



April 2012

HAI AP News

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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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Message from the coordinator

On World Health Day (April 7), WHO launched the theme “**Good health adds life to years**” for 2012. And it is indeed an appropriate theme as we see an increasingly ageing world population. The greying of HAIAP and its founding partners was a topic of some discussion in the last HAIAP Planning Meeting in September 2011 in Penang; and if our work is to

continue, younger health activists must be engaged, trained and empowered to carry on the struggle for Health For All.

There are two noteworthy events on the horizon: the first is the Asia Pacific Conference on National Medicinal Policies to be held in Sydney, Australia from 26 – 29 May 2012, essentially a stock taking event on the status of pharmaceutical policy implementation by countries in the Asia Pacific region, since the last similar conference in 1995. In October 2011, HAIAP had in fact, circulated a questionnaire to all members on its SOPP Project with a view to assessing the state of pharmaceutical policies in the region. Unfortunately, the HAIAP membership has not been forthcoming with responses – I only received four returned questionnaires! – a dismal show indeed despite several reminders and extension of deadlines. Your responses would have allowed HAIAP to feed back and complement any gaps in reporting at the APCNMP event..... But I have not given up hope, a fourth reminder will be going out soon, so let's act like a family and help one another. Can we do that?

The second event is the Third Peoples Health Assembly to be held in Capetown, South Africa from 6 – 11 July. Many of us in HAIAP were part of the first PHA in Bangladesh in 2000, as pioneers and organizers and then again at PHA 2 in Cuenca in 2005. So if you are

able, enthused and have the funds, do try and be a part of this people's event. The Organizing Committee will *consider* funding requests only from PHM country circles who are unable to raise funds.

Institutional support for HAIAP ceased at the end of February 2012 after my contract with the School of Pharmacy at USM ended. This is the age of the virtual office and all that one really needs to work is a laptop and desk. And so HAIAP continues operations as usual. For its duration at USM under the good graces of its former VC and HAIAP member Tan Sri Prof Dzulkifli Abdul Razak, HAIAP had the good fortune to interact and forge relationships with an enthusiastic graduate and postgraduate student body, which of course will continue.

Shila Kaur

Congratulations:



Dr Ken Harvey

And the winner is ... Dr Ken Harvey

HAIAP members heartily congratulate Ken on receiving the CHOICE Consumer Champion Award for 2012.

CHOICE (the people's watchdog) is the public face of the Australian Consumers' Association (ACA).

Throughout his career, and then in retirement, Dr Ken Harvey has campaigned on behalf of consumers to improve the regulations for the use and promotion of therapeutic goods.

While working at Royal Melbourne Hospital in the 1970s, Ken became concerned about the inappropriate prescribing of antibiotics, and so began his interest in ethical promotion of medicines. Elected to the CHOICE Council in 2000, Ken has been awarded life membership of CHOICE for services to the consumer movement and is a member of its Policy Advisory Group.

Ken really put himself on the line when he went up against weight loss company SensaSlim last year. When he lodged a complaint about their advertisements with the TGA, SensaSlim threatened to sue him unless he retracted his comments.

He refused, so they sued. After many months of stressful legal goings-on and great personal expense (though costs were ultimately met by supporters) he won his case. The product was eventually delisted and the principals prosecuted – a real victory for consumers.

Ken admits that the line of work he's in is 'frustrating, but you have to keep on keeping on. Bureaucrats change, politicians change, governments change, but the problems remain the same.'

'I'll continue to pursue consumer rights' he says, 'I'm also focusing on recruiting and training the next generation of health activists. Consumer rights are continually under threat from those who believe in unrestrained capitalism, big business and small government. We need more young people to work with consumer organisations and universities have an important role to play.'

CHOICE is a completely self-funded body that provides consumers with purchasing advice as a result of independent product testing and, where shonky products require legislative redress, political advocacy.

<http://www.choice.com.au/reviews-and-tests/awards/choice-awards/choice-awards/choice-awards-2012/page/consumer-champion.aspx>

Ken Harvey is Chairman of the Governing Council of HAIAP

HAI Activities 2012

New report: Divide and Conquer

<http://haieurope.org/wp-content/uploads/2012/03/28-March-2012-DivideConquer.pdf>

A look behind the scenes of the EU pharmaceutical industry lobby

HAI Europe Research paper - March 2012

Summary

This report surveyed the entries made by pharmaceutical companies and their representatives in the EU's lobby Transparency Register to find out how much the industry claimed to spend on lobbying. According to these findings, the pharmaceutical industry lobby is spending more than €40 million annually to influence decision making in the EU – of which nearly half is spent by drug manufacturers on in-house lobbyists.

It was shown that many pharmaceutical companies lobbying the European Commission on legislation fail to declare their activities to the Register as registration to the Transparency Register is voluntary. If recorded properly, expenditure on lobbying activities by the industry could be shown to be as high as €91 million annually. Civil society organisations active on EU medicines issues, on the other hand, spend a combined €3.4 million per year.

In the USA, the sector has reportedly spent about €85.5 million in lobbying the US government in 2011. The report estimates that 220 lobbyists are active in the EU

on behalf of the industry, which pales in comparison to nearly 1500 industry lobbyists documented in the US in 2011. Clear and enforced reporting rules in the US yield a more accurate picture of pharma's lobby contingent in America as compared to the EU. A number of persistent shortcomings in the EU Transparency Register are also revealed.

