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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.

Editorial

The last year has been very challenging for HAIAP.

Dr Balasubramaniam retired from the position of Coordinator /Advisor to become Honorary Regional Advisor; and relocation to Penang, Malaysia was complete at the end of January 2010 under our new Coordinator Shila Rani Kaur. Shila is not new to HAIAP. She was working alongside Dr Bala in the 1990s when the organisation was previously based in Penang and she has been welcomed back into the family.

A collaborative arrangement has been agreed where Shila will work from the Discipline of Social and Administrative Pharmacy, School of Pharmacy, at University Sains Malaysia (USM) in Penang.

We were devastated by the loss of Dr Bala who passed away on April 19, 2011. Dr Bala was so many things to those of us whose lives he touched - friend, mentor, health activist, researcher, crusader. His passing is a loss not only to the HAIAP family but to the whole international health

community. It is worth reading the Lancet Tribute - <http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2811%2961323-8/fulltext>

Fourteen key members from HAI AP representing Australia, Bangladesh, India, Malaysia, Pakistan, Philippines, and Sri Lanka met in Penang, Malaysia for HAIAP's 9th Annual Planning Meeting in September 2011. Unfortunately the European financial crisis has had an impact on HAIAP funding. Core funding has not been renewed and members must be responsible for their own travel expenses.

Members who met in Penang shared experiences and planned for the ongoing HAIAP activities and the best use of the funds that are available. HAI AP News will be produced electronically and Dr Zafrullah Chowdhury has kindly offered the services of GK to produce a limited number of hard copies when and if they are required.

It was agreed that the most fitting tribute to the memory of Dr Bala would be to continue HAIAP work with enthusiasm and commitment.

Message from the coordinator

I have a soft spot for HAI News, having been its Editor in the late 1980s when I first joined Consumers International and worked alongside Dr Bala, and then later in the 1990s, after I returned from my post graduate studies. Back in the 1980s there was no internet, computers were very expensive and laser printers were unheard of. We used the good old typewriter for word processing and the brother printer for, well printing! Requests for Network News were via fax as were responses and we had a very tight and fixed schedule to follow to ensure HAI News got printed and mailed on time.

And here we are today: HAI News is online and we only print hard copies when and if necessary!

During the last one year, we had to shelve HAI News due to funding constraints, so when Beverley kindly offered to take on its editing during the last HAIAP Planning Meeting in Penang in September this year, I was delighted. Beverley is a do-er and will make things happen.

Going by past experience it is always a challenge getting members to contribute news articles – whether lead articles or network news. But that was then. The internet has made things a lot faster and certainly much easier. I hope that as longstanding members of HAIAP, you will cooperate and assist Beverley with your continued contributions. Let us keep the flame that Dr Bala ignited burning bright.

Best wishes,

Shila Kaur

ANNOUNCEMENT:

National Medicines Policy Conference May 2012

Many readers will remember the conference held in Sydney, Australia in 1995 that was convened by WHO and co-sponsored by the Australian Department of Human Services and Health – now known as the Department of Health and Family Services. That conference was designed to allow the maximum interaction between participants and to achieve an understanding of the issues involved in national medicinal drug policies; and to explore the way forward. It provided the impetus for the development of national policy in many countries along with initiatives to enhance access to essential medicines and their rational use.

In May 2012, The Australian National Prescribing Service in collaboration with the WHO, will convene a 'follow-up' conference to allow participants to share achievements and challenges. In preparation for the event HAIAP is circulating a questionnaire to colleagues in the region to gather data that will be the basis of a report on the status of NMPs in the region.

The first conference in 1995 conference also provided the opportunity for 'satellite' meetings of groups such as Action for Rational Use of Drugs in Asia (ARDA). It was during that meeting that Dr Bala initiated plans for HAIAP to convene the first conference of leaders of pharmaceutical sectors in Pacific Island Countries.

