



April 2016

HAI AP News

Penang, Malaysia

Email: kaur_shila@yahoo.com Web: <http://www.haiasiapacific.org>

HAI AP Est. 1981

Health Action International Asia-Pacific (HAIAP) is part of an independent global network, working to increase access to essential medicines and improve their rational use through research excellence and evidence-based advocacy. HAIAP is an informal network of non-governmental organisations and individuals in the Asia-Pacific Region 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' work.

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We were saddened to learn of the demise of Dr Andrew Herxheimer, a pioneer and supporter of HAI. Andrew left a legacy of the value of evidence-based research that is so vital for effective advocacy and health activism. Many of us remember his remarkable combination of intelligence and wit, and that twinkle in his eyes. And some of us followed him on Facebook. We shall miss Andrew. HAIAP pays tribute to Dr Andrew Herxheimer.

If health is a fundamental human right then the right of access to medicines is an integral component of that right. We see increasing encroachment on this right, as trade agreements and IP issues conspire to keep life-saving medicines out of the reach of the sick and vulnerable through unreal and exorbitant prices. In one of our feature articles Beverley documents stories of health advocacy and activism that have successfully safeguarded this right to essential life saving medicines.

Historically HAIAP has been vigilant on the use and availability of irrational Fixed Dose Combination drugs in the region. When India, in March 2016, banned 344 irrational FDCs, this naturally evoked a regional response from partners, lamenting the lapses in government regulatory responses to irrational drug combinations. Amit and Beverley describe selective country situations in relation to FDCs, with insights on why some FDCs are welcome while others are not.

A final note, as a region we owe it to ourselves to be informed of developments, whether political, social or otherwise in neighbouring countries. We share similar

Message from the Coordinator

I have just returned from a Workshop on *Movement Building in South Asia and Asia and the Pacific*. Organised by the People's Health Movement South Asia, this workshop was a wonderful reminder of international solidarity and why we do the work we do. We often forget the importance of those human connections - national, regional and international - that lend meaning to our work and the heart-to-heart sharings that renew and refresh our outlook. In today's highly connected world where smart technology is increasingly replacing personal human interactions, there is an even more urgent need to cherish, live and build on such moments. For it is at these events that the future of health advocacy and activism is forged.

concerns of health and food safety. We feel the impact similarly in more ways than one of climate change and global, regional and bilateral trade agreements. Micro-organisms do not differentiate between borders when they decide to mutate and become resistant. People will continue to seek a better life away from home without any guarantee that the immigrant country will grant them equal rights. It is really our shared vision of a better – a more humane and just - society that keeps us going in this struggle for the right to health. And it is the people working alongside us that give depth of meaning to that struggle.

In solidarity

Shila Kaur

Vale Andrew Herxheimer, 1925-2016



Andrew Herxheimer, a pioneer and supporter of HAI died on Sunday February 21, at the age of 90. We wish his wife Christine and daughters Charlotte and Sophie all the strength in this difficult period.

HAIAP tributes

Dato' Anwar Fazal

Dr Andrew Herxheimer was the first Chair of the HEALTH WORKING GROUP of the International Organisation of Consumers Union (IOCU) now Consumers International. It was set up in 1978, the year I was elected to the Presidency of IOCU. He was then editor (since 1963) of the Drugs and Therapeutics Bulletin published by Consumers Association UK - an amazing outreach which went to prescribing Doctors in the United Kingdom. He led the first two iconic IOCU medical projects on chloramphenicol and cloquinol and they became the early flagship campaigns of the health movement and helped us grow in visibility and action.

Andrew was with us as part of the core in Geneva when we launched Health Action International (HAI) with representation from 26 countries on 29th May 1981. Our founding press statement called HAI an 'International Antibody' to resist 'Ill-treatment of

Consumers by Multinational Drug Companies'. I shall also never forget two others who were with me at the launching press conference: Ronald Fett of BUKO, a German coalition of development NGOs and Charles Medawar also from the UK who played a key role in the early years of HAI.

Charles wrote *Insult or Injury* on British food and drug products in 1979 published by his Social Audit. It also co-published in collaboration with IOCU the classic *Pharmaceuticals and Health Policy* which was a great compilation of international perspectives by Andrew and Richard Blum in 1981 - which also became one of HAI's early foremost resources.

Thank you Andrew for all the support in those early years.

Ken Harvey

I too have fond memories of Andrew, especially of him dancing around the Eastern and Oriental Hotel in Penang in shorts featuring the Union Jack flag at a HAIAP meeting!

Also for his work as editor of the Drug & Therapeutics Bulletin, his support for the International Society of Drug Bulletins (of which Australian Prescriber and Therapeutic Guidelines are members) and more recently his work with DIPEX on collecting patient experiences of major illness and health-related conditions.

When Health Action International was born, Andrew noted that in German the word 'Hai' means 'shark', and Surendra Patel, Technology Director of UNCTAD, said, 'When the sharks threaten the fishes, the fishes must join together to defend themselves.' As we did and will keep on doing, in memory of Andrew!

Mira Shiva

Dr Andrew Herxheimer's passing away is a loss to all of us. There are many many memories of Dr Andrew.

His coming to India for a Conference organized by the Indian Academy of Paediatrics on Consumer Concerns related to children - Dr Raj Anand had organized it. It was in Gorakhpur and there were floods and we had to wade in the water while going in and out of the meeting place and where we were staying. Dr Andrew never complained.

We discussed irrational hazardous anti diarrheals - diphenoxylate (Iomotil etc), imodium, antibiotic combinations, tonics with chloroform etc, commercial baby foods etc, as well as not accepting gifts and sponsorships for medical conferences from Pharma & Baby Food companies.

We organized a public lecture in Delhi on Rational Drugs by Dr Andrew before he returned. He was very convincing with health professionals and civil society.

For the first time we had organized video recording of a lecture. Sanjai Acharya who was in Geneva later with UNESCO did it for us without charging a paisa.

We also met Dr Andrew at a HAI Meeting in Lunde Sweden, that was also the last time I met Dr Olle Hansson who had given us Dr Andrew's contact when we were engaged with the high dose Estrogen / Progesterone issue.

In 1985 Dr Andrew, Charles Medawar of Social Audit, Dr Zafrullah, Dianna Melrose and I had participated in the International Conference of Experts in Rational Drug Use, organized by WHO in Nairobi Kenya, by Director General of WHO Dr Halfden Mahler .