The industry lobby has been linked to the EU's move to enhance data protection which is resulting in delays to marketing cheaper generic medicines.

The Anti-Counterfeiting Trade Agreement (ACTA) and its Impact on Access to Medicines

Joint statement

Health Action International (HAI) Europe, Oxfam, Médecins Sans Frontières (MSF) and the Trans Atlantic Consumer Dialogue (TACD) call on EU parliamentarians to condemn ACTA

On February 22, the European Commission announced its intent to ask the European Court of Justice (ECJ) for an opinion on the conformity of the Anti-Counterfeiting Trade Agreement with fundamental freedoms. The ECJ referral will only assess ACTA's compatibility with EU Treaty law and not with obligations under international agreements in relation to access to medicines. These concerns remain, whatever the outcome of the ECJ test, and policy makers should act on these concerns.

HAI Europe, Oxfam, MSF and TACD urge members of the European Parliament to adhere to its current timetable and vote on ACTA instead of accepting the European Commission's manoeuvres to postpone the final vote.

Australia, Canada, Japan, Morocco, New Zealand, Singapore, South Korea and the United States signed ACTA on 1st October 2011. The European Union and 22 of its Member States signed on 26th January 2012. Cyprus, Estonia, Germany, Netherlands and Slovakia have not yet signed. For the agreement to become legally binding on a party it must first be signed and then ratified by that party. Within the EU, the agreement must be separately ratified by the European Parliament, individual Member States and the EU Council - this has not yet happened.

As a treatment provider, Médecins Sans Frontières (MSF) is deeply concerned about the impact of the enforcement agenda on the production and supply of affordable, legitimate medicines. It is a public health necessity that the trade in affordable and legitimate medicines functions smoothly and without undue

burdens. MSF has been increasingly concerned by the impediments that have been pushed in a number of different forms – as a part of free trade agreements, international treaties, domestic legislation and customs regulations.

ACTA is a part of the trend of enforcement measures that harm access to medicines. Crucial distinctions between types of IP rights are blurred while excessive punishment increases the likelihood that wrongful searches, seizures and legal actions against legitimate suppliers of generic medicines will be carried out. The whole medicines supply chain becomes affected.

The impact has already been documented, for example in relation to the 2008 Anti-Counterfeit Act in Kenya⁴, which is currently being challenged by people living with HIV.

The Doha Declaration, signed by all members of the World Trade Organization, affirms that TRIPS can and should be interpreted and implemented in a manner supportive of their right to promote public health. This includes in relation to intellectual property enforcement measures, such as the ones contained in ACTA.

While it is claimed that ACTA will protect against falsified medicines by allowing countries and companies to take strong measures in trademark disputes, this may in fact impede access to genuine generic medicines. Only 'wilful trademark counterfeiting on a commercial-scale' - a form of fraud with a deliberate intention to exactly copying a product's branding - presents a legitimate public health concern. The World Trade Organization itself distinguishes between 'counterfeiting' and 'infringement'.

ACTA blurs this distinction. Disputes over allegations of similar sounding names or packaging are common in the medicines field, as companies will often choose brand names for medicines that sound inevitably similar, in that they are derived from the drug's international non-proprietary name (INN). Similar names and packaging are often even desirable to demonstrate medical equivalency, but they do not mean that the medicines are unsafe or indeed that there has been a trademark infringement.

Under ACTA, there could be an impact on suppliers and distributors of active pharmaceutical ingredients (API) used for producing generic medicines.

ACTA allows the border detention of in-transit medicines destined for developing countries, which will interfere with the trade in legitimate medicines, and leaves trade in generic medicines open to disruption.

This means a customs official could decide to detain and even destroy an allegedly infringing good - *without any court oversight or even notification to the rights holder or the generic company alleged to have violated the trademark* - on the basis of the customs official's own view on whether the goods in question infringe a commercial trademark.

The risks to access to medicines of such overbroad provisions have been recently highlighted when medicines were detained in Germany based on the wrong assumption that a generic medicine, using the required international non-proprietary name (INN) 'amoxicillin' to describe the contents, infringed GSK's trademark on the brand name Amoxil (which is itself a use of the INN).

The spectre of harmful fake medicines is a concern that continues to be used to justify ACTA. Yet ACTA is **not** designed to deal with fraudulent, unsafe, and ineffective medicines; its purpose is to protect the commercial interest of companies that hold IP rights. There is one small area of overlap with fraudulent medicines, but even then the measures proposed would pose greater harm to access to legitimate generic medicines than they would act as a safeguard against fake medicines.

Conclusions

ACTA does nothing to address the problem of poor quality and unsafe medicines. ACTA undermines existing international declarations to protect public health.

ACTA should: -

Not be signed and ratified by contracting States unless all concerns related to access to medicines are fully addressed:

- Only be applicable to wilful copyright and trademark counterfeiting on a commercial scale.
- Not establish third party or aiding and abetting liability.
- Not include TRIPS-plus measures on civil and criminal enforcement mechanisms.
- Include protections against abuse, including judicial review, penalties for abusive litigation and baseless allegations, and access to information for the alleged infringer.
- Ensure that any institutional structure established through ACTA be open and transparent.

