EDITORIAL

The Essential Drugs Monitor is a newsletter produced and distributed by the WHO Action Programme on Essential Drugs and Vaccines. Since the Action Programme was launched in 1981, more than 80 countries have either drawn up essential drugs lists or started projects in support of primary health care, providing reliable essential drugs and vaccines which:

- meet people’s common health needs
- have significant therapeutic value
- are acceptably safe
- offer satisfactory value for money

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Strategy for the future

The WHO Revised Drug Strategy, previewed in our last issue, is through the starting-gate with flying colours (see page 2). WHO can now go ahead with a broad four-year programme to rationalise drug use, in cooperation with the health professions, academia, the pharmaceutical industry, NGOs and the public.

A firm mandate goes to the WHO Action Programme on Essential Drugs and Vaccines to step up its work. This will mean accelerating training, drug procurement, guidelines, infrastructure development, and information on the world drug situation as a basis for national drug policies and essential drug programmes.

However, this expansion will cost an extra US $4 million a year. Very little of this funding can come from the WHO budget, already overstretched. The lion’s share will have to come from outside donations.

Our gratitude goes to those countries that have already pledged to go on giving as much — or even more — to the Action Programme. But more funds and enthusiasm are still needed to get the strategy into full swing. To echo our Director-General, we hope that other potential donors will also be generous in favour of the “drug under-privileged”.

Action Programme-linked activities have advanced at a good pace while the strategy was being worked out. Reports in this issue of the Essential Drug Monitor bring news from all five continents of the essential drugs concept steadily gaining ground in countries large and small.

The Editor
Green light for WHO drug strategy

The World Health Assembly has given Dr. Halden Mahler, Director-General of WHO, the go-ahead for an ambitious and wide-ranging strategy to make drug use more rational throughout the world.

The WHO Revised Drug Strategy passed smoothly through the Assembly in May. It was approved by consensus, without a vote.

From the floor

The high cost of pharmaceutical raw materials was a recurring theme as delegates successively took the floor. WHO was several times asked to give more help with price information and procurement.

The Venezuelan delegate called for the WHO Executive Board to study the social and political implications of the drug situation in developing and underdeveloped countries.

A number of speakers asked for pharmacists to be explicitly mentioned in the strategy because of their potential influence on the public in the rational use of drugs. But doctors, according to one comment, would not appreciate being lumped together in a group as “prescribers” with other technical or auxiliary staff. The wording of the strategy was amended to read “health personnel involved in prescription, dispensing, supply and distribution.”

WHO responds

Replying on Dr. Mahler’s behalf to questions from the USA, Cuba, Mexico and other delegates, the WHO Adviser on Health Policy clarified WHO’s role.

WHO would fully support TCDC/ECDC on drugs, as in the Americas region example (see page 8). For local production, WHO would look into technical and economic feasibility, and UNIDO would deal with industrial matters.

WHO would provide governments with information on existing national drug policies and would, on request, help them adapt other countries’ experience to their own local circumstances.

WHO would also provide information on existing legislation. If asked, it had a constitutional obligation to help countries apply this information, but the final decision on legislative content rested with them.

For the “drug underprivileged”, even 200 essential drugs would be 200 more than they have now.

The ICDRAs (International Conferences of Drug Regulatory Authorities) were a useful international medium for the informal democratic exchange of information and it would be advantageous if more countries could take part.

The WHO Model Formulary was intended as an example, to be adapted in each country.

Please turn to page 4
The strategy at a glance

Coordination by WHO

The terms of the strategy require WHO to urge each party concerned to discharge its responsibilities for the rational use of drugs.*

WHO will encourage governments to adopt national drug policies, emphasizing essential drug programmes, objective information for prescribers and public, economic measures, legislation, and ethical criteria for drug promotion.

It will maintain close contact with the pharmaceutical industry on drug information, promotional criteria, developing-country needs for low-cost drugs, and research into badly needed new drugs.

Action Programme

The WHO Action Programme will do more in response to requests from governments wishing to introduce national drug policies and essential drug programmes (accompanied by drug regulatory authorities, legislation, information and materials).

Other operational activities will include: feasibility studies on local production; finding resources to purchase drugs and overcoming currency and hard currency problems; monitoring and evaluation; and technology transfer through intensified training.

Support activities will include: guidelines on national drug policies; market intelligence (the world drug situation, prices of raw materials, intermediates and finished products, and research costs); learning materials; guidelines on communication with patients; and health systems research (drugs and drug practices).

Standards and regulation

WHO will extend its Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce to include exchange of approved product information and, where feasible, certification of bulk raw materials. It will do more to promote the International Pharmacopoeia, the associated Model Small Quality Control Laboratory, and the use of INNs (International Nonproprietary Names).

It will issue Model Drug Information Sheets (see page 12), a Model Formulary for essential drugs, and guidelines on setting up a simple Drug regulatory authority, legislation and related points.

WHO will try to enable more countries to take part in the two-yearly International Conferences of Drug Regulatory Authorities.

