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HAI AP News

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HAI AP Est. 1981

Health Action International (HAI) was formally founded in Geneva in 1981 and coordinated 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 organ 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 April: As well as 'hosting' World Health Day - April 7, this month brings us World Malaria Day - April 25 and Immunisation Week – the last week in April.

There is significant material for discussion around each of these focuses. Universal Health Coverage is the theme for **World Health Day** and as presented explicitly concerns itself with 'coverage' and not comprehensive healthcare.

Malaria remains one of the world's leading killers, claiming the life of one child every two minutes, mostly in Africa where more than 250 000 children die from the disease every year. For the first time a vaccine will be available against malaria - launched in a trial in Malawi on April 25 – **World Malaria Day**, followed by Ghana and Kenya in the next weeks .

We know that vaccines work but WHO reports a 300% increase in measles cases world wide - as a result of a dangerous decline in immunisation rates. **Immunisation week** theme is *Protected Together: Vaccines Work!*

May 23 is **Olle Hanson Day** - Anwar Fazal reminds us.

Our colleagues in AIDAN are still fighting to get the Supreme Court to overrule the ban on the use of oxytocin. With the Indian elections beginning in April, the government is accused of putting cows before people as a perceived vote winner, see page 9.

April Messages

To the people of Sri Lanka and the many other nations affected. We in Health Action International Asia Pacific (HAIAP) are horrified by the vicious attacks on the churches and hotels across Sri Lanka on Easter Sunday. We condemn such senseless acts of violence and we offer our deepest condolences to the victims and their families and to all those affected. We join your struggles to find strength and unity to overcome this dreadful adversity together. May peace prevail on earth.

Medicines prices remain an enormous barrier to access to essential medicines for those who need them. At the WHO Fair Pricing Forum Ellen 't Hoen presented a strong call for transparency on medicine prices and cost of R&D and we share her analysis on page 10.

World Health Day April 7 2019

WHO's theme for 2019: Universal Health Coverage

The WHO rationale for choosing this year's theme is:

Universal health coverage is WHO's number one goal. Key to achieving it is ensuring that everyone can obtain the care they need, when they need it, right in the heart of the community. Progress is being made in countries in all regions of the world. But millions of people still have no access at all to health care. Millions more are forced to choose between health care and other daily expenses such as food, clothing and even a home. WHO's key messages can be seen here

<http://www.haiasiapacific.org/world-health-day-april-7-2019/>

There are indications that the UHC approach as interpreted by governments is not achieving Universal Health Care. According to the PHM position statement

'UHC [is seen] as already legitimizing a model in which big chunks of the system are handed over to networks of private providers'.

However there are instances in India where great gains have been made concurring with the PHM position that:

'UHC must be meant to mean comprehensive care delivered by a system organized around PHC. It must also deal with securing appropriate linkages to higher levels of care, as well as decisively tackling the social determinants of health.'

In India, all States have been given flexibility for implementing the National Health Protection Scheme (NHPS), and Tamil Nadu and Kerala health systems are worth looking at.

Tamil Nadu: Professor KR Sethuraman, Senior Professor of Medicine at AIMST University, Malaysia said 'Having seen the quality and extent of healthcare coverage given to the low-income group in Tamil Nadu at the grass-root level, before and after the introduction of Chief Minister's Comprehensive health Insurance scheme¹, most of us serving in Tamil Nadu areas have noticed the remarkable improvement in healthcare delivery to the needy since 2009, when this scheme was launched. It is most noticeable in secondary and tertiary care.

'As a practicing cardiologist in a tertiary care teaching Hospital run by the Government, I had sent back so many poor people, who needed curative tertiary care services, which they could not afford to pay for. However, since 2009, for the past decade, such patients are admitted in any of the hospitals in the approved panel for totally subsidized care. Government hospitals compete on level-playing field with the private and corporate hospitals to serve the patients and claim reimbursement.

'With increased flow of funds to high performing government hospitals, they have no shortages of supplies like the pre-2009 days.' ... 'The Government of Tamil Nadu had the funds earlier too but it did not reach the needy poor. Due diligence and a robust reimbursement policy of the Chief Minister's Scheme, which has now survived for 10 years under a different Chief Minister is one such model of UHC.'

For more information about the Tamil Nadu scheme see <https://www.indiatoday.in/india/story/ayushman-bharat-chief-minister-health-insurance-scheme-tamil-nadu-modi-1349261-2018-09-26> and visit the official website

<https://www.cmchistn.com/> for more details).

Kerala: Kerala has moved a step closer to achieving universal health care by integrating the numerous health-care protection schemes in the State, including the Karunya Benevolent Fund (KBF), into a new comprehensive health insurance scheme.

<https://www.thehindu.com/news/national/kerala/new-health-insurance-scheme-soon/article24181610.ece>

The new scheme, Karunya Suraksha Padhati, replaces the State's current comprehensive health insurance scheme (RSBY-CHIS/CHIS Plus) and KBF.

Aligning with the Centre's newly announced National Health Protection Scheme (NHPS), which offers a health protection coverage of IR 5 lakh (500,000) for a BPL family, the new scheme will cover all major secondary and tertiary medical care services, including the treatment of cancer or cardiac diseases, in all empanelled public or private hospitals.

Integration of the various health beneficiary schemes had been a promise made in the 2016 revised State Budget presented by Finance Minister T.M. Thomas Isaac. At present, Kerala has at least nine beneficiary schemes.

'Integration of these schemes means that the State can utilise the same budgetary allocation to give better health protection for the people. All States have been given flexibility in implementing the NHPS. We are thus using the NHPS framework and its robust IT platform to integrate and monitor all existing schemes,' a senior health official said.

¹ <https://www.cmchistn.com/>

Universal Health Coverage (UHC): The Peoples Health Movement analysis

From Claudio Schuftan:

What sustainable financing for Universal Health Coverage?

The UHC approach is a step forward -- it has re-focused attention on health systems rather than on priority services and diseases; this is good. But UHC must also be seen as the relaunching of the logic of private insurance participation making health care a veritable health market. Insurance-based systems require demonstrating who is poor and to then segment a portion for 'health for the poor' with a poor man's insurance for them. Such a UHC deepens inequalities.

Universal health coverage explicitly concerns itself with 'coverage' and not comprehensive healthcare.

