World Health Organization
Western Pacific Region

Essential Drugs & Medicines Policy

WPRO-EDM

Issue no. VII, 2007

Access to quality medicines is the right of every patient.

In this issue

ACCESS

Philippines Chosen as a MeTA Pilot Country

The Department for International Development of the United Kingdom (DFID), in coordination with the World Health Organization, the World Bank, other international organizations and local stakeholders is working to pilot the Medicines Transparency Alliance (MeTA) project in the Philippines.

Dr Soe Nyunt-U, WHO Representative in the Philippines, speaking in a MeTA meeting

MeTA is an international multi-stakeholder alliance to promote transparency in the supply of essential medicines, with the aim of improving access, quality and rational use, especially for low-income people. As an initial step, Loraine Hawkins, health policy adviser of Department of International Development and Guitelle Baghdadi-Sabeti, policy officer for good governance at WHO Headquarters, conducted a scoping visit to the Philippines on 23-28 April 2007. The visit and the various meetings undertaken with the stakeholders in the pharmaceutical sector identified current strategies undertaken by the Government for improving access and governance, and identified key points for future interventions.

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Philippines Chosen...

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The following areas were identified as high priority projects for the short to medium term:

1. transparency and information dissemination of prices for essential medicines, supplied in the public and private sectors, based on review and consolidation of various existing initiatives for price monitoring and disclosure;
2. more systematic quality assurance for generics, and information dissemination to physicians and patients on the quality of generics (through the quality seals initiative and/or other means);
3. ethical medicines promotion; and
4. improving capacity and supervision to ensure quality and promote rational use of medicines in the Botika ng Barangay.

The WHO Representative in the Philippines, Dr Soe Nyunt-U, and with support from the WHO Regional Office for the Western Pacific, shall act as an in-country coordinator on behalf of the MeTA international partnership.

MeTA shall be worked along two levels of stakeholder collaboration. The first level is the MeTA Council, which is a core group that will serve as a policy-making body and will coordinate, implement and monitor MeTA activities in the country. The second level is an open consultative forum which will involve other stakeholders in the pharmaceutical sector. WHO shall serve as a lead convenor for both. It shall convene follow-up meetings, facilitate protocols and systems for the work of the Council and lead the development of the national plan of action.

Comparative Trade Prices of Branded Medicines in the Philippines, India and Pakistan (in PhP)



MEDICINE	MANUFACTURER	PHILIPPINES	INDIA	PAKISTAN
Ponstan 500 mg tab	Pfizer	21.82	2.61	1.38
Lopid 300 mg cap	Pfizer	36.39	12.27	2.72
Buscopan 10 mg tab	Boehringer	9.61	2.28	0.57
Bactrim 400/80 mg tab	Roche	15.55	0.69	1.03
Adalat Retard 20 mg tab	Bayer	37.56	1.40	3.63
Lasix 40 mg tab	Aventis	8.99	0.49	1.21
Plendil ER 5 mg tab	AstraZeneca	35.93	4.58	7.78
Diamicron 80 mg tab	Servier	11.46	7.05	4.71
Ventolin 100 mcg inh	Glaxo	315.00	123.31	62.10
Voltaren 50 mg tab	Novartis	17.98	0.86	3.70
Isordil 5 mg SL tab	Wyeth	10.29	0.24	0.22
Imodium 2 mg cap	Janssen	10.70	3.05	1.83
Fortum 1 g inj	Glaxo	980.00	390.00	304.22

Source: MIMS 2005, Philippines; IDR 2005, India; Red Book, 2005, Pakistan (Data Provided by PITC).

Informal Intercountry Consultation on Public Health, Innovation and Intellectual Property

The meeting in progress

The Informal Intercountry Consultation on Public Health, Innovation and Intellectual Property was held in Manila on 5-7 September 2007 to discuss the Draft Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property and to help developing countries participate in the Second Intergovernmental Working Group (IGWG) on Public Health meeting which was held in November 2007 in Geneva.

Participants included those working in medicines legislation, patent, and access and health research from Australia, Brunei Darussalam, Cambodia, China, the Lao People's Democratic Republic, Malaysia, Mongolia, the Philippines, Singapore and Viet Nam.

There was consensus for a need to increase political will and commitment to ensure greater priority to public health. The participants agreed on the importance of Member States organizing national consultations and preparing national positions in preparation for the Second IGWG Meeting which took place in November 2007 in Geneva.