A WHO group of experts will review and update the ethical criteria for drug promotion drawn up by the World Health Assembly in 1968.

On behalf of the United Nations, WHO will also update the Consolidated List of products that have been banned, withdrawn, severely restricted or not approved by governments, analysing notifications and adding commentary as necessary.

Information

The WHO Drug Information Bulletin will appear more often, giving more details of regulatory decisions and procurement.

Special efforts will be made to distribute it in developing countries and to translate it into local languages.

Research

WHO will promote international research into new drugs for priority conditions, and into drug prescribing, consumption and performance (e.g. adverse reactions).
RATIONAL USE OF DRUGS - RATIONAL USE OF DRUGS - RATIONAL USE OF DRUGS

Continued from page 2

NGOs (1)

IFPMA

Dr Richard Arnold, for the International Federation of Pharmaceutical Manufacturers' Associations, said that IFPMA companies accounted for 85% of world production and for virtually all the R&D expenditure of US $6 billion per year. The industry had a vital interest that its products be used rationally and be available in adequate quantities, of impeccable quality, wherever needed.

The most useful and immediately relevant projects in the strategy were the establishment of national drug policies, help to overcome the lack of hard currency, and extension of the WHO Certification Scheme.

The industry did not accept any interpretation of the strategy which would inhibit the development of new medicines through the introduction of subjective criteria. It felt that arbitrary limitations on the number of medicines available could only lead to sub-optimal treatment for many patients.

The industry accepted its social responsibilities, and Dr Arnold cited a number of recent and current projects designed to help with drug procurement, supply and use.

He said that the IFPMA accepted the importance of universal ethical standards in advertising and promotion, although it was highly sensitive to a combination product on the WHO Model List, sulphonamethoxazole trimethoprim.

Proposals to be made by a WHO group of experts on ethical criteria for drug promotion would pass through the Ad Hoc  
Committee on Drug Policy and the Executive Board on their way to the Assembly and interested parties would have ample time to review them. It was a government responsibility to decide how to use these criteria nationally.

The representatives of three NGOs also took the floor towards the close of the debate (see panel).

The resolution adopted by the Assembly calls on the Director-General to disseminate the Nairobi Conference report in all six WHO official languages; to use all available regular and extra-budgetary resources to carry out the strategy; and to report back to both the WHO Executive Board and the World Health Assembly meeting of 1988.

NGOs (2)

WFPMN

Dr Karl Heinz Reisse said that the World Federation of Proprietary Medicine Manufacturers spoke for the providers of non-prescription, over-the-counter medicines in 30 nations. These medicines were not essential to life but useful in the relief of everyday aches and  
illnesses, and so essential to improving the quality of everyday existence for millions around the world.

The WFPMN supported the views of the IFPMA. In addition, it felt that national regulatory policies were of prime importance to the non-prescription medicine industry. The formulation, labelling and distribution of these products must reflect national needs.

WHO’s position on ethical criteria for drug promotion must be recognised, the WFPMN believed, that complete labelling and honest advertising together provide the most direct and effective way for consumers to receive information on the safe and proper use of medicines intended for self-care.

The WFPMN fully supported home country labelling texts being made available at the request of the importing country under the WHO Certification Scheme.

Finally, the WFPMN had unique knowledge and experience on the labelling and promotion of non-prescription medicines. “We offer this expertise to WHO in converting the revised drug strategy into programmes of service to all peoples”.

NGOs (3)

IUCU

Mr Anwar Fazal, of the International Organization of Consumers’ Unions, said that following the conference, the world market had been filled with pharmaceutical products that were ineffective, inappropriate, irrational, useless and needlessly expensive.

IUCU saluted the Member States which were giving life giving to the spirit of Nairobi, particularly the “screening example” of Bangladesh. It applauded those companies which were taking a hard look at themselves and had instituted audits and demarcating of irrational drugs.

Following the Nairobi Conferences, IUCU had published a “Problem Drugs” pack exposing the irrational drug epidemic, and a study on the “ethical Bangladesh Drug Policy.”

IUCU urged that work be speedily completed on four initiatives, the first being the updating of the 1968 WHO Ethical Advertising Guidelines. A proper control system for all drug advertising and promotion and an effective monitoring mechanism including legal and moral sanctions would be essential.

Secondly, IUCU called on drug exporting countries to control exports and to report unethical practices to WHO, in accordance with UN Resolution 37/137.

Thirdly, independent drug information was critical for health personnel and independent journalists must be encouraged. There should be more openness on negative drug discoveries and adverse drug reactions, information on prices and costs, and guidelines on good prescribing.

Fourthly, IUCU offered to work closely with WHO on the provision of independent information, using the vast reservoir of experience among its membership.

On behalf of IUCU and the many consumer, women’s, development, health and professional organisations working together through the Health Action International network, Mr Fazal thanked WHO for the opportunity to be an active participant  
in the revised drug strategy.

