

# **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 from Penang by Action for Rational Use of Drugs in Asia (ARDA). In 1995 Health Action International Asia Pacific (HAI AP) was formed as a collaborative network in the Asia Pacific Region 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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HAIAP held a 40<sup>th</sup> Anniversary celebratory 'Zoom' meeting with 65 participants on May 29. We heard from three of our Founders: Dato' Seri Anwar Fazal, Dr Mira Shiva and Dr Zafrullah Chowdhury along with our Governing Council Chair – Dr Niyada Kiatying-Angsulee - then stories from the field were presented by Professor Kris Weerasuriya, Dr B Ekbal, Professor Michael Tan, Dr Tanveer Ahmed, Professor Manuj Weerasinghe, Dr Sun Kim and Dr Chee Yoke Ling. The presentations had extraordinary depth and breadth and there was something for all generations.

We are extremely grateful to the presenters and participants who shared our celebration. It was wonderful to see so many familiar, and new faces. Thank you.

During this year we will develop a book that features historic events and plans for the future – to be released later in the year. We look forward to receiving contributions to the book from all – long or short - and as soon as possible.

As part of the May 29 Anniversary Proceedings two important **Awards** were announced:

**Award 1. The Dr Olle Hansson Award** in recognition of long activism.

**Award 2. A 3-6 month Fellowship** at Gonoshasthaya Kendra (Bangladesh) for a young person activist.

Details of both Awards are on Page 2.

A special **Student Research Project** has been designed by Dr Ken Harvey. If you would like more details or if you would like to participate, please contact Ken. See page 14.

In this issue we trace some HAIAP history and also address pressing issues that remain with us: AMR, IP issues, access to essential medicines....

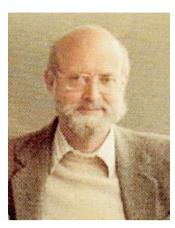
We acknowledge 100 Years since the discovery of Insulin and 60 years since the withdrawal of thalidomide.

A study on indoor pollution by the Sri Lankan Students Interested in Rational Health Activities (SIRHA) is featured along with a Memorial Debate organised by the SIRHA in honour of the 101st birthday of Professor Senaka Bibile.

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# **Two Important new AWARDS**

#### 1. Dr Olle Hansson Award 2022



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.

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

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 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.

'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.'

The Award was first given in 1987. Recipients have included Dr Mira Shiva of India; Dr Alfredo Bengzon of the Philippines; Prof Dzulkifli Abdul Razak of Malaysia; and Dr K Balasubramaniam.

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

This Award for 2022 recognises the work of an individual from a low or middle income country according the reference list <sup>1</sup> 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.

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 November 30 2021.

Please send nominations to: Beverleyfsnell[AT]gmail.com

The award, which is given annually, is in the form of a commemorative certificate and a special oration and ceremony.

**Management:** The Award 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 <a href="http://www.haiasiapacific.org/?s=Olle+Hansson">http://www.haiasiapacific.org/?s=Olle+Hansson</a>

# 2. Gonoshasthaya Kendra/HAIAP Award 2022

A Fellowship will be provided at Gonoshasthaya Kendra (GK), a people-oriented healthcare based non-governmental organisation in Bangladesh, which provides community and institutional services in the fields of healthcare, women's empowerment, disaster management, education, agriculture, and basic rights-based advocacy.

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

GK was founded by Dr Zafrullah Chowdhury in 1972.

The candidate will cover his/her own travel expenses to GK but all living expenses and incidental travel expenses and a small allowance will be covered by GK for the duration of the Fellowship. This Fellowship Award will be conferred on a younger person – up to 40 years of age-from a low or middle income country within this list² who demonstrates promising leadership qualities and an interest in promoting self-determination and health for all especially the poorest of the poor. It will be awarded to a person who can be seen to have the qualities to learn from such an experience and to go forward to make a contribution to the wellbeing of the their own or another community.

#### About Gonoshasthaya Kendra (GK)

### (The People's Health Centre)

GK set out with the key objective of 'health for all'. All projects are interwoven with this basic aim. Concentrating on the poor, GK began by providing preventive and primary health care for the surrounding villages where access to health services was almost non-existent, through trained para medic outreach health workers – mostly young women. Over the years, GK has developed into an integrated rural development project which includes education, nutrition, agriculture, environment, vaccine research, herbal medicinal plant research, income generation and vocational training with an emphasis on empowerment of women.

GK's overall objective is to use primary health care as an entry point to work with the people, for the people, to develop a just society. GK works towards this end by developing a people-oriented health care system and making people aware of health issues.

#### Learn more about GK here:

https://gonoshasthayakendra.com https://www.youtube.com/watch?v=vBqi7N5K-f8 https://www.youtube.com/watch?v=FzLuI54RYDE https://www.youtube.com/watch?v=bfE0zlsWQf4

# The Fellowship Award

The award, to be given annually, is in the form of a 3-6 month placement at GK between July and December. The duration will be negotiated between the candidate and the interview panel.

#### The Successful Candidate

Candidates will be interviewed to determine their adaptability to a new setting and different culture, food and language. The successful candidate will be a non-smoker who will be accommodated at GK and will experience and learn from as many features of GK as

possible in the time. S/he will also have the opportunity for placement in other related settings with the support of GK. The candidate will cover his/her own travel expenses to GK. GK will provide free full board and incidental local travel expenses as well as a monthly allowance for pocket expenses paid by GK. Following the placement the successful candidate will provide a succinct report of activities during the fellowship and will be available to share the experience in other settings at the host's expense.

# Nominations are invited for the GK/HAIAP Fellowship Award.

This Award for 2022 recognises the work of a male or female individual up to 40 years of age from a low or middle income country<sup>1</sup> who has demonstrated a commitment to learning from and working with the community with a desire to contribute to solidarity based community health and development.

### How to apply or nominate an individual

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, involvement in projects, achievements and testimonials from two authoritative mentors).
- 2. A 500-word statement of the nominee's qualities and achievements in the field of community based health involvement.
- 3. Mentors' names, affiliations and addresses.

Please provide:

- a. documentation of work done.
- b. what could be a possible contribution to GK
- c. expectations from the fellowship
- d. a recent photograph of the nominee.

Closing Date: Nominations will close on Nov 30 2021.

#### **Announcement of the Fellowship Award winner**

The recipient will be chosen by an international panel of judges from GK and HAIAP. The successful candidate will be announced late January /early February 2022.

#### Please send nominations to:

HAIAP Beverleyfsnell(AT)gmail.com

cc Zafrullah Chowdhury zaf.chowdhury(AT)gmail.com

**Management** The GK/HAIAP Fellowship Award is managed by Health Action International Asia - Pacific (HAIAP) and the GK Fellowship Committee.

**For further information:** Please contact Health Action International Asia Pacific<sup>3</sup>

 $<sup>^2\,\</sup>underline{\text{https://wellcome.org/grant-funding/guidance/low-and-middle-income-countries}}$ 

<sup>3</sup> HAIAP <BeverleyfsnellATgmail.com>

# Significance of HAIAP: past present and future

Niyada Kiatying-Angsulee

Who are we? We are an informal network of non-governmental organisations and individuals in the Asia Pacific Region committed to strive for health for all now.

Our founders, Dr Mira Shiva, Dr Zafrullah Chowdhury and Dato' Seri Anwar Fazal are still with us and guiding us; and Dr Kumariah Balasubramaniam – who we lost in 2011 still guides us and inspires us.

Our Remembrance is a big part of HAIAP. As well as losing Dr Bala in 2011 we lost Shila Kaur 2017, Amit Sengupta in 2018, Sumlee Jaidee in 2019, Martin Khor in 2020, and Mongkol Na Songkla 2020 but they remain part of our existence.