Prevailing proposals for UHC emanate from technocracies and organizations with clear geopolitical interests with debates centering around how different actors interpret UHC in ways reflecting narrow self-interests and policy preferences. At PHM, we understand UHC as making the right to health of citizens universal - with the largest gains accruing to poorer people. This approach requires deeper reforms than the ones on the table including engaging with the politics around UHC, beyond merely its technical and financing challenges. We are told: 'UHC is the single most powerful concept that public health has to offer'. Fair enough. But such a statement surely needs qualifiers.

Many continue to understand UHC as a 'package of services'. It is argued that such is unaffordable for Less Developed Countries that will need to continue to rely on foreign aid.

Others have proposed that, under UHC, governments should also be funding and universally providing preventive interventions on top of an Essential Health Package of clinical services that the government would finance, but not necessarily directly provide; it would be for the private sector to provide these. The government would thus play the role of a purchaser of care services (with public money) literally revamping the private health sector - and progressively doing away with the public health system.

UHC must be meant to mean comprehensive care delivered by a system organized around PHC

UHC must not only protect against out of pocket expenditures for health. It must also deal with securing appropriate linkages to higher levels of care, as well as

decisively tackling the social determinants of health. PHM further argues for much stronger community mobilisation and for greater accountability of service providers (and of foreign donors). PHM will support WHO on this as long as it insists that UHC means comprehensive coverage of services of the entire population covering close to full cost. Arguments that governments cannot afford to fund comprehensive publicly provided health care is, at best, relative. The priority challenge is to move the ongoing debate on how increased financial resources now available for health care are to be spent. The widening income inequality we see is linked to the call being made for mixed public-private provision. PHM strongly urges governments not to move further in this direction of privatization. Private providers will flock to serve the health needs of the better off and ignore the needs of poor people. Worse, private providers are being publicly subsidized with these subsidies going to the better off. Consequently, all nationally and internationally supported health care delivery systems must be carried out within the public sector rather than deliberately boosting the private sector. UHC is already legitimizing a model in which big chunks of the system are handed over to networks of private providers. About this, health practitioners must be vigilant. Clearly specifying what UHC is to mean is a must, because it risks throwing out the whole notion of comprehensive primary health care.

The vision for UHC we should be pursuing

PHM's vision has the following attributes:

UHC is to:

- be truly universal and human rights-centered (means universal availability of a full range of services according to need; provided at high level of quality; based on primary health care principles; not causing health care-related impoverishment; and with no significant financial barriers to accessing higher level services);
- provide horizontally integrated health services;
- cover a comprehensive range of services for local communities at full cost;
- be organized around the principles of comprehensive PHC with effective referrals to higher levels of care according to need;
- include mixed public-private provision only IF the private component is fully regulated.
- be supported by foreign aid, but the aid must be routed to the public sector;
- move away from vertical approaches;
- move away from project/program approaches and instead be directed to budget support;

- be non-negotiably based on community involvement, mobilization and monitoring for assured accountability;
- strengthen district health systems including their funding, procurement, supervision, continuing education, etc;
- use appropriate technology and appropriate workforce policies;
- pay special attention to the social, economic and political determination of health.

Problematic questions still left to resolve include those related to: the role of the private sector and the not-for-profit NGO sector; the role of foreign assistance; governance arrangements; the articulation between horizontally integrated health systems and vertical programmes; the role of traditional practitioners; the role of community health workers; the role of community involvement; strategies for addressing the SDH; approaches to mobilise funds, funds pooling and payment modes.

Philippines

Universal Health Coverage: Everyone, Everywhere

From Delen de la Paz

On April 5, PHM Philippines staged a rally in front of the WHO WPRO Headquarters in Manila to highlight their concern about the way the Philippine government and even WHO is pushing for universal health coverage financed by health insurance, rather than taxes. The approach is seen as commercialization and privatization of health services, instead of strengthening of public health systems.

Around 50 members of the health sector including doctors, nurses, dentists, medical technicians, hospital and community health workers participated in the rally.

A press release was issued explaining that the Philippines UHC is really 'social health insurance' - a health market innovation that would provide population with 'health service packages.' With corporate management power a portion of the funds can be invested in businesses and tied up with health providers - mainly private hospitals and Health Maintenance Organizations - and limits can be set for insurance claims.



The Duterte government recently enacted the Universal Health Care Law that makes UHC nothing but a health insurance program which requires compulsory inclusion of every Filipino in the National Health Insurance Program/PhilHealth where they must pay a premium. Health care delivery will now be based on this 'health insurance package' defined by the PhilHealth.

This is not the health care system the people need. The People's Health Movement-Philippines, together with the people, pushes for a free, comprehensive, progressive and unified public health care system that is tax-based and anchored on the principle of health as a fundamental human right.

World malaria day April 25: A vaccine to celebrate

<https://www.who.int/news-room/detail/23-04-2019-malaria-vaccine-pilot-launched-in-malawi>

In Malawi, the vaccine, known as RTS,S, will be made available to children up to 2 years of age; Ghana and Kenya will introduce the vaccine in the coming weeks.

WHO Director-General Dr Tedros Adhanom Ghebreyesus said: 'We have seen tremendous gains from bed nets and other measures to control malaria in the last 15 years, but progress has stalled and even reversed in some areas. We need new solutions to get the malaria response back on track, and this vaccine gives us a promising tool to get there.' 'The malaria vaccine has the potential to save tens of thousands of children's lives.'

Thirty years in the making, RTS,S is the first, and to date the only, vaccine that has demonstrated it can significantly reduce malaria in children. In clinical trials, the vaccine was found to prevent approximately 4 in 10 malaria cases, including 3 in 10 cases of life-threatening severe malaria.

Dr Matshidiso Moeti, WHO Regional Director for Africa said 'We know the power of vaccines to prevent killer diseases and reach children, including those who may not have immediate access to the doctors, nurses and health facilities they need to save them when severe illness comes.'

'This is a day to celebrate as we begin to learn more about what this tool can do to change the trajectory of malaria through childhood vaccination,' she added.

The pilot programme is designed to generate evidence and experience to inform WHO policy recommendations on the broader use of the RTS,S malaria vaccine. It will look at reductions in child deaths; vaccine uptake, including whether parents bring their children on time for the four required doses; and vaccine safety in the context of routine use.

The vaccine is a complementary malaria control tool – to be added to the core package of WHO-recommended measures for malaria prevention, including the routine use of insecticide-treated bed nets, indoor spraying with insecticides, and the timely use of malaria testing and treatment.