“We shall work with you and provide you with ‘people power,’ and together we shall prevail even over the allergists” that seem so eager to prevent WHO from asserting its conscience and leadership to provide for health for all now.”

* Dr Martin had earlier told delegates that “It was not always true of all the allergists that we fight for ourselves to cut back in verbal exchange, but all sorts of communities and allergists eagerly potted to see us at the end.”

An international network alerts WHO when patients get adverse reactions to drugs. (Photo WHO/W. Liehr)

Post-marketing surveillance was of increasing importance. Having no research facilities of its own, WHO relied on national institutions. The director of monitoring centres had recently agreed to divulge information on ADRs (adverse drug reactions) as soon as a tentative conclusion became possible. WHO would publish research findings.

Drug technology assessment referred to field studies on the usefulness of vaccines and drugs. For example, pneumococcal in infants in developing countries had been shown to be highly sensitive to a combination product on the WHO Model List, sulphonamethoxazole trimethoprim.

The IFPMA Code of Pharmaceutical Marketing Practices was being strengthened: three distinguished advisors were now assisting the President’s Committee. Some 2,000 copies of an information pack on this Code were sent out last year, to health departments in many Member States, among others.

Dr Arnold concluded: “We cannot afford to be content with what has been done so far and to ignore the need for new and better treatments. Nor can we afford to follow policies which encourage further advances. For this is precisely the danger of some of the ideas which we heard in Nairobi from certain delegates… For the essential drugs of the future, therefore, the encouragement of continuing and even greater research efforts than the current 50 billion a year is of paramount importance.”

Consumers: independent drug information crucial for health personnel. (Photo WHO/O. Yotsuji)

Industry: search for new and better treatments must go on. (Photo WHO/W. Liehr)
Dr George Grant writes from Newcastle-upon-Tyne, UK:

I was very interested to receive the first edition of the Essential Drugs Monitor. Its bright and clear presentation illustrated vividly the progress of the WHO Action Programme on Essential Drugs and Vaccines.

The Kenya programme is very impressive, but I feel that the four precepts of the Action Programme should be implemented in developed countries as well as in less economically fortunate developing nations. Working as I do in the United Kingdom, where the primary health care is provided by the general practitioners in the National Health Service, I believe that self-discipline is essential in prescribing.

Two colleagues and myself, who are general practitioners and lecturers in the Department of Family and Community Medicine of Newcastle University, have researched and compiled a Formulary for General Practice.* Many, perhaps most, of the conditions treated in general practice are self-limiting and need only symptomatic treatment. Other more serious diseases respond well to simple, well-tried and cheap drugs. Too many drugs are prescribed because they are new and fashionable. British doctors write 100 million more prescriptions per year than they did 25 years ago. Numerous factors have brought this about, but probably not a high incidence of illness.

In the process of compiling this formulary, which started as an interesting academic exercise, we prepared the United Kingdom’s first Limited List of prescribable drugs, which only covered certain groups, by about eight months. None of our listed drugs had to be changed because of it.

We set out the following criteria:

- To cover at least 90% of conditions seen in general practice.
- To provide simple and appropriate treatment for 90% of patients presenting with these complaints.
- The formulary was to be acceptable to a diverse group of general practitioners.
- To provide a useful tool for teaching medical students.
- To use only generic names for drugs apart from some proprietary combination preparations.
- Unless there were overwhelming reasons for inclusion, drugs which had been in use for less than five years were to be excluded.
- Cost of drugs was to be a factor in reasons for inclusion, but not the paramount reason.

"We feel that it is easier to become familiar with the effects of a limited number of preparations..."

The formulary was to be compiled by general practitioners, seeking specialist advice when necessary.

- Drugs used mainly in emergencies or prescribed normally in the first place by hospital colleagues were to be included as extras in an Appendix.

We drew up a list of the common conditions seen in general practice, some being symptoms (e.g. nausea), some specific diagnoses (e.g. urinary tract infections), and some broad categories (e.g. skin conditions). We then wrote a brief text on each condition with appropriate drug treatment (including formulation, dosage and price) and short notes on them.

When completed, this draft was submitted to about 20 general practitioners at a residential weekend. They were all tutors of general practice but worked in different practices. When the draft had been suitably modified by consensus within the group, the members used it for a two-week period, keeping detailed records of all consultations. Ten other general practitioners who had no knowledge of the formulary were also asked to keep similar records of consultations and prescriptions, thereby acting as controls.

Following this exercise and after further meetings with the participants, the formulary was altered and submitted for another two-week trial. The teaching group were able to prescribe within the formulary for 83% of patients needing prescriptions, as against 34% of the control group’s recorded prescribing. Generic prescribing would have increased this percentage.

Today, after nearly two years of modification and revision, the formulary contains 145 of the possible 17,000 drugs or formulations available to UK general practitioners. If patients who do not normally need a drug prescription are excluded (e.g. sick certification, antenatal, or routine examinations for other purposes), the 90% objective is almost achieved. Thus all our criteria have been satisfied.