Sumlee Jaidee and Mongkol Na Songkla were from Thailand. Professor Sumlee was the mother of the Thai Drug Study group - a long time HAIAP partner - and Mongkol na Songkla was the courageous Public Health Minister who made the unprecedented decision to invoke a public health safeguard, a compulsory license (CL), to address the lack of lifesaving medicines at affordable prices. He was the Minister when the decision was made to invoke another public health safeguard, known as 'Government Use'. The Thai Government Pharmaceutical Organization (GPO) was able to produce a triple cocktail of ARVs at low cost from the off-patent medicines; and the government announced the extension of the health benefit package of the national health insurance system to cover ARV treatment. Medical devices and affordable essential medicines in other categories are also made under compulsory license and for government use by the GPO. The decision also acted as a good example for other developing countries - that the TRIPS public health safeguard is not limited to addressing HIV challenges only.

#### HAIAP Partner Organisations include:

- All India Drug Action Network (AIDAN), India
- Annamalai University Department of Pharmacy
- Community Development Medicinal Unit, Odisha, India
- Consumer Association of Penang (CAP) Penang Malaysia
- Gonoshasthaya Kendra (GK) Bangladesh
- Health Action Information Network (HAIN) Philippines
- Health and Nutrition Development Society (HANDS)
   Pakistan

- Thai Drug Watch/ Drug Study Group (DSG) Thailand
- Third World Network (TWN) Penang Malaysia
- People's Health Movement (PHM)

The PHM was launched at the First People's Health Assembly held at Dhaka, Bangladesh in December 2000. Several international organisations and civil society movements including HAIAP, decided to work together towards Health for All. Committed to the principles of primary health care and people's perspectives the People's Health Assembly had been organised and took place from 4-8 December 2000 in Bangladesh, at Savar, on the campus of Gonoshasthaya Kendra (GK – People's Health Centre).<sup>4</sup>

# Waves of impetus between 1981 and 2021

There were two very important activities our founders were involved in even *before* the launching of HAI:

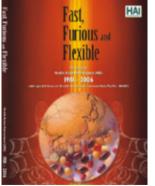
1979 -The International Baby Food Action Network (IBFAN)] born in Geneva<sup>5</sup> and also in 1979 – the Kyoto International Conference against Drug-Induced Sufferings <sup>6</sup>.

In 1981, there was the 10<sup>th</sup> Congress of the International Organisation of Consumer Unions (IOCU) and also in 1981 the 34th World Health Assembly (WHA) in Geneva where representatives of NGOs from 26 countries decided to form Health Action International (HAI) that would have a clearing house in Penang.<sup>7</sup>

In 1983 the International Conference on Consumer Health and Safety was held in Japan and in 1986 Action for Rational Drugs in Asia (ARDA) was launched by CIROAP. That was the springboard for the development of HAIAP. Later, in 2001, HAIAP was registered as a regional organisation to be located in Sri Lanka.

# Fast Furious and Flexible published in 2006 The Story of HAI 1981-2006: Special Focus on HAIAP available http://www.haiasiapacific.org/wp-

content/uploads/2014/03/Fast Furious Flexible HAIAP 2006.pdf



This book was launched at the 25<sup>th</sup> anniversary HAI meeting in Amsterdam, The Netherlands in 2006.

Section I: Keeping Memories Alive

Section II: Health Action International Asia Pacific

Section III: Moving Ahead

Section IV: Selected writings of Dr K.Balasubramaniam.

<sup>&</sup>lt;sup>4</sup> https://phmovement.org/the-peoples-charter-for-health/

<sup>&</sup>lt;sup>5</sup> https://www.who.int/nutrition/publications/code english.pdf

<sup>&</sup>lt;sup>6</sup> https://katalog.slub-dresden.de/id/0-01234530X

<sup>&</sup>lt;sup>7</sup> http://www.haiasiapacific.org/

The writings of Dr Bala covered major issues that are still relevant today.

Annexures included international Codes and Charters, organisation contact details and a publication list.

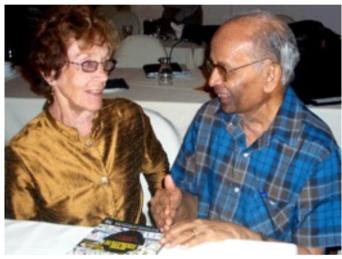
### HAIAP Regional Consultation in Colombo, Sri Lanka 2010

**In 2010** the last HAIAP Regional Consultation - on Health and Medicines Financing - was held in Sri Lanka; and then we moved back to Penang.

#### Where There are No Pharmacists

Available from TWN.org

It was at that 2010 meeting that Where There are No Pharmacists was launched.



Dr Bala and Co-author Beverley Snell discuss the book after the launch

The book does not aim to train people to replace pharmacists. The reality is, in the remote and rural areas of Africa, Asia, the Pacific and Latin America, that there are not enough trained pharmacists. Several categories of health workers, whose activities involve managing and handling medicines, find themselves in front line healthcare without any pharmacy training and with no opportunity at all for continuing their pharmacy education and professional development. These health workers, who in fact, take on the role of pharmacists, include community health workers, owners of drug stores, nurses, auxiliary health workers and pharmacy assistants both in the formal and informal health sectors. People with little or no formal education can be trusted to grasp what is communicated the communication comprehensive enough. And Where There are No Pharmacists is just that. Empowering health workers is empowering whole communities.

#### The book covers:

 Principles of medicines selection: Therapeutics Committees, Treatment Guidelines, Standard Medicines Lists

- Procurement, stock management and supply: sources and prices, quantification, quality issues, storage and stock control
- The process of dispensing, and dispensing according to treatment guidelines
- Rational Use of Medicines
- Integrating vertical programs like IMCI, STI and HIV programs, Reproductive Health
- Explaining to patients and communities the role of medicines and how to use medicines safely
- The concept of National Medicines Policies

As part of the 2010 Sri Lanka meeting a report was presented on the follow-up seminar with Indian partners: 'Towards a pharmaceutical policy in India in the changed perspective' - Pharmaceutical policy and access to essential medicine. It covered:

- Access to Medicine
- Rational Use of Medicine
- Campaign recommendations from the seminar to policy level

# Collaboration between HAIAP and the Faculty of Medicine, University of Colombo

That 2010 regional meeting in Sri Lanka was a collaboration between HAIAP and Faculty of Medicine, University of Colombo and discussion included Establishing a Baseline to Monitor Public Health Implications of New Intellectual Property Rights Regime on Pharmaceuticals in Sri Lanka – 2010 with the following objectives:

- To determine the patent status of the new chemical entities registered in Sri Lanka during 2005-2010.
- To describe the price fluctuation in the market of new chemical entities/ patent drugs registered during the period.
- To determine the proportion of the new chemical entities/ patented drugs of therapeutic groups appearing in prescriptions dispensed at a selected state-owned pharmaceutical retail outlet.
- To determine the perception of personnel involved in pharmaceutical regulation on public health implications of new IPR regime.

When Dr Bala retired following the 2010 meeting, Shila Kaur who had worked with HAIAP in Penang from the early days was appointed our new coordinator. Unfortuunately the HAIAP funding from the Dutch Government had not been renewed so from May 2010 Shila became the *Honorary* Coordinator of HAIAP to be based in Penang from then on. As we know, Shila was not new to HAIAP. She had been working alongside Dr Bala in the 1990s when the organisation was previously based in Penang and she was welcomed back into the family.



# Farewell and thank vou Dr Bala

Following the meeting – April 29, 2010, a special tribute gathering was held to thank Dr Bala and to share images and memories of our time together.

# 2013: a joint ReAct-TWN-HAIAP workshop

In 2013 a joint ReAct-TWN-HAIAP workshop was held in Malaysia – marking the arrival of antimicrobial resistance as a multisectoral challenge that would need urgent global attention.

In 2018 the TWN/HAIAP core members meeting in Penang focused on addressing anti-microbial resistance within a *One Health* framework in our region.