A counterfeit pharmaceutical product is a product that is deliberately and fraudulently mislabeled with respect to identity, contents and/or source

- It can be branded and/or generic
- It is a deliberate imitation of a genuine product
- It can include products:
 - With correct ingredient(s)
 - With wrong ingredient(s)
 - Without active ingredient(s)
 - With insufficient quantity of active ingredient(s)
 - With fake packaging

ACTA was negotiated through an undemocratic and secretive process to establish a new global norm which will have direct impacts upon developing countries that did not participate in negotiations. It does not properly distinguish between different types of intellectual property rights, widens the enforcement net to hold liable third parties such as purchasers of generic medicines, endorses excessive punishment, and increases the likelihood that legal authorities will carry out wrongful searches, seizures and legal actions against legitimate suppliers of generic medicines. Since ACTA does not properly limit strong enforcement measures to counterfeits, ACTA enables multinational drug companies to ask customs officers to seize legitimate and safe generic medicines on the false grounds that they are counterfeit goods. ACTA contributes to a damaging confusion between crucial legitimate generics and counterfeit medicines, which is

harmful for public health.

Today, more than ever, access to quality, safe, and affordable medicines remains a critical priority for low and middle-income countries across the developing world.

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Feature: Primary Health Care and Community Health Workers in Iran

Mohammad Ali Barzgar

Beginning in 1971

In order to compare the health situation before and after the Primary Health Care (PHC) era, it is useful to look at the vital statistics pre- and post- PHC time. IMR was 131/1000 live births, MMR 140/100,000 and the Birth Rate was 42/1000 population compared with the present Birth Rate of 17/1000 and IMR of 16/1000 live births respectively.

In 1971, there were only 18,000 physicians and 8000 registered nurses for a population of 40 million. There were only 5 medical schools - in large cities. Today there are around 40 Medical Sciences and Health Services Universities scattered all over the country especially in remote and disadvantaged areas and there are over 100,000 physicians and over 120,000 registered nurses plus numerous nurse aid auxiliaries including 20,000 *Behvarzan* - our successful community health workers.

How and why we did started our PHC program?

The program began with a joint Health Services Research Development (HSDR) project by the School of Public Health, University of Tehran, Ministry of Health and WHO. In 1972 a survey was undertaken to assess the health needs of the population, the efficiency of health services system dealing with the health problems and the behavior of the population in relation to the health services.

It was found that about 80% of the medical problems could be categorized into ten complaints and six diagnoses including common cold (33%) in the winter and diarrhoea (22%) in summer, conjunctivitis, osteomuscular pains, etc. Health services were only curative-oriented and physicians attended 120 patients during their two hours work in rural health centres, spending only 30 seconds to one minute with each patient (the patient was literally only *seeing* the doctor).

Health problems were more prevalent in rural and poor urban areas but health facilities were located and available in affluent parts of urban areas, mainly in major cities. Responsibility for management of health services lay with numerous organisations like the Imperial Organization for Social Services, Red Cross, Army, Ministry of Justice, oil companies, and the Ministry of Health was the weakest politically.

The survey found that people preferred traditional practitioners rather than organised health services; they

would not travel more than five kilometers to facilities except for emergency; were not happy with the way that health services staff dealt with them; and they could not afford to buy the prescribed medicine. There was no health insurance in rural areas.

The survey also found that in the family, the best food was given to the man, then to the boys and if anything was left, to the girls and then the mother, even though she was providing the family food.

Based on the findings, an alternative strategy was devised for establishing an efficient health services system to provide universal health coverage especially in remote areas.

If a comprehensive and integrated promotive, preventive, curative and community based rehabilitative intervention were to be introduced, not only would it improve the health situation of 70% of the population of the country, it would have an impact on the other levels of health services and even medical education.

It would be cheaper and more practical, and if the people in need were to be properly involved and consulted at the beginning, they would support the intervention.

A proposal was made concerning all the numerous ministries and organisations. If it was not politically possible for them to be integrated into the Ministry of Health at least they should be coordinated by a Functional Unit within the Ministry of Health. This proposal was agreed under the influence of WHO during the Shah regime. After the Revolution, fortunately all of them were integrated into the Ministry of Health and medical schools also came under the authority of the Ministry of Health. The new integrated Ministry was re-named the Ministry of Health and Medical Education. The integration put a lot of emphasis on Public Health and Community Oriented Medical Education.

Implementation of the primary level intervention

The selected primary level intervention was tested in a pilot area of 30,000 population in 30 villages around a rural health center called Chonghoralo where the University of Chonghralo was later established. This became the centre where thousands of nationals, International visitors, Ph,D students, including Australians, have been trained in PHC.

For comparison, a control population of about 22,000, with existing health services and no PHC was selected in a nearby area.

The Primary Health Care (PHC) program

The intervention in the pilot areas was introduced through recruitment and training of selected local boy and girl graduates of primary schools. So in 1973, well before Primary Health Care and its concept of community health workers had been launched, the first batch of community health workers to be known as *Behvarz* - plural *Behvarzan* (*Beh* = good, *Varz* = skill) were posted in 10 Health Houses which overall covered the 30,000 population as a pilot project in rural Azerbaijan. After block system training, the *Behvarzan* were supported by the community they served.

A female *Behvarz* was to be responsible for, among other things, child and maternal health; a male *Behvarz* for sanitation and environmental projects. Training materials were in line with the findings of the survey and the sequence of the training block was organized according to the priority health problems shown in survey findings. For example infant mortality and maternal mortality was high, therefore the first teaching block of the *Behvarzan* was child care and the second block was MCH/Family planning and the third block was control of communicable diseases and curing the diseases.