**RATIONAL USE OF PUBLISHED LATELY**


**Drugs and Money,** 1985, WHO Regional Office for Europe and University of Groningen, Netherlands. Discusses the question of pharmaceutical pricing and drug cost to the community, and the measures governments can take to ensure short-term direct savings. Chapter headings include: refusal to pay the costs of trivial, ineffective or unproven therapy; measures to encourage or obligate physicians to prescribe critically and economically; and undesirable effects of cost containment. Copies (English only) can be obtained from: Action Programme on Essential Drugs, WHO, CH-1211 Geneva 27, Switzerland.

Guidelines and recommendations for the establishment of a large volume parenteral solvent production plant in developing countries, DAP/85.11, Action Programme on Essential Drugs, WHO, CH-1211 Geneva 27, Switzerland. Gives guidelines for buildings, equipment, instruments and infrastructure, and outlines training programmes for operative personnel. Also includes health and safety standards, GMP guidelines and ecological considerations at the least possible investment cost.

**Development Dialogue 1985: 2,** The Dag Hammarskjöld Foundation, Övre Slottsgatan 2, S-752 20 Uppsala, Sweden. Selection of papers from a seminar on “Another Development in Pharmaceuticals”, published as an independent contribution to the international debate on this global theme. The central issue of the “International Regulation of the Supply and Use of Pharmaceuticals” is dealt with at length, supplemented by an account of the WHO Action Programme. Identifies areas needing further research, and basic policy issues for meeting objectives. An extensive bibliography and selection of annotated references enable the reader to pursue areas of interest in greater depth.

**Registration and Marketing Practices** in the Third World. Three papers based on research in Spain, Nicaragua, Thailand and India cover the crucial question of “Healthy Use of Pharmaceuticals” in both the industrialised countries and the Third World. A paper on the role of the pharmaceutical industry emphasizes that it is in the industry’s best interest to devote more of its resources to innovative research and development — meeting the real needs of the world and particularly the Third World — and to spend much less on promotion and the production of inessentials.

**Essential Drugs and Developing Countries,** by Masuma Mandani and Godfrey Walker, Evaluation and Planning Centre for Health Care, London School of Hygiene and Tropical Medicine, Keppel Street, London WC1E 7HT, United Kingdom, price £4. Considers problems encountered in providing cost-effective therapeutic drugs to treat the major illnesses in developing countries, the rationale for — and initiation of — the essential drug concept, and its implications for developing countries. Also reviews the standpoint and role of various groups involved in development and implementation of the concept. The final section examines national essential drug policies in developing countries and the role of the WHO Action Programme. Identifies areas needing further research, and basic policy issues for meeting objectives.

**Prescribing Practice and Drug Usage,** 1980, edited by Roy Mapes, Croom Helm Ltd., 2-10 St. John’s Road, London S.W.11, United Kingdom. Attempts to show that the processes involved in prescribing are as much social and psychological as they are clinical. Identifies the actions of doctors, medical associations and patients as social aspects of the problem of excessive and irrational prescribing.
Italy aids Africa and Asia

Italy is a staunch supporter of the Action Programme, and Italian experts helped to draw up the first WHO Model List of Essential Drugs. Dr Guido Bertolaso, Head of the Medical Section, Department for Development Cooperation, Ministry of Foreign Affairs, describes how Italy contributes to essential drug programmes in developing countries.

In Italy we believe that an essential drug policy is the proper approach for developing countries, in that it will enable them to avoid the financial, political, ethical and scientific problems we face today in the developed world. This is why we decided to sponsor certain UNICEF activities in the essential drugs field, and why we also apply the ED concept to our bilateral aid programmes. For the latter, we actually use a slightly enlarged version of the WHO Model List, adding a few more drugs that we feel are important for health in developing countries.

African goals

Just now we are sponsoring a five-country WHO/UNICEF programme in Africa which will cost US $15 million over five years — in Guinea-Bissau, Burkina Faso, Ethiopia, Somalia and Mozambique. The goals of this programme are to supply essential drugs, train drug management personnel, improve distribution networks and quality control, and educate patients receiving the drugs.

Italy funds this programme, sits on a steering committee with representatives from WHO, UNICEF and the countries involved, and proposes candidates to act as project officers in the five countries. We also have bilateral experts already on the spot in each location, who cooperate with people in charge of the multilateral programme.

Another of our activities is the supply of essential drugs on a bilateral basis to countries facing a severe shortage. Under an agreement we have with the Italian pharmaceutical companies, they undertake to supply us within one month with the quantity of drugs from our standard list requested by any particular country. We test the drugs for quality before sending them out, and add instructions in four languages. It is also our practice, whenever necessary, to provide experts along with the drugs, to help the national authorities with the distribution. In this way we are able to check where every single tablet of aspirin goes and how it is used.

Emergency supplies

During 1985 we supplied about 13 million US dollars' worth of drugs on a bilateral basis, in some cases for emergencies such as the drought in Ethiopia or the earthquake in Mexico. These drugs are supplied free of charge under Italian Government grants. But in some ways this assistance is a less important goal of our ED policy.