Informal Consultation on Access to Essential Medicines and Human Rights

Participants and speakers of Informal Consultation on Access to Essential Medicines and Human Rights

The Pharmaceuticals Unit of the WHO Regional Office for the Western Pacific, with assistance from WHO Headquarters, conducted an Informal Consultation on Access to Essential Medicines and Human Rights for the Philippines and Mongolia on 29-30 November 2007 in Manila.

The participants, speakers and observers discussed and analysed the problems of access to essential medicines and the human rights approach for improvement. They reviewed the situation in their countries with regard to whether or not rights to health are enshrined in their constitutions, national laws and legislation, as well as in relevant medicines programmes.

The delegates devised a draft workplan to integrate rights in their national legislation, policies and programmes.

UNIVERSAL DECLARATION OF HUMAN RIGHTS (1948)

Art.25.1 "Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services".

Cheaper Medicines Bill in the Philippines

Affirming that access to essential medicines is of utmost public health concern, the WHO Representative's Office in the Philippines supports the passage of the Cheaper Medicines Bill. The WHO Representative in the Philippines, Dr Soe Nyunt-U and staff from the country office attended committee hearings in the Senate and House of Representatives to discuss WHO strategies and provide technical input to the proposed measures.

The Cheaper Medicines Bill

The cost of medicines in the Philippines is the second highest in Asia. According to the 2006 WHO Health Action International survey, medicines cost 3.4 to 184 times higher than the international reference prices. Also, the availability of core essential generic medicines is only 11% and 15 % in private and public sectors respectively.

(From left to right) Dr Soe Nyunt-U, Senator Mar Roxas and former Secretary of Health Alberto Romualdez, Jr. discussing the proposed Medicines Bill

The objective of the Philippine Government is to bring down the cost of medicines to 50% from the 2004 level. One of its major strategies is the passage of the Cheaper Medicines Bill which primarily aims to amend the current Intellectual Property Law and incorporate the flexibilities provided for in the Trade-Related Aspects of Intellectual Property (TRIPS) Agreement.

In particular, both the Senate and House versions include provisions on parallel importation, compulsory licensing, and early working for generics and the criteria for patent eligibility.

The House version, however, includes a provision on the establishment of a Drug Price Regulatory Board, intended to provide price control of medicines in the market.

Legislative Forum

On 15 August 2007, the WHO Representative in the Philippines, in coordination with the office of Representative Risa Hontiveros-Baraquel, sponsored a legislative forum on TRIPS and price control. Dr Dennis Degnan, an expert from the WHO-Harvard Collaborating Centre for Medicines Policy, was the featured speaker. The forum served as a venue for policy discussion and provided technical input into the pending legislative work on access to medicines. More than a dozen members of the House of Representatives and 50 staff from the different congressional committees, media and nongovernmental organizations attended the forum.

Policy Brief

The WHO Representative in the Philippines has provided policy briefs for several of the proposed bills, including those dealing with TRIPS flexibilities and drug price control.

The policy brief affirmed the importance of incorporating the TRIPS safeguards to improve access to medicines. It also highlighted best practices from other countries which have lowered the cost of certain medicines through parallel importation, compulsory licensing and improved competition brought about by the entry of generic medicines.

It also provided a careful analysis on drug price controls. The policy brief presented both the advantages and disadvantages of price controls and some country experiences as part of a discussion on the behavior of market competition for pharmaceuticals.

Way Forward

The WHO Representative in the Philippines continues to monitor the progress of the bill and is on hand to provide further technical input when requested by Congress and is now helping draft the bill on Ethical Medicines Promotion. Strong collaboration for coordination with the legislative bodies must be continued in order to achieve the goal of improving access to essential medicines for all.

EC/ACP/WHO* Partnership on Pharmaceutical Policies

Strengthening the pharmaceutical sector has been a long-term priority for the Pacific island countries and areas based on the recommendations of the meetings of the Ministers and Directors of Health for the Pacific Island Countries held in Yanuca, Fiji, (March 1995), Rarotonga, Cook Islands (August 1997), and Palau (March 1999). The recommendations urged the Pacific island countries to closely collaborate in the areas of rational use of medicines, quality of medicinal products and drug information exchange. Although progress has been made in these areas, some common problems persist. These include irregular access to essential medicines, lack of quality assurance and effective regulation of pharmaceutical products, and irrational medicines use practices by health care providers and consumers.