Also long ago - I think it was when I was invited as speaker to deal with Pharmaceuticals at the TOES Conference we met – at the 'The Other Economic Summit ' at which Susan George, Ela Bhatt and the late Wangari Mathai were also present. It had been organized by Paul Eikens and James Robertson.

With Dr Andrew Herxheimer I had hunted for Dr Isabel Gal who had helped get children together who suffered congenital malformation following Hormonal Pregnancy tests.

It was so very long ago.

We had a close relationship across regions with other Rational Drug enthusiasts in different countries - relationships of mutual warmth and respect. Anwar and Dr Bala, from our region played a networking role. This was when we wrote letters and sent them by post, when emails and faxes were not there, nor mobile phones.

I feel deep regret at not having continued closer communication with Dr Andrew as with many others who are in their golden years and we as individuals and as HAIAP must remember their tremendous contributions and let them know we have not forgotten them.

May Dr Andrew's soul rest in peace. We remember him with warmth.

Manuj Chrishantha Weerasinghe

I would like to pay tribute to the man and his work - Dr Herxheimer - on behalf of all from PHM Sri Lanka. He inspired us to come and contribute towards preserving the right to health.

Tariq Bhutta

It is very sad to hear about Dr Herxheimer's demise. I had the good fortune of meeting him when he invited me to his house in London in 1990. At the time, I was on a visit to UK on a British Council Fellowship.

Soon after I had worked on Imodium drops and got it banned worldwide after making a documentary along with Channel 4 .

He was very keen to know the whole story and made me write it on his computer. He then helped me in getting it published in *The Lancet*. We then had lunch together along with his wife - a memorable day indeed.

May his soul rest in peace

Edelina Dela Paz

I am deeply saddened by the news of Dr. Andrew Herxheimer's passing away. Dr Andrew was indeed one of the strong pillars of HAI and a big support to the campaign on rational drug use. He, together with Philippa Saunders, gave strong support to Health Action Information Network (HAIN) and the Philippine Drug Action Network (PDAN) at the height of our campaign for the National Drug Policy and for RDU in the late 1980s. He discussed with us the elements of a good national drug policy which we incorporated in our campaign. I also remember how he supported our HAI advocacy work in WHO Geneva during our lobby activities in the 1990s for policies that will ensure access to essential medicines for all.

He will continue to be an inspiration to us who continue to advocate for universal access to essential medicines and strict regulation of the pharmaceutical companies to prevent their unethical conduct and amassing huge profits at the expense of the people's health.

May Dr Herxheimer rest in peace. Amen.

Andrew Herxheimer's lecture in memory of Olle Hanson, *Essential Drugs in Developing Countries*, to students in Gothenberg, Sweden, was reproduced as an edited version in [HAI News, Number 57, 1991](#).

The tribute from the World Health Organisation can be seen [here](#)

Here is an extract from an interview Andrew gave to celebrate his 90th birthday in November, 2015.

<https://youtu.be/bhyEVz7aVE8>

Read more:

<http://www.healthtalk.org/content/andrew-herxheimer-1925-2016#ixzz40ydMGLTQ>

Tributes can be found on Andrew's facebook page:

<https://www.facebook.com/andrew.herxheimer>

Peter Mansfield posted the following with a photo on Andrew's Facebook page:

www.facebook.com/andrew.herxheimer

Tim Reed from HAI Global posted on the HAI Facebook page with a link to his blog..

'With a heavy heart, I write with news of the passing HAI founder, life member of the HAI European network, and our dear friend, Andrew Herxheimer, who passed away on Sunday, 21 February, at the age of 90.'

<http://haiweb.org/farewell-to-access-to-medicines-pioneer-andrew-herxheimer/>

Workshop on 'Building the PHM Movement for Health in Asia and the Pacific'
26 – 29 April 2016
Colombo, Sri Lanka

Shila Kaur 3 May 2016



From 26 – 29 April 2016, 39 health advocates from nine countries of Asia and the Pacific participated at a *Health Movement Building* workshop in Colombo, Sri Lanka. Organized by PHM India, this four day workshop was hosted by Sarvodaya, Sri Lanka, a highly respected civil society organization with wide reach throughout the country. Hailing from India, Pakistan, Bangladesh, Sri Lanka, Nepal, Philippines, Malaysia, Cambodia and Australia, participants shared strengths and weaknesses of their specific country circles and highlighted campaigns, events and notable activities.

It was clear from the workshop that the People's Health Movement is alive and functioning in many countries in the region. However while some circles had clear established work programmes others were loosely affiliated and functioned as coalitions. PHM Philippines with a history of mass movements showed that its strength lay in its ability to plug into the broader peoples movement and harness solidarity for its own campaigns through this broad movement. The Jan Swasthya Abhiyan (JSA) of PHM India also draws its strengths from the broad range of movements that are its members, demonstrating that the whole is certainly more than a sum of its parts. The struggles of the science, literacy and women's movements as well as trade unions, service delivery organizations, campaigns, health civil society groups and academic institutions combined make the JSA a formidable force and a voice that cannot be ignored.

With a history of strong pioneers and leadership from health luminaries such as the late Dr K. Balasubramaniam, PHM Sri Lanka has evolved into a

representative people's health movement. Its activities have ranged from workshops and campaigns organized with diverse people's groups on issues ranging from access to medicines, trade agreements, HIV and AIDs, gender sensitization, labour and peace and more recently changes to the Constitution of Sri Lanka.

Similarly leaders from the health movement in Pakistan such as Dr Sheikh Tanveer Ahmed have been instrumental in the expansion of PHM Pakistan with training of the next wave of leaders for the movement, bringing into its embrace also the struggle for the rights of women. The struggle for health in Bangladesh was described eloquently by Farhad Mazhar, who more importantly provided history, context and substance, including how the movement evolved from its essentially left and socialist roots.

Apart from sharings from country circles, the workshop also heard findings on a PHM Research Study on 'Civil Society Contribution to Health for All' involving six countries: Brazil, Colombia, Italy, South Africa, Democratic Republic of Congo and India. Funded by IDRC, this research project is aimed at examining different movements within those countries and asking questions in the five themes: movement building; campaigning and advocacy; capacity building and training; knowledge generation and dissemination; and engaging with global health governance.

The country reports from these six countries will be used to generate discussions within the different PHM regions. For example the India report formed the basis for discussion on PHM in the South East Asia, South Asia and Asia and the Pacific regions, during this workshop.

Participants discussed points that emerged during the presentations on Globalization and Health; Social Determinants of Health and Health Systems and Access to Medicines.