### HAIAP Core Meeting GK Bangladesh - May 2017

A small core group of members met to discuss the way forward and the challenges and concerns.

**Challenges and Concerns** remain much the same today as they were throughout our previous years but the contexts have changed and now we must address the issues appropriately for the times we are living in.

- Access to Essential Medicines
- Intellectual Property related Issues including TRIPs
- Availability of good quality, affordable medicines
- Rights to health
- Financing systems (affordability)

- Promotion of medicinal substances
- Antimicrobial Resistance

The future of HAIAP will continue to involve networking, coordinating, sharing information and activities.

- HAIAP members are still working with shared information and collective goals.
- HAIAP News continues to be produced three times a year. It is the official newsletter of HAIAP and presents the happenings of our partners and news of regional campaigns for more rational and fairer health policies. It carries material in support of participants' activities
- The website will continue to be a 'presentation' of HAIAP and a repository for resources and records.

### PHA4 – 4th Peoples' Health Assembly November 15-19, 2018 at Gonoshasthaya Kendra (GK), Bangladesh

HAIAP together with the Third World Network (TWN) presented a self-organised workshop during the assembly.

# Workshop: Challenges of Antimicrobial Resistance in the region

# Overview: The AMR Situation and Challenges in Developing Countries

- Affordable access to existing and new antimicrobialsreference to hepatitis C treatment and the Malaysian Compulsory License
- Affordable access to existing and new anti-microbials
   India and our region
- Philippines NAP
- Some specific practical issues and innovative health system opportunities to counter AMR e.g. Thailand Smart Use; measuring the impact of interventions.

### **HAIAP** meeting during PHA4



The opportunity arose during PHA4 for delegates to hold a HAIAP meeting. Beverley Snell, who had been Acting Coordinator since we lost Shila, was asked to continue in the Honorary Coordinator position.

We look forward to staying in touch with our HAIAP family and friends and to collective working; and coordinating and sharing information and activities through HAIAP News and our website.

### Working with and learning from HAI/HAIAP

Dr Mira Shiva

It has been a privilege and pleasure as well as continuous learning having been engaged with HAI, HAIAP, and some of the most inspiring, committed individuals and organisations associated with HAI and HAIAP.

Mentors, colleagues, co-travellers and friends, have earned trust and mutual respect over the four decades.

In the late 70s and 80s we worked together as likeminded people with optimism and enthusiasm with the strong belief that with genuine collective effort we could change the health situation and ensure health rights for the people, especially for those most vulnerable, marginalized and discriminated against. It was a time when democratic spaces had not shrunk as they are at present.

The 1978 Alma Ata Charter on Comprehensive Primary Health Care and its principles galvanized many, even though several comprehensive health programs already existed in our region, for example the Gonoshasthaya Kendra Program founded by Dr Zafrullah Chowdhury in Bangladesh and the Jamkhed Comprehensive Rural Health Project in Maharashtra State founded by Doctors Rajanikant and Mabelle Arole.

The Comprehensive PHC approach recognised the fact that access to essential medicines was an important component just like nutrition. This approach was of course well known and recognised by those working on the ground and in existing PHC programs and therefore the engagement of many in HAIAP was around working towards ensuring access to affordable essential medicines and health care.

Working towards access to essential medicines went side by side with working towards ensuring Rational Use of Medicines - a Rational Medicines Policy had to complement a health promotive Comprehensive Health Policy.

The health destructive activities of powerful transnational corporations (TNCs) needed to be regulated. Therefore, many HAIAP members were also active in the Baby Food Action Campaign, (action against marketing of dangerous baby formulas); and action against hazardous pesticides and against tobacco - and many continue to do so. They are active even today, recognising the newer forms of threats to the right to health and right to food etc.

Besides focussing on selection of essential medicines and their rational use, another major thrust was for withdrawal of irrational and hazardous medicines.

The Estrogen-progesterone (EP) Campaign (against high dose combinations of estrogen and progesterones) was launched in India on 8th March 1982. It was a major campaign against Fixed Dose Combinations of high dose estrogen and progesterone in which consumer, medicine, health and women's groups actively associated. The campaign high-lighted the double standards of unethical marketing - provision of biased information even to doctors - suppressing vital information regarding serious adverse effects on pregnant women and teratogenic effects (birth defects) on the unborn baby when given to pregnant women who were wanting to continue their pregnancy.

HAI's Women and Pharmaceuticals - Adverse Effects has a chapter on EP medicines, as does Banned and Bannable Medicines published by the Voluntary Health Association of India (VHAI).

HAI published *Problem Medicines* by Andrew Chetley (1985) that highlighted many of the irrational and hazardous medicines that continued to be promoted aggressively and sold in developing countries. Prevention of unethical marketing of pharmaceuticals was given high priority. After the Baby Food Marketing

Code<sup>8</sup> brought due reward for the efforts of baby food activists, HAI attempted to launch a Code for marketing pharmaceuticals. However, that was opposed by the USA, and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) published a very diluted version to scuttle the efforts. Even today, efforts to have something mandatory and statutory continue – for a Uniform Code for Pharmaceutical Marketing Practices (UCPMP) at India's Department of Pharmaceuticals.

Monitoring of promotional material for irrational medicines was undertaken by many groups, for example, for Boehringer Knoll's *Chlorostrep*, a combination of chloramphenicol and streptomycin being promoted for childhood diarrheas.

Promotional material was shown at the International Consultation of Experts on Rational use of Medicines in Nairobi in 1985, where, for the first time, some of us rational use of medicines activists were invited. In fact most of us were associated with HAI. HAIAP subsequently undertook the project to monitor sales of such medicines in the Asian region.

In India, Public Interest Litigation (PIL) was filed in 1993 in the Supreme Court of India by DAFK, AIDAN and the NCCDP<sup>9</sup> in favour of banning irrational and hazardous medicines. Efforts continue until the present.

Access to affordable medicines is another issue. There have been many attempts to make medicines prices rational - from defending the Essential Commodities Act (ECA) to the Medicine Price Control Order. A PIL was filed in the Supreme Court of India in 2003 regarding the issue of medicine pricing. The efforts continue. At present, there are efforts to regulate and cap prices of COVID-19 diagnostic tests, N95 masks and medicines.

In 2009, a PIL had been filed when three Public Sector Vaccine Units were asked to stop manufacture of vaccines and to purchase from private entities - at much higher cost. The PIL was undertaken to prevent asphyxiation of Vaccine Public Sector Units (PSUs).

In view of Covid vaccine shortages and high prices, as well as many being locked up in Intellectual Property Rights, trade mark, technology transfer issues for which TRIPS Waiver efforts are being made, another PIL has been filed regarding support to Vaccine PSUs.

Some major mile stone events

 Pharmaceuticals conference organised by IOCU (International Organization of Consumer Unions)
 bringing together activists from across the region -

- when Dato Anwar Fazal was Director in Penang Malaysia
- International Conference of Experts on Rational Use of Medicines under WHO's Director General, Dr Halfdan Mahler (Nairobi 1985).
- 'Drugging of Asia' Closely followed the above meeting in 1985 in Chennai organised by IOCU-ACHAN (Asian Community for Health Action Network)-VHAI.
- Rational Use of Medicines in Medical Education by HAIN and ARDA (Action for Rational Medicines in Asia) in Manila, Philippines. (1988)
- As part of the HAI team at the annual World Health Assembly to support Rational use of Medicines – held- in May each year. HAI /HAIAP have a long history of attendance at World Health Assemblies.
- Issues of IPR in World Health Assembly, International Commission on IPR, Innovation and Public Health as part of HAI team representing HAIAP (2006).

