

## Conference report

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# Twenty-five years of essential drugs: the challenge remains

### *A symposium*

On Friday November 21st 1997, the International Dispensary Association – better known simply as IDA – held a symposium to mark the 25th anniversary of its foundation. Highlights from that symposium are presented on the pages which follow.

IDA is by any standards a remarkable organization. In a pharmaceutical sector in which financial interests, profits and commerce sometimes seem to play every significant role, IDA is a non-profit organization devoted solely to serving the interests of public health in the poorest parts of the world. Established in 1972 by a group of young Dutch pharmacists with common ideals. IDA set out to bring good drugs at low cost to those countries where they were commonly inaccessible and almost always unaffordable for the bulk of the population. At almost exactly the same time the International Labor Organization, disturbed at the poor state of health in many developing countries, was beginning to sketch out a bold plan for the provision of “basic” health services to all populations. Developing that theme further, the World Health Organization created the concept of “Essential Drugs” – at first little more than a typewritten list of those well-known and well-proven medicines which could serve a community’s most pressing needs. That even these drugs were not available to most of the world’s poor reflected the fact that medicines as a whole had become an expensive commodity, their price reflecting the costs of maintaining a thriving heavily capitalized and research-based industry. What IDA realized was that for the bulk of the world’s best medicines, patent protection had expired or was about to expire. There were already places where they were being made cheaply and well for sale at a tiny fraction of the prices paid in the Western world. If those low-cost medicines could be made available to the poor, if they could be properly distributed and appropriately used, health over much of the globe would stand to benefit. This symposium tells how IDA tackled that challenge, working increasingly with the World Health Organization and others of like mind to achieve its ideal.

### **Quality assurance of medicines**

*At the IDA symposium, the view of the International Federation of Pharmaceutical Manufacturers Associations on Quality Assurance was presented by Dr Jan J.R. Wolters, Director of Worldwide Economic Affairs of Merck Inc. A summary of the IFPMA view, as issued by the Federation, is given below. The full position paper, of which it forms part, is available from IFPMA, P.O. Box 9, CH-1211 Geneva 18.*

Quality Assurance within the pharmaceutical industry is a broad concept embracing research and development through manufacturing, quality control, storage and distribution, to the information provided to the prescriber and the patient.

- All elements of Quality Assurance are equally critical to the whole; a weakness or breakdown in any part of the system or procedures could give rise to the release on the market of a defective product that could have serious or even fatal consequences.
- Good Manufacturing Practice (GMP) is the most fundamental element of Quality Assurance and internationally recognized, basic standards of GMP have been published by WHO. In view of their special nature, the manufacturing of medicinal products should only be permitted under strictly controlled and monitored conditions, in accordance with GMP.
- World-wide, reputable multinational companies abide by self-imposed standards of GMP wherever they manufacture products. National regulations and requirements must always take precedence, but internal company guidelines and self-auditing procedures are often more stringent than those applied externally.
- If a government allows local manufacturers which do not meet GMP standards to operate within its territory, the responsibility for such a decision must be taken on a national basis. To permit or sanction the export of products which have not been manufactured under GMP conditions, and thus allow such products to circulate in international commerce, is unacceptable.
- Quality standards for pharmaceuticals have been built up over the years by experts from industry, pharmacopoeial authorities, regulatory agencies and academia and are based on experience and the need to safeguard the safety and efficacy of the product, for the sake of the patients' health. There can be no "double standards" in the quality assurance of pharmaceutical products.
- Quality Assurance has cost implications and a preoccupation with procuring products at the lowest possible price must, inevitably, favor sources that put cost before quality, with consequent risks for the patient and public health.