In the concluding session, each participant contributed views on how the movement for health could be taken forward at the country and regional levels.

The workshop's Coordinator Dr Amit Sengupta in his wrap-up summed it up well when he said that: 'To answer the question why do we need PHM when we are already doing work in our respective organizations? It is the solidarity that is generated through PHM that gives added power and impetus to our work.'

Prescrire - Drugs to Avoid

Prescrire International April 2016; Vol 25 No 170 Page 105



Towards better patient care: drugs to avoid in 2016

Announced in conjunction with the annual Prescrire Awards and published in the April issue of Prescrire International, the 2016 update of Prescrire's list of drugs to avoid includes 74 drugs that are more harmful than beneficial in all of the indications for which they are authorised in France. Notable changes this year include the addition of the widely prescribed drugs citalopram, escitalopram and diclofenac amongst the drugs to avoid. Full review (7 pages) available for free download here:

<http://english.prescrire.org/en/81/168/51897/0/NewsDetails.aspx>.

Prescrire's assessments of the harm-benefit balance of new drugs and indications are based on a rigorous procedure that includes a systematic and reproducible literature search, identification of patient-relevant outcomes, prioritisation of the supporting data based on the strength of evidence, comparison with standard treatments, and an analysis of both known and potential adverse effects.

This 2016 review of medications examined by Prescrire over a six-year period, from 2010 to 2015, identified 74 drugs that are more harmful than beneficial in all the indications for which they have been authorised in France.

In most cases, when drug therapy is really necessary, other drugs with a better harm-benefit balance are available.

Even in serious situations, when no effective treatment exists, there is no justification for prescribing a drug with no proven efficacy that provokes severe adverse effects. It may be acceptable to test these drugs in clinical trials, but patients must be informed of the uncertainty over their harm-benefit balance, and the trial design must be relevant. Tailored supportive care is the best option when there are no available treatments capable of improving prognosis or quality of life, beyond the placebo effect.

Heavy lobbying by pharmaceutical companies in Europe

Prescrire 1 May 2016

[Intense pharma lobbying in the EU](#)

[Prescrire Int 2016; 25 \(171\): 116.](#)

[\(Pdf, free\).](#)



Each year, pharmaceutical companies spend tens of millions of euros on lobbying EU institutions, and have dozens of lobbyists working on their behalf.

European institutions make many decisions affecting the day-to-day life of people living in Europe. A study carried out by Corporate Europe Observatory (CEO) reveals the intense, many-pronged lobbying of these institutions by pharmaceutical companies.

Drug companies, trade associations, and the 10 main lobbying firms working for these companies declared a lobbying spend of 40 million euros in 2014. Among them, 40 pharmaceutical companies declared spending 23 million euros on lobbying. That is considerably more than the amounts declared by non-governmental organisations dedicated to protecting public health and operating in the pharmaceuticals field (2.7 million euros).

These 40 pharmaceutical companies declared 108 full-time lobbyists, including 89 people with permanent access to the European Parliament. Furthermore, 18 pharmaceutical trade associations declared that they had 68 full-time lobbyists, 24 with permanent access to the European Parliament.

In the words of those EU institutions, 'Citizens can, and indeed should, expect the EU decision-making process to be as transparent and open as possible. The more open the process, the easier it is to ensure balanced representation and avoid undue pressure and illegitimate or privileged access to information or to decision-makers.'

In 2016, we still have a long way to go in terms of serving the interests of citizens.

Doctors who take company cash are more likely to prescribe brand name drugs, analysis finds (USA study)

BMJ 2016; 352 doi: <http://dx.doi.org/10.1136/bmj.i1645>
(Published 21 March 2016) BMJ 2016;352:i1645

Michael McCarthy

An analysis by the independent investigative news organization *ProPublica*¹ has found that doctors who accept gifts or receive payments from the medical industry tend to prescribe more brand name drugs than doctors who do not accept such benefits.¹

Records of payments from drug companies and medical device makers in 2014 were matched with data on doctors' medication choices in Medicare's prescription drug program, Medicare Part D, which covers more than 39 million patients. The analysis looked at doctors family medicine, internal medicine, cardiology, psychiatry, and ophthalmology who wrote at least 1000 prescriptions via the program.

ProPublica reported, 'Doctors who got money from drug and device makers—even just a meal—prescribed a higher percentage of brand-name drugs overall than doctors who didn't, our analysis showed. Indeed, doctors who received industry payments were two to three times as likely to prescribe brand-name drugs at exceptionally high rates as others in their specialty.'

For example, family physicians who accepted industry payments were twice as likely to be a high brand name prescriber as those who did not (relative risk 2.04 (95% confidence interval 1.92 to 2.16)), and ophthalmologists who accepted payments were more than twice as likely to be high brand name prescribers (3.63 (2.76 to 4.79)).

The *ProPublica* analysis found that doctors who received more than \$5000 from companies in 2014 typically had higher brand name prescribing percentages.

They noted, '*ProPublica's* analysis doesn't prove industry payments sway doctors to prescribe particular drugs, or even a particular company's drugs. Rather, it shows that payments are associated with an approach to prescribing that, writ large, benefits drug companies' bottom line.'

ProPublica has been tracking drug company payments to US doctors. These payments are on public record because of the Physician Payment Sunshine Act, a provision in the Affordable Care Act 2010 that requires all drug and device companies to publicly report their payments. The payments in the *ProPublica* analysis

include promotional speaking, consulting, business travel, meals, royalties, and gifts, among others, but not payments for research.

Holly Campbell, spokesperson for the industry group Pharmaceutical Research and Manufacturers of America, said that many factors affect physicians' prescribing decisions, including their clinical experience, articles in peer reviewed journals, and clinical practice guidelines, and she defended the industry's relationships with physicians.

Campbell said, 'Manufacturers engage with physicians to keep them current on new indications for approved medicines, potential side effects of medicines, and both emerging benefits and risks of medicines. Physicians provide real world insights and valuable feedback and advice to inform companies about their medicines to improve patient care.'

Ornstein C, Jones RG, Tigas M. Now there's proof: docs who get company cash tend to prescribe more brand-name meds. ProPublica. 17 Mar 2016.

Ketamine status

In November, 2015, WHO's Expert Committee on Drug Dependence (ECDD) reviewed ketamine among drugs 'with potential for dependence, abuse and harm to health', to make recommendations to the UN Commission on Narcotic Drugs (CND) on the need for their international control. The ECDD had recommended unequivocally that ketamine should not be placed under international control as they concluded that ketamine abuse does not pose a global public health threat and that such control would limit access for those who most need it as a life-saving anaesthetic.