The duration of the training of the *Behvarzan* was overall two years: in the first year two months training in classroom with two months serving in the community under the direct supervision of the instructors (public health nurse, nurse aid and sanitarian), then one month training in the class on MCH/FP and then three months practice in the field on child and maternity care and lastly one month in class room for block three on communicable diseases control.

One of the very restricted criteria for the recruitment of the *Behvarzan* was that they must be from the community and reside where they will serve (being from the community and supported by the community).

After 3 years of services delivered by the *Behvarzan* in Iran, the IMR was reduced from 131 to 76/1000, Birth Rate from 42 to 27/1000 population.¹ It should be mentioned that in a neighbouring community without the services of community health workers, IMR was 122/1000 and Birth rate was 41/1000. For problems beyond the capacity of the *Behvarzan*, the health houses were linked to referral centres.

Inspired by the Iran program, the late Ms Benazir Bhutto approved the training of 100,000 Community Health Workers (CHW) in Pakistan where I was working with WHO. While I was with WHO in Pakistan - until December 1999 - around 60,000 (CHW) were trained and posted to Health Houses in their own villages.

Where the Behvarzan are located and practicing now

Practice takes place in a Health House (HH), which I call the Ministry of Health of the village community. It means all the functions of the Ministry of Health and health related issues can be managed through a *Behvarz* in coordination and with support of the village development committee (VDC). Sometimes a husband and wife couple work together. Outreach and home visits are also conducted.

Conclusion

I believe that our most significant intervention at the primary level was introducing a local community health worker as an agent of change for the community and for the whole health services system - with a promotive and preventive emphasis rather than only curative emphasis. We brought the services to the people rather than waited for people to come to the services. The health services became a part and parcel of communities through selected community girls or boys and their village health house - where the community had a role in construction, management and supervision. The whole process solved their health problems and contributed to community development. The *Behvarz* became a representative of the community and also brought a lot of resources and services to the community.

The impact can be seen in the vaccination coverage in more than 50,000 villages of Iran: above 90%, while in the urban area it is much less. If a mother does not go to the Health House the *Behvarz* will go to her home and vaccinate the child. In the city there is no such home delivery care.

All pregnant women have excellent pre-natal care and because the *Behvarzan* are aware of all the pregnant women and children under five years in their community, there are accurate statistics and schedules for the delivery of health care and home visits, in contrast to the urban areas.

Lessons to learn:

The primary level is the most sensitive level of care for positive change of the health of the people.

Curative, hospital based, technological and biological medical education is a great barrier to the Primary Health Care approach; that is why we had to bring the medical education under the Ministry of Health. (Unfortunately the universities returned to the Ivory tower approach rather than people oriented one.)

Poverty and unemployment are the root causes of ill health. Without addressing those, the poor will get sicker and being sick will become poorer, making a

vicious circle and neutralising the 25% impact of health services on health situation.²

Community involvement, ownership and empowerment are the missing parts of health services systems which have been called an Illness Industry by the former Director General of WHO, Dr. Halfdan Mahler.

Intersectoral Collaboration is crucial: Peoples' needs are inter-related and specialists divide them, based on their specialty. An intersectoral collaboration towards health for all policy approach is required for achieving equity and *Health For All* through meeting the basic needs of the people and addressing socio-economic determinants of health.

The whole educational system right from the kindergarten to Postgraduate University, should be re-organized so the graduates of such system, and especially the leaders of the world will be able to meet the basic needs of the people rather than to sustain a miserable life for the poor people of the world.

¹ Barzegar MA, Djazayeri A. Evaluation of rural primary health care services in Iran: report on vital statistics in West Azarbaijan. *Am J Public Health*. 1981 Jul;71(7):739-42.

² Barzegar MA, Kore IA. A Solid Base for Health. *World Health Forum* Volume 12, 1991

Feature: After the floods - rebuilding Pakistan: A story HANDS Relief, Early Recovery & Rehabilitation Activities

6th August 2010 – 30th November 2011

Tanveer Ahmed

Pakistan, a country that is renowned for its fertile lands, rich crops and agricultural diversity, was ravaged in 2010 by one of the worst floods in the history of mankind. Apart from the death of more than 2000 men, women and children, thousands were injured. Over 20% of the country was submerged under water. Over 1.5 million acres of agricultural lands and crops were destroyed. Over 20 million people were rendered homeless. There were over seven million Internally Displaced Persons (IDPs) in 12 Districts of Sindh Province alone.

The Health And Nutrition Development Society (HANDS) is a registered, Not for Profit Organization working in the health and social sectors since 1979 under the leadership of founder and Chairman Prof. Abdul Gaffar Billoo Sitra-e-Imtiaz. HANDS provides benefits to more than 13 million population of more than 17000 villages in 24 districts of Pakistan.

State of emergency

At the time of the floods, HANDS immediately declared an emergency in the organization. The operation, led by the Disaster Management Program divided the operational area into three hubs, the northern Sindh hub based in Sukkur, southern hub in Thatta and the Quetta hub. Each was looked after by a hub manager.

HANDS mobilisation

HANDS immediately mobilized its 1264 staff and 10,000 volunteers along with 40 vehicles and two boats were

deployed in each city: Thatta, Kashmore and Jacobabad. A total of 83,163 people were evacuated from the most vulnerable points to more than 500 Relief Camps. Support was provided to more than 245,000 family members.