The new formula for ORS (see Monitor 1-1985, p. 7) has already been adopted by our suppliers. One of our current priorities is to establish large-volume parenteral solution production plants in developing countries. The first such plant will be constructed in Kenya this year as part of a project including training, health and safety standards, and guidelines on GMP. The project takes into account the role that — in my opinion — the WHO Action Programme must play, as a coordinating body for the different activities carried out through various channels.

Asian factory

Italy is just starting some activities in Asia. In Indonesia, for instance, we shall be providing technical assistance to the government to build a factory for the local production of 230 essential drugs, and we shall also train the factory managers.

I should like to add that we hope many donor countries will in future participate in the Action Programme, because Italy believes that this is an excellent way of helping developing countries to improve their situation in the health sector.

Zimbabwe ED plan includes re-training of prescribers

The Government of Zimbabwe is committed to the concept of essential drugs in primary health care, and has drawn up a national list of essential drugs. What now remains to be done is to reorganize and rationalize the system of drug procurement, storage, distribution and usage, according to good management principles. This will make the most cost-effective use of the slim budget and also ensure that the health facilities get a constant and sufficient supply of the most needed drugs.

With assistance from the WHO Action Programme on Essential Drugs, the government appraised the Zimbabwe programme in 1984, and in 1985 drew up a plan of operations with the Danish International Development Agency (DANIDA). This plan includes selection of essential drugs, strengthening of procurement and logistics, operations at the Central Medical Stores, health information and management support.

The budget is estimated at US $1 million over three years, excluding drugs but including a national re-training programme for prescribers and other health workers. Funding has been secured from WHO and DANIDA. Recruitment of a management advisory team is under way, and this team will work closely with counterparts in the Ministry of Health.

The programme is expected to begin in September or October of this year, WHO will continue to provide technical expertise, in order to help the Health Ministry establish its system of drug supplies on a sound and rational basis, from planning of needs right through to availability and rational usage at the periphery, where the majority of the nation's primary health care is provided.
ASEAN Pharmaceuticals Task Force

"A success story by six ASEAN nations" was how Dr U Ko Ko, WHO Regional Director for South-East Asia, described the work of the Task Force on ASEAN TCDC in Pharmaceuticals, holding its sixth session in Jakarta, Indonesia in December 1985.

The Task Force reviewed progress made in quality assurance with WHO collaboration, emphasising good manufacturing practices, drug information systems, drug evaluation, improved laboratory quality control, preparation and reference substances, and better drug supply management.

The ASEAN grouping has now drawn up a third phase of the project, identifying several areas for strengthening and development: hospital pharmacies; training for drug management at peripheral levels; communication, information and education on medicines for the community; and standardization for quality control of herbal medicines.

NEW health information material in Kenya

The Drug Management Unit of the Ministry of Health in Kenya is now distributing five new full-colour posters to primary health care facilities (health centres and dispensaries).

The purpose of the posters is to upgrade the patients' knowledge about essential drugs and to promote good drug-taking habits. Along with the pictorial messages

a technical assistance agreement in drug production and quality control with Nicaragua.

In the area of joint procurement, USAID has recently approved US $3.1 million to establish a pooled tendering and procurement system for the Organization of Eastern Caribbean States. The Central American countries and Panama will also manage a revolving fund for the joint procurement of essential drugs, the initial grant having been secured from the Netherlands.

A network of official health sector drug control laboratories was formed in 1984. Since then, the network has organised training courses in drug analysis and laboratory management; a bulletin for laboratory managers; distribution of technical publications; an external quality control programme; and a working group meeting to launch the reference substances programme. The Caribbean Drug Testing Laboratory for the smaller territories in the region got off to a slow start in the 1970s, but recent efforts are likely to expand the services it offers.

Investigators have produced extensive documentation of the wide variations between and within countries in prices of raw materials and finished pharmaceutical products. For example, the data show that prices of imported pharmaceutical products fluctuate widely: the difference between the lowest and highest prices for the same drug entering a country during a given six-month period can soar as high as 600%. However, a number of promising initiatives have been taken to promote information systems on prices of drugs and chemicals, for example by the Southern Cone countries collaborating with Brazil.

Brazil and Colombia have built up an emergency supply of yellow fever vaccine from which the vaccine can be shipped to any country within 24 hours of request. Several countries now have the capability for testing viral vaccines.

The village health worker tries to raise a smile. Not amusing for importers: drug prices can fluctuate by 600% in six months.
Cash crisis triggers Mexican industry revival

Hit below the belt by the world economic crisis, Mexico discovered serious structural weaknesses in its pharmaceutical industry: overdependence on imports, control by multinationals, inap-propriate technology, poorly coordinated R&D, and a private sector market described as unreasonably large and chaotic. But there had also been positive developments that the government could build on to launch reforms designed to put the control and distribution of drugs in Mexico on a more re- national footing. Dr Mario Liebermann, Director-General of the Control of Inputs for Health for the Mexican Secretary of Health, discusses the results.