WHO's analysis was that the medical benefits of ketamine far outweigh potential harm from recreational use. Some disagree with ECDD's and WHO's opinion and consider that ketamine should be banned because of misuse as a recreational drug.

In March 2016, the 59th CND was to vote on this issue but we have been told it did not come to a vote, so it has been rejected. However, China clearly kept the possibility open to bring it up again, so we need to remain alert. (Thank you Willem Scholten)

According to the IDPC report

'WHO's recommendation is clear and sane, taking into account the wider context of public health and balancing drug control objectives against a recognition of medical need.'

<http://idpc.net/blog/2013/03/who-recommends-against-international-scheduling-of-ketamine>

¹ www.propublica.org/article/doctors-who-take-company-cash-tend-to-prescribe-more-brand-name-drugs.

Feature: Access to medicines: Impact of prices and the role of advocacy

Compiled by Beverley Snell

Introduction

The cost of new medicines can be far out of reach of most people who need them due to the high prices charged by pharmaceutical companies for medicines under patent for 20 years.

Medical innovation is steered towards drugs, diagnostics and vaccines that give the biggest commercial rewards and not the greatest therapeutic benefits. This is a result of the current philosophy of product development that relies on charging high prices for the final product allegedly to recoup the costs of R&D (and to satisfy share-holders).

Access to affordable medicines can also be obstructed by industry attempts to prevent the lawful production of less costly generic versions of patented medicines.

The TRIPS agreement² was introduced in 1995 to underpin universal 20 year patent to 'promote technological innovation and transfer to the mutual advantage of producers.' The introduction of the TRIPS agreement would have put all new drugs out of reach of all but the very rich. However, under successful pressure from less rich countries, articles 30/31 were introduced to allow compulsory licensing to manufacture patent medicines without permission of the 'rightful owner' in a national emergency. Parallel Import and Differential Pricing would allow countries to import at the best available price. Medicines for 'government use' ie not for profit, could be imported or manufactured using the TRIPS flexibilities.

Doha Declaration (2001)

The 4th World Trade Organisation ministerial conference in Doha (Oct 2001) provided a clear political statement that public health concerns must override commercial interests - 'a road map to key flexibilities in TRIPS'.

- It leaves countries free to determine what is a national emergency
- Where patent medicines are beyond the reach of people who need them, governments can override patents without negotiations with companies and without threat of retribution
- Countries can make their own rules about parallel imports
- Procedures for issuing a compulsory license becomes easier and faster.

Indian generic companies were notable in their use of the TRIPS flexibilities to manufacture good quality essential medicines at affordable prices so the people in resource-poor countries could access them. Among the needed medicines were important new medicines, at the time notably for HIV infection, that were still under patent and only available at extremely high prices. Companies in India, Brazil and Thailand had the capacity to produce these drugs and the TRIPS flexibilities provided the legal framework to allow production and supply.

How much does R&D cost

It is very difficult to find out how much is really spent on R&D. Industry has alleged that the cost of R&D is around average \$82 billion³. But their real costs are hidden from any outside scrutiny. Companies never link their alleged costs to how quickly they earn them back at high prices⁴. They also develop and patent 'new' forms of existing entities ('me-too' products) that involve less time and effort to bring to market.

According to Light et al³

It can take from 3 months to 30 years to discover a new active ingredient that works. Much of that cost is borne by others -- NIH, other national research programs, venture capitalists funding bio-techs, foundations, and others. Finally, half of the industry's average cost of R&D is not real R&D costs at all, but an estimate of profits foregone – a highly inflated estimate of what companies would have made had they put their money in an index fund and not developed new drugs in the first place!

Note that Gleevec began testing in 1998 and was first approved for marketing on May 10, 2001. If clinical testing started in June 1998 - that is less than three years, or just 35 months.

Costs can be broken down into different stages of the development and of clinical trials and more, so the total cost is very difficult to calculate. Knowledge Ecology and formerly CPtech have investigated the history of development of many medicines and have documented findings that support the assertion that much of the cost

³Light D, Warburton R. The Costly Myths about Pharmaceutical R&D

<http://www.forbes.com/sites/matthewherper/2012/02/10/the-truly-staggering-cost-of-inventing-new-drugs/>

⁴<http://www.pharmamyths.net/>

² http://www.haiasiapacific.org/?page_id=1175

of R&D is borne by research programs, governments, Foundations etc.⁵

Breakdown of funding sources of early research concerning Gleevec/Glivec (imatinib mesylate) was presented by Thiru Balasubramaniam in Copenhagen in 2013.

- 50% National Cancer Institute
- 30% Leukemia and Lymphoma Society
- 10% Novartis
- 10% Oregon Health and Science University

So only 10% of the cost of initial research was born by the company.

Marketing and promo costs higher than R&D costs

What has been shown is that the cost of marketing and promotion is actually higher than the cost of R&D. They show that 9 out of 10 Big Pharma companies do in fact spend more on marketing than on R&D, in some cases, twice as much. A study supporting that claim was reported by the BBC in November 2014.⁶

World's Largest Pharmaceutical Firms Source GlobalData

Company	Total Revenue \$Bn	R&D spend \$bn	Sales & Marketing \$bn	Profit \$bn
Johnson & Johnson (US)	71.3	8.2	17.5	13.8
Novartis (Swiss)	58.8	9.9	14.6	9.2
Pfizer (US)	51.6	6.6	11.4	22.0
Hoffmann-La Roche (Swiss)	50.3	9.3	9.0	12.0
Sanofi (France)	44.4	6.3	9.1	8.5
Merck (US)	44.0	7.5	9.5	4.4
GSK (UK)	41.4	5.3	9.9	8.5
AstraZeneca (UK)	25.7	4.3	7.3	2.6
Eli Lilly (US)	23.1	5.5	5.7	4.7
AbbVie (US)	18.8	2.9	4.3	4.1

⁵ <http://www.cptech.org/ip/health/aids/druginfo.html> and <http://www.cptech.org/ip/health/aids/gov-role.html>

⁶ <http://www.fiercepharma.com/sales-and-marketing/new-numbers-back-old-meme-pharma-does-spend-more-on-marketing-than-r-d> and <http://www.bbc.com/news/business-28212223?>

Medicine priced to match the cost of its peers

The case of Daraprim® is possibly the most outrageous of all. The anti-parasitic drug pyrimethamine (Daraprim®) has been available since 1953 and the Drug Price Indicator Guide gives a price \$US.005 per 75 mg capsule. The commercial price was considered shocking at \$13.50 per pill.

