Essential Drugs Action Programme in the late 1980s I was a member of the Oncology Committee that addressed these issues. The committee published an article in Health Policy and Planning in 1980 titled Rational Use of cytotoxic drugs in a developing country.

The article is available at
<https://academic.oup.com/heapol/article-abstract/5/4/378/559364>

Books from TWN

Intellectual Property Rights Series no. 18

Remedies Against Excessive Pricing of Patented Medicines Under Competition Law

By *Shiju Mazhuvanchery*

Publisher: TWN

Year: 2022

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<https://www.twn.my/title2/IPR/pdf/ipr18.pdf>

About the Book

Exorbitant medicine prices, especially for medicines subjected to patent protection, are increasingly coming under the spotlight. This paper considers whether and how this serious concern can be addressed within the framework of competition law.

Differing perspectives exist over the appropriateness of intervention by competition authorities in cases of excessive pricing, particularly when these involve patented products. However, there are no legal barriers to such intervention; competition authorities can act – and have acted – against firms deemed to have charged unfairly high prices for medicines, including those under patent.

In fact, this paper contends, competition enforcement against excessive pricing of patented medicines would not only advance consumer welfare but also contribute to safeguarding the fundamental human right to health. The remedies available under competition law – such as compulsory licensing – can be effectively applied to keep a lid on the prices of essential, potentially life-saving medicines.

SHIJU MAZHUVANCHERY is a professor at Sai University, Chennai, India. He has published extensively on issues relating to environmental law, constitutional law and competition law. He sits on the editorial board of the Indian Journal of International Law and is a regular contributor to the Oxford Yearbook of International Environmental Law. He is also associated with the Daksha Fellowship, India's first fellowship programme in law, as adjunct professor. His current area of research is competition law, including competition issues in the digital economy.

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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

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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.

SEAN FLYNN is a Professorial Lecturer and Director of the Program on Information Justice and Intellectual Property (PIJIP) at American University Washington College of Law, Washington, DC. ERICA NKUMAH is Information Justice Fellow at PIJIP. LUCA SCHIRRU is Arcadia Fellow at PIJIP.

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