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Expert Group Meeting on
Commercialization of Biotechnology
Vienna, Austria
28 October - 1 November 1991

REPORT*

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* This document has not been edited.

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I. INTRODUCTION

1. An Expert Group Meeting (EGM) on Commercialization of Biotechnology was held by United Nations Industrial Development Organization (UNIDO) during 28 October to 1 November 1991 at its Headquarters in Vienna.

2. The overall objectives of the meeting were to review both general and product-oriented policies and programmes in developed and developing countries related to commercialization of biotechnology in selected areas, focusing on health care and food processing; identify the elements for success and constraints for bringing products to markets; and propose modalities for promotion of application of biotechnology, in particular through international cooperation.

3. The meeting was attended by 34 experts of some 20 countries (Annex I) from governments, academia and industry from North and South.

4. The EGM was opened by the Deputy Director General of the Department for Industrial Promotion, Consultations and Technology, UNIDO, who briefly reviewed the Organization's initiatives in biotechnology including the establishment of ICGEB and the development of a Voluntary Code of Conduct for the release of genetically modified organisms into the environment for industrial applications. This was followed with a brief speech by Mr. Hara, President of Seiko Instruments, Japan, highlighting the importance of biotechnology innovations for industrial development.

5. The first two days of the meeting were largely devoted to presentations on healthcare and food processing/agro sectors with special reference to aspects on successful commercialization in developed countries and opportunities available in developing countries in these areas. Presentations were also made on the second day of the meeting on education and training requirements necessary for application of biotechnology to these areas and on the safety issues connected with introduction of biotechnology-based products.

6. Country-specific experiences from the Asian, South-East Asian and Latin American regions in commercialization of biotechnology-related products were covered in the presentations of the third day of the meeting.

7. Group discussions were held on the fourth day of the meeting concerning the key elements that contributed for success of commercialization in industrialized nations, constraints facing the developing countries and modalities for promotion of commercialization.

8. The EGM adopted its conclusions and recommendations on 1 November 1991 which was the final day of the meeting.

II CONCLUSIONS AND RECOMMENDATIONS

A. Human Resources

9. Given limitations in the availability of relevant skills, capabilities, training and experience in all of the necessary fields of science, technology, engineering and management in the continuum of research through development

to commercialization of biotechnology in developing countries, it is recommended that:

(i) Maximum utilization of existing resources and programmes in specialized institutions be made to provide broader exposure and training in biotechnology which should include engineering, technology and, in particular, management, in addition to scientific training. UNIDO should facilitate the coordination of resources and programmes for such training.

(ii) Innovative mechanisms be implemented to permit collaboration with expatriate residents in developed countries, as well as local specialists from other sectors, to ensure the full complement of skills necessary for biotechnology commercialization.

B. Collaboration

10. There is inadequate collaboration between the various sectors such as academic, financing institutions and industry, the interaction of which is a prerequisite in the development of commercial biotechnology. It is recommended that:

(i) countries develop appropriate incentive mechanisms to encourage active involvement of scientists in product commercialization;

(ii) countries allow scientists to gain rewards from the commercialization of technologies developed by them in public institutions, and provide adequate support in securing patent rights;

(iii) UNIDO promote the concept of "development parks" by encouraging, in the first instance, the International Centre of Genetic Engineering and Biotechnology (ICGEB) to consider setting up such infrastructure adjacent to its centres. This should include process engineering and physical facilities to take development beyond the concept stage. Such development parks could then be set up in many of the developing economies with models suited to local needs and requirements;

(iv) UNIDO's Trust Fund mechanism be used by companies and institutions for commercialization of research results.

