WORKSHOP ON DEVELOPMENTS IN DRUGS AND PHARMACEUTICAL TECHNOLOGY, INDIAN INSTITUTE OF CHEMICAL TECHNOLOGY (IICT), HYDERABAD (INDIA), NOVEMBER 6-10, 2001

PARTICIPATING COUNTRIES: 12 (INCLUDING 11 MEMBER COUNTRIES OF THE CENTRE)

NUMBER OF PARTICIPANTS: 18 (INCLUDING 17 FROM THE MEMBER COUNTRIES OF THE CENTRE)

Medicinal chemistry is an interdisciplinary area to design molecules for use as therapeutic agents. The global pharmaceutical industry has been playing a prominent role in developing innovative process routes for the synthesis of drugs. With continuing escalation in drug prices by the multinational drug corporations, which they justify as due to investment in R&D, coupled with slow developments of indigenous capability in developing countries and restrictions due to IPR and TRIPS, the availability of even essential drugs in developing countries at reasonable cost is becoming scarce and is a matter of concern. There have been many innovations and developments during the last decade or so in the technology for drugs and pharmaceuticals.

In view of the importance of the subject for the member countries of the Centre, the Governing Council of the Centre has identified, among others, Drug Development and Evaluation and Screening of Medicinal Plants as the areas of priority. In pursuance thereof, a workshop on Medicinal Plants, their Bioactivity, Screening and Evaluation was organized during 2-5 December 1997 (reported under Item III.14 above) and earlier in February 1994, on the Anti-Malaria Evaluation and Biocide Essay for Control of Malaria (reported under Item III.3 above), both at the Central Drug Research Institute (CDRI), Lucknow, India.

The above events were followed by the organization of the workshop on Developments in Drugs and Pharmaceutical Technology by the NAM S&T Centre in association with and at the Indian Institute of Chemical Technology (IICT) of the Indian Council of Scientific and Industrial Research (CSIR) at Hyderabad (India) during November 6-10, 2001. The Asian and Pacific Centre for Transfer of Technology (APCTT) co-sponsored the workshop. This workshop turned out very timely, as the non-aligned and other developing countries with the advent of restrictions under TRIPs of WTO Treaty were under tremendous pressure to adopt the product patent system by the year 2005.

The workshop was attended by 16 participants from 11 selected member countries, who have active programme in this area and included one each from Bangladesh (Dr. Zafrullah Chowdhury of Ganoshastha Nagar Hospital in Dhaka), Egypt (Prof. Kassem Mahfouz of the National Research Centre in Cairo), Indonesia (Dr. Leonardus Broto S. Kardono of the Indonesian Institute of Sciences), Mauritius (Mrs. Sheesha Jankee of the Ministry of Health), Nepal (Mr. Bhupendra B. Thapa of the Ministry of Health), Sri Lanka (Dr. Tuley De Silva, former Special Technical Advisor, UNIDO and Consultant to the National

Committee for Science and Technology of Sri Lanka) and Syria (Ms. Majid K. Haddad of the Ministry of Health), two each from India (Dr. Laxman Prasad of the Department of Science & Technology, Government of India and Dr. A.K. Saxena of the Central Drug Research Institute, Lucknow), Malaysia (Dr. Ms. Noor Rain Bte. Abdullah and Dr. Ms. Ami Fazlin Bte. Syed Mohamed of the Institute for Medical Research in Kuala Lumpur), and Zambia (Mrs. Martha Mariam Mungiwira of the University Teaching Hospital Board of Management in Lusaka and Mr. F. Chizu of the Ministry of Health) and four participants from Iraq (Mr. Adnan Hashim Mahmood and Mr. Alaa Maher Ahmad Al-Douri of the Veterinary Drug Research and Production Centre in Baghdad, Mr. Mahdi Saleh Mohamed Hussain of Iraq Atomic Energy Commission and Mr. Abdulrazak Y. Ali of the State Company for Drug Industries and Medical Appliances). Dr. Mark Butler of the Centre for Natural Products Research, Singapore also attended the workshop besides a number of participants from Indian R&D Institutions and industry. The United Nations Conference on Trade and Development (UNCTAD) was represented by their representative in Delhi, Dr. Veena Jha, and APCTT by its Director, Dr. J. Bischoff and Mr. Srinivasan. The nominees of Pakistan however could not attend.