Representatives from the pharmaceutical sectors in 15 PICs came together for the first time in Fiji in September, 1996, with the support of Consumers Regional Office for Asia and Pacific, to

- share detailed information about drug policies, availability, supply logistics and usage
- identify the major constraints to improving the pharmaceuticals situation
- develop strategies to improve the situation and incorporate them into action plans for implementation
- build cooperation and mutual support in the Pacific Region.

For more than 14 years since then, pharmacists and other health workers involved in day-to-day management in the Pacific Island Countries have been meeting together with technical advisers at regular workshops under the auspices of the WHO Western Pacific Regional Office to share their problems and learn together. Plans are made for training and interventions that will strengthen the capacity of both the workforce and the whole pharmaceuticals system. Components of the system have been notably strengthened as a culture of sharing experiences, approaches and resources has developed.

We look forward to the meeting in May where the achievements and challenges of the last 16 years in the Asia-Pacific Region can be shared and strategies for ongoing activities can be developed.

See <http://www.apcnmp2012.com.au/>

ASIA PACIFIC CONFERENCE ON
NATIONAL MEDICINES POLICIES
Better Health Through National Medicines Policies
SYDNEY AUSTRALIA 26-29 MAY 2012

Feature: Sri Lanka: Report of an exploration of medicine-taking by older people in the estate sector in Nuwara Eliya district, 2010.

Acknowledgements

The study team:

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The team thanks all the elders and their family members who participated in this study.

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Executive summary

The Ministry of Health in Sri Lanka is adapting the primary health care system towards better management of chronic diseases, which are increasing with the ageing of the population. However, strengthening the health system and training health care staff will be inadequate if older patients do not take their prescribed medicines for chronic conditions in the correct doses, at the right times, and continuously. There have been few studies of the influences on treatment compliance of older people in low income settings.

As part of a collaborative community-based project that aims to improve the health and well being of older people in the tea estate sector in Sri Lanka we undertook a small qualitative study of knowledge, attitudes and practices in relation to medicine taking.

Focus group discussions were conducted with people over 60 years attending meetings of Elders' Clubs in three estates in Nuwara Eliya district. We also undertook a small trial to explore potential benefits and problems associated with the use of 'dosette' boxes to assist older people to take their medicines regularly and correctly.

Key findings

- A high proportion of elders have been prescribed medicines for chronic conditions.
- Most elders seem to trust their health care providers and believe that it is their duty to take their medicines correctly.
- Many elders lack knowledge about their chronic conditions and the medicines they have been prescribed.

- It is difficult to ensure a continuous supply of medicines for many elders. Major obstacles include lack of money to attend the clinic or to pay for the medicines, and lack of transport to make regular monthly clinic visits.
- Prescribing and dispensing practices are often poor, with insufficient information provided, and inappropriate packaging.
- In the crowded, dark and damp living conditions in the estates it is difficult to store and use medicines safely.
- Family members are often willing to assist elders to take their medicines correctly, but also often lack knowledge.
- Many elders were not taking their medicines at the correct time or in the correct dosage.
- The routine of meal times is used by many elders to remind them when they should take their medicines.
- Changes in routine such as journeys or increase in workload can cause elders to forget to take their medicines.
- Dosettes can be a convenient way to help some older patients take their medicines correctly. However, introduction of a dosette box may be harmful resulting in taking medicines at the wrong time or in the wrong dose.

Recommendations

Health care providers at all levels need training, reference materials and treatment guidelines to improve the management of chronic conditions. Awareness should be raised of the special needs of prescribing and dispensing for older people. Health care providers should be trained in communication skills and to assist older patients to think about how they can remember to take their medication correctly. Recruitment of Tamil speaking dispensers at hospitals in the estate sector (as has happened recently at Nuwara Eliya base hospital) would help to overcome communication problems. Health care providers also need to be aware that they may need to communicate with family members or other carers who assist older people to take their medicines regularly and correctly. Many families now have a mobile phone which could be set as an 'alarm' to remind elders when they should take their medicines.