C. Financing

11. Adequate financing is an essential element for the development as well as the commercialization and sustainable market entry and diffusion of biotechnology-based products. Traditional risk capital, such as venture capital, is not yet commonly adopted in developing countries: public equity markets for technology-driven companies are also not readily available. It is recommended that:

(i) creative methods be established for providing seed capital in developing countries. In addition, other means and modes of financing should be sought;

(ii) the consortium approach be fostered as one means of providing capital, encouraging university - industry - investor linkages and maximizing the utilization of existing infrastructure resources;

(iii) in order to be attractive to investors, research programmes have a product focus;

(iv) UNIDO coordinate and disseminate information concerning funds available to developing countries for commercialization of biotechnology;

(v) UNIDO seek funds from international sources as well as from industry, in order to assist developing country enterprises;

(vi) UNIDO assess projects on request from individual enterprises in order to improve their chances for funding;

(vii) as convertible currency may be critical for acquisition of specialty reagents, inputs, equipment and spare parts to jumpstart commercialization, researchers should actively recruit corporate sponsors, or Trust Fund support, early in the development process.

D. Science, Technology and Industrial Policy

12. Government policies need to be adjusted in line with entrepreneurial development in the world. It is recommended that:

(i) research and development priorities are focused on selected areas according to each country's competitive advantage;

(ii) government departments play a more pro-active role in science-based enterprise development with appropriate incentive mechanisms to promote public private interface, technology transfer from abroad, university-industry links, tax policy and financial incentives;

(iii) policies facilitate the recognition that ecological/environmental costs are no longer to be considered external to projects or products;

(iv) UNIDO cooperate with developing country governments in the formulation of industrial policy guidelines for biotechnology development.

E. Regulatory Policy

13. It is recommended that:

(i) coordination be established at the national level on regulatory issues;

(ii) regulations be scientifically based, flexible and commensurate with risks;

(iii) regulators, industry, policy makers, consumer groups and the general public be kept up to date on regulations;

(iv) collaboration be encouraged at the national level between academics, industry and government staff in the field of regulation;

(v) UNIDO taker a more active role by promoting international cooperation for the adoption of common principles of safety guidelines for biotechnology applications;

(vi) UNIDO collect and disseminate appropriate information regarding regulations or guidelines applied in other countries;

(vii) UNIDO facilitate the training of regulators.

F. Intellectual Property Rights

14. It is recommended that:

(i) developing countries devise appropriate strategies on intellectual property rights and patents as this will be an enabling factor in creating an environment for unrestrained development of science-intensive commercial enterprises.

G. Information

15. Timely access to quality and reliable information is a serious constraint to the development of appropriate research and industrial programmes in developing countries. It is critical that information be made available to the public on biotechnology developments. It is recommended that:

(i) the information services of UNIDO and others be strengthened and extended in order to provide the information in appropriate form for utilization by researchers and enterprises in developing countries;

(ii) national level information systems be established for the specific users in each country;

(iii) specific efforts be made, in developing countries, to widely disseminate information in order to increase consumer awareness of biotechnology developments and their implications for and benefits to society;

(iv) networks of individuals or institutions within countries and between countries should be established to promote information exchange and other activities.

H. Infrastructure

16. It is recommended that:

(i) infrastructure be strengthened by national governments to enable the development of internationally competitive biotechnology

enterprises as well as marketing and distribution channels for biotechnology products;

(ii) requests for support for international funds aimed at strengthening appropriate infrastructure be presented by national governments and institutions as an integral component of biotechnology development proposals;

I. Socio-Cultural Factors

17. In order to overcome the general aversion to financial risk that exists in many developing countries, it is recommended that mechanisms to encourage risk ventures, incorporating attractive financing options, be established.

18. To address issues related to public acceptance of biotechnology and its products, it is recommended that UNIDO integrate components on consumer aspects of the commercialization of biotechnology in its information and seminar activities.

J. Promotion

19. It is recommended that:

(i) UNIDO take steps to establish a promotion service for commercialization of biotechnology and constitute, if need be, a task force of experts for advice.

III. PRESENTATIONS AND DISCUSSIONS

20. Modern biotechnology has acquired a new dimension over the past two decades with phenomenal advances in biomedical sciences. These advances resulted in new techniques which facilitated introduction of desirable traits in existing biological species with unprecedented speed and precision. Universities are important sources of these innovations. Both the public and private sectors of industrialized nations, having realized early on the enormous potential of these techniques, have undertaken intensive R & D by establishing firm linkages with universities and have been successfully commercializing products of biotechnology.