Under Dr Bala's leadership HAIAP organised consultations on Intellectual Property Rights (IPR)

- HAIAP with Chulalongkong in Bangkok (2008)
- HAIAP with TWN in Kuala Lumpur (2015)

Some of us from HAIAP were actively involved in the Peoples Health Assembly at Gonoshasthaya Kendra Savar, Bangladesh in 2000, with the International Peoples Health Council (IPHC), Consumers International (CI) (new name for IOCU), and the Dag Hammerskjold Foundation. HAIAP was one of the Founding members of Peoples Health Movement (PHM) at that first Peoples Health Assembly - PHA-1 (2000).

At the Conference organised by Thai MOH on Compulsory Licensing, in Bangkok Thailand I represented HAIAP in the team led by Dr Bala.

In 2004, HAIAP organised a conference on the 'Role of Traditional Medicine' in Colombo Sri Lanka since the Asian region is rich in biodiversity and has developed traditional systems of medicines as well as local health traditions, traditional knowledge, and traditional resources. There is increasing threat of biopiracy and ecological destruction. There has been notable absence of any teaching and building of mutual understanding of different systems of medicines; or medical anthropology for community health.

HAIAP and TWN partnered to deliver a workshop on Anti Microbial Resistance at PHA 4 in Dhakar, Bangladesh in 2018. We had been closely allied with the Third World

<sup>&</sup>lt;sup>8</sup> https://www.who.int/nutrition/publications/code english.pdf

<sup>&</sup>lt;sup>9</sup> Drug Action Forum – Karnataka, All India Drug Action Network, National Campaign Committee for Drug Policy

Network (TWN) and the South Centre through Martin Khor and more recently with their Anti-Microbial Resistance movement based in Penang. We were very sad to lose Martin in 2020.

HAIAP is currently working with TWN and the PHM on the TRIPS Waiver Campaign, (2020/2021) with HAIAP celebrating 40 years of activism.

There is an enormous list of major threats to medicine and health movements The increasing push for privatisation by International Financial Institutions is being followed by national governments of health and education. Conditionalities of loans is reminiscent of structural adjustment programs.

- Marginalization and asphyxiation of public health institutions and those involved in public pharmaceutical and vaccine production as well as medical education is occurring. Public health institutions are understaffed and staff are overworked and under remunerated. A large number of front-line workers, nurses, and other health workers are women who are particularly overworked and underpaid.
- The Increase in health challenges have been worsened by COVID-19. There has been growth of unregulated private and corporate sectors in health together with increasing power. Increasingly space is occupied and the role of corporates, philanthrocapitalists, and profit oriented investors has expanded in policy formulation - whether related to global governance, global health governance, global health or influencing national policies.
- Multistakeholderism is replacing multilateralism.
  There are shrinking democratic spaces for public
  interest Civil Society Organizations in every field, with
  actual targeting of health human rights, tribal rights and
  forest rights defenders.
- There is corporate hijack of food, health, land, traditional knowledge and resources, and natural resources.
- There is climate chaos and ecological destruction; and there are climate change related public health problems including zoonotic diseases and pandemics.
- There is increasing poisoning of food, soil, water and environment. There are safety and biosafety concerns associated with genetically modified (GM) foods, and ongoing genetic modification and gene editing - besides patenting of genes. GM seeds have been introduced into agriculture and have destroyed the ongoing independence and livelihood of farmers

who have saved and grown their own seeds for eternity.

Remember Bhopal! Remember Union Carbide! December 1984. <sup>10</sup> The issue disappeared after the chemical plant was bought by DOW Chemicals. Dupont and DOW have formed CORTEVA. No one is watching their regular programs and their advertisements do not show anything negative.

There are unjust International Trade Regimes and Trade Related Intellectual Property Rights (TRIPS), Free Trade Agreements (FTA)s with clauses such as ISDS (Investor State Dispute Settlement), agreements on agriculture, digitilisation of traditional resources and data control.

There is systematic marginalization, dilution and blindspotting of conventions and international regimes that have potential for protection of the poor, marginalized and vulnerable communities and sections of society. The Human Rights Council, the Convention on Biodiversity (CBD), ILO's protection of workers are examples of organisations targeted. There are increasing inequities worsened pathologically by COVID-19.

WHO's Bridging the Gap 1995 included new International Classification of Diseases ICD Z -59.5 <sup>11</sup> - basically showing increasing disparities between countries and within countries. Instead of bridging the gap we see widening of the gap.

# Bridging the gap: Access to COVID-19 vaccines

Academics support the TRIPS Intellectual Property Waiver Proposal <a href="http://infojustice.org/archives/43313">http://infojustice.org/archives/43313</a>

The TRIPS agreement of the WTO provides for a 20 year patent on new entities meaning they are marketed at the price – very high – determined by the patent holder - as explained in HAIAP News April 2021, under the DOHA Agreement 2001.

http://www.haiasiapacific.org/wp-

content/uploads/2021/06/HAIAPNewsApril2021Rev.pdf Pages 7.8

TRIPS Flexibilities are available to cover emergencies and countries have an absolute RIGHT to use those flexibilities. To cover 'emergencies' Articles 30/31 in the TRIPS Agreement spells out flexibilities that allow compulsory licensing and other mechanisms to manufacture patented products without permission of the 'rightful owner'. Because these mechanisms are in reality extremely difficult to operationalise, a Waiver has been proposed by India and South Africa and signed by 100 other countries. In July 2021 nearly 50 Academics signed an open letter in support of the TRIPS Intellectual Property Waiver Proposal calling on the governments opposing the waiver to drop their opposition - opposition in face of the early statements that 'Whoever Finds a Vaccine Must Share It' and 'no one is safe until all are safe'

The letter from the Academics in support of the Waiver is quite long but it does cover all issues. **See next page:** 

<sup>&</sup>lt;sup>10</sup> https://www.britannica.com/event/Bhopal-disaster

<sup>11</sup> https://www.psychdb.com/teaching/dsm-v-icd-z-codes

# Academic Open Letter in Support of the TRIPS Intellectual Property Waiver Proposal

The full letter with references and signatories can be found here: <a href="http://www.haiasiapacific.org/wp-content/uploads/2021/08/Trips-waiver-open-letter-final-1-1.pdf">http://www.haiasiapacific.org/wp-content/uploads/2021/08/Trips-waiver-open-letter-final-1-1.pdf</a>

#### July 202112

The temporary TRIPS waiver<sup>[1]</sup> – as proposed by India and South Africa and supported by more than 100 countries – is a necessary and proportionate legal measure towards the clearing of existing intellectual property barriers to scaling up of production of COVID-19 health technologies in a direct, consistent and effective fashion. We call on the governments of the United Kingdom, Australia, Brazil, Japan, Norway, Switzerland and the European Union to drop their opposition to the TRIPS Waiver proposal at the World Trade Organisation and to support the waiver.

Intellectual Property (IP) rights - including patents, copyrights, trade secrets and other undisclosed information - are not, and have never been, absolute rights and are granted and recognised under the condition that they serve the public interest. IP rights must not be allowed to stand in the way of measures designed to make accessible the health technologies needed to fight the COVID-19 pandemic, where universal global access is essential for the global public good. We acknowledge that legal factors beyond IP, such as trade and export restrictions, also shape the ability to produce and access COVID-19 vaccines and therapeutics. Nonetheless, it is the case that IP rights, and monopolies over tacit and informal information, are also implicated in the current lack of global capacity for vaccine production and other health technologies, as well as in enabling their inequitable distribution.