Pyrimethamine is used currently for opportunistic toxoplasmosis infection in patients with HIV. So in 2015 Turing pharmaceuticals hiked the price to \$750 per pill on the grounds that it was in keeping with the price of its peers. Martin Shkreli, CEO of Turing Pharmaceuticals said the hike should have been even higher because his duty is to make a profit for his shareholders.⁷

Prescrire is also concerned at the increasing abuse of the orphan drug policy.⁸ Perhaps pyrimethamine fits the definition of orphan drug. Orphan drug status has existed within the EU since 2000 to encourage the development of drugs aimed at patients with rare diseases, the established threshold being diseases that affect one in 2000 people, or fewer. Pharmaceutical companies commercialising orphan drugs benefit from a number of financial incentives, in particular being permitted to charge very high prices.

Industry strategies to maintain high medicines prices

HIV infection was a death sentence but as antiretroviral medicines became available, HIV positive people could look forward to a long life treated with appropriate medicines – if the medicines were affordable. In the 1990s there was a very heavy focus on access to HIV medicines. Indian companies began making generic versions of antiretroviral medicines that could be accessed by resource poor countries. Brazilian companies were making anti-retrovirals for use in their own populations.

Drugs made under compulsory license for HIV infection in Brazil, 2005 - price differences

Drug	Patent Date Expiry	US Cost/mth	Brazil Cost/mth
Zidovudine (180 tabs)	2005	\$304.20	\$32.40
Didanosine (120 tabs)	2007	\$218.40	\$61.20
Zalcitabine (90 tabs)	2006/2008	\$169.20	\$7.20
d4TStavudine (60 tabs)	2008	\$273.60	\$16.80
Lamivudine (60 tabs)	2009/2016	\$259.80	\$49.80

All except lamivudine were developed in the public sector. Data sources Brazil MoH Prices & US Red Book prices (T. Balasubramaniam)

⁷ <http://www.dailymail.co.uk/news/article-3347441/Martin-Shkreli-said-raised-price-Daraprim-more.html#ixzz47HromcPt>

⁸ <http://english.prescrire.org/en/81/168/51920/0/NewsDetails.aspx>

Industry activities to undermine access to affordable medicines and the role of activist advocacy

Ever since the TRIPS flexibilities were introduced there have been many factors to get in the way of smooth production under compulsory licenses leading to availability of these medicines. In noteworthy cases activist advocacy has been able to overcome the attempts to stifle the legal right to access to affordable medicines.

The Chill Factor 2001 in Thailand - didanosine (ddl)

The USA had put Thailand on a 'Watch List' – to keep an eye on what Thailand was doing in the way of producing affordable essential medicines in line with the TRIPS flexibilities. Trade pressure in the form of threatened sanctions was imposed when Thailand's Government Pharmaceutical Organisation was about to produce a particular dosage form of didanosine according to the TRIPS flexibilities - as legally allowed.⁹

A group of 15 public health activists supported by the Thai Law Society agreed to help but Thai politicians feared trade sanctions (the 'chill factor') and manufacture was not begun. Because of pressure from the US, they thought they should not persist (After an increased campaign, in March 2004 the US company gave up)

The fluconazole case in South Africa

Over the years countries have entered into 'free trade agreements' (FTA's) that can over-ride national policies. Trade Agreements have included clauses that direct import of pharmaceuticals from particular sources and from certain manufacturers.

Under a trade agreement South Africa recognised the Pfizer patent for fluconazole, an important medication for the management of fungal infections, particularly in HIV +ve people. The cost of the Pfizer product was \$US 4.15/day v \$US 0.29/day for the generic product. In the year 2000 Zackie Achmat, a prominent South African HIV+ve activist, travelled to Thailand and bought fluconazole for South African patients. He was imprisoned on return to South Africa.

MSF and the South African Treatment Action campaign, with the support of many international groups campaigned for Pfizer to reduce the price to 60c/day - or allow a voluntary license for access in South Africa.¹⁰

Pfizer refused and offered to donate fluconazole under very specific conditions. The exercise was actually a clinical trial for Pfizer - restricted to cryptococcal meningitis (not for oral thrush and other life threatening

candidiasis that were problem for HIV+ve people). There would be onerous reporting and training requirements involving doctors specifically selected by Pfizer. There was also a time limit imposed on the donation.

Under pressure from activists, finally the government and Pfizer allowed generic fluconazole to be imported for pilot programs, for example in the Khayelitsha program supported by MSF. MSF would be required to purchase the product. When the Patent expired in January 2004 access to affordable fluconazole became possible in South Africa.

South Africa and the 39 companies - 2001

South Africa's Medicines Act 1998 allowed patented medicines from places other than the big pharmaceuticals, and allowed imported copies of those patented drugs. Thirty nine drug companies sued the South African government to prevent the Act – claiming the Act violated their commercial rights and patents rights. A Court Case was planned for May 2001.

Armed with the facts, the South Africa TAC (Treatment Action Campaign) with support of MSF, Oxfam and many INGOs raised awareness - wrote to companies, newspapers and so on and 300,000 people from 130 countries signed a petition. The European Parliament passed a resolution against the case. Eventually the 39 companies withdrew in shame – there was no case – the court case was cancelled.

The Novartis case in India regarding imatinib

Imatinib is a medicine that is used for the treatment of certain types of leukaemia and some forms of gastrointestinal stromal tumors.

In 2013, Novartis fought in the Supreme Court of India to retain its patent in India for imatinib (Gleevec®) - the mesylate salt of the blood and intestinal cancer drug, arguing that they deserved a patent in India on imatinib to cover their R&D costs.

Novartis set the price of Gleevec at US\$ 2666 per patient per month (generic companies were selling their versions at US\$ 177 to US\$ 266 per patient per month) even though the Indian government had enacted laws covering patentability criteria that discourage patenting of new forms of known medicines. India's ability to continue production of affordable medicines for the developing world depends a great deal on the country's patentability standards and how they are interpreted by the courts in India.

It had been shown that imatinib was not in fact a new drug but a modification of a known drug (the raw form of imatinib, which was publicly disclosed in the 1993 patent application and in scientific articles), and that Novartis did not present evidence of a difference in therapeutic efficacy between the final form of Gleevec and the raw

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http://www.patentoppositions.org/de/case_studies/500e9b8c7718ea0002000018

¹⁰ <http://www.thebody.com/content/art32050.html>

form of imatinib, and that therefore the patent application was properly rejected by the patent office and lower courts.