21. Most developing countries are aware of the advances in biotechnology and its great potential in contributing to rapid economic development, sustained health care and nutrition and to industrialization. However, for several reasons they are lagging behind in full development of biotechnology and its application to commercialization.

22. UNIDO has been active in strengthening the developing countries in biotechnology and its applications through ICGEB. In addition to engaging in research with a view of advancing basic knowledge in the field, the Centre is also keen to liaise with industry to bring the research outputs into meaningful products for commercialization. The ICGEB has an elaborate programme initiated about five years ago in human resources development through a network of activities which includes seminars, colloquia, workshops and funding of collaborative research projects and bioinformatics. UNIDO has also promoted the establishment of a regional biotechnology network in Latin America.

23. It is against this background that UNIDO organized the EGM which, the Organization hoped, would play a catalytic role in helping countries, particularly the developing ones, to strengthen research-industry linkages that would facilitate commercialization of biotechnology products.

24. Dr. S. Burrill of Ernst & Young gave the keynote address with an overview on the global scenario of present and future prospects of commercialization of biotechnology. Dr. Burrill touched upon the essential elements that make companies succeed, the issues to be considered for product development and discussed the impact of government policies on biotechnology growth. He listed a sound research and technology base, team work, financial strategies and acceptance of a product in the market, among the elements that contribute to the success of biotechnology industry. In this context, he underlined the importance to developing countries of involving relevant expatriates in building healthy biotechnology industry in their home countries. Several participants, while emphasizing the value of expatriates, observed that there is a great need on the part of the countries to appreciate such intellectual capital and for devising attractive terms seeking their active participation.

25. The keynote address was followed by some 15 presentations from participants on commercialization aspects, regulatory issues and training opportunities in the areas of health care and food processing.

26. The group endorsed that advances in biotechnology have opened up new horizons to health care and agro-industry. Successful commercialization is already evident in biotechnology-based medicinals and agro-products. The biotechnology industry is just beginning to unfold and is expected to grow at a rapid rate in the 90s.

27. There is an increasing trend in the West of technology flow from academia to multinational companies through direct links, skipping in the process the entrepreneurial set up. However, it has been argued that for developing countries and even for industrialized nations, entrepreneurial intermediaries are important sources of venture capital.

28. An ideal example of how to start a small company with an initial venture capital was presented by Dr. T. Chang. The key for success according to him is to possess proprietary technologies targeted to large market segment. A point has been well made that it is the quality of the personnel and the conducive environment of the company and not the quantum of budget that determines its success. A suggestion has been that companies in the developed countries should establish manufacturing facilities in developing countries, as the demand for the products increases. This seems to be true of vaccines, particularly the recombinant ones. Developing countries may achieve rapid success if they promote tie-ups of their companies with large multinationals as was illustrated by Dr. A. Kumar of Astra Research Centre. It was pointed out that in many developing countries, expertise in gene technology is available in arriving at a candidate compound but to bring it to commercialization, which involves a gamut of preclinical and clinical studies, collaboration with a multinational is desirable. In contrast, Dr. H. De Boer, Gen-Pharm, Europe, whose studies demonstrated of the value of transgenic cows in providing large volume low cost proteins, felt that initial high-tech part is to produce transgenic animals which could be done in a developed country and isolation and purification of the proteins involving downstream processing, could be done in a developing country. The concept of using transgenic

animals in making commercially viable biologicals seems very attractive since they tend to secrete the product in their milk which facilitates relatively easy isolation and purification of the products.

29. Mr. K. Venkat of Genmap Inc., predicted that biotechnology industry in the field of agriculture will have a lasting beneficial effect on the average citizen. While detailing some of the successful products on the market, he observed that for success of commercialization, the industry should take due note of market needs and consumer perception and strive for employing cost-reducing technologies. The governments in developing countries should acquire profitable technologies for rapid commercialization, even by licensing them on phased payment basis.