Current strategies to address the vast inequity in the distribution of COVID-19 vaccines have focused on solutions that build on the existing IP system, such as the World Health Organisation (WHO) COVAX initiative or voluntary licensing provisions. Such proposals have had limited and insufficient success to date at providing vaccines to low- and middle-income countries. We note that as of June 2021 the voluntary COVAX donation scheme has delivered only 90m out of a promised 2bn doses.<sup>[2]</sup>

Pharmaceutical companies who hold relevant IP rights have also failed to engage with the WHO's voluntary COVID-19 Technology Access Pool (C-TAP) of IP and know-how. [3] Meanwhile, several solicitations of collaboration to produce vaccine by companies, such as from *Teva* in Israel, *Biolyse* in Canada, *Bavarian Nordic* in Denmark, and *Incepta* in Bangladesh, have not engendered a positive response from vaccine IP holding companies. [4] Moreover, the shortcomings of vaccine

production are not the only problem: distribution of existing vaccine supply has been profoundly unequal, with pre-purchasing and hoarding of doses by several high-income countries. This has underlined the need for globally distributed, local vaccine manufacturing hubs in low and middle-income countries in order to guarantee sustainable supply.<sup>[5]</sup>

Given the ongoing absence of sufficient voluntary engagement by the pharmaceutical industry with proposed global mechanisms to share IP rights, data and know-how to address the pandemic, the ability to suspend rules under the TRIPS Agreement is crucial to enable a radical increase in manufacturing capacity, and thus supply, of COVID-19 vaccines. This will facilitate a globally coordinated and transparent pathway to achieve global equitable access. The proposed TRIPS waiver would provide more companies with freedom to operate in order to produce COVID-19 vaccines and other health technologies without fear of infringing another party's IP rights and the attendant threat of litigation.

Furthermore, in light of the considerable public financing of COVID-19 vaccine research, development, production and purchase, claims of inviolability of private IP monopoly rights cannot be justified. The IP system has failed in the past to create market incentives for vaccine development — a finding that is acknowledged and analysed by scholars in the field. In the case of COVID-19 vaccines, such a market failure has been mitigated with unprecedented public funding and de-risking of R&D costs through advance market commitments by governments. In these tailored public interventions addressed the pressing need for vaccine development, and in doing so compensated for the failure of IP incentives on their own to promote vaccine research and development.

The TRIPS waiver is necessary at this time because the existing provisions within the TRIPS Agreement are not sufficient in a pandemic context, whereby global access to vaccines produced at speed and scale is in all our interests. For example, compulsory licence provisions under Art. 31 and Art. 31bis of TRIPS are insufficient to tackle already existing and emerging patent thickets and data exclusivity rules that impede production by manufacturers other than the IP rightsholders.[9] Furthermore, compulsory licences do not address the need for technology transfer and the sharing of know-how needed to build local and regional manufacturing capacity. Building such capacity would sustainable solutions for this and future pandemics by increasing domestic/regional manufacturing capacity for vaccine production.

<sup>&</sup>lt;sup>12</sup> http://infojustice.org/archives/43313

Governments must work with IP holders to make available and incentivise the disclosure of information held as trade secrets (and other undisclosed information) on grounds of Art. 73 (b)(iii) TRIPS, as well as through the strengthening of domestic public interest provisions under Art. 39(3) TRIPS. There are precedents for this, including US production of penicillin in WWII in which the US government oversaw the necessary pooling of technology and knowledge by companies and universities to rapidly increase penicillin production. Last year, the US government used the Defense Production Act to prioritise the production of components for national supply as needed to combat COVID-19.<sup>[10]</sup>

The proposed TRIPS waiver will enable the temporary suspension of the relevant TRIPS rules for the duration of the COVID-19 pandemic, allowing freedom to operate. It is thus a necessary ingredient as part of a multipronged approach to combat the pandemic. This approach must also encompass other steps, including: global co-ordination of supply chains; streamlining regulatory approval processes and sharing exclusive data from regulatory dossiers; and investment in the WHO's C-TAP and the mRNA technology transfer hub in South Africa.[11] The TRIPS waiver will thus facilitate the technical resilience of lower- and middle-income countries in view of present and future pandemic action and preparedness. This is in line with the commitment in the TRIPS Agreement to balance the rights of IP holders in high-income countries with the promise of technology transfer to lower- and middle-income countries. It is time to fulfil this promise and, in so doing, to end the pandemic.

# Defending access to medicines in regional trade agreements:

Lessons from the Regional Comprehensive Economic Partnership – a qualitative study of policy actors' views Townsend Globalization and Health (2021) 17:78 Read the whole article here: https://doi.org/10.1186/s12992-021-00721-4 Belinda Townsend

#### **Abstract:**

Background: The Regional Comprehensive Economic Partnership Agreement (RCEP) is a mega regional trade agreement signed by fifteen countries on 15 November 2020 after 8 years of negotiation. Signatories include the ten members of the Association of South East Asian Nations (ASEAN) plus China, New Zealand, Japan, South Korea and Australia. India was a negotiating party until it withdrew from the negotiations in November 2019. The RCEP negotiations were initially framed as focused on the needs of low income countries. Public health concerns emerged however when draft negotiating

chapters were leaked online, revealing pressures on countries to agree to intellectual property and investment measures that could exacerbate issues of access to medicines and seeds, and protecting regulatory space for public health. A concerted Asia Pacific civil society campaign emerged in response to these concerns, and in 2019, media and government reporting suggested that several of these measures had been taken off the table, which was subsequently confirmed in the release of the signed text in November 2020.

**Results:** This paper examines civil society and health actors' views of the conditions that successfully contributed to the removal of these measures in RCEP, with a focus on intellectual property and access to medicines. Drawing on twenty semi-structured qualitative interviews with civil society, government and legal and health experts from nine countries participating in the RCEP negotiations, the paper reports a matrix of ten conditions related to actor power, ideas, political context and specific health issues that appeared to support prioritisation of some public health concerns in the RCEP negotiations.

Conclusions: Conditions identified included strong low and middle income country leadership; strong civil society mobilisation, increased technical capacity of civil society and low and middle income negotiators; supportive public health norms; processes that somewhat opened up the negotiations to hear public health views; the use of evidence; domestic support for health issues; and supportive international public health legislation. Lessons from the RCEP can inform prioritisation of public health in future trade agreement negotiations.

HAIAP comment: This article (Open Access) is worth reading in full as it documents a significant victory for Public Health, with the rejection of TRIPS Plus IP Clauses and other Monopoly attempts. The forces that opposed these clauses were led by the low and middle income countries in ASEAN

#### Insulin Centenary

www.thelancet.com/diabetes-endocrinology Vol 9 April 2021

The Lancet reported March 13 that 2021 marks the centenary of the discovery of insulin and represents a golden opportunity to improve access to insulin and diabetes care in general. At the global level, in April, WHO will launch the Global Diabetes Compact, a major initiative aiming to improve diabetes prevention and management. Hopefully, the Compact will emphasise the need to improve access to diabetes medications, including insulin, particularly in low-income and middle-income countries. Meanwhile, in the USA, the Biden administration is faced with those who profiteer from people with diabetes leading to the country's insulin crisis.

<sup>&</sup>lt;sup>13</sup> www.thelancet.com/diabetes-endocrinology Vol 9 March 2021

100 years after its discovery, insulin should be accessible and affordable to everyone who needs it, worldwide - that this cannot even be said for one of the wealthiest countries in the world is a scandal that must come to an end.

WHO Director-General Tedros Adhanom Ghebreyesus, made this statement as he opened the annual WHO Executive Board meeting in January, 2021,

'I need to be blunt: the world is on the brink of a catastrophic moral failure—and the price of this failure will be paid with lives and livelihoods in the world's poorest countries.'

#### The HAI ACCISS Mission

https://haiweb.org/about-acciss/

We live in a world where only 1 in 2 people have reliable access to the insulin they need. Over the past four years, the HAI ACCISS Study has looked at access issues from multiple perspectives to gain a comprehensive understanding of the insulin landscape and factors impacting access. Through this ongoing research, we have gathered non-biased evidence and developed useful evidence-based tools to help decision-makers and others at both the global and national levels. Our objective is to increase access to affordable, quality-assured insulin for everyone who needs it.