Food rations, hygiene kits and non-food items were supplied to around 35,000 families. Water supply and toilet facilities were provided under the most challenging circumstances.

HANDS' mobile Health Teams provided services in camps in 13 districts. Fixed Medical Camps were stationed at all Relief Camps in the flood-affected areas. Around 10,000 women were provided with antenatal and postnatal care ensuring safe deliveries. Reproductive Health Kits including requested contraceptives were provided after counseling sessions.

The New Approaches for Reproductive Health Initiatives (NARI) maternal and child health project provided free of cost services through a voucher scheme in dozens of health facilities in the public and private sectors. The Education Program organised more than 350 Temporary Camp Schools where more than 9500 children continued their education in camps. Meantime, the HANDS agriculture and livestock department worked on vaccination, de-worming and provision of fodder for more than 57,000 goats, buffalos, and bulls.

Early Recovery Plan

HANDS started its 'Early Recovery Plan' from December 15 to February 15, 2011. The residents of

camps started moving back to their villages as soon as water receded, through transport provided by HANDS. 35,000 families moved back to their homes. The scene was shocking for them; everything had been washed away. HANDS staff supported them and assured them of help. Soon camps were again installed over the debris of their houses. Later, people were provided with rations and winter kits.

Rapid assessment and the TAMEER strategy

Rapid Assessment of the most affected villages was conducted with Union Councils and 16 union councils in seven districts of Sindh and one district of Baluchistan embarked on TAMEER (The Appropriate Measures For Early Recovery and Early Rehabilitation). The HANDS TAMEER strategy is focused on family and village holistic development. We have estimated the required funds of Rs. 08 billion (US\$100 million) for the next three years. The project will transform 1000 villages into model villages, in collaboration with 14 Union Councils and 50,000 families: building houses; developing small businesses; reviving live stock activities; constructing village streets, water channels, roads; installing hand pumps and drainage; and health and education services (to a total cost per family of US\$ 2482).

Once a village was selected after the rapid assessment survey analysis report, the HANDS team of Social Organizers arrived in the villages to initiate the process of community participation. All the community members were gathered and using the principles of Participatory Reflection Analysis, were asked to develop a village map on the ground and to talk about it.

It is explained to the villagers that they should have a Community Based Organization to partner with HANDS. Later community members are helped to form a Community Based Organisation (CBO). The CBO signs a 'Term of Partnership' for better understanding and trust with the HANDS District Executive Manager.

Training of CBOs assisted their preparation of a village development plan. A joint bank account with HANDS was opened to ensure the transparency and community participation during TAMEER implementation. CBOs identified the most vulnerable and needy for shelters and for entrepreneur, live stocks and agricultural input benefits. HANDS engineers assessed the village and developed feasibility and master plans accordingly. After assessment of quotations from accredited suppliers a complete proposal was developed and submitted to HANDS District Manager for review and verification by the District Office and then sent to the HANDS head office for approval. When a system for transfer of funds was in place the model villages started taking shape with the arrival of material for shelter, live stocks, kits for masons, veterinary workers, carpenters and other entrepreneurs.

Most deserving and needy were given priority. Each shelter costs Rs. 110, 000 and the CBO contributed at least 10% in cash or in unskilled labour. Shelters are usually a single room, veranda, kitchen, energy efficient stove, and toilet. Street pavements, drainage, water bores, hand pumps and culverts were constructed. Live stocks were provided to those who had lost it or in need of it. Tools were provided for men and women to re-establish businesses destroyed during the flood; as well as seeds, fertilizer and tools for poor *Haris* (the most poor and landless).

Health service delivery and the MARVI workers

HANDS health and education programs were initiated. HANDS health promotion program identified community based women workers called MARVI Workers for each village who were trained in health service delivery and provided with health products like safe delivery kits, contraceptives, ORS and Basic medicines from HANDS. In a corner of their houses a *Sehat Markaz* or Health House was made.

HANDS also identified practicing Traditional Birth Attendants (TBAs). MARVI Workers in partnership with TBAs take care of health of women and children with the support of the field team. MARVI Workers receive a stipend from HANDS and they can additionally generate income from sale of health products. Importantly, MARVI Workers also facilitate the referral strategy of the village so in case of complications, women and newborns could be referred to already identified Hospitals under the cover of the NARI voucher project. The voucher scheme therefore bears all the out-of-pocket cost of clients.

Education programs

HANDS education program also focuses on Early Child Hood Interventions for under eight year old children and offers an adult literacy program to illiterate adults of communities and 'Life Skills Based Education' for youth in secondary schools.

Emergency preparedness

The Monsoon came back again in 2011. Around 8.1 million people were affected and 1.9 million acres crop area badly damaged. Around one million houses were damaged partially or destroyed and more than 360 people lost their lives. There were hundreds of severe injuries. District Governments established around 2,938 relief camps accommodating 625,293 IDPs. (Reference: PDMA; Summary of losses, and damages due to rains/flood 2011. Dated 20 September 2011)

HANDS was already prepared as soon as rain hit on the basis of weather forecasts from the Meteorological Department. The Badin office was declared an Emergency Response Centre. Soon all the affected districts offices converted to emergency response

centres. As described for the 2010 floods, HANDS responded and distributed relief items and tents and plastic sheets for temporary shelter. Around 30,000 patients were treated in medical camps and four Diarrhea Treatment Centres. Health awareness sessions were conducted with the help of 15 mobile floats equipped with audio visual facilities. Clean water was distributed among needy persons and toilet facilities provided to IDPs.