The WHO-coordinated pilot programme is a collaborative effort with ministries of health in Ghana, Kenya and Malawi and a range of in-country and international partners, including PATH, a non-profit organization, and GSK, the vaccine developer and manufacturer, which is donating up to 10 million vaccine doses for this pilot.

Ministries of health will determine where the vaccine will be given; they will focus on areas with moderate-to-high malaria transmission, where the vaccine can have the greatest impact.

Delivering the world's first malaria vaccine will help reduce the burden of one of the most pressing health challenges globally.

World immunisation Week - the last week in April

Vaccines Work !

The theme of this year's campaign is Protected Together: Vaccines Work!, and the campaign will celebrate Vaccine Heroes from around the world – from parents and community members to health workers and innovators – who help ensure we are all protected, at all ages, through the power of vaccines.

<https://www.who.int/campaigns/world-immunization-week/world-immunization-week-2019>



Measles in 2019

WHO says measles cases are up 300% in 2019

According to the New England Journal of Medicine,² measles vaccination has prevented an estimated 21 million deaths worldwide since 2000. Despite these substantial gains, global elimination goals have not been met, and previous strides are now being threatened by an increase in the number of measles cases reported globally. There is a growing number of travel-related infections and local outbreaks in the United States, Australia, Europe and UK.

In Europe, the number of reported cases in 2018 was triple that in 2017 and 15 times that in 2016. In addition, it is likely that endemic measles has now been reestablished in several European countries where transmission had previously been interrupted.

In the Western Pacific Region, nine countries and areas in the Region had been verified as having eliminated measles: Australia, Brunei Darussalam, Cambodia, Hong Kong SAR (China), Japan, Macao SAR (China), New Zealand, the Republic of Korea and Singapore. Elimination means there has been no prolonged local transmission of the virus for at least three years.

So far this year, Australia, Cambodia, China, Hong Kong SAR (China), Japan, the Lao People's Democratic Republic, New Zealand, the Republic of Korea, Singapore and Viet Nam have all recorded measles cases.

The increase in cases is particularly disturbing since the disease is entirely preventable through vaccination with a safe and affordable vaccine. Measles has all the components of an eradicable disease.

The failure to vaccinate comes partly from complacency, partly from less effective public health programs, partly from misconceptions and partly from misinformation spread by a range of anti-vaccine movements.

The WHO has named 'vaccine hesitancy' as a top global health threat.

Misconceptions and misinformation

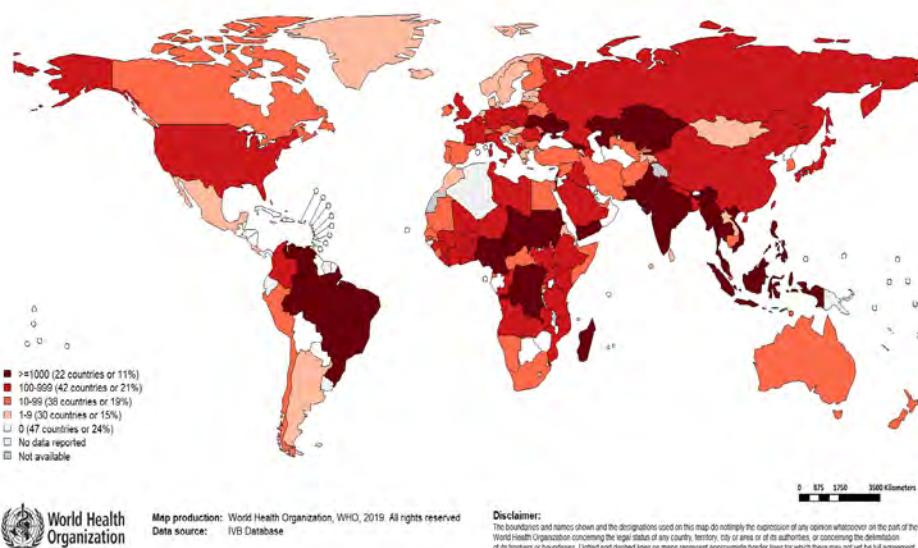
WHO describes six main misconceptions³

- 'Giving a child multiple vaccinations for different diseases at the same time increases the risk of harmful side effects and can overload the immune system'.

²<https://www.nejm.org/doi/full/10.1056/NEJMp1905099?query=TOC>

³https://www.who.int/vaccine_safety/initiative/detection/immunization_misconceptions/en/index2.html

Top 10*	
Country	Cases
Madagascar	69696
Ukraine	49073
India	16222
Brazil	9168
Philippines	8767
Venezuela (Bolivarian Republic of)	5668
Thailand	5389
Kazakhstan	3988
Nigeria	3830
Pakistan	3799



Number of reported measles cases 6 months to April 2019; Source WHO : Based on data received 2019-04 - Surveillance data from 2018-09 to 2019-02 - * Countries with highest number of cases for the period

- 'Diseases had already begun to disappear before vaccines were introduced, because of better hygiene and sanitation'.
- 'The majority of people who get disease have been vaccinated.'
- 'There are 'hot lots' of vaccine that have been associated with more adverse events and deaths than others. Parents should find the numbers of these lots and not allow their children to receive vaccines from them.'
- 'Vaccines cause many harmful side effects, illnesses, and even death - not to mention possible long-term effects we don't even know about.'
- 'Vaccine-preventable diseases have been virtually eliminated from my country, so there is no need for my child to be vaccinated.'

In addition there is wide range of cultural, political or conspiratorial misinformation that can undermine vaccination programs.⁴

For example:

- Religious belief systems can raise objections
- Suspicion and distrust can be based on oppressed groups' distrust of the services of their oppressors
- Misinformation has been spread that vaccination will sterilise children
- In parts of Africa, people have thought that vaccinations cause HIV.

There is also a belief that measles is not a serious disease – if you catch the disease and recover you will be protected, so it is best to just let it be caught. Others believe that measles can be cured by antibiotics. So it is clear there is no one way to overcome the beliefs and misinformation that undermine measles vaccination programs. Strategies will need to be developed to specifically address the different erroneous beliefs.

Strategy example: Mandatory vaccinations

Italy: Italian children have been instructed not to appear at school without proof of vaccination, and Italian officials say vaccination rates have improved since the introduction of that rule.