Dr. R.A. Mashelkar, Director General of the Indian Council of Scientific & Industrial Research (CSIR) and Secretary to the Government of India inaugurated the workshop. He felt that the present global patent system is not compatible with world health. While exclusive right for inventor is valid, the accessibility of patented drugs to society is equally important. He referred to the high cost due to the patent monopoly exercised by some of the MNCs, who charge as much as $10,000 for HIV treatment compared to $350 offered by Indian drug companies, and $4.63 per dose for Anthrax treatment against $0.63 by Indian drug companies. The Director of the NAM S&T Centre, Mr. K.N. Johry, informed that a special session is being planned in the workshop for discussions on TRIPS with a view to adopt a resolution for consideration of WTO in Doha. Dr. K.V. Raghavan, Director, IICT and Workshop Director explained the IICT's programme on the development of drugs and need of member countries to cooperate closely in areas of common interest. Dr. J. Bischoff, Director APCTT, felt that the workshop was very timely and stressed on the importance of transfer of technology of drugs between developing countries.

The workshop was spread over 9 Sessions. The plenary session on Global Drugs and Pharmaceutical Sector – Situation Analysis was chaired by Dr. G Thyagarajan, Scientific Secretary of ICSU Committee for Science & Technology in Developing Countries (COSTED) and included country report presentation on drug industry by the respective participants and a presentation on Strategies for Discovering New Therapeutics in Developing Countries by Prof. R. Kumar of the Indian Institute of Science (IISc), Bangalore, who alongwith Dr. K.V. Raghavan, shared experiences on management of inter-laboratory co-coordinated programme on isolation and evaluation of herbal formulation and single molecules of natural origin in India. Dr. (Mrs.) Veena Jha of UNCTAD spoke on Implications of WTO and IPR in developing countries and Dr. Rama Mukherjee of Dabur India on Current and Emerging Horizons in Global Drugs

and Pharmaceutical Sector. Dr. Jha's presentation served as background for discussion on TRIPS at the end of which a resolution was adopted unanimously for submission to WTO in Doha.

The second session started with a special lecture by Dr. A. Venkateswarlu of Dr. Reddy's Foundation (DRF), Hyderabad on the New Drug Development – an Indian Success Story and lecture by Dr. Zafrullah Chowdhury of Bangladesh on Proactive Governmental Policies for Sustainable Growth under a Competitive Regime. Dr. Tuley De Silva, former Special Technical Advisor, UNIDO and Consultant to the National Committee for Science and Technology of Sri Lanka and Dr. Mark Butler of the Centre for Natural Products Research, Singapore gave invited lectures on Potential of Medicinal Plants as a Source for New Drug Development and Modern Techniques of Screening Natural Products for Drug Discovery, respectively.

In the subsequent sessions presentations were made on Discovery Strategies for New Herbal Formulation Chemistry by Dr. J Madhusudana Rao of IICT; Lead Optimization of INDs by Dr. Javed Iqbal of Dr. Reddy's Research Foundation (DRF); Structure – Activity Studies through Computer Aided Modelling by Dr. A.K. Saxena of the Central Drug Research Institute (CDRI), Lucknow; Parallel Synthesis and Combinatorial Libraries by Dr. S. Raghavan of IICT; Rapid Screening of Combinatorial Libraries by Dr. C Sesagiri Rao of DRF; Chemistry of Important Unit Processes in the Manufacture of Bulk Drugs by Dr. A.V. Rama Rao, Chairman of A.V. Ramarao Foundation, Hyderabad; Clean Process Options – Technological Challenges by Dr. A.A. Khan of IICT; Impact of Biotechnology on Bulk Drug Sector by Dr. M. Kuppuswamy of Bharat Biotech, Hyderabad; Cluster Servicing Approach for Technology Transfer to SMEs – An Indian Case Study by Dr. K.V. Raghavan and Dr. M. Hari Babu of IICT; Pharmacology / Toxicology Screening by Dr. P.V. Diwan of IICT; Clinical Evaluation by Dr. M.U.R. Naidu of the Nizam Institute of Medical Sciences (NIMS), Hyderabad; Regulatory Aspects of Drugs and Pharmaceuticals – Trends and Challenges by Dr. M. Venkateswarlu, Deputy Drug Controller of India; Fingerprinting and Pharmacopea for Herbal Drugs by Dr. I Sanjeeva Rao of Varun Herbals Pvt. Ltd., Hyderabad; Good Manufacturing Practices in Drug Industry by Dr. P.S. Ramanathan of M/s Gharada, Mumbai; and Drug Master File by Dr. R. Nageswara Rao of IICT.

During the visits to the laboratories at IICT, demonstrations were arranged on automatic separators on Seplox, new HPCL techniques for fingerprinting, drug design and parallel system. A demonstration on clinical trials was also arranged at the NIMS, Hyderabad. Industrial visits were also arranged to SMS Pharmaceuticals, Arandy Laboratories and Srinivasa Pharma.

In view of the WTO Conference scheduled to start from November 9, 2001 at Doha, detailed discussions were held on the provisions and implications of TRIPS for drugs, in which the participants, faculty and session chairman participated at a special session on the 6th November evening. The workshop at the end of the special session adopted a resolution with a set of

recommendation, copy of which is reproduced below. The resolution was forwarded to the WTO for consideration through the Indian delegation.