Insulin, discovered in 1921, was first used in 1922. At the time, it was considered a medical miracle that changed the diagnosis for those living with type 1 diabetes from a death sentence to a manageable condition. Today, all those living with type 1 diabetes, and an estimated 63 million living with type 2 diabetes, use insulin. Despite the fact that insulin has been used for nearly 100 years, an estimated 1 in 2 people who need it cannot afford and/or access this much-needed medicine. Since its inception in 2015, HAI's Addressing the Challenge and Constraints of Insulin Sources and Supply (ACCISS) Study has been working to identify and address the inequities and inefficiencies in the global insulin market.

### PHASE I (2015-2018)

In its initial phase, ACCISS produced a comprehensive, first-of-its-kind evidence base of the global insulin market. In doing so, it created innovative policies, tools and interventions to overcome barriers to insulin access globally, which have been brought together under the ACCISS Toolkit.

### PHASE II (2018-2021)

The second phase focuses on piloting the tools and interventions developed in Phase I at country level, while continuing to work globally to address inequities and inefficiencies in the insulin market. Our Phase II work streams are:

- Work with global partners to develop evidence-based tools that address worldwide barriers to insulin access, and strengthen tools already developed
- Develop, with national partners in four countries, comprehensive and contextualised national strategies to address the range of challenges that people requiring insulin face, and to pilot and evaluate the interventions
- Further expand the ACCISS network and develop civil society networks, amplified in international/ regional/national fora, to reduce, or eliminate, the barriers to insulin access

The study is co-led by Dr Margaret Ewen and Molly Lepeska (HAI) and Dr David Beran (Geneva University Hospitals and the University of Geneva). It also brings together a large group of leading international experts as members of its Advisory Group. The study is funded by a grant from The Leona M. and Harry B. Helmsley Charitable Trust and Stichting ICF.

Find out more about the principles and ideas behind ACCISS here.<sup>14</sup>

# 2021 60th anniversary since thalidomide

**withdrawal** Published by the University of Melbourne <a href="https://blogs.unimelb.edu.au/sciencecommunication/2019/10/17/thalidomide-lest-we-forget/">https://blogs.unimelb.edu.au/sciencecommunication/2019/10/17/thalidomide-lest-we-forget/</a>

Thalidomide is a drug that was marketed as a sedative and treatment for morning sickness in pregnant women in the late 50s and early 60s. This drug subsequently caused babies to be born with a range of disabilities.

Thalidomide was first developed by Chemie Grunenthal in Germany in 1954 and introduced into the UK in 1958, primarily under the brand name *Distaval*. It was withdrawn from the UK in 1961.

### The Timeline

Thalidomide was discovered and produced by the German pharmaceutical company, Chemie Grünenthal. It was introduced as an over-the-counter sedative and relaxant to many European countries in 1956. It was also found to relieve nausea and was given to pregnant woman for morning sickness. The drug was marketed as being extremely safe and thalidomide soon became a very popular drug. In 1960 it was sold in 46 countries, including Japan and Australia.

However, there was a corresponding surge of birth defects in this time. Notably, limb deformities were estimated at 10,000 newborns worldwide. It was described as an epidemic but the cause was unknown.

<sup>14</sup> https://haiweb.org/about-acciss/

In 1961, two clinicians, Dr William McBride from Australia, and Widukind Lenz from Germany, connected thalidomide to the birth defects.

This discovery sparked widespread public outrage and a huge media coverage of the drug. This resulted in the Australian government removing it from the market in late 1961. Tragically, some countries such as Japan, continued to prescribe thalidomide into 1962. This was due to confusion between the different trade names of thalidomide. After 8 months of thalidomide being banned in Australia, there was a marked decrease in birth defects.

#### The Science

Thalidomide is broken down by the body into different byproducts. Some of these by-products effect human embryos between 8 to 14 weeks of pregnancy - the critical period where limbs and organ systems develop.

Specifically, a by-product interferes with the development of blood vessels. Blood vessels are crucial for tissue, bone and organ growth. When they do not grow properly, the nearby cells do not receive oxygen and die, causing birth defects in the embryo.

It was previously believed that the placenta protected embryos from drugs. However, the discovery of the deformities caused by thalidomide, changed this view.

When pregnant women took thalidomide during the critical time period, birth defects occurred in up to 50% of the babies born. Nearly 40% of the affected babies died soon after birth.

The defects almost invariably involved deformed limb. Also, there were facial and spinal deformities, absent ears and deafness, as well as malformations of organs including the heart, kidneys, and bowel.

The thalidomide tragedy illustrated the dangers of drug side effects to the world. This spurred Australia to reform its medical safety procedures.

Researchers now know drug testing on animals must occur in more than one type of animal. Initial testing of thalidomide on pregnant mice showed the drug only had a weak effect. However, testing on other animals, including rabbits, showed that thalidomide caused severe birth defects during pregnancy.

### Transformation of Drug Testing in Australia

Drug toxicity and the potential effects on developing embryos are now carefully evaluated for any new drug before being introduced to Australia.

Organisations were formed to advise on the introduction of new drugs and to monitor existing drugs. The Australian Drug and Evaluation committee was formed in 1963. In 2010, it was replaced by the Therapeutic Goods Administration.

#### The future

The United States never introduced thalidomide to the market, saving lives and preventing countless deformities. This is because in 1960, the Food and Drug Administration in America reviewed the drug and found the it had not been appropriately tested for safety.

Our world faces exciting scientific developments each day. When thinking about the thalidomide disaster, it is important to remember how important safety is. Science and medicine has the capacity to help, but we have to be wary of what we introduce to the public.

[Thalidomide was a global event/tragedy. The drug was heavily marketed in many countries. There were early reports of possible congenital malformations which were strongly denied by the company with insufficient scientific evidence. Therefore Chemie Grünenthal, allowed thalidomide to remain on the market, a decision based on profits rather than public health. A description of the events is given in <a href="https://theconversation.com/why-did-thalidomides-makers-ignore-warnings-about-their-drug-47092">https://theconversation.com/why-did-thalidomides-makers-ignore-warnings-about-their-drug-47092</a> However thalidomide resulted in the beginning of Medicines Regulation - pharmaceutical companies could no longer simply release medicines into the market but had to submit dossiers on the medicine, that had to be officially approved. So out of tragedy, arose prevention and safety. Ed]

### ReACT: Three key take-aways after WHA74

https://www.reactgroup.org/wpcontent/uploads/2021/05/ReAct-Briefing-Pandemic-Preparedness-and-Antibiotic-Resistance.pdf

# 1. Global vaccine inequality dominated the WHA74

One issue that dominated most of this year's discussions was the inequitable global vaccine distribution and its consequences. General Director for the WHO Dr Tedros noted in his opening remarks that

"...doses administered globally so far would have been enough to cover all healthcare workers and older people, if they had been distributed equitably".

In the following debates one low-and middle-income country after the other took the floor with testaments of the desperate situation on the ground of responding to the pandemic with the necessary tools to keep medical personnel safe and to treat patients often being in shortages, and lack of access to the vaccines volume needed to bring the pandemic under control.

The contrasts between rich and poor countries were stark. Mozambique for example, home to 31 million people, noted that they so far had been able to vaccinate less than 1% of their population. Several low-and middle-income countries noted that the global distribution mechanism COVAX that many rely on for getting access to vaccines, was insufficient and hampered by delays. Israel, in contrast, noted that they were so far in vaccine roll-out [at the time] that they planned to lift all COVID-19-related restrictions in coming weeks, and simultaneously called for vaccine passports to be strengthened as a

measure to be able to prevent importing the virus through travellers

#### 2. Antimicrobial resistance

Against the backdrop of the ongoing and – as noted by many countries – still overwhelming COVID-19 pandemic, attention to other global health threats, such as antimicrobial resistance, continued to be limited. However one silver lining in the debate was the increasing number of Non-State Actors taking the floor to make interventions on antimicrobial resistance including new stakeholders in the field such as the Union for International Cancer Control. ReAct has focused on mobilizing other adjacent communities on antimicrobial resistance, and in particular the cancer community, over the past years, and is therefore very encouraged to see the field of actors concerned about antimicrobial resistance grow.