Germany: This month, the German state of Brandenburg became the first in Germany to introduce compulsory vaccination for children, amid calls for such a rule to be implemented nationwide as the number of measles cases rises.

According to the World Health Organization:

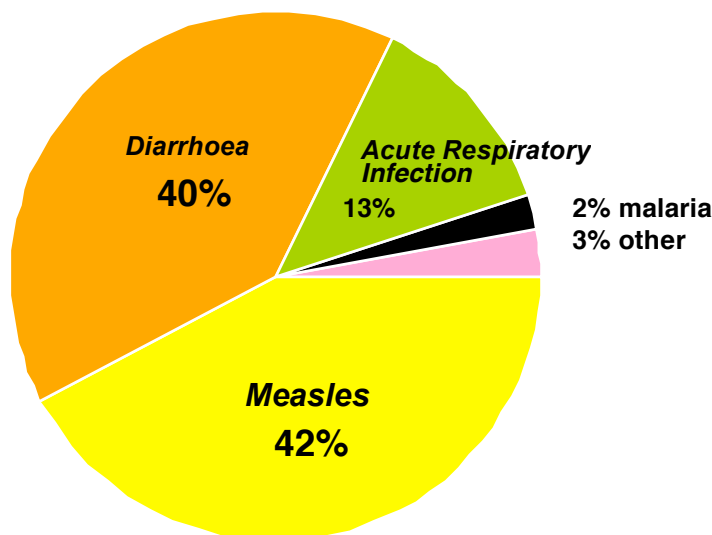
'Responding to measles requires a range of approaches to ensure all children get their vaccines on time, with particular attention to access, quality and affordability of primary care service ... It will also take effective public-facing communication and engagement on the critical importance of vaccination, and the dangers of the diseases they prevent.'

⁴<https://www.historyofvaccines.org/index.php/content/articles/cultural-perspectives-vaccination>

Measles in Somalia 1980-1988 ⁵

At the beginning of 1980, 35 camps housing 1.4 million refugees had been established in five regions of Somalia following displacement of populations from the 'Ogaden' region of Ethiopia. In the Gedo Region of southern Somalia, CDC reported that 42% of the deaths in camps had been caused by measles.

Somalia: Gedo refugee camps 1980



By the end of 1980, the Somali Refugee Health Unit had established a health program based on the Primary Health Care (PHC) model that rapidly brought the situation under control by development of a comprehensive community based program that included priority measles immunisation coordinated by community health workers followed by maintenance of vaccination coverage for six vaccine preventable diseases. ⁶



⁵ Personal notes: Beverley Snell

⁶ <http://www.haiasiapacific.org/wp-content/uploads/2019/04/Somalia-RHU-Summary.pdf>

When the refugee health situation was under control, the PHC approach was extended to the host population in the northern region of Somalia. Within two years 93% full measles coverage was achieved in the host population as well as the refugee population.

In 1988, new political upheaval caused a flow of refugees from northern Somalia back into Ethiopia and camps were established in the Hartisheik and Harshin areas in Ethiopia. Implementation of measles vaccination is first priority in management of humanitarian emergencies. Here was the first case ever where this protocol was not necessary.⁷ It was known that the herd immunity of the refugee population was 93%. (The 2nd case was of Iraqi refugees in Turkey 1989). However, within 3 months a routine immunisation program was established in these eastern Ethiopia camps to maintain protection against measles and other vaccine preventable diseases.

In the Somali population, vaccination was welcomed and mothers carefully kept their children's vaccination record cards for reference and for follow-up and booster vaccinations – even when they were displaced and carrying only very few possessions. Perhaps the willingness resulted from their knowledge of the devastating effects of the diseases which could now be prevented.

March 24 – World TB Day: 2019 Theme: It's time to end TB ⁸

WHO has issued new guidance to improve treatment of multidrug resistant TB (MDR-TB). WHO is recommending shifting to fully oral regimens to treat people with MDR-TB. This new treatment course is more effective and is less likely to provoke adverse side effects. WHO recommends backing up treatment with active monitoring of drug safety and providing counselling support to help patients complete their course of treatment.

The recommendations released in March are part of a larger package of actions designed to help countries increase the pace of progress to end TB.



⁷ http://www.haiasiapacific.org/wp-content/uploads/2019/04/CDCMMWRFamineAffected_Refugee_HealthRecommendations1992.pdf Page 11

⁸ <https://www.who.int/news-room/detail/20-03-2019-new-who-recommendations-to-accelerate-progress-on-tb>

New TB Regimen for drug resistant TB

*From the Executive Summary of the **WHO consolidated guidelines on drug-resistant tuberculosis treatment 2019**⁹*

Tuberculosis (TB) strains with drug resistance (DR-TB) are more difficult to treat than drug-susceptible ones, and threaten global progress towards the targets set by the End TB Strategy of the World Health Organization (WHO). There is thus a critical need for evidence-based policy recommendations on the treatment and care of patients with DR-TB, based on the most recent and comprehensive evidence available. In this regard, the WHO consolidated guidelines on drug-resistant tuberculosis treatment fulfill the mandate of WHO to inform health professionals in Member States on how to improve treatment and care for patients with DR-TB.

Between 2011 and 2018, WHO has developed and issued evidence-based policy recommendations on the treatment and care of patients with DR-TB. These policy recommendations have been presented in several WHO documents and their associated annexes, including the WHO treatment guidelines for multidrug- and rifampicin-resistant tuberculosis, 2018 update, issued by WHO in December 2018.

The present consolidated guidelines include a comprehensive set of WHO recommendations for the treatment and care of DR-TB, derived from the eight WHO guidelines documents, which they now replace.

The consolidated guidelines include policy recommendations on treatment regimens for isoniazid-resistant TB (Hr-TB) and multidrug- and rifampicin-resistant (MDR/RR-TB), including longer and shorter regimens for MDR/RR-TB, culture monitoring of patients on treatment, the timing of antiretroviral therapy (ART) in MDR/RR-TB patients infected with the human immunodeficiency virus (HIV), use of surgery for patients receiving MDR-TB treatment, and optimal models of patient support and care.

The full list of 29 policy recommendations, grouped into eight sections, is provided in the **WHO consolidated guidelines on drug-resistant tuberculosis treatment**.

The new guidance will be complemented with further advice on their implementation in a revised edition of WHO's 'how-to' handbook for the programmatic management of TB.