When medication is prescribed, the patient and if relevant, a family member or other carer, should receive verbal and written information including:

- Generic name of the medication
- Dose
- Timing of doses
- How long the medicine is likely to be needed
- Expected benefits of the treatment and whether these will be noticed by the patient or not
- Whether the medicine is expected to cure or control the condition
- How often the patient will need to come for review of the condition and medication
- Whether there are likely to be adverse consequences of stopping the drug abruptly. The patient needs to know this and that if they are unable to obtain a new supply in time they should reduce the dose gradually
- The possibility of side-effects and interactions with other medicines
- Where to obtain supplies of the medicine and the likely cost.

Medicines should be supplied in an appropriate airtight plastic screw-top container or zip-top plastic envelope with a label showing:

- Name of patient
- Generic name and strength of the drug (in English)
- Date dispensed
- Dose and frequency (in patient's language)
- Amount prescribed
- Name of prescriber
- Expiry date.

When a patient with a chronic condition is prescribed medicines for the first time the health care provider should ask the patient how they will obtain further supplies and whether they will be able to pay for the medication. If not, an arrangement should be made to ensure that the elder receives their medication free of charge or at a subsidised price.

Relevant staff at hospitals and clinics should receive training in management of supplies including awareness of the relationship between use of medicines and forecasting, stock cards, and inventory management to avoid stock-outs of supplies of medicines.

Health care providers, including pharmacists and other dispensers of medicines, should have dosette boxes available to provide to older patients. They should observe and check that the patient is able to open the box, understands the meaning of the layout of the box and the different compartments, and is able to fill the box correctly. Health care providers should explain clearly to the patients (and carers if

relevant) that the slots should only be refilled with pills once a week so that the patient can see whether they have taken their medication each day. They should explain that if the patient continues to take medicines from both the usual container and the dosette, they become confused about whether they have taken their medicines or not and can mistakenly take a double dose or miss a dose. At the next consultation the health care provider should check that the dosette box is being used correctly. If there is a doubt about elders' understanding of how to use the dosette, it should not be given to them.

With the increase in prevalence of chronic diseases in Sri Lanka, efforts to improve older patients' ability to take their medicines correctly and continuously are becoming more important. We hope that the findings of this small qualitative study can help to inform strategies that will contribute to this aim.

News from the region

Pakistan: Devolution of the Health Ministry:

Briefing by Professor Tariq Bhutta.

In July 2011, the Pakistan Parliament passed a constitutional amendment abolishing the institutional structure for healthcare – the Ministry of Health - state department, directorate, or equivalent structure – at the federal level in charge of national responsibilities for health.

This 18th constitutional amendment has granted provinces greater autonomy, and has devolved decision-making in many sectors including health. This move is part of a long-standing provincial demand and long over-due federal initiative to grant provinces their due share of autonomy. While in principle, devolution of powers can improve governance and potentially improve health equity, it is vital that national policy is supported and national health matters identified with related responsibilities entrusted to a federal institution.

The Pakistan government had first embarked on the experiment to devolve decision-making to the district level in 2001 and in 2004 they appraised the situation in the health sector and the study data showed a mixed result. Wherever verbal success was claimed by the district authorities, it could not be substantiated by evidence based data. Improvement in care, drug supply, referral system and access for end users had not been significant. Many of the Primary Health Care facilities were still in need of repairs, more staff, medicines, information systems and stronger referral systems.

Dr Bhutta explained that there are a number of reasons for recasting the health ministry – all of which are related to concerns over the most effective way of delivering health care services. The main argument was that health services would be more effectively managed and delivered by provincial governments that are closer to and more responsive to their citizens.

In the past, the MOH had stepped into areas that were provincial prerogatives, resulting in its being overwhelmed with micromanagement and day-to-day operations. By restructuring the MOH, it could extricate itself from managing a large dispersed workforce and focus its attention instead, on roles that are clearly national in scope – roles associated with health information and disease security, drug regulation and health care quality assurance.

Prof Bhutta explained further that while there are justifications for the need to reconsider the decision to abolish the MOH, it is also critical that the mandate of the MOH is recast so that it divests itself from roles such as day-to-day micromanagement and supervising a large workforce, that lead it away from its core functions. Strengthened capacity in regulatory, analytical and oversight tasks is needed.