Another highlight from the discussions was the Germany announcement to commit additional €4 million to the Tripartite and the Multi-Partner Trust Fund bringing total contributions to this mechanism up to nearly 20 million USD in support of implementation efforts of national action plans in low-and middle-income countries.

Finally, a number of countries also called for more critical and comprehensive global evaluation of countries' and WHO's work on antimicrobial resistance, including a critical review of the Global Action Plan, the need to establish key performance indicators, as well as ensuring that monitoring and evaluation of the WHO's work should be done by external reviewers.

#### 3. Pandemic treaty proposal moving forward

A large number of countries from all income groups took the floor in support of the proposal made ahead of the WHA to establish a new global pandemic treaty or similar legal framework to strengthen global preparedness and response. The Assembly decided to hold a special session in November this year dedicated to further discuss the merits of a new global legal framework and in preparation of these discussions a Member States Working Group should be tasked with assessing the pros and cons of developing a pandemic treaty.

Ahead of the WHA74, ReAct developed and circulated a briefing to Member States on the obvious overlaps between interventions needed to strengthen global pandemic preparedness and response and antibiotic resistance. As such, it will be important for a new legal framework to also include antibiotic resistance in its scope, if it moves forward. The political momentum to act multilaterally to prevent a new pandemic should be used to tackle antibiotic resistance, which is increasingly referred to as 'the silent pandemic'.

#### HAIAP - Pharmaceutical Promotion Action Research Project 2021

**Why?** Promotion claims for medicines that cannot be substantiated are common and cause harm. Regulation is weak and poorly enforced. There is a need to bring this situation to the attention of consumers, health professionals, the media, and the government.

**How?** Experienced members of HAIAP will provide health sciences students with experience and assistance in critically assessing medicines advertising claims against scientific evidence, working up complaints to regulators, and publicising the findings.

Full details are available in the proposal. If you are interested to become involved follow the instructions in the proposal.

**Methodology: 1.** Find and document the promotion of a medicine (or supplement) with dubious claims: 1.1. Take a screenshot of the product pack &/or website page(s) containing suspect claim(s), date it, and add it to your report.

- 1.2. Identify who is responsible for the advertisement; if a website's provenance is not apparent, try WHO IS.\* The advertiser must be based in your country to be within the jurisdiction of your regulator.
- 1.3. Identify the therapeutic product advertised and the suspect claim(s) and add it to your report
- 1.4. Check if your medicines regulator has registered the product and the claims match the approved indications of the medicine. Add results to your report.
- 2. Check your selection is suitable by emailing it to HAIAP via <a href="mailto:ken.harvey@medreach.com.au">ken.harvey@medreach.com.au</a>.
- 3. Search for evidence that supports or refutes the claim: Summarise the evidence and add it to your report.
- 4. Does the evidence support the claims(s)?
- 4.1. Add your conclusion to your report.
- 5. Are the claim(s) in breach of local (or international) advertising codes?
- 5.1. Add your conclusion to your report.
- **6.** Send your report to HAIAP (via ken.harvey@medreach.com.au) to check and discuss the possibility of submitting a complaint and publicity via HAIAP News, short videos, etc.

http://www.haiasiapacific.org/wp-content/uploads/2021/06/HAIAP-Pharmaceutical-Promotion-Action-Research-Project.pdf \* ICANN Lookup

#### **Feature: Indoor Pollution**

Yuvini Mapalagama

Students Involved in Rational Health Activities (Sri Lanka)

The Lancet Editorial June 28, 2019<sup>15</sup>, reported the publication by the National Institute for Health and Care Excellence (NICE) of draft guidance <sup>16</sup> on indoor air quality at home, highlighting some perhaps unexpected sources of indoor air pollution. The Lancet has often spoken about indoor air pollution problems in countries where the burning of fuels inside the home is a common occurrence, but the NICE guidelines offer some thoughts on the sorts of pollution problems that can affect households worldwide.

The guidelines, which cover household activities such as use of cookers and cleaning products and common problems like persistent damp, suggest that the burden of unseen indoor air pollution will fall on the most vulnerable, especially those in poor-quality housing. Problems attributed to these sorts of pollutants include exacerbation of asthma symptoms. They are particularly troublesome for people with pre-existing medical conditions. The key is to ensure greater ventilation in housing, by opening windows and using extractor fans when performing such tasks.

In March 2021 the World Health Organization released a roadmap <sup>17</sup> to improve indoor ventilation in the context of COVID-19, focussing largely on quite sophisticated

mechanisms to control air flow. Clearly ventilation is extremely important in the context of the very efficient aerosol spread of current strains of COVID-19.

In the June Edition of the SIRHA Newsletter Yuvini Mapalagama looks at the actual situation in Sri Lanka and by identifying major contributors to harmful indoor pollution in that setting she recognises practical courses of action that could improve the situation.

#### The Invisible Threat that Lurks Indoors

SIRHA Quarterly Newsletter Vol 1 Issue 3 June 2021 Yuvini Mapalagama

#### **Background**

With lockdowns, quarantine, and the current pandemic status, (in spite of months long continuous stays at home and being otherwise healthy) some of us have experienced many random days of unexplained allergic rhinitis, unexplained asthma or respiratory symptoms.

https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(19)31574-0/fulltext

Sri Lankan studies suggest indoor air pollution (IAP) is more severe than outdoor air pollution, despite Sri Lanka being a tropical country.

A variety of essential oil diffusors, humidifiers, strong aroma-infused incense sticks, scented candles, mosquito coils and liquid vaporizers, air fresheners and various aerosol sprays and dust have contributed to the indoor air composition in the modern home.

#### **Indoor Air and Health**

The WHO estimates that 3.8 million people a year die prematurely from illness attributable to the household air pollution caused by the inefficient use of solid fuels and kerosene for cooking. Exposure to household air pollution almost increases the risk for childhood pneumonia, acute lower respiratory infections (pneumonia) in adults, stroke, ischemic heart disease COPD and lung cancer.

A hospital-based case-control study in Sri Lanka relates that the presence of dust at home was a significant risk factor for asthma.

Another study based in Kegalle and Kalutara districts reports that using less clean cooking methods and not having adequate ventilation in the cooking area were significant predictors of low birth weight.

A study conducted in suburban Colombo also reports that the use of firewood for cooking was a significant risk factor for respiratory symptoms.

#### The Sri Lankan Situation

A study conducted to measure SO<sub>2</sub> and NO<sub>2</sub> levels indoors and outdoors of 30 low-income households at five different locations in Colombo reported that indoor pollutant levels were higher than those outdoors in all households.

Cooking fuel is the main source of IAP in most Sri Lankan households while other sources include tobacco smoke, essential oil diffusors, humidifiers, strong aroma-infused incense sticks, scented candles, mosquito coils and liquid vaporizers, air fresheners and various aerosol sprays; and dust and smoke from outdoor sources.

The Ministry of Health, Nutrition and Indigenous Medicine of Sri Lanka recognises indoor air pollution as a modifiable risk factor for NCDs in the national

<sup>&</sup>lt;sup>16</sup> https://www.nice.org.uk/guidance/ng149/documents/draft-guideline

<sup>&</sup>lt;sup>17</sup> https://www.who.int/publications/i/item/9789240021280

multisectoral action plan for the prevention and control of noncommunicable diseases 2016- 2020. The action plan includes many notable ventures such as developing indoor air quality guidelines, advocacy with stakeholders to promote clean fuel for cooking, conduct research on interventions to reduce indoor air pollution in local context, introduction of cleaner technologies and ovens with less fumes, improved cooking stoves and improving public awareness of the dangers of passive smoking and IAP.

#### **Indoor Smoke**

Most traditional local stoves using firewood have incomplete combustion resulting in highly pollutant emissions. This effect coupled with poor ventilation can produce very high levels of IAP. Women and young children who usually stay around their mothers while they are cooking may be the most vulnerable.