Dr Olle Hansson Day May 23

How easy it is to forget a HAI Legend

*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 like to share the foreword written by **Anwar Fazal**, former President of International Organisation of Consumers Union (IOCU), co-founder of Health Action International (HAI) and the instigator for the idea of a People 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.

23 May has been designated as Olle Hansson Day and is celebrated as a day of action in India and several other countries. An Olle Hansson Award used to be made each year to a 'Third World' person whose action for rational drug policies demonstrate the fine qualities of Olle, whose words, 'Now is the time for Action' will be a rallying call for all times.

What this book is about is stated below by the four editors

This book is in three parts.

The first part is the story of a drug, clioquinol, which ruined many more lives than thalidomide did, but this disaster is much less widely known and its lessons have not yet been learned. The story spans over 20 years, from the early 1960s until now, and is told by Dr. Olle Hansson who became deeply involved early on and did more than anyone else to bring the issue towards a conclusion. The main actors are the patients who were injured, the doctors who prescribed the drug, Ciba-Geigy the Swiss multinational pharmaceutical company which introduced **Entero-Vioform**, and the lawyers and Hansson who helped the patients obtain compensation. It is not only a thrilling story but also raises the question as to whether anything like it could happen again. How exceptional was it?

In the second part of the book Dr Hansson looks at other more recent examples of drug marketing by Ciba-Geigy and other companies to try to answer this question. What is unique here is the wealth of information on the discussion and decision process within Ciba-Geigy. The picture is disturbing, but although Hansson himself had much less inside knowledge of other companies, it seems likely that Ciba-Geigy's behaviour was no worse than that of most

⁹ http://www.haiaiapacific.org/wp-content/uploads/2019/03/WHO_TBRegimen2019.pdf

of its competitors. Are pharmaceutical companies behaving more responsibly now than in the recent past? How can we tell? Hansson died before he could finish this book, but the last month of his life saw a dramatic development in his long struggle with Ciba-Geigy. The company decided that the top management should meet him personally for discussions and perhaps negotiations.

In the last part of the book Milton Silverman, who interviewed all the chief participants, describes these meetings and the events that followed. 'The fight to get rid of clioquinol increased public awareness of underlying problems in many countries, and in the developing world this encouraged consumers to campaign for more rational use of drugs. Olle Hansson acted as a catalyst and adviser for this movement. For example, as Dr. Mira Shiva of the Voluntary Health Association of India notes: 'The relevance of this fight for right to information, the right to socially just and rational drug use have increasingly made sense to us and many others. If today the drugs issue is increasingly being recognised as a health issue, a consumer issue, it is because we are ourselves convinced about it being so, and can therefore convince others. Olle Hansson facilitated this process. An important characteristic was that he never ignored (my) requests for expert comment, and responded very promptly - even when he was in hospital'.

Olle Hansson's relationships with the media were another important element in his work. 'He had a way of combining scientific fact with hard fact and a campaigning zeal that is every reporter's dream. His nose for a story made it easy for him to pick up his way through unnecessary detail and hit where it hurts'. (Joan Shenton, TV journalist, London).

Oliver Gillie, then medical correspondent of the London Sunday Times adds: 'As a journalist I have met many people obsessed by a cause. Such obsession is essential if an individual is going to make battle with governments or large international corporations. Olle Hansson had a righteous cause, and the stamina to see the battle through'.

Barbro Jobberger, of Dagens Nyheter, Stockholm, was struck by Hansson's respect for journalists' professional skill: 'Unlike many doctors he had no contempt for journalists. He knew that journalists had their own code of honour. He understood that it was in his own interest to learn as much as possible about the way the media works, so that he could achieve the best results'. What is important now is that all of us should learn the lessons - doctors and other health professionals, administrators of health services, politicians and the public.

The World Health Organisation has now embarked on a major programme to encourage the rational use of drugs in all countries, especially the poorest ones. This essential work needs the wholehearted cooperation of the pharmaceutical industry, which has many important contributions to make. If this book helps to improve the ways in which we use medicines. Olle Hansson's hope will have to be realised.

Editors: Dag Nilsson, Kongsvinger, Norway; Andrew Herxheimer, London England; Eva Lachkovics, Penang, Malaysia; Mats Nilsson, Malmo, Sweden.

Healers or Predators: book excerpts

<https://www.newsclick.in/healers-or-predators-excerpts>

Keshavo Desiraju, Samiran Nundy, Sanjay Nagral, Amartya Sen 14 Aug 2018

In April 2018 Oxford University Press published 'Healers or Predators?' It examines the corruption which ails the Health sector in India. Amartya Sen wrote the Foreword to the book and a chapter was written by Amit Sengupta.

In this collection of well-researched essays on the state of healthcare in India, the editors (Samiran Nundy, Keshav Desiraju, and Sanjay Nagral) have offered us a timely opportunity to understand how badly things have gone wrong in India - our beloved country. They have also offered illuminating analyses of the causes and remedies of the observed failures.

Amartya Sen wrote

.....'The low allocation of public resources to healthcare is merely one of the relevant factors, and important as it is as an account of what ails India's healthcare, the neglect of resource commitment probably hides as much as it reveals. As the studies included in this important collection bring out, India's healthcare failure is far more extensive than the resource story alone can capture. The entire organization of Indian healthcare has become deeply flawed in nearly every respect.....'

Amit Sengupta pointed out 'Universal Health Coverage is the key reform introduced at the global level by the neoliberal system, to restructure healthcare globalization and corruption in the health sector systems. In its essence, UHC is the reflection of the shift in the role of the state as a facilitator of public enterprise and a 'manager' and 'regulator' of healthcare services. By the turn of the millennium most low and middle income countries had inherited crumbling healthcare systems as a consequence of fiscal austerity policies advocated in the previous two decades by multilateral agencies. To remedy the situation, there could have been efforts to prioritize the rebuilding and strengthening of the public systems. Instead, the emphasis shifted from how services should be provided

to how services should be financed. The World Bank played a key role in consensus-building around reforms that were to become precursors to UHC, much before the World Health Organization formally adopted them as part of its policy plank. ‘

‘Universal Health Coverage was conceived as a system that would progressively move towards: (i) coverage of the entire population by a package of services, (ii) including an increasing range of services, and (iii) a rising share of pooled funds as the main source of funding for healthcare, with a consequent decrease in co-payments by those accessing healthcare services. Such a system required a clear ‘provider–purchaser’ split, the issues of financing and management being entirely divorced from provisioning. A provider–purchaser split puts a price on services, that is, it commodifies them, which is the precondition for their transaction in the marketplace.