Novartis lost the case. A win for Novartis would have set a dangerous precedent, severely weakening India's legal position against 'evergreening', a common practice in the pharmaceutical industry.¹¹ It is worth noting that Novartis sales for Gleevec in 2012 were \$4.675 billion, or \$390 million per month. In 2012, Novartis realized more than \$100 million in Gleevec sales every 13 days.

Hepatitis C treatment: DNDi and Pharco to test affordable hepatitis C regimen

Source MSF

On April 13, at the 2016 International Liver Congress in Barcelona, the Drugs for Neglected Diseases initiative (DNDi) announced the recent signing of licensing agreements with Egyptian company Pharco, with the support of the Malaysian and Thai governments; and the forthcoming start of clinical trials which we hope will bring about more affordable hepatitis C treatment options for patients.

DNDi will be launching clinical trials to test a combination treatment of the drug candidate ravidasvir and the registered hepatitis C drug sofosbuvir in pan-genotypic patient populations in Malaysia and Thailand, as soon as the necessary approvals are received. Ravidasvir is an NS5A inhibitor, one of a new generation of direct-acting antivirals (DAAs) that are revolutionizing the treatment of hepatitis C.¹²

The medications for a three month course of hepatitis C treatment in the USA (2015) typically run between \$80,000 and \$120,000.

Pharco has agreed to supply DNDi with the combination sofosbuvir plus ravidasvir for its clinical studies for \$300 per course of treatment. For the scale-up of this regimen, once approved, Pharco has agreed to set the commercial price at \$294 or less per treatment course.

Malaysia and Thailand are among the many middle-income countries that are excluded from the voluntary licensing agreements that Gilead and Bristol-Myers Squibb, the intellectual property holders of the hepatitis C drugs sofosbuvir and daclatasvir, respectively, have concluded with generic companies. Of the up to 150 million people infected with chronic hepatitis C globally, approximately 75% live in middle-income countries. Egypt has the world's highest hepatitis C prevalence. Dr Bernard Pécoul, Executive Director of DNDi said:

'Once these trials have been successfully completed and the safety and efficacy data of this combination assessed, we will encourage governments to design their national health strategies to use all options at their disposal to gain access to life-saving DAAs, including price negotiation, voluntary licensing, or the use of TRIPS flexibilities such as patent oppositions and compulsory licensing.'

Before DAAs became available, hepatitis C treatment consisted of multiple injections over a period of up to one year and frequently caused severe side effects. Treatment was only successful 40-80% of the time. DAAs have transformed treatment options for patients and clinicians, but multiple barriers to access for patients exist, in particular, price. As with the introduction and scale-up of antiretroviral therapy for HIV infection over the past 15 years, new and innovative public health approaches to HCV treatment will require affordable access to DAAs.

Dr. Sherine Helmy, CEO of Pharco Pharmaceuticals said

'We hope that our collaboration with DNDi to develop a combination treatment that costs \$3.50 per day or less – as opposed to \$1000 per day for only one pill – will lead to widespread access to safe, effective, and affordable treatment for hepatitis C patients around the world.'

The Current Chill

Source MSF

In the United States Trade Representative's (USTR) 2016 'Special 301 Report' released on April 12, many countries are targeted for pressure for using legal tools to protect public health and access to affordable medicines.

Of particular concern is that India remains on the 'Priority Watch List', as in previous years, for what the USTR considers to be inadequate protection of intellectual property. India, known as the 'pharmacy of the developing world,' for its wide-scale production of generic lifesaving medicines has in recent years repeatedly been singled out for abuse by the US government and the multinational pharmaceutical industry for insufficient protection of the US pharmaceutical industry's interests.

India's policies, which promote generic competition and limit abusive pharmaceutical industry practices, including patent 'evergreening' are entirely compliant with global trade rules, and these actions save lives.

<http://content/evergreening-drugs-attack-access-medicines-0> ,

Indian generic companies supply affordable, life-saving medicines used to treat communicable and non-communicable diseases in many developing countries; these medicines are essential to continue scaling up

¹¹ <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3680578/>

¹² <http://www.businesswire.com/news/home/20151116005444/en/Pharco-Pharmaceuticals-Reports-Ravidasvir-Achieved-100-Cure>

treatment programs. For example, two thirds of all the drugs MSF purchases to treat HIV and malaria in medical humanitarian operations are generic medicines made in India.

Statement from Médecins Sans Frontières (MSF) USA:

'It's outrageous that the US government is once again attempting to stand in the way of India and other developing countries' efforts to increase access to affordable, lifesaving medicines. India's policies save lives and are fully consistent with global trade rules. The US government should support countries, rather than penalize them, for not bowing to the persistent efforts of the multinational pharmaceutical industry to severely restrict generic competition in India and worldwide.'

Judit Rius Sanjuan, US Manager & Legal Policy Adviser Médecins Sans Frontières/Doctors Without Borders USA' Access Campaign.

Conflicting agendas

The case for compulsory licensing and parallel importation of essential life saving medicines is clear

- Governments are responsible for the health of their people. Ensuring access to effective drugs is one of their many responsibilities.
- Pharmaceutical companies have a responsibility to their shareholders to develop effective drugs which can be sold profitably

Conflicts between agendas are inevitable and national and international laws try to regulate activities.

Patent monopolies lead to high prices of drugs.

Although the World Health Assembly declared public health takes priority over commercial concerns and the DOHA agreement endorsed the use of the flexibilities of *TRIPS*, hurdles must be jumped and there is a great deal of misinformation circulated about what is allowed

and what is not that tends to confuse people and discourage their use of what is rightly available. There would have been little success without Advocacy. We in HAI have been campaigning for many years for affordable access to essential medicine.