The flood was misery for millions of people but HANDS converted this calamity into blessing. HANDS is on the way to achieving the target of 1000 model villages. Millions of Pakistani women, children and survivors are looking forward to this.

Communities are now provided with disaster preparedness strategies including pre-positioning tents and other supplies and establishing coordination structures with local authorities and communities. There has been work on river banks, irrigation channels and other infrastructure.

[It is worth looking at the following two very good videos about the situation in Pakistan and the response that has been led by HANDS. Ed.]

<http://www.youtube.com/watch?v=OIECA4JDQtQ>

<http://www.youtube.com/watch?v=Knf3Ob3Tfg4&feature=related>

and <http://www.docstoc.com/docs/74012364/Lessons-Learned-by-Dr-Shaikh-Tanveer-Ahmed-National-MNCH>.

[We look forward to hearing more about the HANDS MARVI workers and Lady Health Workers in a later edition.]

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News from the region

India: compulsory licence for anti-cancer medicine issued

Source: TWN IP Info

New Delhi, 13 Mar (K.M. Gopakumar) - India's Patent Office issued a compulsory license on Bayer's anti-cancer medicine sorafenib tosylate on 12 March to a domestic manufacturer Natco Pharma, opening the door to a much cheaper generic version of the life-saving medicine. Sorafenib is an anti-cancer medicine for the treatment of primary renal cell carcinoma (kidney cancer) and advanced primary liver cancer known as hepatocellular carcinoma that cannot be treated with surgery. Sorafenib can extend the life of patients with kidney cancer by 4-5 years and with liver cancer by 6-8 months (see SUNS #7326 dated 9 March 2012).

The compulsory license (CL) is granted to Natco under Section 90 of the Indian Patents Act with 13 terms and

conditions and is operational for the remainder of the term of the patent till 2020. When the patent expires in 2020, there will be no restriction on other generic production.

The patented version produced by German pharmaceutical giant Bayer costs about US\$5,600 per month and under the CL, the price of the generic medicine sold by Natco shall not exceed Rs. 8,880 (about US\$176) for a pack of 120 tablets, required for one month of treatment. This constitutes a price reduction of nearly 97 per cent.

Natco must maintain records including accounts of sales in a proper manner and shall report the details of sales to the Controller of Patents as well as the Licensor (Bayer) on a quarterly basis, on or before the fifteenth day of the succeeding month. Natco shall have the right to manufacture the medicine covered by the patent at its own manufacturing facility and shall not outsource the production.

The licence is non-exclusive (ie others may be licensed to manufacture) and non-assignable. Natco shall pay royalty to Bayer at the rate of 6% of the net sales of the drug on a quarterly basis and such payment shall be fulfilled on or before the fifteenth day of the succeeding month.

The licence is granted solely for the purpose of making, using, offering to sell and selling the medicine covered by the patent for the purpose of treating the two types of cancer in humans within the territory of India.

Natco shall supply the medicine to at least 600 needy and deserving patients per year free of cost. It has to annually submit in the form of an affidavit the details of such patients, ie name, address and the name of the treating oncologist to the Office of the Controller of Patents and such report shall be submitted on or before 31 January of the year, in respect of the preceding year. [This requirement seems particularly excessive. Ed]

Natco shall not have the right to import the medicine. The licence does not include any right to represent publicly or privately that Natco's generic product is the same as Bayer's or that Bayer is in any way associated with Natco's product.

The generic product must be visibly distinct from Bayer's product (eg in colour and/or shape), the trade name must be distinct, and the packaging must be distinct. Bayer will provide no legal, regulatory, medical, technical, manufacturing, sales, marketing, or any other support of any kind to Natco. Natco is solely and exclusively responsible for the product and for all associated product liability. Bayer, its directors, officers, employees, agents and affiliates shall not be held liable in any manner whatsoever for any action of Natco.

Bayer is free to do whatever it wishes with its residual patent rights subject to the non-exclusive licence to Natco, and is free to compete with Natco and to grant its own licences to third parties to compete with Natco. [It has been shown in previous cases that the availability of generic versions of a patented medicine results in competition that drives prices down, making essential medicines much more accessible to patients.]

According to several experts, this is a landmark decision in the post-TRIPS Agreement era. Even though many CLs were issued after the conclusion of the TRIPS Agreement especially after the adoption of the Doha Declaration on the TRIPS Agreement and Public Health, these have mainly been HIV medicines and have been in the form of a 'Government Use' order. This is the first time that a CL is granted at the request of a generic company. Experts also pointed out that this initiative would pave the way for issuance of more CLs especially for medicines for non-communicable diseases that are increasingly becoming a public health problem.

More details can be found at

<http://donttradeourlivesaway.wordpress.com/2012/03/16/india-issues-compulsory-licence-for-anti-cancer-medicine/>

Pakistan: Drug regulation follows heart patient deaths

[Copied from Scidev.net as fair use]

Shahzada Irfan Ahmed, 12 March 2012

<http://www.scidev.net/en/south-asia/news/drug-regulation-follows-heart-patient-deaths.html>

[LAHORE] The deaths of at least 125 heart patients in Pakistan, after being given a common cardiac drug contaminated with an anti-malarial, have underlined the need for a strong central drug control authority to oversee testing and quality in the country. Tests conducted on the drug 'Isotab' in a laboratory in the UK revealed that it was contaminated with pyrimethamine, an anti-malarial, which apparently affected the bone marrow of the heart patients being treated at the Punjab Institute of Cardiology, a government hospital in Lahore. Investigation into the deaths, most of them in January, showed up jurisdictional confusion following the passage of 18th amendment in Pakistan's constitution in April 2010 that decentralised public health and other socio-economic sectors, making them provincial subjects.

