

ANNIVERSARY ISSUE



Memories of the First Expert Committee Meeting and celebrating 25 years later

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IN 1968 when I joined the WHO Research Project for Adverse Drug Reaction (ADR) Monitoring after the thalidomide disaster, I started to develop a Drug Dictionary for drugs in the ADR reports received from the 10 developed countries participating at that time. I remember being amazed that so many brand names existed, and that the generic or nonproprietary names were so little used. The chemical name was often used to describe the active substance of a medicine in the then frequently unobjective and commercial drug information sources. In this plethora of names and substances and lacunae of good objective information how could prescribing physicians and others be expected to practice rational drug use? For developing countries with their enormous needs and cost-constraints, the problem was even more serious and their situation became acute in the 1970s. In 1974 a Chief Medical Officer wrote to WHO "our latest indent is 105% more expensive than last year's. I need hardly say that this makes complete nonsense of our financial estimates, and my Government cannot, in the near future, double the money allocated for medicines". That Chief Medical Officer was Dr Ebrahim Samba of the Ministry of Health of The Gambia, now Regional Director for WHO'S Regional Office for Africa.

Need for selection of essential drugs

With the focus on developing country needs, health priorities and primary health care, Dr Hiroshi Nakajima, chief of a small three staff unit (Drug Policies and Management) at WHO Headquarters, in 1974 began preparations for the First Expert Committee on Essential Drugs to be held in October 1977. The work had strong backing from World Health Assembly resolutions and WHO senior management, notably Dr Mahler, WHO's Director-General and Dr Fattorusso, Director of the Division of Prophylactic, Diagnostic and Therapeutic Substances.

Dr Nakajima often spoke about the need to have a limited list of about 150 drugs that would cover the majority of health needs and achieve the widest possible coverage of the population. In the first Consultation on the Selection of Essential Drugs that took place in October 1976, the annotated list of essential drugs (active substances) came to around 200.

The 1977 Expert Committee on the Selection of Essential Drugs

Preparing a WHO Expert Committee is a complex task with strict rules and regulations. One major criterion is that any person considered for an Expert Committee has to be on a WHO Expert Panel. To place someone on a Panel took a very long time so one had to choose from people on existing Panels. In 1977 there were two Panels related to drugs: one for Drug Evaluation and another for Pharmaceutical Specifications.

The Drug Evaluation Panel included mostly pharmacologists and clinical pharmacologists, as safety of medicines had been of major concern at WHO since the 1960s. But very few members were from developing countries where this discipline was rare. Dr Darmansjah from Indonesia and Dr Lionel from Sri Lanka, among the eight members of the 1977 Expert Committee, were exceptions. The other Panel members consisted mainly of pharmaceutical technologists, and even fewer were from developing countries. Mr Yeap Boon Chye from Malaysia was selected because of his considerable experience of collaborating with WHO.

Geographical distribution was another criterion for Expert Committee membership selection. Four pharmacologists/clinical pharmacologists from teaching, research and clinical institutions in Brazil, France, Italy and the USA respectively (Professors Zanini, Lechat, Garattini and Azarnoff) were chosen from the Drug Evaluation Panel. Professor Babajan from the USSR was also selected but could not attend. But there was no one from Africa on either of the two Panels (nor on many others either). The Committee needed to have an expert from Africa; – someone who would know about the problematic situation of medicines in Africa. I remember going to the WHO Library searching all the Panels for a subject that would come close to or touch that of medicines. Dr Beausoleil, Director of Medical Services at the Ministry of Health, Ghana, was thus invited. Dr Probst and Mr Richman of UNICEF were the only representatives from other organizations. The pharmaceutical industry was only invited

to the second expert committee in 1979, when dosage forms were added to the Essential Drugs List. The criterion of having a woman on an Expert Committee came years later. Women were very rare on any Expert Panel 25 years ago – it was truly a man's world in which we somehow survived.

Why such details on the composition of members? Because I am convinced that the eight competent committee members, backed by a secretariat of four temporary advisers – all Drug Evaluation Panel members (Drs Borda, Lunde, Tognoni and Ulianova) – and WHO staff (Drs Fattorusso, Nakajima and me, together with our excellent secretary, Ms Burford) – had a fine catalytic effect on each other. We represented a good balance between sound scientific knowledge, common sense, vision and experience, coupled with political awareness and astuteness.

The Model List and Technical Report Series No.615

Of course there were some heated exchanges in the Committee, in an otherwise quite sophisticated and scientific atmosphere. One major issue was whether or not explanatory text and justification should be included for each selected or rejected drug. Luckily wisdom prevailed. The text of the Expert Committee only gives some examples and lists scientific criteria and other guidelines that need to be applied in the selection of essential drugs. In its report it did not provide details of why each drug was selected or not. It was felt that this would have led to endless discussions after the report's publication, particularly with the pharmaceutical industry. The three well-prepared and widely circulated working papers, including a draft Model List, were excellent reference sources on which the Committee could base its final decisions and from which large parts of text could be used. The clinical comments – the ones not included in the final Expert Committee text but so important in the decision-making process – were in the major working paper (DPM/WP/77.3 I. Borda). These later became very useful when WHO undertook country support in drug selection.