A five-year (2004-2008) collaborative project "EC/ACP/WHO Partnership on Pharmaceutical Policies" was implemented in Pacific Island countries in March 2004, focusing on problems related to medicines supply management and pharmaceutical policies. The project is guided by the Regional Strategy for Improving Access to Essential Medicines in the Western Pacific Region, 2005-2010.

Exchange of information on regulatory-related issues and publication of a pharmaceutical newsletter for Pacific Island countries were addressed at the Workshop on Pharmaceutical Policies and Access to Good Quality Essential Medicines for Pacific Island Countries for the period June to September 2006 (year 2).

* European Commission/African, Carribean and Pacific Group of States

New Six-Year System of Pharmaceutical Education in Japan and Its Relevant Policy Implementation

With the advent of advance health care, the promotion of rational use of medicines is highly encouraged, which leads to the need for more qualified pharmacists, especially in hospitals and pharmacies. To deal with social demands, the six-year pharmaceutical education system got underway in the 2006 fiscal year, and new curricula have been introduced to enrich training courses such as medical pharmaceutics and clinical training aimed at developing more practical and clinical capabilities.

Two related courses have also begun:

1. special training courses for cancer medicines (2006 fiscal year) based on the need for more qualified participation by pharmacists in cancer therapy in hospitals; and

2. additional educational courses (2007 fiscal year) to obtain more practical and clinical capacity-building for pharmacists registered under the former four-year educational system.

Biregional Informal Consultation on Good Governance for Medicines

The Biregional Informal Consultation on Good Governance for Medicines was held in Kuala Lumpur, Malaysia, from 18 to 20 June 2007. There were nearly three dozen participants, 15 from Cambodia, Indonesia, the Lao People's Democratic Republic, Malaysia, Mongolia, the Philippines, Papua New Guinea and Thailand; observers from Malaysia and Management Sciences for Health; seven temporary advisers, WHO consultants who attended the consultation. The secretariat was composed of WHO staff from Headquarters, the WHO Regional Office for the Western Pacific and country offices in Malaysia and the Philippines.

The objectives of the consultation were:

1. to share progress and experience in developing and adopting national ethical infrastructure aimed at promoting good governance in medicines regulation and procurement;
2. to review current global experiences in promoting good governance in medicines regulation and procurement; and
3. to define effective ways of advocating and socializing national ethical infrastructure.

The participants gave country presentations, exchanged experiences and discussed the development and promotion of national ethical infrastructure. Case studies on promoting good governance in the pharmaceutical sector were also presented.

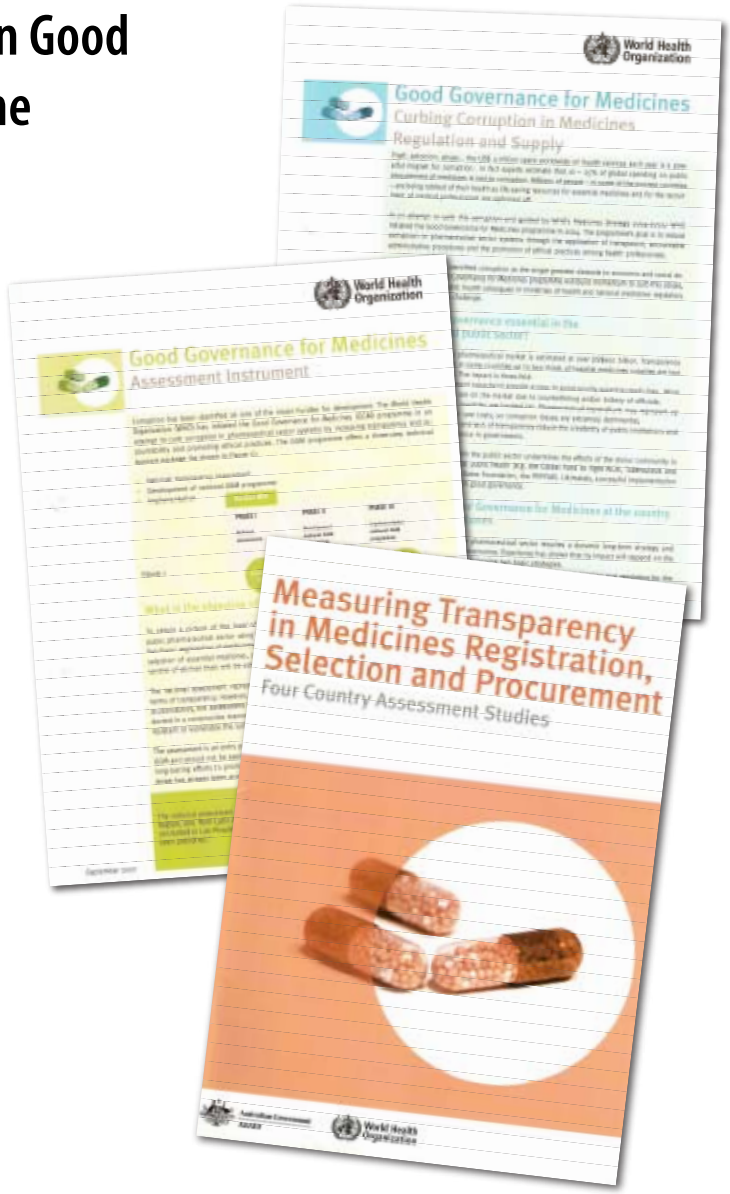
The participants recommended that WHO should continue to provide support Member States in promoting good governance for medicines and to expand the project to other regions.