Advocacy is needed

- To support peoples' rights - solidarity
- To counter misinformation about what is possible and legal
- To clear up legal uncertainty of rights under TRIPS
- To counter efforts to weaken provisions of the Doha agreement - advocacy for delegates at regional meetings, 'ministerials'
- To counter pressure on countries from vested interests eg MNCs and US government
- To address poor coordination between ministries or lack of awareness of implications of actions eg trade agreements
- To prevent the 'chill factor' - to support governments who are scared to use their rights because of perceived threats
- To counter myths

Examples of myths - Advocacy is myth busting

- Companies will donate
- Donors can donate medicines
- Developing countries don't have the infrastructure
- Compliance (adherence) is not possible
- Africans don't use watches
- Community myths
- Myths from politician who have been mis-informed

Public health activists have challenged and achieved major gains

HAI Global

Overtoom 60 (2)
1054 HK Amsterdam, The Netherlands
info(at)haiweb.org <http://www.haiweb.org>

HAI Europe

Overtoom 60 (2)
1054 HK Amsterdam
The Netherlands
info(at)haiweb.org <http://www.haieurope.org>

HAI Asia Pacific

Penang Malaysia Email: kaur_shila@yahoo.com

HAI Africa

P.O. Box 66054 - 00800 Nairobi Kenya Email: info@haiafrica.org Web: www.haiafrica.org

HAI Europe

Overtoom 60/II 1054 HK Amsterdam The Netherlands Email: info@haiweb.org Web: www.haiweb.org

HAI Latin America (AISLAC)

Accion Internacional Para la Salud Apdo 41 - 128 Urb Javier Prado Ca. Mario Florian Mz 3 Lote 22 San Borja, Lima 41 Peru Email: ais@aislac.org Web: www.aislac.org

Feature: The availability of Fixed Dose Combinations and other problem medicines

Compiled by Beverley Snell and Amit Sengupta

Countries with strong and operational regulatory authorities can control the manufacture, import and circulation of all medicinal products. Regulatory authorities control what can be manufactured by companies within the country and with Customs Authorities ensure that only permitted medicinal products can be imported.

In our region Australia, New Zealand, Singapore, Hong Kong, and Malaysia, have regulatory authorities that are able to control the availability of medicinal products to ensure that the products are safe, effective and appropriate for the needs of the people.

There are other countries where the regulatory mechanisms are weak or absent or inappropriate for a number of reasons; so a vast range of irrational and dangerous medicinal products have become available.

Some of the available medicines contain ingredients that have become obsolete or found to be dangerous and withdrawn from the markets of countries with strong regulatory authorities. Examples are phenylbutazone, dipyron, reserpine, several 'sulfa' drugs. Many of the products circulating are fixed dose combinations (FDCs).

The rationale for FDCs

Combination products are not new.¹³ They are commonly available, particularly in the 'over-the-counter' area. Combination analgesics (eg paracetamol with codeine) have been available for years and special cases have also been made, and accepted, for combinations such as sulfamethoxazole with trimethoprim, or amoxicillin and clavulanic acid to broaden their antimicrobial spectrum.

Other examples where a mixture of medicines in one product is useful and generally safe are the medicines needed for treating tuberculosis (TB) and HIV infection. For both those illnesses, patients need a combination of medicines and they need to be taken for a long period: at least six months for TB and for the rest of life for HIV. Single medicines are not effective for those illnesses. In both cases it is extremely important that no doses are missed. Having more than one medicine in each tablet or capsule means the patients have less tablets to remember and less bottles of tablets to look after. But there are pros and cons with FDCs.

It is expected that the number of FDCs promoted for the treatment of cardiovascular and related diseases will increase on the grounds that combinations could cover the wide spectrum of cardiovascular and other problems that are commonly suffered by one patient. A pharmacological strategy behind a FDC could be for using antiplatelet, antihypertensive, lipid lowering and glucose lowering therapies together in combined products.

Dr Robert Moulds says about FDCs¹³

'Although there is little firm evidence to guide us, factors in favour of their use include better patient compliance, simplicity for prescribers, and in some cases reduced cost. Factors against their use include the inability to adjust the dose of each component separately, exposing the patient unnecessarily to more than one drug, and incompatible kinetics.'

So although the rationale for such products is clear, the actual development of safe, effective, appropriate products presents difficulties due to the factors described.

Irrational FDCs are commonly available in several countries

In Asian countries, for example, it is possible to see an enormous range of irrational and/or dangerous FDC products on the shelves of retail businesses that sell medicines, including pharmacies.

Thailand

The Thai 'Drug Act 1967, B.E.2510' and its four amendments:

- Require registration before importing or manufacturing; and
- Categorise licenses into household remedies, dangerous drugs, special controlled drugs. Psychotropic drugs (such as midazolam, alprazolam).

Narcotic drugs (such as morphine) are regulated by the Psychotropic Act, Narcotic Act.

The Medicines Research and Management Program (MRMP) at Chulalong Uni with Thai NGOs and activists and the Thai FDA set up a re-evaluation subcommittee (under the Drug Board) to develop a re-evaluation policy. Suggestions from the subcommittee for banning drugs were heavily rejected by industry so different approaches were needed. Again after pushing by the MRMP, and the Thai FDA, another re-evaluation policy

¹³ Moulds R. Combination products: love them or loathe them. (*Aust Prescr* 2001;24:127-9)

was developed with the target to finish in three years - in 2011. Since then no re-evaluation subcommittee meeting was convened.

The latest attempt has been focused on anti-bacterials. The MRMP is pushing for the re-evaluation (banning) of very seriously irrational combinations of antimicrobials. Because Antimicrobial Resistance (AMR) is now a hot issue to be addressed as part of the National AMR strategy there is hope for more success.

Some examples

1. lozenges / pastilles with antibiotics
(neomycin+bacitracin+local anesthetic)
2. Antidiarrhoeal containing antibiotics,
kaolin+pectin+neomycin, furazolidone+clioquinol+etc.,

There is also concern about the availability of products such as antibiotics with steroids in topical creams.

Philippines

Mike Tan informed us that in 1986, after the fall of the Marcos dictatorship, their activist groups pushed the government to ban dangerous and ineffective drugs and succeeded to get some 250 preparations off the market. Registration also tightened to slow down the introduction of new products.

'Alas', he says, 'through the years, we've seen ineffective drugs creeping in again, usually as supplements, which have far more lax registration requirements. Meanwhile, the Internet has become a new marketplace to sell all kinds of drugs, with all kinds of claims'.

Some banned health products include slimming and anti-obesity pills. A few examples:

- Ballet Dancer Fat Reducing
- Brazilian Slimming Coffee
- New Original Lightness Fat-Reducing
- Seven Days Miracle

The Philippines FDA website displays this statement

Remember, FDA cannot test all products on the market that contain potentially harmful hidden ingredients. Enforcement actions and consumer advisories for tainted products only cover a small fraction of the tainted over-the-counter products on the market.