Supporters of UHC are happy to emphasize the key role played by governments in strategically ‘purchasing’ care to improve ‘efficiency’, rather than advocating for them to get involved in providing services. For example, an issue of the WHO Bulletin argues: ‘Countries cannot simply spend their way to universal health coverage. To sustain progress, efficiency and accountability must be ensured. The main health financing instrument for promoting efficiency in the use of funds is purchasing, and more specifically, strategic purchasing’.

Amit Sengupta saw the Indian developments as ‘Institutionalized Corruption’: Public Policy as Facilitator of Private Profit Extraction

‘The change in trajectory of the state, which we have described earlier, applies as well to the role of the Indian government in institutionalizing avenues for profit-making by private industry. Ideological shifts accompanied by changes in public policy combine to create conditions for profit extraction at a systemic scale in different arms of the health sector.

We trace several instances in the healthcare and medicines sector where public policy has created opportunities for private enterprises. At the same time these policies have not contributed to advancing public health goals, thus creating the net effect of a transfer of



public resources (or foregoing of public revenues) to benefit private players without any clear public health gains.

Oxytocin: How India is 'prioritising cow welfare' over women's health with continued ban on lifesaving drug for new mothers

From *The Independent*, Saturday 30 March 2019 16:58

By Adam Withnall Delhi

<https://www.independent.co.uk/news/world/asia/india-oxytocin-ban-supreme-court-bjp-cows-women-health-a8845601.html>

The Government argues new measures are needed to prevent misuse of oxytocin in cattle, but doctors and patients groups warn it could cost human lives

The Indian government has been accused of prioritising cow protection over the health of women, as it attempts to force through a ban on private production of a lifesaving drug for mothers in labour.

The drug has sparked controversy in India after media reports claimed it was being abused by dairy farms to control cows' lactation. Some reports have also variously alleged, without scientific evidence, that oxytocin treatment leads to cows becoming infertile and producing milk that is then harmful to humans.

With cows considered sacred by India's Hindu majority and the country going to the polls in April for a general election, the Hindu nationalist-led government has seized on the issue as a potential vote winner.

But doctors' and patients' groups say the ban on private production has not paid due consideration to the impact it would have on women's lives.

Despite progress in recent years, India still has one of the worst maternal mortality rates among the world's major economies. Around 26 million live births take place across the country in a single year, and according to government figures 130 in every 100,000 mothers die during childbirth.

The Indian Medical Association (IMA), the country's largest group representing doctors, said that oxytocin's ability to prevent bleeding after birth meant it was 'not a drug that doctors can compromise on'.

In a submission to the Supreme Court, the IMA said banning private production of the drug could lead to a shortage of supplies and thereby 'impair the lives of thousands of innocent young mothers'.

'Oxytocin should be available for every childbirth – you can't predict which women are going to suffer postpartum haemorrhaging,' said Malini Aisola, co-convenor of patients' activist group the All India Drug Action Network (AIDAN), which is one of the parties fighting the government in court.

The government first ordered a ban on private production of oxytocin in April 2018, saying that in order

to control the supply chain it needed to give sole responsibility to a single, public manufacturer based in Karnataka state.

Doctors raised concerns over the ability of the company, Karnataka Antibiotics and Pharmaceuticals Limited (KAPL), to meet all new mothers' needs, in part because at that point KAPL had never produced oxytocin before.

In December 2018, the Delhi High Court ruled that the ban should not stand, and in its ruling criticised the government for failing to support its case with 'scientific data or objective justification'. The judges noted that 'there is no scientific data or reliable material to show that oxytocin has a deleterious effect on cattle'.

The court also noted the role played in lobbying for a ban on oxytocin by the prominent animal rights activist Maneka Gandhi, a senior figure in the government of Mr Modi's Bharatiya Janata Party (BJP).

It produced a timeline showing that Ms Gandhi first brought up the matter at a meeting of the main statutory body on drugs, the Drugs Technical Advisory Board (DTAB), in 1999. She proposed a ban on private production in 2014 'despite the expert group finding that there was no data to support [her] allegation of misuse', the court said.

HAIAP member Amitava Guha added that banning of private sector to produce Oxytocin is one thing but a ban on its sale in retail stores - even when it is produced in a Government sector company - is even more dangerous. This ban will severely hamper access in emergency situations, particularly during post partum haemorrhage.

As explained, the Government has ordered production of oxytocin in Rajasthan State Drugs and Pharmaceuticals Limited, a public sector joint venture of State and Central Government. However, RSDPL has been notified by the central Government that it can only sell the product to private outlets. So oxytocin may not remain available in the public sector.

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Where there are no Pharmacists

Coming soon: Revised edition

Where There Are No Pharmacists is about managing medicines. It explains how to order them, store them, prepare them, dispense them and use them safely and effectively. Advice is provided on all these aspects for people working with medicines along with information to help communities benefit from the use of medicines.

It provides guidance for anyone who is doing the work of a pharmacist; anyone who sells, dispenses, prepares, manages, or explains to others how to use medicines.

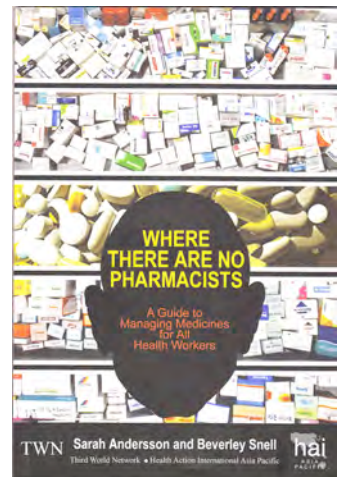
Where there are no trained pharmacists serving communities, other categories of health workers are called upon to order, buy, store, dispense and advise people on rational use of medicines. This book walks them through each step, covering topics ranging from policy issues to patient education:

- The concept of National Medicines Policies
- Principles of 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 first edition was published by TWN and HAIAP in 2010 and launched at the final meeting of HAIAP in Sri Lanka.

This new edition will be freely available electronically until funds are found for printing.

It includes expanded sections on antimicrobial resistance and medicines for older people; a new section on waste management; and the use of zinc with ORS for diarrhoea management. The content and references have been updated to be current.