Participants, temporary advisers, consultants and WHO staff of the Biregional Informal Consultation on Good Governance for Medicines

WHO Informal Global Consultation on Good Governance for Medicines Programme

WHO Headquarters, in cooperation with the Pharmaceutical Services Division of the Ministry of Health, Malaysia, conducted the WHO Informal Global Consultation on Good Governance for Medicines Programme on 21 June 2007 in Kuala Lumpur.

The objective of the meeting was to discuss the outcome of the Biregional Informal Consultation on Good Governance for Medicines held three days earlier. The consultation also discussed the calendar of events for 2007 including the next Good Governance for Medicines Global Meeting in September 2007. The participants reviewed the draft Good Governance for Medicines Strategy 2007 to 2011.



New Strategy of Pharmaceutical Industry Published by Ministry of Health, Japan

The Ministry of Health, Labour and Welfare in Japan published "New Vision for the Pharmaceutical Industry" (New Vision) in August 2007, which aimed to strengthen the international competitive power of Japanese pharmaceutical industry, resolving the "drug lag" problem and supplying nationals with safe and high-quality medicines at reasonable prices in time.

The recommendations are:

1. support to research and development (prioritizing budgets for promotion of new medicines, developing second-generation vaccines, nurturing of venture companies, and promoting study for model animals and biological resources);
2. promotion of clinical research and trials (establishing clustered medical facilities, strengthening infrastructure of medical facilities, improving core research facilities for regenerative medicine, and advancing international clinical trials);
3. improvement of approval system (accelerating approval process, drawing up standard guidelines for new technologies, fulfilling consultations for clinical trials, and adjusting approval process for multinational clinical trials); and
4. pharmaceutical pricing and reimbursement system (studying evaluation of innovation with good price during patent period, duration of reexamination period for new medicines, and promotion of generic medicines after expiration of patent).

Philippines Develops Quality Seal System for Pharmaceuticals

Bureau of Food and Drugs

Promoting the use of quality-assured generics is one strategy that is pursued by the Government of the Philippines to improve access to essential medicines. Ensuring quality of pharmaceutical products has thus been identified as a pillar of the *Fourmula I for Health Reform* of the Department of Health.

With the support of the World Health Organization, the Bureau of Food and Drugs is developing the framework for the Quality Seal System (QSS) for pharmaceutical products and manufacturers. Programme development will be undertaken in three phases. Phase I which involves the development of the QSS framework is now underway. Other important aspects of this phase include the setting up of the QSS Board, alignment of protocols and strategies with the ASEAN Harmonization initiative and WHO standards and setting up of systems for review and appeals.

Phase II will involve capacity and institution building within the Bureau of Food and Drugs. Accreditation of bioavailability/bioequivalence laboratories and clinical trial centres shall also be undertaken. Phase III would link the QSS to overall health system operations. For instance, government procurement should be guided by the criteria for QSS and Philhealth reimbursement may only be secured with the use of pharmaceutical products with quality seal.