30. Mr. G. Oldham of the Science Policy Research Institute, Sussex University, expressed concern that ethical and environmental considerations may come in the way for a real take-off of biotechnology industry. Consumer acceptance and regulatory issues have been covered in depth at the EGM. It was agreed that these novel technologies should be employed in a manner that promoted environmentally sound development keeping socio-economic needs, country-specific issues and a balanced safety policy in view. Mr. T. Medley of USDA urged that a risk-based regulation should be the norm with logical reasoning rather than by empirical methodology. Any regulation should reduce risks without inhibiting innovation. He cited bioremediation as a project of great potential but its progress is slow because of regulatory uncertainties. In his view, public acceptance of a product is a prerequisite and the governments should develop appropriate biosafety review structure essential for technology transfer for commercialization.

31. In the context of regulatory issues, it is worth noting that the biosafety guidelines and Voluntary Code of Conduct developed by UNIDO on behalf of the informal UNIDO/UNEP/WHO/FAO Working Group lay down the minimum commonly accepted principles on the subject. They aim at promoting innovation and commercialization of biotechnology products in an orderly manner that is conducive to consumer acceptance.

32. It was recognized that enormous amount of information accumulated on biotechnology industry and there is a great need of not only preparing data banks but also processing the information into packages designed to help the user. In this context, the Deputy Director-General of the Department for Industrial Promotion, Consultations and Technology emphasized the importance of developing a techno-economic intelligence (INTEL) programme for biotechnology.

33. The importance of human resources development in the application of biotechnology, particularly in the developing countries, was emphasized by the participants. This could be done by way of strengthening centres active in this area such as ICGEB and conducting course programmes, preferably under university auspices. It was observed that some training centres for biotechnology at research level are available in several developing countries but no such organized activity exists to accelerate industry skills. Therefore, a need has been felt for providing training in private sector in fields such as bioengineering with emphasis on down-stream processing technologies.

34. Presentations of case studies by some 23 participants from countries of Latin America and Asia revealed several opportunities, constraints and methods in promoting commercialization of biotechnology products. Among the constraints identified in these countries have been political instability; economic and financial difficulties; shortage of investment resources; lack of support from governments by way of customs duty exemption on equipment and bioreagents and tax incentives; general paucity of experience of investors; and inadequate scale-up skills to bring products to markets. However, efforts are being made to overcome these constraints and countries such as Argentina, Brazil, Cuba and India are forging ahead in application of these technologies in industrial development. Concerted efforts are made in these countries to increase human resources in biotechnology; bridging university-investor-industry links; promoting regional cooperation; forming alliances and networks with industries of developed countries; and establishing mechanisms for raising venture capital. It is apparent that much needs to be done in most developing countries in exploiting natural resources; making traditional technologies more competitive; promoting product-oriented researches in universities with equity participation and profit sharing concept applicable down to the level of scientist to retain the best talent; in orienting research to meet the industry needs; building strategic partnerships; and designing appropriate cost-effective biotechnological methods. It is vital that these technologies should be applied judiciously without posing threats to established export markets from these countries.

35. The EGM underlined the urgency of international cooperation in promotion of commercialization in developing countries. This could take the shape of forming information networks; science and technology capability strengthening including research, bioprocessing, manufacturing and safety; and facilitating technology transfer. A suggestion worth pursuing is to establish science parks or development parks around centres engaged in biotechnology and genetic engineering research in order to bring awareness in governments, investors and industry on the commercial potential of biotechnology.

36. Wide-ranging conclusions and recommendations emerged from group discussions held on the key elements for success, constraints facing countries and modalities to promote commercialization of biotechnology products. Several specific recommendations were made by the experts to UNIDO to assist developing countries in rapid industrialization through biotechnology, the implementation of which entail substantial inputs from the Organization.

ANNEX I

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Commercialization of Biotechnology
28 October - 1 November 1991

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ANNEX II

Expert Group Meeting on
Commercialization of Biotechnology
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5. Biotechnology: A Worldwide Perspective - G. S. Burrill
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8. The Role of Biotech Consortium in Commercialization of Biotechnology - S. Chandrasekhar
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17. Development of Biotechnology Research and Industry in India - H. F. Khorakiwala
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