Pakistan's central drug regulatory authority, along with its parent ministry of health, ceased to exist following the decentralisation. Its four provinces were to develop individual regulatory mechanisms, but were hampered

by weak infrastructure and lack of qualified personnel. On February 6, taking note of the Isotab tragedy, Pakistan's Supreme Court directed the federal government to establish a central Drug Regulatory Authority (DRA) and an ordinance was passed accordingly on 17 February. Riaz Ahmed, chairman, Pakistan Pharmaceutical Manufacturers Association, told SciDev.Net that five countries had banned drug imports from Pakistan following the tragedy. WHO headquarters in Geneva, issued an alert against the use of Isotab on February 7. The factory that manufactured the drug was ordered sealed by local authorities on February 2. Ahmed said Pakistan's pharmaceutical industry was worth US\$2 billion and exported drugs worth US\$190 million annually to some 60 countries. Fareed Khan, member, Pharmacy Council of Pakistan, said the DRA ordinance will be in force for 120 days from passage, and becomes a law if approved by parliament. 'Therefore, I request the parliamentarians to take up this matter on priority and pass the draft after necessary changes without delay.' Khan hoped that satisfactory 'bioequivalence' tests would now be introduced under the new laws. The ordinance already proposes to set out guidelines for the licensing and registration of therapeutic goods as well as sound drug testing laboratory practices.

Sadia Moazzam, executive director of Pharma Bureau, the representative body of multinational pharmaceutical manufacturers operating in Pakistan, said she hoped the DRA will use the opportunity to devise new and rational rules for drug procurement by government hospitals. An investigating committee had found the manufacturer of Isotab ignoring standard manufacturing procedures in order to supply the drug cheaply to the Lahore hospital. The committee had also noted that there were several other medicines that were neither registered nor subjected to examination by drug testing laboratories being distributed to patients.

[<http://www.scidev.net/en/health/access-to-medicine/>](http://www.scidev.net/en/health/access-to-medicine/)

Vietnam

Declaration on the Trans-Pacific Partnership Agreement and access to medicines

The following declaration was signed by representatives of 100 organisations making up the Vietnam Network of People Living with HIV (VNP+)

29 February 2012

Vietnam is negotiating a Trans-Pacific Partnership Agreement (TPPA) a 'free trade' agreement with the United States, Australia, New Zealand, Chile, Peru, Brunei, Singapore and Malaysia.

We, the undersigned, declare our opposition to the Trans-Pacific Partnership Agreement as it puts the

profits of multinational pharmaceutical companies ahead of the people's right to health. We are aware that the United States has tabled intellectual property proposals that would require significant changes to Vietnamese law. If adopted, the U.S. intellectual property proposals to the TPPA would restrict generic competition, making medicines less affordable. Medicines for HIV, Hepatitis C and lifesaving medicines for cancer and other chronic diseases are under threat. Many people in Vietnam already lack access to lifesaving medicines and new trade barriers could make this worse.

In 2008, 94% of funding for care and treatment of HIV came from programs that rely on generic medicines to provide treatment to as many people as possible, with generics accounting for over 98% of the ARVs purchased. The high cost of some patented products already limits the ability of donor programs to expand treatment access. Heightened patent protections could make this problem worse. We stand in opposition to any and all proposals that negatively affect access to medicines in the TPPA including:

- **Expansive patent protection** for new forms, uses and methods of using known substances. These aggressive low patenting standards can extend pharmaceutical monopolies for minor variations on old products, including those that contribute nothing to efficacy.
- **Patent term extensions** that stretch the duration of a patent beyond 20 years.
- **Patent linkage** that prevents registration of generic medicines and facilitates abuse.
- **Eliminating safeguards** against patent abuse, such as pre-grant opposition.
- **Biased procedural requirements** that presume challenged patents valid and measure damages by the patent holder's assessment of value.
- **Data Exclusivity** that prevents health authorities from relying on clinical trial data to register generic versions of medicines.
- **Border measures** that could lead to unjustified seizures of generic medicines.
- **Investment rules** that could allow multinational companies to sue governments over application of domestic health regulations and that may prevent governments from promoting local manufacturing.

We call on:

- The **Government of the United States** to immediately withdraw any and all TRIPS-plus provisions in the intellectual property chapter of the TPPA, and to immediately cease all other forms of pressure and lobbying against Vietnam and Vietnamese officials.

- **Governments of other TPPA negotiating countries** to come together and refuse to accept any further restrictions on production, registration, supply, import or export of generic medicines; to launch Asian-Pacific collaboration on an urgent basis to put in place a sustainable, affordable pipeline of generic medicines for future generations; and to call for an immediate review of TRIPS and its impact on access to medicines in developing and least developed countries.
- The **Vietnamese Government** to immediately end secrecy around the TPPA negotiations, make negotiation texts available for public scrutiny and to support open, transparent and public consultations, and assessments of the impact on the right to health and other rights.
- **The Vietnamese Parliament and constitutional bodies** to immediately review the TPPA negotiating texts, their impact on the right to health and access to medicines and refuse to endorse or ratify any Agreement that includes provisions that undermine the people's right to access affordable treatment; and to review Vietnamese patent laws and medicine regulatory rules to ensure all aspects of the Doha Declaration are incorporated in them.
- **Civil society groups, people living with HIV, all communities facing communicable, chronic and/or non-communicable diseases in the TPPA negotiating countries** to join forces to halt any and all trade agreements that restrict access to generic medicines.