Good Clinical Practice Training Workshop for Evaluators

The Bureau of Food and Drugs (BFAD) in coordination with the National Institute of Health, University of the Philippines, conducted a training workshop on Good Clinical Practice (GCP) for the product evaluators on 5-8 November 2007 in Manila. Participants to the workshop were drug evaluators, Product Services Division of BFAD, members of the Ethics Review Board of selected government and private hospitals, representatives from the academe, Department of Health, country office of World Health Organization in the Philippines and a consultant of BFAD.

The workshop discussed the principles of the International Conference on Harmonization of Good Clinical Practice and defined the roles and responsibilities of different stakeholders in conducting clinical trials. The stakeholders identified were the investigators, the sponsors and the Institutional Review Board or Ethics Review Board. Issues on principles of human subjects protection, ethics and good clinical trial procedures, conflict of interest, privacy and confidentiality of data were also discussed.

The participants drafted a flow chart for GCP implementation which identified the roles of stakeholders. The participants agreed to conduct a series of workshops to ensure better understanding and effective implementation of good clinical practice.

Regional Workshop on Improving Medicines Surveillance and Regulatory Functions

The Regional Workshop on Improving Medicines Surveillance and Regulatory Functions was held in Manila on 19-21 November 2007. The participants discussed issues and country experiences related to medicines surveillance and regulatory functions, safety surveillance, quality assurance and combating counterfeit drugs. They also discussed the ongoing project in Malaysia and the Philippines on medicines surveillance involving consumers.

The workshop concluded that various forms of medicines surveillance, in particular, the post-market safety surveillance, are integral parts of medicines regulatory functions in ensuring the safety, efficacy and quality of medicines and therefore should not be taken in isolation. In combating substandard and counterfeit medicines, enforcing relevant regulatory measures are critically important and effective collaboration with law enforcement agencies should be pursued.

The workshop recommended that medicines surveillance involving consumers should be part of the existing regulatory functions that have been proven to be feasible and effective.

Standard Treatment Guidelines and Essential Drug List for the Ministry of Health in Tonga

The Minister of Health and Deputy Prime Minister of Tonga, The Honourable Viliami Ta'u Tangi (FRACS), officially launched the first edition of the "Standard Treatment Guideline and Essential Drug List for the Ministry of Health of Tonga", on 24 August 2007, at the Tonga Medical Association Centre at Nuku'alofa. The occasion was attended by the WHO Country Liaison Officer for Tonga, senior doctors, dentists, nursing staff and pharmacy staff of the Ministry of Health. Members of the media were also present to record the historic event.

The production of this book is one important strategy aimed at achieving the three main objectives of the National Drug Policy for Tonga, which are:

1. to ensure the consistent availability of drugs with acceptable quality, safety and efficacy;

2. to ensure equity of access by the public to medicinal drugs;

3. to ensure that drugs are used rationally by prescribers, other health professionals and consumers.

The Essential drug list (EDL) was drawn up using the standard WHO guideline for producing a national EDL.

The activity itself was greatly enhanced by the fact that Tonga has already in place, the "Therapeutic Goods Act" and "Pharmacy Act". These Acts have guided the implementation of the various relevant strategies undertaken by the Ministry of Health in these areas.

The production of the book itself was a collaborative effort by senior clinicians, dentists, pharmacists and nurses, using the latest scientific evidence available to them. The funding of the project was provided by WHO.

The book is unique in the sense that it covers common conditions seen in Tonga, in relatively wide areas, such as: outpatient/accident and emergency, internal medicine, obstetric and gynaecology, surgery, paediatrics, psychiatry, infectious diseases, ear, nose and throat surgery, ophthalmology, sexually transmitted infection, immunization, contraceptives, dermatology and dentistry. The last chapter covers the national EDL for Tonga. This book is planned to be updated regularly.

Officials of Tonga Ministry of Health with WHO official at the launching of Standard Treatment Guidelines and Essential Drug List

Several training workshops will soon be conducted to provide a forum for training and dialogue, with relevant local health staff, on the proper use of this guideline.

Training Course on Drugs Therapeutics Committee and Rational Use of Medicines in Shandong Province, China

A training workshop on Drugs Therapeutics Committee (DTC) and Rational Use of Medicine has been organized in Jenan, Shandong province, from 23 to 27 July 2007, by the Ministry of Health, China, and supported by the provincial government. The workshop aimed to improve the function of hospitals' Drugs Therapeutics Committees and to improve rational use by utilizing a focused intervention called MTP (monitoring training and planning).