Australia: The case of SensaSlim and the Therapeutic Goods Administration

Acknowledgements: Dr Ken Harvey and *The Conversation*

<http://theconversation.edu.au/tga-all-bark-no-bite-as-labor-botches-response-to-a-series-of-reviews-4640>

SensaSlim has been promoted in Australia as a miraculous product sprayed on the tongue to induce weight loss. Its promotion has been accompanied by TV testimonials and reports of clinical trials (which turned out to be fabricated) supporting its efficacy.

At the HAIAP meeting in Penang (September 2011), Dr Ken Harvey shared with the group the challenges he had faced over the previous several months with regards to a court case he was faced with for confronting the SensaSlim promoters. He described the notable events in chronological order, beginning with unsubstantiated and outlandish claims by the manufacturers of SensaSlim about its miraculous slimming properties, his first complaints lodged with the Complaints Resolution Panel, the Therapeutic Goods Administration (TGA) and the Australian Competition and Consumer Commission (ACCC) and then threats of legal action by SensaSlim unless he withdrew his complaints.

Ken declined to withdraw his complaints and SensaSlim Pty Ltd then issued a SLAPP (Strategic Litigation against Public Participation) defamation writ against him. This legal action also halted the investigation of the Complaint Resolution Panel.

The defamation action was eventually thrown out of the NSW court but it cost Ken time, energy and \$42,000 in legal fees – which were thankfully covered by donations from members of the public health, skeptics and consumer communities. Regardless, a director of SensaSlim followed with a similar defamation action in the State of Queensland; this is still proceeding but fortunately this time Ken found a legal firm to defend him pro bono (in the public interest, without charge).

Meanwhile, the ACCC initiated their own legal action against SensaSlim (for misleading and deceptive conduct) and the eventually TGA cancelled the listing of this product on the Australian Register of Therapeutic Goods,

Despite the above, pharmacists and others continued to promote and sell SensaSlim in Australia, parts of Europe, and on TV.

Dr Harvey used the SensaSlim case as an example of problematic areas of regulation of therapeutic goods in Australia which have resulted in a number of government reviews. By the end of 2011 these have now all reported and the government has responded.

Dr Ken Harvey's comments follow.

TGA Transparency review

<http://www.tga.gov.au/newsroom/review-tga-transparency-1101.htm>

Most recommendations of the [TGA Transparency Review](#) will be implemented. These include the establishment of an Australian therapeutic goods advisory council for oversight of the implementation, ongoing monitoring, and evaluation of review recommendations over the next four years. A dedicated communications unit will also be created within the TGA to inform and educate the public.

Some positive moves regarding the [regulation of medical devices](#) include reclassifying the load bearing component of a hip, knee or shoulder joint replacement from medium-high risk to high-risk. This means such devices will require more assessment before entering the market.

The information on medical devices on the [Australian Register of Therapeutic Goods \(ARTG\)](#) will be amended so sponsors will nominate names for each product. This will make it easier for consumers and health professionals to find information about specific devices. The amount of available product information

on the [TGA website](#) relating to medical devices will also be increased.

Working Group on Promotion of Therapeutic Goods

A key concern of this [Working Group \(which dealt with promotion to health professionals\)](#) that compliance with an industry code should be a condition of including a product on the ARTG was not accepted. The government's view was that this departed from their preferred self-regulatory model. However, group members noted that the worst perpetrators of unethical promotion were usually not members of industry associations and these cowboys would be unlikely to sign up to code compliance voluntarily.

Without addressing this problem, the likely outcome of 'strengthening' and creating a 'level playing field' for self-regulatory codes is that the good guys (industry association members who are code compliant) will increasingly be restrained while the bad guys (non-members of industry associations) will laugh all the way to the bank.