Monitor: What exactly triggered off these quite profound changes in the Mexican industry?

Dr Liebermann: We had a devaluation, and a very serious shortage of dollars. For 20 or 30 years prior to that, the national and international industry had imported all raw materials and in-termediates, so once we had no dollars there was no importation, but instead a critical shortage of drugs for both the public and private sectors. Three months into 1983, the government and the health authorities were obliged to make significant changes. First they pronounced an emergency decree concerning the importation and production of vital drugs, and the crisis subsided. But by that time we had realised that our local production was too weak. A new presidential decree was announced together with an integral pro-gramme for developing the national industrial production of drugs from raw materials and in-termediates. In 1982, we produced only 20% of the raw materials and intermediates we used, but today the figure is 45% and still increasing.

M: Was it at that time that you adopted the National Drug Formulary?

ML: That’s right. It was actually drawn up earlier, but in 1984 the National Formulary of Mexico was accepted by the entire health sector. I should say that this Formulary is more than just a list of essential drugs. It also includes a therapeutic guide, pharmacological procedures, and advice for the doctors and prescribers in the health sector. It covers 329 generic drugs, in 485 presentations or pharmaceutical forms, selected by 120 top specialists who studied the various therapeutic groups for six months. The Formulary gives complete prescribing information, not only the generic name but the indications, dosage, duration of therapy, precise therapeutic activ-ity, contraindications, adverse ef-fects, precautions and interac-tions. This goes to the 60,000 phys-i-cians who work for the health sector in Mexico. Prescribing in-formation also appears in bul-lets and in the national journals.

M: The new legislation adopted in 1984 was challenged by a certain number of pharmaceutical com-panies. Why was this challenge made, and what was the result?

ML: The challenge was probably made because people did not fully under-stand the direction of the pro-gramme for development of the local industry. The pro-gramme did not discriminate against international production in Mexico. What we wanted, and still want, is for both national and in-ternational laboratories to pro-duce in the country. But at first this was not understood. A sec-ond reason for the challenge was that we were using generic names in the health sector, and not the com-mercial brand names. We have since negotiated with the 40 international companies that were making a legal recourse, and to date 35 have withdrawn, so we have been successful.

M: How good has the new pro-gramme been for Mexican in-dustry? Are you now self-reliant?

ML: Not completely, of course — but you know no nation has com-plete, 100% self-reliance. We are now producing 45% of our raw materials and intermediates from a 20% beginning in 1982. If we can keep up this pace until 1988, we shall be producing 65-70% of our raw materials and shall not need to import. Furthermore we are developing both the national and the international industry, and in particular we are developing pharmaceutical research to a very high level.

M: What would you say have been the other overall advantages for Mexico of the new system?

ML: The lower cost of medicines. Thanks to the National Formu-lary, it has been possible to make what we call a consolidated sale of drugs for the whole health sec-tor. This has been going on for four or five years, but recently the sale has been on an annual basis.

Self-service: safe, non-toxic, reasonably priced basic drugs are available in Mexican supermarkets. Cartoons: Peter Caputo
people and plac
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and the national industry is a little bit favoured, so the cost has gone down by more than 50%.

M: Certain widely used basic drugs can now be sold without restriction in Mexico at preferential prices. What is behind this?

ML: This is a programme to make about 50 of these essential drugs available not only in pharmacies but also over-the-counter in supermarkets and other shops. These are all very safe, non-toxic drugs which, being 35% cheaper, should be reduced in price. We also hope with these drugs to educate people for good, rational self-medication.

M: They can be obtained without a prescription?

ML: That’s right. They are OTC products which don’t need a prescription.

M: How then do you educate people in better self-medication — do you give instructions with the drugs?

ML: Yes, we do. When this campaign begins, they will be sold complete with posters, mass-media information and booklets on exactly how to use the drugs. Each package will also include precise instructions.

M: Why did you decide on this method?

ML: There were many reasons. One was to relieve the load on the health service, but the most important thing for us was to enable people to get good products at lower prices with good information. And within the most important part is self-reliance and education for rational, instead of irrational, use.

M: Sixty-five per cent of the Mexican population have some access to health care and drugs — does the government have any plans for reaching the remaining 35% who do not have access to drugs?

ML: Of this 35%, half — 17 million people — belong to the upper or middle class and go to a private doctor, so they do not need a health sector service. For the remaining 17.5%, the government has a programme to construct and extend the health sector so that it reaches a further 10 million people by the end of 1988.

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Swedish/Vietnamese cooperation on drugs

Sweden and Vietnam have decided to collaborate within the framework of a health programme which includes five projects, one of them dealing with the provision of drugs. Sweden has allocated $58 million Swedish kronor to this project.

Vietnam has been more or less cut off in recent years from modern information on developments in the pharmaceutical sector. Therefore it was decided to offer qualified managerial pharmacists from Vietnamese factories a training course which would promote their understanding of modern concepts in pharmaceutical production, including related subjects such as quality control, inspection and quality assurance.