On the concluding day a panel discussion on the 'Inter-Country Cooperation in Bulk Drugs Sector – Opportunities and Challenges in Developing Economies' was held. After detailed discussions the following recommendations were adopted:

- There is need to harmonize the regulatory practices in the drugs / pharmaceutical sector in the developing countries, the current disparities being mainly due to differences in standards, practices and implementation of regulations. In order to harmonize regulatory practices, there is need to adopt the guidelines evolved by the national bodies on the lines of the guidelines evolved by the International Conference on Harmonization of Drugs / Pharmaceuticals. This should be followed by strengthening the existing quality control, manufacturing facilities and standards.
- There is need to adopt international protocols viz. good clinical practices for enhancing the quality of clinical investigations in the developing countries. Special schemes can be drawn-up to identify the appropriate centres for conducting clinical trials, which satisfy the international guidelines.
- Human Resource Development (HRD) has been identified as an important component of cooperation between the developing countries. Special training programmes need to be organized in the quality and testing and creating awareness programmes on intellectual property rights and their protection. There is also a strong need for specialized training programmes in drug development from natural products to treat the tropical diseases.
- In view of the fast developments in the global pharmaceutical sector and drug development including biotechnology aspects, the Workshop recommends a series of similar workshops particularly until 2005 to be held in member countries.
- APCTT and NAM S&T Centre should assist member countries in evolving or synergizing the natural products based drugs, technology development and transfer networks based on existing networks like CSIR network in India.
- Following areas were identified for inter-country collaboration:
    - Development of new medicines and herbal formulations from natural products and traditional drugs;
    - Technology transfer in bulk drugs manufacture through horizontal or vertical mechanism preferably through joint venture between the companies in the developing world;

- Industry associations facilitated horizontal transfer of technologies for bulk drugs;
- Quality management;
- R&D on tropical diseases;
- Bio-evaluation of drug molecules (in vitro and in vivo);
- Modern methods of screening of natural products for developing new bioactives.

Mr. Venkat Joshi, President of the Bulk Drugs Manufacturers Association of India (BDMA) distributed certificates to the participants.

Resolution adopted at the NAM Science & Technology Workshop on Developments in Drugs & Pharmaceutical Technology held at Indian Institute of Chemical Technology, Hyderabad during November 6-10, 2001

Recognizing that mankind in general, and the people of the developing economies in particular are beset with multifarious challenges and barriers in meeting goals of socio-economic developments, including public health;

Emphasising that knowledge is the common wealth of mankind and, therefore, unhindered access to scientific and technological knowledge be recognised as fundamental to human right;

Recalling that the development of appropriate and adequate R&D base of a developing country is often rendered ineffective by various impediments including those encountered in some of the prevailing regulatory regimes, both regional and international, like Trade Related Intellectual Property Rights (TRIPS of WTO) despite best intentions of the concerned stakeholders;

Apprehending that the barriers to access for scientific knowledge and technologies relating to drugs & pharmaceuticals unless removed through concerted interventions and co-operation, is destined to adversely affect the well being and public health of the masses in developing countries threatened with diseases and epidemics.

Now, therefore, the member countries of the non-aligned movement (NAM), meeting to consider developments in Drugs & Pharmaceutical Technologies at Indian Institute of Chemical Technology, Hyderabad from November 6, 2001 have adopted the following for consideration at the forthcoming meeting of the World Trade Organisation to be held at Doha from November the 9th, 2001:

1. That nothing in the TRIPS agreement shall be implemented in a manner, which will prevent NAM countries from taking adequate measures to protect public health.

2. That all NAM members have the freedom to determine the conditions under which compulsory license can be issued and under which government use can be permitted, without the authorization of the patent holder.

3. That the circumstances, which warrant not seeking a voluntary license prior to seeking a compulsory license or authorizing government use, could include public health crises such as epidemics in NAM countries.

4. That in countries with limited domestic manufacturing capacity, other NAM countries should assist by obtaining the authorization from the patent holder on reasonable commercial terms and conditions. If this fails the other NAM countries will be free to supply to the former any excess supply of such drugs.

5. That each member should be free to establish their own regime for the exhaustion of intellectual property rights for drugs and parallel imports;

6. That the NAM countries can establish their own pricing system, tiered and discounted pricing to provide access to public health to all;

7. That the TRIPS should be a part of the wider national and international initiatives in NAM countries to address public health problems.

The members of the non-aligned movement attending this meeting therefore urge that their common stand stated above be considered at the WTO meeting in Doha for adoption and required modification carried out in the existing provisions of TRIPS at an early date.