Not addressing this concern also perpetuates the difference between health professionals and industry. Health professionals now have government-mandated national registration and must comply with [Australian Health Practitioner Regulation Agency \(AHPRA\)](#) code while the latter (non-members of industry associations) have no controls placed on them at all.

The recommendation that the effectiveness of voluntary registration be evaluated annually required government acceptance of a number of other recommendations, such as creating an advisory group. But apparently '[the government] is not yet persuaded there is a need to establish a permanent advisory group' and 'aspects of the Report which require either Government assistance or legislative amendments to move towards co-regulation have not been accepted by the Government at this time'.

Given this background, I cannot see how it'll be possible to evaluate the impact of Working Group on Promotion of Therapeutic Goods recommendations or how 'longer term changes will be considered if necessary'. But perhaps that was the aim of rejecting these key recommendations. So what was the point of setting up a broad-based stakeholder 'Working Group on Promotion' and then ignoring their key concerns and recommendations?

Complementary medicines

There are positive measures for the [regulation of complementary medicines](#) and information provision, which include:

- amending the Therapeutic Goods Regulations with guidelines for the levels and kinds of evidence required to support claims;
- changing the way products are electronically listed so sponsors can't just add free text; and
- working with stakeholders to create better labelling.

However, it's disappointing that clear labelling requested by many has been assigned to further work with stakeholders. What's required to assist consumers making decisions about complementary medicines is a clear statement on the label, on promotional material and above the shelves with complementary medicines that honestly reflects the regulatory reality.

Indeed, the TGA media spokesperson has recently been using a useful set of words, 'The TGA does not evaluate the effectiveness of listed complementary medicines and cannot guarantee that these products work'. This labelling reform can and should be implemented now – why further delays?

[Advertising reforms \(promotion to consumers\)](#)

This was the most disappointing area of all. For the last decade, numerous reports to government and submissions from consumers and health professionals have highlighted the need to ensure that the [Complaints Resolution Panel \(CRP\)](#), on its own or along with the TGA, can readily apply escalating and effective sanctions on product sponsors who breach the [Therapeutic Goods Advertising Code](#) and [Therapeutic Goods Act](#).

But the government response is – 'changes to the approach of sanctions and penalties for advertising breaches, including civil penalty provisions which parallel offences and act as a deterrent, will be investigated.'

Currently, the CRP is under-resourced, overloaded and has no power to enforce sanctions. Sponsors are merely 'requested to comply'. It takes between six and nine months for complaints to be heard and judgements to be made public. All this takes place while misleading promotion continues. The CRP also lacks resources to follow up its own decisions, which make them more easily ignored.

It often takes multiple complaints before non-compliance by a product sponsor is passed to the final regulator – the TGA. The TGA may write letters 'ordering' compliance but, due to the low financial penalties available, it has never prepared a brief of evidence for consideration of prosecution (see ANAO report).

Paper tigers

Industry knows that the CRP and TGA are paper tigers, so serial advertising offenders and conmen flood the market with dodgy products, undeterred by escalating (and ultimately ineffectual) complaints.

Recently, SensaSlim (and other dodgy products) have been referred from the TGA to the Australian Competition and Consumer Commission (ACCC), but this has, as yet, failed to stop the continued sale of these products or their imitators, or their use.

We need legislation to give the CRP and TGA timely and meaningful sanctions for advertising violations (civil penalties, enforceable undertakings) now. I cannot see why 'further investigation' and 'further input by stakeholders' is needed apart from the sake of letting sections of industry profit by continuing to rip off consumers unchecked.

Like the Curate's egg, the government's reform blueprint appears to be good in parts. But it also displays a timidity to grapple with key issues, such as therapeutic goods advertising reform, and that seems to be a common failing of this Labor government.

HAI Activities 2011

Conferences, Seminars, Meetings, Courses

Coordination of the HAIAP Fringe Meeting on 'The State of Pharmaceutical Policies (SOPPs): The Need for Global Reporting,' 3 May 2011, Hong Kong.