UNIPAC Indicative Prices

An up-to-date list of indicative prices for essential drugs is now available from UNIPAC/NIPCEP: Procurement and Assembly Center, United Plads, Postpark, DK-2100 Copenhagen Ø, Denmark.

The course took place at various government and industrial sites in Sweden in November and December 1985. It was organized under the auspices of the Governmental Committee on International Cooperation on Pharmaceuticals and administered jointly by the Department of Drugs and the Swedish Pharmaceutical Industries.

The main subjects covered in the course were: an introduction to the Swedish drug supply system; industrial production and quality assurance; good manufacturing practices; the hospital pharmacy; wholesaling and retailing; and drug control and inspection.

The eight Vietnamese participants will now launch and carry out local training activities in Vietnam for staff involved in pharmaceutical production. They will also undertake internal inspection of their own factories for quality assurance and good manufacturing practices.

Jordan: logistics training

An 11-day WHO inter-regional training course for primary health care was organized in Amman, Jordan, in March 1986.

Thirteen participants from 13 Arabic-speaking countries received an in-depth training in all aspects of procurement, storage and distribution of essential drugs. To put the theoretical part of the course into a practical framework, they visited three pharmaceutical factories in Jordan, several health facilities and the Central Medical Stores.

The participants were in favour of organizing national training courses for their own staff with help from WHO. Countries particularly interested in this were: Bahrain, Egypt, Jordan, Sudan and Tunisia.

active who programme in europe

WHO’s European Region Pharmaceuticals Programme, launched in 1969/70, was reformulated in 1982 under five broad headings:

- Drug regulation and supply
- Drug information
- Drug utilisation studies
- Training and quality control
- Clinical pharmacology and drug research

Each of these headings covers a number of active projects.

Lately, the Programme has published the second issue of the Drug Regulation Index, which reports on documents likely to be of value to regulatory authorities, drug assessors, drug research scientists and the pharmaceutical industry.

Another publication, Drugs in Hospitals, represents the outcome of the 14th European Symposium on Clinical Pharmacological Evaluation in Drug Control, held in Schlangenbad, Federal Republic of Germany, in October 1985.

Also available is the report of the WHO Drug Utilisation Research Group, which met in Cologne in November 1985 to exchange information and views on the status and experience of drug utilisation research projects, and to design a strategy for future activities.

If you are interested in these publications, please write to: The Pharmaceuticals and Drug Utilisation Unit, WHO Regional Office for Europe, 8 Scherfigsvej, DK-2100 Copenhagen Ø, Denmark.

Drugs in pregnancy and lactation: see EMRO Drugs Digest from WHO, Alexandria (above left).
DSE course on drug regulation

DSE (the German Foundation for International Development) organised a four-week training course in drug regulation during April last at the DSE Conference Centre in West Berlin.

Eighteen pharmacists from English-speaking African countries took part. They discussed drug legislation, essential drug policies, drug registration, drug information, quality assurance and GMP inspection.

The course teachers came from WHO, the pharmaceutical industry, and German and other European regulatory authorities. WHO guidelines and other basic documents were distributed.

Participants visited the German Drug Regulatory Authority (BGA), which has started a Drug Information Centre. Developing countries can ask this centre for information on any drug. Similar offers were made by other European countries.

DSE plans to organise four more courses in 1987 and 1988. For information, please write to: Mr. Rudiger Merchert, DSE Health Section, Rehberwerder, D-1 Berlin-West 27, Federal Republic of Germany.

Joint plan of action for Southern Sudan

GTZ (German Technical Cooperation), AMREF (the African Medical Research Foundation) and the Directorate of Health and Social Welfare for Southern Sudan ran a joint three-day workshop on coordinating an essential drug programme for Southern Sudan in Nairobi at the end of October 1985.

Their aim was to bring together all groups involved in primary health care services and drug supply in the region. This workshop was in part the follow-up to another on the infrastructure for essential drugs in Southern Sudan held in Juba in 1982.

The participants discussed selection and procurement of drugs, management and administration of the drug supply, storage and transport, and training.

They drew up a plan of action and a time-frame as follows:

Immediate activities (4-6 months): convene a meeting of all groups involved in drug supply in early 1986, to establish a formal body for the coordination of activities and to introduce an "operations arm" to handle day-to-day work.

Short-term activities (up to 18 months): develop a coordinated logistical plan; establish guidelines for training people who handle drugs; establish guidelines for community enlightenment programmes.

Medium-term activities (up to 36 months): establish a uniform stock management system with supervisory, review, reporting and control procedures.

Long-term activities (beyond 36 months): establish a centralised storage facility, transport services and vehicle maintenance; draw up a plan for developing a cooperative drug procurement venture.

All participants agreed that developing the Sudanese government's ability to meet its own essential drug needs was a high priority.

GMP (good manufacturing practices) are the rule in this Kenyan factory.