Feature: Access to medicines - Strong call for transparency on medicine prices and cost of R & D

Ellen 't Hoen

Strong call for transparency on medicine prices, cost of R&D - presented at the WHO Fair Pricing Forum

By Ellen 't Hoen, April 19, 2019

<https://medicineslawandpolicy.org/2019/04/strong-call-for-transparency-on-medicine-prices-cost-of-rd-at-who-fair-pricing-forum/>

'Medical innovation has little social value if most people cannot access its benefits.... this is a global human rights issue,' said Mariângela Simão, Assistant Director General at the World Health Organization (WHO), at the opening of the second WHO Fair Pricing Forum, co-hosted by South Africa, which took place 11-13 April 2019 in Johannesburg, South Africa.

The Forum brought together over 200 delegates from government, NGOs, academia and industry to discuss how to design a fairer pharmaceutical system where medicines are affordable to those in need and the development of effective new treatments is financed appropriately. Medicines Law & Policy was invited to present the TRIPS Flexibilities Database at the Forum; this database lists instances of the use of provisions in patent law to reduce prices on needed medicines, shedding light on how often they have been needed.

Calls for drug price and cost transparency grew louder at the second Forum, though they began at the first Fair Pricing Forum held in the Netherlands in 2017. High prices are defended by pharmaceutical companies as necessary to recoup costs of research and development (R&D) and incentivise further research, but with little clarity on how much R&D truly costs nor how medicines prices are set it is difficult to objectively determine what price is fair. Cases of exponential increases in the price of previously affordable drugs when market exclusivity was obtained were cited as examples that current prices seem to be more about profit than recouping costs.

Cancer took centre stage

The cost of cancer treatment took centre stage at the Forum, with the WHO's report on the pricing of cancer medicines providing important background. The study found that the costs of R&D and production may bear little or no relationship to how pharmaceutical companies set prices of cancer medicines. Return on investment is more than generous with an average income of US\$ 14.50 for every R&D dollar spent.

Cancer patients from South Africa gave powerful testimony at the Forum (and outside where activists were demonstrating and addressing the media) of the hardship caused by the high cost of the treatments.

One patient, who asked to remain anonymous, described his quest to gain access to the treatments he needs. Three years ago, he was diagnosed with multiple myeloma. His doctor prescribed lenalidomide, a derivative of thalidomide, which is sold under the brand name Revlimid by Celgene. In India, generic lenalidomide is available for R32,000 (US\$ 2289) per patient per year. Until 2016, South African patients had access to generic lenalidomide from India under a section 21 authorisation that allows the sale and use of unregistered products. This authorisation was withdrawn once Celgene registered the product in the country. Celgene priced it at R882,000 (US\$ 63,000) per patient per year. While the health system provides the drug, patients are struggling to pay the 20% co-payment. South Africa's GDP per capita is US\$ 6,160. According to the Cancer Alliance, South African patents block access to generic lenalidomide and this may last until 2028. Celgene told its shareholders earlier this year that it expects sales of Revlimid to be around US\$ 10.8 billion in 2019. Bristol-Myers Squibb is currently in the process of taking over Celgene for US\$ 74 billion.

There are similar issues with other cancer medicines. Trastuzumab (Herceptin), a WHO essential medicine for the treatment of HER2 positive breast cancer, costs R130,632 (US\$ 9,295) in the public sector and R475,380 (US\$ 33,827) in the private sector in South Africa. Biosimilar versions of trastuzumab are beginning to become available elsewhere in the world because the basic patent expired in 2016. But not in South Africa, where the company Roche continues to benefit from a market monopoly. The production cost of this same treatment is around US\$ 240 for a one-year supply. Roche's annual sales for the product is around US\$ 7.5 billion.

Pembrolizumab (Keytruda) is a second-line treatment of non-small cell lung cancer and is priced at R180,000 (US\$ 43,000). The Forum was told that to treat all in need would cost the South African health system R200 million (US\$ 48 million).

These stories helped to set the scene and impress on participants to the Forum that there is no fairness in the

system and that finding solutions to the problem of high drug pricing is urgent - just as it was 20 years ago for HIV.

Pharma vs Nelson Mandela

In the past, South Africa has been the scene of some of the fiercest battles for access to medicines. Director General for Health, Precious Matsoso, recalled some of the histories at the opening ceremony. In 1998, at the height of the HIV crisis, 39 mostly multinational drug companies took the South African government to court over new provisions in its medicines law designed to accelerate access to lower-priced medicines. The companies claimed that the provisions were unconstitutional and in conflict with South Africa's obligations under the TRIPS Agreement. Three years later, in 2001, the companies dropped the case after a global outcry and after it became clear that the legal text in question was based on draft legislation provided by the World Intellectual Property Organization (WIPO).

By then the case had become widely known as Pharma vs. Nelson Mandela and spurred global action on access to HIV medicines, strengthened flexibilities in patent law and made an industry in need of atonement agree to lower prices and later to offer patent licences to ensure low priced generic HIV medicines could be made available. Twenty years ago, access to medicines was predominantly a problem for developing countries. 'Today access to medicines has become a global issue', said Simão.

Drug pricing a global issue

In Switzerland, the civil society organisation Public Eye requested the government for a compulsory licence on the patents related to the breast cancer medicine pertuzumab, sold by Roche under the brand name Perjeta. The US\$ 100,000 price tag of Perjeta in Switzerland underscored the point that medicines pricing is a global issue. Similar demands have been made in other countries. Wilbert Bannenberg, chair of the Dutch Pharmaceutical Accountability Foundation described the case of a rare disease medicine, CDCA, used for the treatment of the metabolic illness *cerebrotendinous xanthomatosis* (CTX). For years, the product was available for € 300 per patient per year and prescribed off-label to treat CTX. After the drug company, Leadiant was granted exclusive rights to market the product in Europe for CTX in 2017, it increased the price to € 153,300 per treatment-year. Bannenberg's presentation emphasised the need for competition authorities to take action against excessive drug prices. He further outlined his organisation's plans to use the law (competition law, patent law, human rights law, civil law) to challenge unfair medicines pricing. It may have been coincidence that shortly after the start of the Fair Pricing Forum, the Dutch Minister of

Health Bruno Bruins announced his plans to reduce the exclusivity for orphan drugs from 10 to 5 years in the European Union (EU) and to establish a commission to study the use of compulsory licensing to gain access to lower priced medicines in the Netherlands. A review of the pharmaceutical incentives in the EU is underway. Bruins also decried the lack of transparency in drug pricing and cost of R&D.

