



## **GUIDELINE ON INTELLECTUAL PROPERTY RIGHTS**

### **BENEFIT TO THE PEOPLE IN DC'S: KNOWLEDGE DISSEMINATION, IP-RIGHTS**

#### **1 : PREFACE**

One of the objectives of EDCTP is to ensure that the projects funded will benefit the people in developing countries. One aspect of this is securing the results of the research projects and providing these results to scientists, policy makers and pharmaceutical industry working in developing countries.

The guiding principle of how to handle the IP-rights is provided by the decision (ref.: 1209/2003/EC) of the Parliament and Council of (at 16 June 2003), being that the funding is conditional on the:

“formulation of the provisions relating to intellectual property rights in such a way that they also aim at ensuring that the people of developing countries have easy and affordable access to the research results produced by activities under the EDCTP Programme and to the products directly deriving from its results.” (Article 2(g), JO L169 of 08July2003)

A general policy will be difficult to define that is applicable to the various combinations of potential partners. Thus, the specific IP-rights issues should be addressed on a project-by-project basis. Nevertheless EDCTP will develop a policy holding a strategy how to handle IP-rights. This policy will address issues as ownership of knowledge; tiered pricing agreements including provisions on time schedule, availability and easy access to affordable new medicines; and the dissemination of knowledge in order to inform policy decision.

The subject of IP-rights can be divided into three parts, namely: knowledge dissemination, managing IP-rights, and the transfer of IP-rights.

#### **2 : KNOWLEDGE DISSEMINATION**

One of the objectives of clinical trials supported by EDCTP is to produce information to inform policy decision. EDCTP supported research results should thus be available as much as possible to scientists, doctors, public health authorities and participants in a clinical trial of the results of the trial. Every grantee will need to establish a dissemination plan with timelines and EDCTP will ensure that the results of the research will, wherever possible, be in the medical and scientific literature.

Generally, the aim will be to ensure that the results of trials enter the public domain in order to inform Public Health practice in a timely fashion. EDCTP will by contract always retain the right to publish research results themselves in case a grantee, after given due notice, does not publish all results.

In publications, the role played by local scientists will be properly and fully acknowledged through authorship of publications.

#### **3 : MANAGING IP-RIGHTS**

The EDCTP acknowledges that IP-rights protection is paramount particularly for a commercial partner wanting to market a medicine in developed countries. The EDCTP on the other hand acknowledges that developing countries may have no direct advantage by a patent on a medicine in their country. Therefore the EDCTP, while accepting in principle the need for strong IP-rights protection in developed countries, will not seek in general IP-rights protection in developing countries. As a general principle, each party to an EDCTP project remains the owner of its pre-



existing know-how, but shall make it available as needed for carrying out the project and serving the mission of EDCTP.

Before the start of a project all IP-rights concerned shall be identified, including all obligations already contracted by the third parties. The EDCTP shall endeavour to assess whether the actual IP-rights position might prevent the project from ultimately resulting in an affordable intervention for developing countries. During the execution of a project the EDCTP shall assist the research sites with legal matters concerning IP-rights wherever necessary.

On the question what is meant with making interventions readily available against an affordable price to the people in developing countries, EDCTP shall reflect to the EC policy on tiered priced products as formulated in the Council regulation (EC) No 953/2003 of 26 May 2003. Furthermore the best practises as accumulated and discussed by The Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) of the World Health Organization, will serve as examples.

#### **4 : TRANSFER OF IP-RIGHTS TO PRIVATE PARTIES**

The basic principle is that the EDCTP will favour the transfer of IP-rights whenever appropriate in order to ensure production and availability of affordable medicines to the people in need in developing countries. The main legal issue regarding the transfer of IP-rights is to seek and obtain guaranties that third parties shall meet the objectives of the EDCTP. Other relevant legal issues are the ownership, exclusivity, liability, and pricing of the IP-rights and products covered thereby.

As a starting point EDCTP will agree on these issues with the grantees but in certain circumstances retain the right to handle IP-right issues ourselves. This approach provides the grantee with full ownership of its own research results while having the possibility to ensure that the objectives of EDCTP on making new interventions available to developing countries as set forth by the European Council and Parliament can be met.