President opens Bangladesh conference

General Ershad, President of Bangladesh, opened a Conference on Essential Drugs and Primary Health Care arranged by the Institute of Postgraduate Medicine and Research in Dhaka in February 1986.

Around 50 professors of medicine, pharmacology and other disciplines from all the Bangladesh medical colleges and universities took part, joined by resources persons from abroad, including WHO officials.

They examined Bangladesh's national drug policy and recommended that the essential drugs concept be taught in all the training schools.

Other recommendations were: to strengthen the drug administration and in particular quality control and assurance; to produce a national formulary and a therapeutic manual; and to promote the essential drugs concept widely among professionals and the public.

The conference was widely publicised by the press, radio and television.

The organising committee, under the chairmanship of Professor Nurul Islam, will publish the proceedings. To obtain a copy, please write to: Institute of Postgraduate Medicine and Research, Dhaka 2, Bangladesh.
WHO AT LARGE - WHO AT LARGE - WHO

Expanded Programme on Immunization

Choosing injection equipment for EPI: WHO & UNICEF issue joint guidelines

"Since the possibility exists that unsterile needles and unsterile syringes can transmit not only HIV/HTLV-III (AIDS-related virus) but other infectious agents including hepatitis viruses, immunization programmes have the obligation to ensure that a sterile needle and a sterile syringe are used with each injection", (EPI Global Advisory Group, November 1985).

Countries which for many years have tolerated unsterile immunization and injection techniques are becoming increasingly aware of the risks they run.

Sterile needle and sterile syringe — absolutely essential for any type of injection. Reusable equipment is recommended. (Photo WHO/EU)

* Reusable needles and syringes are recommended for use in most developing countries. They should be steam-sterilised between uses. Boiling is an acceptable alternative procedure until steam-sterilisation is available. The number of reusable needles and syringes, and sterilisers, should be adequate to ensure that clinic operations are not impeded by sterilisation requirements.

* Those very few developing countries where disposable needles and syringes are already in widespread use, and where they are actually being destroyed after a single use, may consider adopting a policy of using disposables as the preferred method of ensuring the safety of immunizations.

* The use of jet injectors should be restricted to circumstances in which reusable or disposable equipment is simply not feasible because of the large number of persons to be immunized within a short period. Until further studies clarify the risks of disease transmission with injectors, general caution in their use is recommended.

WHO/EPI and UNICEF have now issued a Joint Statement on how to choose injection equipment which will prevent diseases being transmitted by injection.

The Joint Statement makes four recommendations:

* A single sterile needle and a single sterile syringe should be used for each injection.

<table>
<thead>
<tr>
<th>Item</th>
<th>Size</th>
<th>Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Needle</td>
<td>10 mm, 26 gauge</td>
<td>For BCG</td>
</tr>
<tr>
<td>Needle</td>
<td>20 mm, 22 gauge</td>
<td>For other vaccines</td>
</tr>
<tr>
<td>Needle</td>
<td>76 mm, 18 gauge</td>
<td>For reconstitution of vaccine BCG, single dose</td>
</tr>
<tr>
<td>Syringe</td>
<td>0.1 ml</td>
<td>Other vaccines, single dose</td>
</tr>
<tr>
<td>Syringe</td>
<td>1.0 ml</td>
<td>For reconstitution</td>
</tr>
<tr>
<td>Syringe</td>
<td>5.0 ml</td>
<td></td>
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</tbody>
</table>

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Control of Diarrhoeal Diseases

ORS meets half of world demand

The number of ORS packets available worldwide increased from 110 million in 1983 to about 270 million in 1985, representing about 40-50% of the estimated total global need. (In 1981, only 50 million packets were available.)

Local production more than doubled between 1983 and 1985, and continues to account for about half of all available ORS. This should increase as more countries undertake production.

UNICEF remains the major external supplier of ORS to countries, providing 30% of the world's imported supplies in 1984 and 1985. UNICEF supplied 59 million packets to 73 countries in 1984 and 81 million packets to 69 countries in 1985. Other external donors have provided about 25% of the total ORS supply in the last three years (25 million packets). Commercially imported packets accounted for the remaining 15%.

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Pharmaceuticals

Drug information for community health workers

Model Drug Information Sheets on 22 essential drugs that can be used by community health workers are being circulated to governments by WHO.

These drugs are: acetylsalicylic acid (aspirin), activated charcoal, antacids, antibacterial preparations/oral suspension/ointment, benzene acid/salicylic acid ointment, benzyl benzoate, calamine lotion, chlorhexidine, chloroquine, chlorphenamine, ephedrine, ergometrine, gentian violet, iodine solution, ippecacuanha (syrup of), iron/folic acid tablets, lindane, mebeverine, oral rehydration salts, paracetamol, piperazine, tetracycline eye ointment/suspension.

The model sheets advise on uses, dosage, precautions, adverse effects, use in pregnancy and lactation, overdosage and storage. They are intended to be adapted by national authorities.

For information, please write to the Pharmaceuticals Unit, WHO, CH-1211 Geneva 27, Switzerland, which invites users' comments.