Malaysian Compulsory License

Dr Salmah Bahri, Director of Pharmaceutical Services at the Malaysian Ministry of Health, described her country's comprehensive approach to selecting and financing access to essential medicines. Malaysia does not shy away from using compulsory licensing when needed and has reduced the cost of hepatitis C treatments from US\$ 72,000 to less than US\$ 300 in the public sector by allowing generic import and supply of the product. They are also working with the Drugs for Neglected Diseases initiative (DNDi) on the development of a low-cost hepatitis C treatment.

Gaëlle Krikorian, from Médecins Sans Frontières (MSF), told the meeting about vaccine pricing challenges the organization deals with. MSF's Access Campaign succeeded in persuading Pfizer and GlaxoSmithKline to significantly drop the price of the pneumococcal conjugate vaccine (PCV) for humanitarian organizations. Organisations working in emergency settings can now obtain the vaccine for US\$ 9 per child under the 'humanitarian mechanism'. It took seven years of negotiation to obtain the lower price. While this is good news for children in crisis settings others cannot benefit from this price. The list price of the vaccine is US\$ 540 per child. In reality, prices vary but are high: France pays US\$ 189, Lebanon US\$ 243 and the price in local Greek pharmacies is US\$168. MSF recently announced that it will use the 'humanitarian mechanism' to protect refugee children in Greece against pneumonia, the world's 'number one childhood killer' according to MSF. Since 2009, Pfizer and GSK have earned \$49.1 billion in sales from the pneumonia vaccine, said MSF.

Othman Mellouk from the International Treatment Preparedness Coalition (ITPC) also drew attention to the plight of people in middle-income countries. He mentioned the case of dolutegravir, an essential medicine for the treatment of HIV which will be available for US\$ 75 per patient per year in low and middle-income countries. The patent license agreement reached by the Medicines Patent Pool with ViiV and the price deal brokered by the Clinton Health Access Initiative and partners exclude 39 countries, mostly upper middle-income countries. The World Bank defines lower middle-income economies as those with a GNI per capita between \$1,006 and \$3,955 and upper middle-income countries as those with a GNI per capita

between US\$3,956 and US\$12,235. Above this figure, the country is considered high-income.

Transparency, transparency, transparency

The call for transparency emerged as the central theme of the meeting, in particular with regard to medicines pricing, production cost and expenditures on R&D. 64 civil society organisations published a statement before the meeting calling for greater medicines pricing and R&D cost transparency.

Andrew Hill presented data on the production cost of essential medicines that demonstrated most of them could be produced for a fraction of their current prices. For example, the price based on production cost for the US\$ 30,000 per patient per year cancer drug imatinib can be as low as US\$ 180 per patient per year. Insulin, which was discovered in 1923, cost US\$ 1 per vial to make but is sold at US\$ 240 per vial today. The global insulin market is valued at US\$ 28 billion. Greater price transparency will help countries to understand the savings they can make by buying generics. The same call could be heard earlier this year at the Executive Board of the WHO. Since then, Italy has proposed a World Health Assembly resolution to improve the transparency of markets for drugs, vaccines and other health-related technologies. The resolution is expected to be discussed at the 72nd World Health Assembly that takes place from 20 – 28 May 2019.

Thomas Cueni, director general of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) fiercely resisted the calls for transparency on medicines pricing. He warned greater transparency on medicine prices could backfire, and drive up drug costs in low and middle-income countries. This could, for example, be the case if high-income countries would refer to low prices available in low-income countries and demand the same lower prices or use it for reference pricing. Meeting participants seemed to agree with making provisions needed to allow for significant differential pricing. However, Suerie Moon from the Graduate Institute in Geneva pointed out that this would require more reasonable pricing in high-income countries as well. A fair price, she explained, is one that covers the cost made by the seller (including R&D, manufacturing and distribution, and fair profit) and assures affordability, value to the individual and the health system and security of supply to the buyers.

Jamie Love, director of Knowledge Ecology International, warned against using patient coverage as leverage in price negotiations. 'Put the compulsory licensing of patents on the table, so that the monopoly is at risk, rather than the patient,' he said. He further outlined a proposal to finance the cost of R&D in a different manner. 'Temporary monopoly is the primary incentive today, enforced by patents and a variety of

regulatory monopolies. This is expensive and the primary reason why prices are high and access unequal,' Love said. By implementing models that de-link the cost of R&D from the price of medical products to finance drug development, high prices are no longer required to recoup R&D expenditures. He mentioned market entry awards and product prizes as two possible such models. He proposed a progressive implementation of de-linkage awards to gradually replace market exclusivities. A next step should be a feasibility study of the proposed new models. Such exploratory work would also benefit from greater transparency.

One successful example of an innovation initiative that works with a delinked model is the Drugs for Neglected Diseases Initiative (DNDi). The Medicines Patent Pool is another example of an organisation committed to transparency. The MPP publishes all its agreements in full on its website. The MPP initially focussed on HIV and later hepatitis C, but has expanded its mandate to negotiate licenses for all patented essential medicines. Forum indicated that it is in talks with the MPP.

At the closing of the meeting, Fatima Suleman, a professor in pharmaceutical sciences at the University of KwaZulu-Natal and chair of the National Medicines Pricing Committee, noted the striking increase in research, available data and analysis to inform better policy making on medicines pricing and cost. Indeed, telling examples presented at the meeting included the WHO report on cancer drug pricing, the research on production cost of essential medicines by Andrew Hill, analysis on how to determine a fair medicine price and work on transparency by Suerie Moon, the TRIPS Flexibilities Database by Medicines Law & Policy, the patent opposition database, medicines patent analysis by I-Mak, the patent status information databases Medspal by the Medicines Patent Pool and Patinformed maintained by WIPO in collaboration with the IFPMA, and the drug research, development and pricing information database by Knowledge Ecology International.

What next?

The WHO announced it would set up working groups to further develop proposals put forward at the meeting before the next Fair Pricing Forum in 2021. WHO will also launch an online public consultation in the coming weeks to collect suggestions for a definition of what constitutes a 'fair price'. The next milestone will be the discussions on price and R&D cost transparency at the World Health Assembly this May of year. The presentations made at the meeting will be available at the Fair Pricing Forum