One hundred and fifty participants, clinicians and hospital pharmacists, coming from 75 hospitals in Shandong province attended the meeting. The topics discussed during the meeting included the overview of DTC functions, problems of medicines use and antimicrobial resistance, evaluation of efficacy, evaluation of safety, and strategies for improving medicines use including the MTP intervention. The experience of MTP implementation in Zhuhai province was also presented at the Shandong provincial hospitals.

Guests and speakers during the Training Course on Drugs Therapeutics Committee and rational use of Medicines in Shandong Province

WHO and the Management Sciences for Health (MSH) jointly provided technical support for the training. The facilitators were Dr E. Carandang (WHO, Geneva), Dr S. Suryawati (Indonesia), Dr S. Jing (WHO/China), Dr M. Joshi (MSH) and Mr T. Green (MSH). Rational Drug Use intervention using MTP will be implemented in Shandong province.

ASEAN Training Course on Rational Use

A training course on Strengthening Drugs and Therapeutics Committee to Improve Medicine Use in Hospitals for the ASEAN member countries took place in Brunei Darussalam, 22-27 April 2007. The general objectives of the training course were to understand the process and strategies of the Drugs Therapeutics Committee and to have practical knowledge and understanding of promoting rational use of medicines.

The training was attended by 20 participants from Brunei Darussalam and other member countries of ASEAN (Cambodia, Indonesia, Malaysia Singapore, Thailand and Viet Nam). They are doctors, pharmacists or other health professionals who are involved in the programme for rational use of medicines. The training involved trainers from WHO Regional Office for the Western Pacific (Dr B Santoso), WHO Headquarters, Geneva (Dr E Carandang) and WHO Collaborating Centre for Research and Training in Rational Drug Use, Gadjah Mada University, Yogyakarta, Indonesia (Dr S. Suryawati) and coordinated by the host organizer (Ms Wong Wai See) Ministry of Health, Brunei Darussalam).

Relevant topics were presented and discussed during the training. These included problems of irrational use of medicines, measuring drug use, key interventions for rational use, treatment guidelines and formularies, qualitative and quantitative methods in drug use study, strategies for improving medicines use etc. At the end of the training participants presented their workplan in promoting rational use in their respective countries.

Dr Henk Bekedam

Dr Henk Bekedam is the new director of Health Sector Development (DHS) in the WHO Regional Office for the Western Pacific. He joined DHS division in mid-August this year. He was the WHO Representative in China prior to his assignment at DHS where he led the team that successfully contained the SARS outbreak.

In 1996 he joined WHO as a health planner at the WHO Representative's Office in Cambodia and later became the Team leader of Health System Reform also in Cambodia. Two years later, he was promoted as the WHO Representative in China.

He is a medical doctor with a degree in Master of Science in Economics. He had been a senior House Officer in Nij Smellighe Hospital, Netherlands. He also worked as Technical Advisor on Health at the Ministry of Development Aid, The Hague, the Netherlands, where he was born, studied and lived prior to his assignment as a District Medical Officer, Ministry of Health, Zambia in 1988 to 1991. Following his stint in Zambia, he worked as Regional Health Officer in the Ministry of Health, Malawi.

Dr Bekedam has never compromised his work wherever he was and whatever assignment he had. This is evident from the posts he held and where he is now, DHS Director. He wants to build the capacity of DHS division to carry out the strategies of the health systems agenda and come up with concrete results. He emphasized that we should not only be talking but we should be able to deliver with the best of our skills of what is expected of us. We have to be responsive to the needs of countries and the divisions. "We must have a clear vision that is laudable, that we are promoting good health", he added. He compared the Organization to a big machine _ even if the big parts are functioning well but the small parts are not, the machine will not work as it should. He said that everyone should be aware and be responsible of their roles and responsibilities. He, however, stressed that "people should work with a smile".

Dr Henk, as he is fondly called by colleagues, is a person you always see with a smile. He is a person full of enthusiasm that radiates in his facial expression, in his voice and in his actions. His enthusiasm reflects confidence, spreads good cheer, raises morale and inspires associates not only in the division but in the whole organization. In fact, he received two awards, Beijing Great Wall Friendship Award from the People's Government of Beijing and the Friendship Award by the State Administration of Foreign Experts Affairs of the People's Republic of China.

Dr Henk wants to spend his free time with his family in his house. He is married and has two daughters. He loves music, photography, and wants to find good ways to make in good shape.