

Item 8

Statement of Mr. Decio Ripandelli – Director, Administration and External Relations – International Centre for Genetic Engineering and Biotechnology (ICGEB)

Thank you for giving me the floor, Mr. President. I have the honour to provide the Board with the views of my organisation, the International Centre for Genetic Engineering and Biotechnology, on agenda item 8, dedicated to UNIDO's support in fostering local pharmaceutical industry in developing countries. In particular, I wish to refer to document IDB.38/15, which properly describes some of the critical aspects related to the development of the pharmaceutical industry in the developing world. ICGEB shares some of the concerns expressed in this document and, in particular:

- The insufficient access in developing countries to quality assured essential drugs to treat the most significant pandemic diseases, such as HIV/AIDS, malaria and tuberculosis, and the need to upgrade local industries;
- The ever-increasing incidence of malaria in the developing world affecting in particular children;
- The increase of chronic diseases;
- The urgent need of implementing tailor-made assistance programmes aimed at increasing the productive capacity of local industries, while building the scientific and technological capabilities within the developing world.

Mr. President,

Since 1987 the ICGEB, now an autonomous intergovernmental organisation, but originally a special programme of UNIDO, operates in close contact with the UN Common System as a centre of excellence for research and training in genetic engineering and biotechnology, with special attention to the needs of the developing countries and of the economies in transition. When it started its activities, by virtue of the generous contributions provided, in particular, by the Government of Italy, as well as by the Government of India, UNIDO considered that the ICGEB could provide to the industrial sector of developing countries a "scientific and technological" arm that would enhance the capabilities of those same countries while developing its own scientific agenda. I think I can state that UNIDO's vision, coupled with the constant support we

receive from Italy

receive from Italy, India and, now, South Africa, was, and still is, correct: 61 Governments are currently full Members of the organisation, while another 22 are finalising their membership, more than 500 scientists are operating in our three components located in Trieste, New Delhi and Cape Town, where major scientific and training programmes are developed and implemented in fields covering human health, agriculture, industrial development and basic science, while providing the ICGEB constituency with scientific and institutional assistance on subjects of major impact related to biotechnology.

Particularly, in respect to human health, the Centre is very active in bringing its experience at the service of the developing world, along a double track constituted, on the one hand, by high level research, at the forefront of international scientific excellence, and, on the other hand, by developing innovative technologies for the production of "bio-similars" which are then provided to industrial partners in developing countries. Concerning the latter, Mr. President, I think it would be useful for the Members of the Board to know that ICGEB has established in its three Components scientific groups dedicated to the development of simple and innovative technologies for the production of biotechnology-based pharmaceuticals, and to their transfer to the industrial sector. The aim of these activities is to increase the know-how and capabilities of the pharmaceutical industries in ICGEB Member States by transferring technologies for the production and quality control of pharmaceutical recombinants, such as erythropoietin, interferon, granulocyte colony stimulating factor and Insulin. The laboratory procedures can be adapted to the conditions existing in Member States with only minimal financial investments necessary to set-up the production facilities. The transfer of these technologies involves the training of scientists from pharmaceutical companies for periods of one to two months. During this time ^{they} learn the manipulation of recombinant strains, practice the downstream process and perform quality control procedures in accordance with the guidelines of the European Pharmacopoeia. Over the past few years, ICGEB has trained more than 100 scientists from some 20 pharmaceutical companies operating in different ICGEB Member States and in most of these countries ^{products} ~~bio-similars~~ based on ICGEB-developed technologies, are present in the local and international markets where the annual total value of recombinant products is estimated in excess of 20 billion US\$.

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In addition ICGEB is also very active in pursuing research at the top of international excellence. For instance, and in collaboration with the Government of India, ICGEB has developed a number of candidate vaccines against malaria, the first of which has recently started phase 1 clinical trials, in collaboration with an Indian industry. We expect to be in the position of entering soon into phase 2 and 3 trials and our governing body is overseeing with interest these developments, as well as the industrial strategy that the Centre will adopt to ensure that, should the trials prove effective, this potential vaccine becomes available to the entire international community at an affordable price and in the shortest possible time. Furthermore, our scientists are obtaining considerable results in their research aimed at the definition of novel ~~drugs~~^{treatment} against ~~antibiotic~~^{drug} resistant tuberculosis, and, also in this case, contacts are well underway with potential industrial partners to develop a strategy that maintains the needs of the developing countries as its main target.

Mr. President,

The above description is far from being exhaustive, but is intended to provide the Members of the Industrial development Board with a glimpse of the activities being implemented in this field by the ICGEB and of its potential for further assistance to the pharmaceutical sector in the developing world. It is our firm conviction that ICGEB, in addition to the other partners quoted in document IDB.28/15, could bring its added value to the efforts made by UNIDO in this respect: the ICGEB Management strongly believes that ICGEB represents a true success story for UNIDO, given UNIDO's initial efforts aimed at its establishment. Indeed, from the adoption of the ICGEB's Statutes, in 1983, through the commencement of its operational activities, in 1987, until its complete independence, in 1996, ICGEB has been in all effects part of UNIDO. ICGEB's availability to closely collaborate with UNIDO in this endeavour (but not only in this one, as there are other fields of potential synergic activities, such as the recently established International Industrial Biotechnology Network -IIBN), would be in line with the relationship agreement between the two organisations, entered into in 1996 and aimed at ensuring proper synergies in fulfilling their respective mandates, in order to avoid any possible duplication and/or loss of financial resources.

I thank you