There were two presenters at this meeting: Dato Anwar Fazal and the HAIAP Coordinator, Shila Kaur. Participants expressed support for a report card on SOPPs and gave concrete suggestions on questionnaire content as well as other areas of work of interest to consumer groups. The report of the proceedings is available.

Coordination and convening of the People's Dialogue on Health: 'Our Health is Not For Sale', 18 – 19 June 2011, USM, Penang

The majority view was that the Dialogue should become an annual event for groups to meet, interact and plan action on health issues.

Core team members of PHF Malaysia participated and agreed on a plan of action to carry on the Dialogue process.

Planning Meetings for the 'People's Dialogue on Health', 18 – 19 June 2011

Meetings were held on 4 March 2011, 29 April and May 2011 with a core group of founding members of PHF Malaysia, to discuss and plan for the Dialogue. This core group included key individuals from TWN, RLC, WABA, PANAP, PSM and HAIAP.

Coordination and Signing of the HAIAP-USM Memorandum of Understanding ceremony, 26 August 2011

The signing of the MOU took place on 26 August 2010 at the offices of the Vice Chancellor, USM. The VC Tan Sri Prof Dzulkifli Abdul Razak signed on behalf of the University; Dr Ken Harvey, Chairperson, Governing Council, signed on behalf of HAIAP. Witnesses to this event were Dato Prof Anwar Fazal and Assoc Prof Dr Azmi Hassali [Head, Discipline of Social and Administrative Pharmacy (DSAP)].

HAIAP-DSAP International Seminar on 'Antibiotic Resistance, Pharmaceutical Promotion and Health Activism', 26 August 2011.

Dr Mary Murray, Dr Andreas Heddini and Dr Michael Chai from ReACT (Action on Antibiotic Resistance), and Dr Ken Harvey presented material around the theme. It was well participated by faculty from various departments, DSAP post graduate students and 1st year undergraduate students from the School of Pharmacy. DSAP post graduate students assisted with logistical arrangements.

HAIAP/DSAP/ReACT Meeting with Post graduate Students, 27 August 2011

Again this meeting was convened to utilise the opportunity presented by the presence of Ken, Mary and Andreas and was well attended by post grad students of DSAP. Students presented a summary of their theses and received feedback from Ken, Mary and Andreas. Ken also utilised his time with us by having one-to-one meetings with specific post-grad students and offered his expertise (in keeping with MOU) to assist students with theses supervision.

Participation in International Conference on Improving the Use of Medicines (ICIUM) Turkey, November 14-18, 2011 – Where There Are no Pharmacists

On behalf of HAIAP, Beverley Snell participated in the conference and presented a poster describing the role of the HAIAP publication *Where There are No Pharmacists*.

HAIAP-RLC Meeting with Prof Kwa Boon of University of South Florida, 17 December 2011

Future collaboration on a Health Course for USF undergraduate students was discussed.

Prof Kwa discussed broadened content for a Course in 2012 with Prof Anwar and the HAIAP Coordinator.

Where There are no Pharmacists – French Translation

Work has begun on a French translation of Where There are no Pharmacists according to an agreement signed between Albert Peterson, Pharmaceutical Aid Department, Difam German Institute for Medical Mission and Chair of Ecumenical Pharmaceutical Network (EPN) and HAIAP. Albert will work with a French translator and supply the copy to Beverley Snell for editing in collaboration with French speaking colleagues and formatting for printing. TWN has agreed to publish the book in partnership with HAIAP and print the French edition according to agreed specifications.

New edition of Drug Donation Guidelines



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The issue of drug / medicine donations is often a hot topic especially when disaster strikes. There is an updated WHO Guidelines for Medicine Donations that became available last year.

The 3rd edition of Guidelines for medicine donations has been developed by the World Health Organization (WHO) in cooperation with major international agencies active in humanitarian relief and development assistance. The guidelines are intended to improve the quality of medicine donations in international development assistance and emergency aid. Good medicine donation practice is of interest to both donors and recipients.

The PDF file can be accessed from the following page [Please fix link if broken in browser]:
http://www.who.int/medicines/publications/med_donationsguide2011/en/index.html

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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