Margaretha Helling-Borda

Approving every word before closing

There is no such thing as a draft report from an Expert Committee. Every word in the text and content of a Committee has to have *final* approval before the Committee disperses on the last day of the five-day meeting. But in 1977 we were not of the computer generation. Most professionals wrote their material by hand and gave it to a secretary for typing, and I think that this favourably reduced our "word output". Moreover, none of the Committee members or the temporary advisers were people of many words. These may be the reasons why a very concise and clear main text of only 12, A5 pages resulted from our work – a text that still stands the test of time. In total, the small blue booklet of 36 pages included, apart from the text, the first Model Essential Drugs List with 220 main and complementary drugs, an alphabetical index, recommendations for the development of the WHO programme on essential drugs, a glossary and a bibliography. When published, Technical Report Series No. 615 became an instant WHO bestseller, which sold out in three months and had to be reprinted several times.

Country situation analyses following the Committee meeting

Apart from serving in the WHO secretariat during the Expert Committee

Photo: WHO

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meeting, my own strong recollection from the historic days 17–21 October 1977 are my visits to the WHO medical services, preparing for the country visits right after the Committee. Two vaccinations were mandatory then – against cholera and against smallpox. I had both during that week. They put me in a state of febrile euphoria and malaise. Perhaps this was a premonition of what was to come with the bouts of malaria and diarrhoeal diseases that I experienced during my first trip to developing countries – a real “eye opener”.

Only a few days after the committee meeting closed, Dr H. Nakajima, Dr F.S. Antezana and I took off for our six countries, six-week country situation analysis trip to Asia – to Sri Lanka, Indonesia, then Burma, Nepal, Thailand and India. And to be consistent with the “sixes” I also lost six kilos in weight during those weeks. But I learnt a lot about the conditions in a developing country. I started to understand why a national essential drugs list and programme were needed. I realised that WHO had produced a great tool to get the process started and tried in my then very inexperienced way to assess the situation and write a prototype report of the pharmaceutical situation in “my three countries”. These were Sri Lanka where Dr Lionel helped me, Indonesia where Dr Darmansjah guided me around and

Burma where I met up with Dr Nakajima. When the three WHO “assessors” met again during a final three-day period in Delhi, India, to try to get a grasp of the problems in that huge country, I remember retreating to my hotel in a state of exhaustion, overwhelmed by all my impressions. But that was 25 years ago. Hundreds of country visits, assessments and evaluations later on all continents, I am very happy to see the great progress countries have made. Nepal provides just one example. In 1977 pharmaceuticals were handled by the Ministry of Forestry and there was only one pharmacist, Dr Suwal. He was later responsible for building up and modernising that country’s pharmaceutical supply system.

25 years later – celebrating the anniversary

For 21 October 2002 I was invited to Cambodia by WHO’s Regional Office for the Western Pacific to participate in an inter-country workshop to evaluate National Drug Policy implementation. Twenty-seven participants from 14 countries in the Region attended, from places as diverse as Australia, Brunei, China, Fiji, Laos, Malaysia, Solomon Island, the Philippines and Viet Nam. It was good to see that at least half of the workshop participants were women – a great change

from 25 years ago when, as mentioned earlier, it was very much a man’s world in this professional area.

The workshop coincided with the 25th Anniversary of the WHO Model List of Essential Drugs and a half-day seminar on this topic started the workshop. I was very pleased to be given the opportunity to speak about the “WHO Model List of Essential Drugs/Programme – start and evolution: global perspective and reflections”. For me it was a great opportunity to hear about progress – but also new, challenging and difficult problems in Western Pacific countries. For example, I recalled my first visit in 1985 to Viet Nam and the many subsequent visits, to Mongolia in 1991 and 1992, Malaysia for the first time in 1977, to China in the early 90s, the Philippines, and to Australia where an important WHO-sponsored meeting on national drug policy took place in 1995. I learnt about the host country, Cambodia, and its fine essential drugs programme, developed in such a short time and after all the difficulties the country had endured. It was gratifying to report to the workshop that the essential drugs concept has become nearly universal over a 25-year period. More than 150 countries have a national list of essential medicines, major international agencies now base their catalogue on the WHO Model List, 101

countries had a national drug policy in 1999 (only five in 1985), and access to essential drugs has almost doubled between 1977 to 1997. But one-third of the world’s population still does not have regular access to essential medicines. This preoccupying fact means that there still is very much to do, and the essential medicines concept is therefore more valid than ever for the challenges of today, such as the emergence of new epidemics of HIV/AIDS, resistant malaria and tuberculosis. Another challenge is to expand and introduce the concept’s use in the private sector.

I am indeed very grateful to have had – and to continue to have – the opportunity and privilege to work with so many committed, knowledgeable and fine people in and outside WHO, and in countries. We work together towards the worthwhile cause of increased access to the most needed medicines, through the essential medicines concept and its core, an essential medicines list, modelled on WHO’s List – born at that first Expert Committee in 1977. □

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