We stand in solidarity with all peoples whose rights to life, health, livelihood, equality, equity, food, environment, knowledge and traditional systems of life and livelihood will also be negatively affected by these free trade agreements that threaten to widen the gap between the rich and the poor not only between countries but within countries as well.

For further information, please contact: Do Dang Dong Vietnam Network of People Living with HIV (VNP+) e-mail: dongdodang@gmail.com

Tobacco control

Australia: Tobacco labeling legislation

From TWN

http://www.twinside.org.sg/title2/health.info/2012/health2_0120301.htm

Australian legislation is in place for plain packaging of cigarettes and regulations are being finalised for plain packaging for non-cigarette tobacco products like cigars.

Geneva, 5 Mar (Kanaga Raja) - The WTO TRIPS Council, at its meeting on 28-29 February, discussed,

inter alia Australia's tobacco plain packaging bill. During the discussions concerning Australia's legislation last year on plain packaging for tobacco products, the Dominican Republic expressed concerns that the Australian measure is not consistent with the TRIPS Agreement, and that it will destroy the value of trademarks and limit information for consumers, which would create confusion in the marketplace.

The Dominican Republic said that Australia has not responded adequately to these concerns. It also said that Australia should have chosen other TRIPS-consistent measures. The measure could, on the contrary, encourage more tobacco consumption with the lowering of prices due to reduction of packaging costs, it added. It further said that it could also open a Pandora's Box with respect to other products that might be considered harmful to public health. Cuba, El Salvador, Honduras, Ukraine, Chile, Zimbabwe and Mexico also expressed concerns about the compatibility of the Australian measure with the TRIPS Agreement.

Australia responded that the measure, adopted by its Parliament last November, would be implemented at the retail level on 1 December 2012. According to trade officials, Australia defended the measure as being in the interest of public health, and that this was based on a broad range of studies and was supported by public health advocates.

Norway, New Zealand and Canada expressed general support while China, Brazil and Switzerland cited the need for a balance between public health and intellectual property rights. The WHO, speaking as an observer, said tobacco use kills six million people every year, and is a major cause of diseases such as cancer and diabetes. The WHO said that tobacco companies have now shifted their marketing to developing countries, and warned about the economic impact of higher tobacco consumption for those countries.

According to media reports, a complaint may be filed against the Australian measure at the WTO. Trade officials said that the item remained on the agenda.

Europe: Tobacco control up in smoke?

Alain Braillon¹, Gérard Dubois²
Addiction: Letter to the editor
Published online: 21 MAR 2012

<http://onlinelibrary.wiley.com/doi/10.1111/j.1360-0443.2012.03797.x/full>

Experts from the United States, Canada and Europe have warned recently that the Dutch government is

flying in the face of the evidence for reducing the burden of disease caused by tobacco consumption. In June 2011, Edith Schippers, the Dutch Minister of Health, announced the end of the reimbursement of quit-smoking aids and withdrawal of funding from the National Centre On Tobacco Control (STIVORO). This abdication of public health responsibility comes as no surprise: the Netherlands was the first European country to overturn the smoking ban imposed on bars and cafés in 2010 and has not yet implemented pictorial health warnings on tobacco product packaging. The Netherlands appears to be in breach of Article 5.3 of the Framework Convention on Tobacco Control (FCTC), which requires protecting public health policies from the tobacco industry's influence.

Sadly, the Netherlands government is not alone in what can only be regarded as a pro-tobacco industry stance. On 31 May 2011, the World No-Tobacco Day, Xavier Bertrand, the French Minister of Health, announced that France would continue its moratorium on tobacco taxes and would ban varenicline from the very limited €50 coverage for smoking cessation under the mandatory French Health Insurance scheme. In 2009, his predecessor Roselyne Bachelot cut funding to the only non-governmental organization (NGO) that fights smoking during pregnancy. Since the election of president Nicolas Sarkozy in 2007, the government has accepted several demands from the tobacco industry to limit increases in cigarette prices to 6%, a level that is inadequate to decrease sales. Accordingly, cigarette sales in France have remained unchanged from 2004 (54.9 billion) to 2010 (55.0 billion). Sales for tobacco products showed a 3% rise from 2008 to 2009, despite the world economic crisis.

Overall, France has failed properly to implement the FCTC treaty despite its ratification in October 2004: the prevalence of daily smoking among 17-year-olds increased from 28.9% in 2008 to 31.5% in 2011

^{1,2} *Dr Braillon, a senior tenured consultant, was sacked in 2010 from Professor Dubois' unit by the French Department of Health against the advice of the National Statutory Committee. Professor Dubois was sued for libel by the French Tobaccoists Union. Professor Dubois is honorary president of Alliance Contre le Tabac and chairs the Addiction Committee of the National Academy of Medicine.*

We would like to produce HAIAP news at least 3 times a year.

Please send suggestions, and contributions for inclusion to:

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