<http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm234539.htm>

The FDA does issue frequent 'Notifications'. Here are two examples

03/17/2016 [Public Notification: Salute Capsules contain hidden drug ingredients](#)

11/19/2015 [Public Notification: Australia Kangaroo Essence contains hidden drug ingredient](#)

India

India bans 344 irrational Fixed Dose Combinations



In March 2016, the Health Ministry of India banned 344 irrational Dose Combinations which include several common cough syrup solutions, several painkillers in one FDC and pain killer and antibiotic combinations, many of which are sold over the counter. See Gazette notification issued on March 10 2016 under Section 26A of the Drugs and Cosmetics Act, 1940:

see <http://cdsco.nic.in/writereaddata/GSR705E.pdf>

The gazette lists the scientific reasons why certain combinations are banned.

Out of the 344 products listed it is hard to pick the most outrageous combination.¹⁴

Here are a few examples:

- Diclofenac + Tramadol + Chlorzoxazone
- Nimesulide + Pitofenone + Fenpiverinium + Benzyl Alcohol
- Azithromycin + Cefixime
- Paracetamol + Mefenamic Acid + Ranitidine + Dicyclomine
- Cetirizine + Phenylephrine + Paracetamol + Caffeine + Nimesulide
- Ergotamine Tartrate + Belladonna Dry Extract+Caffeine + Paracetamol
- Drotaverine + Clidinium + Chlordiazepoxide
- Allantoin + Dimethicone + Urea + Propylene + Glycerin + Liquid Paraffin
- Clobetasol + Ofloxacin + Miconazole + Zinc Sulphate
- Clobetasole + Gentamicin + Miconazole + Zinc Sulphate
- Clobetasol Propionate + Ofloxacin + Ornidazole + Terbinafine
- Ciprofloxacin + Fluocinolone + Clotrimazole + Neomycin + Chlorocresol

¹⁴ Also see Indian Express:

<http://indianexpress.com/article/india/india-news-india/do-you-take-one-of-these-300-banned-drugs/#sthash.T7lme6t9.dpuf>

Why India's problem is hard to fix

As the Parliamentary Standing Committee of Health Report explains¹⁵ (pp 27-28 on FDCs) - the problem lies in the fact that the products are Fixed Dose Combinations (FDCs) of already approved drugs. They were not considered new drugs in the Drugs and Cosmetics Rules with the result that legally authorized state level drug controllers issued thousands of Indian producers with manufacturing licences for hundreds of combinations of already approved medicines without the need to consider rationality or safety.

Since matters concerning drugs are under the jurisdiction of both central and state governments, there is some lack of coordination between the powers of the authorities. The Drug Controller of the Government of India (DCGI) can approve 'new drugs' while state controllers are empowered to issue manufacturing licences for old medicines already approved by DCGI.

The problem was rectified in May 2002 when the licencing procedure was changed to make it mandatory for state controllers to insist on prior approval of **new FDCs** while issuing manufacturing licences. By then thousands of FDC formulations had already hit the market.

State governments can only prohibit manufacture of drugs, including FDCs, if the drugs are found to be substandard, misbranded, adulterated, spurious or if the manufacturer has violated any rules. On the other hand Central Government can ban drugs in the 'public interest' if they involve risk to humans or do not have claimed therapeutic value [which is what they have just done].

The People's Health Movement of India issued a Press Release¹⁶ on March 19 2016 complimenting the GOI for its action in banning the 344 FDCs. It noted that 'the agency has sat on a huge body of evidence for decades, which has consistently shown that a significant proportion of drug formulations available in India have no scientific validity.'

Noting also that the 344 products were only a fraction of the large number of irrational FDCs available, the PHM urged the authority to 'take proactive measures to weed out all irrational and hazardous formulations that are not validated by current scientific literature'. 'The Central Drug Standard Control Organization (CDSCO) 'should specify inclusion criteria based on clear scientific evidence for FDCs, and all FDCs that do not fulfill the criteria should be banned.'

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<http://164.100.47.5/newcommittee/reports/EnglishCommittees/Committee%20on%20Health%20and%20Family%20Welfare/59.pdf>

¹⁶ <http://phmindia.org/wp-content/uploads/2016/03/JSA-FDCs-Press-Release.pdf>

HAIAP member Dr Amit Sengupta discussed the issue of FDCs with Prabir Purkayastha in the Newslick Studio (see video¹⁷). He explained the rationale for specific FDCs such as amoxicillin/clavulanic acid and for Tuberculosis and HIV but emphasised that 'the government should have a clear policy to control the fixed dose combination drugs, rather than banning selective ones'. He also emphasised the irrationality of using combinations of different medicines for cough, as widely occurs in India - 'the leading global pharmaceutical companies have major stakes even in the cough syrup business in India.'

The way forward

HAIAP Member Dr Gopal Dabade, in the Decan Herald March 27, 2016 under the heading *Healing fast, killing slowly*, suggests a way forward.¹⁸

'The drug companies have approached the court seeking a stay on the ban issued by the DCGI.

The drug controller may try to urge the courts that a stay should not be granted. But the drug companies have mastered the art of overcoming the ban. How do the companies do it? Very simple! Let us say when the government issues a ban for a combination of Vitamin B1+B6+B12, the drug companies just add another Vitamin B2 (Riboflavin) to this and overcome the ban.

So instead of banning each and every single FDC (which in any case is impossible) the government should come out with a list of FDCs that are scientific. It should be noted that, all FDCs are not bad. WHO has a list of essential drugs (19th WHO Essential Model List of Essential Medicines, April 2015).

This list which is revised every three years has totally 425 drugs of which 27 are scientifically approved FDCs. Examples are ORS (Oral Rehydration Solution) or Iron + Folic acid (for anaemia).

The drug regulatory authorities should insist that only these FDCs are to be manufactured and nothing else. If that does not occur, then this big exercise of banning of 344 irrational FDCs, with huge media attention, will just be another mockery.'

News from HAI Europe

(18 April 2016) [Civil Society Urges Member States to Support the Dutch EU Presidency's Vision on Access to Affordable Medicines](#)

(7 April 2016) [ACCISS Study Reveals Numerous Barriers Hindering Access to Insulin for Millions in Need](#)

(22 February 2016) [Study Finds Access to High-priced Medicines May Differ Across EU](#)

¹⁷ <http://newslick.in/tags/banning-irrational-drug-combinations-right-step-wrong-method>

¹⁸ <http://www.deccanherald.com/content/536920/healing-fast-killing-slowly.html>