Gas stoves, indoor use of charcoal for barbeque drills, under-ventilated fire places in the hill country may also be responsible for CO, SO2 and NOx emissions and particulate matter emissions.

While the National Authority on Tobacco and Alcohol Act has banned smoking in health-care institutions, educational institutions, government facilities, universities, indoor offices, and other indoor workplaces, children might be exposed to second hand parental smoking in household settings.

# Indoor practices commonly found in traditional Sri Lankan households

### **Incense Sticks**

Fog incense cones, essential oil infused incense sticks and various smoke and particulate matter generating incense sticks are popular in both national international markets, and the social media hype about aromatherapy values negates the problems associated with impaired air quality and respiratory tract related risks – so that practice is also concerning.

A Chinese study provides epidemiologic evidence between long-term exposure to IAP from incense burning may substantially contribute to the risk of cardiovascular mortality increasing the risk of CHD deaths and strokes.<sup>18</sup>

### **Insect Repellents**

Particulate matter, complex chemical compounds and carbon monoxide and other toxic gases, and vapours including formaldehyde pose a threat. Furthermore coils, are burnt in closed rooms and as is burning mosquito repellent papers. Various liquid vaporizers, bug sprays and aerosols may also contribute to a decline in indoor air quality. Most of the negative impacts are yet to be studied.

<sup>18</sup> Environ Health Perspect 2014 Dec;122(12):1279-84. doi: 10.1289/ehp.1307662.

# Burning one mosquito coil would release the same amount of particle matter as burning 75–137 cigarettes.

The emission of formaldehyde from burning one mosquito coil can be as high as that released from burning 51 cigarettes.

#### **New Trends**

Scented candles may release respiratory irritants upon burning. Candles made of petroleum and paraffin also pose a problem. Releasing unburnt particulate matter in the form of soot, triggering asthma etc. Also candles in jars are more deprived of oxygen and may pose a bigger threat. A new type of candles introduced as slow burning candles may be much hazardous, as the included chemicals may be released to the air creating irritation and worsening of symptoms in asthma prone people.

Undermaintained, uncleaned humidifiers can be a breeding site for mould and using such a humidifier could be a health hazard as blowing spores and mould all over the house.

Essential oil diffusors might be trending but might be irritants which might worsen already existing respiratory conditions like asthma or cause hypersensitivity.

No safe doses or regulations strictly regulate the standards of the diffusors and the quality of essential oils in the local market, even for cinnamon oil (which is an important export product).

#### Conclusion

A plethora of factors combined with low ventilation and increased indoor activity have a negative impact on the indoor air quality of Sri Lanka. It is crucial to pay attention to new societal trends that may affect indoor air quality. With the pandemic situation prolonged until an unseen future, focus on IAP should be continued - especially at the community level.

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## The Revolutionary Foreseer

# SIRHA Event to commemorate the 101<sup>st</sup> Birthday of Professor Senaka Bibile

Professor Senaka William Bibile was the founder of Sri Lanka's National Drug Policy. He was born on 13th February in 1920 at Kathaluwa Walauwa. He received his primary and secondary education at Trinity College,

Kandy and entered the Medical College Colombo for his higher studies. After being an outstanding student he graduated from the

college with a 1st class honours degree with two gold medals - for Medicine and Surgery. He was a passionate doctor and later in his carrier he became the first Professor of Pharmacology in Sri Lanka. His drug policy was the model for development of policies based on rational pharmaceuticals use in many countries as well as in WHO (World Health Organization). This great personality died on 29th September 1977 at 57 years.

Students involved in the rational health activities (SIRHA) society of the Faculty of Medicine, University of Colombo, organised a hybrid event to commemorate the 101st Anniversary of his birth on 13th February 2021 as an initiative of the Trail Blazers project of the society.

The Commemoration Day was named 'Senaka Bibile; The Revolutionary Foreseer'. It was held in the New Building Lecture Hall of the Faculty of Medicine, University of Colombo with participation of less than 50 guests, following COVID-19 Safety precautions. The event was sponsored by the Colombo Medical School Alumni Association and Vidya Jothi Dr. Prasad Katulanda.

The Commemoration Day was graced by participation of the Honourable Vidva Jothi Professor Vaiira Dissanavake. Dean of Faculty of Medicine, University of Colombo, Professor Laal Jayakody, Professor Manui Weerasinghe, Professor Indika Karunathilaka, Prasad Katulanda, Dr. Sachith Abayarathne, Professor Priyadarshani Galappatthy, Dr. Palitha Abeykoon, Mrs. Sujathi Javarathne, Mr. Upasena Javarathne, Mr Hiran Senaka Bibile; grandson of Professor Senaka Bibile, Mr Sathilka Dissanayake; President of Medical Faculty Students Union, Colombo, Mr. Tharindu Nimantha; President of Medical Students Welfare Society, Colombo and Mr. Nimsara Abeysekara, President of Medical Faculty Students Union, Sri Jayawardhanapura.

Professor Krisantha Weerasuriya, Professor Narada Warnasooriya, Professor Shalini Sri Ranganathan, Mr Ranil Bibile, Mrs Leela Bibile, Mr Hiranjan Bibile, Mrs Lilani de Silva, Dr Mahesh Rajasuriya and Dr Manuja Perera also joined the event via Zoom online platform.

A documentary video on Professor Senaka Bibile and his work was launched as one of the main events in the Commemoration Day.

A debate competition was the second main event - named the 'Professor Senaka Bibile Memorial Debate' and eight medical students representing eight state medical faculties participated on the topic 'The level of implementation of Professor Senaka Bibile Drug Policy in present Sri Lanka is satisfactory' is not satisfactory'.

The proposing team was led by Prishal Morapitiya from

Faculty of Medicine, Rajarata University with team members Nipulul Rupasinghe, Faculty of Medicine, Kelaniya University; Dumindu Rashan, Faculty of

Medicine, Wayamba University; Induwara Wishwakith Faculty of Medicine, Colombo University.

The opposing team was led by Dunya Jayasekara, Faculty of Medicine, Sabaragamuwa University with team members Vidya Rashmi, Faculty of Medicine, University of Ruhuna; Ishanthi Priyanjala, Faculty of Medicine, University of Peradeniya; Amal Weerathunga, Faculty of Medicine, University of Sri Jayawardhanapura.

The debate was judged by Honourable Judges Professor Laal Jayakody, former President of National Medicines Regulatory Authority and Professor in Pharmacology, and Professor Manuj C Weerasinghe, Professor in Community Medicine and Senior Lecturer in the Faculty of Medicine, Colombo.

Talents of both team members were praised by the judges but with strong arguments and rebuttal the opposing team gained the victory. Dunya Jayasekara, leader of the opposing team, won the trophy for The Best Debater.

Professor Laal Jayakody, former President of the National Medicines Regulatory Authority and Professor in Pharmacology, addressed the gathering about Professor Senaka Bibile's Drug Policy and the responsibilities of Doctors and Medical Students. Professor Bibile's son Ranil Bibile, via the Zoom platform, shared his thoughts and memories of Professor Senaka Bibile with the gathering.

'Men of principle can be harsh and stiff-necked. But, once in a generation comes a man whose unchallenged integrity and humorous friendliness are in perfect balance.

Prof. Senaka William Bibile, the pharmacologist, the doctor, the humanist, the educationist, the socialist, the aesthetician, was such a personality who had a vision ahead of his time. We shall never see his like again. But, his ideas will be reverberated and implemented by those who were and will be influenced by him, until the end of time.'

On behalf of the Bibile Family, Mr. Hiran Senaka Bibile, the grandson of Professor Senaka Bibile, accepted the token of appreciation which was created by the Trail Blazers team to commemorate this great personality, Professor Senaka William Bibile.

'I do not want loyalty towards

myself. I want loyalty to my ideas'