

Issues paper

Day 4: Thursday, 6 November 2003

Theme: Building the knowledge base for health

During the discussion of this theme, participants are invited to address the following topic:

Research and product development

Background information

The lack of a significant market for drugs, vaccines, diagnostics and other pharmaceutical products in developing countries means that the pharmaceutical industry will not, on its own, make the multi-million dollar investment that is necessary for new products to obtain regulatory approval and be brought to the market. Public sector agencies therefore need to engage in and drive the research and development (R&D) agenda and activities necessary to generate products appropriate to the health concerns of developing countries. This activity is usually most successful when undertaken in association with the private sector through public-private partnership.

Of particular relevance to such research are the drugs, vaccines and diagnostics required to treat the infectious diseases that predominantly affect developing countries. Also of central importance are vector control tools together with appropriate tools for improved reproductive health.

There is no doubt that much work is needed: in the area of drugs for neglected infectious diseases (excluding HIV/AIDS), it is reported that of the 1393 new chemical entities registered by western health authorities during the period 1975-1999, only 13 were specifically indicated for such diseases. Indeed, for many important diseases (malaria, tuberculosis, human papillomavirus, HIV/AIDS and all human parasitic diseases) there are as yet no vaccines. Appropriate, effective and easy-to-use diagnostics are also lacking, as are tools for prevention in reproductive health, such as contraceptive methods for men or microbicides.

Major challenges facing WHO in this work include:

- Ensuring that a good level of basic research is in place for the diseases and indications mentioned above.
- Obtaining the involvement of and partnerships with industry in undertaking R&D for products required by developing countries.
- Identifying mechanisms in which public sector resources and expertise can be matched with private sector resources to ensure product development.
- Identifying mechanisms by which the public and not-for-profit sector may undertake and coordinate aspects of product R&D by themselves where necessary.
- Undertaking product R&D in a manner designed to promote downstream access to products.
- Generating resources and finances to undertake high-cost, high-risk R&D projects.
- Building research capacity and ensuring technology transfer to developing countries.

WHO, working with partners, is involved in several areas of research for new tools to support health care in developing countries. The Organization is also active in research directed toward the optimal use and implementation of these tools. The major research-oriented units are as follows:

– the UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR), and the WHO/UNAIDS Initiative for Vaccine Research both of whose work is focused on drugs, vaccines and diagnostics for a range of important infectious diseases; and

– the Special Programme of Research, Development and Research Training in Human Reproduction (HRP), which focuses on products relating to fertility regulation and the prevention of sexually-transmitted diseases.

TDR was a critical and instrumental partner in the development of over half the 13 drugs for neglected diseases produced between 1975 and 1999. Vaccine research partnerships promoted by WHO have yielded evidence for expanding the use of vaccines such as Hib to developing countries, and have promoted several large R&D initiatives. HRP has also yielded new tools (e.g., injectable contraceptives, products for emergency contraception) that are now marketed and in use. All three units work through partnerships and, where necessary, help to establish other "independent" not-for-profit initiatives in order to take certain activities forward.

The biotechnology and informatics revolution, combined with increased research activity in recent years, has led to an unprecedented supply of products for certain diseases. However, much remains to be done, and many indications have no significant R&D activity directed against them. All three WHO units have product R&D partnership activities and programmes expected to deliver new products in the coming years.

These activities are not taking place in isolation and due note should be taken of the following:

– other WHO units participating in research-related work and which make an assessment of research evidence for their policies;

– the WHO Research Policy and Cooperation unit;

– broader global research issues; and

– the broader global activities of many other organizations: national and international, nongovernmental, public and private.

Points for discussion

- How can WHO best add value to global efforts for accelerated research and product development targeted at the diseases that affect low-income countries?

- Research capacity building, technology transfer and the involvement of developing country institutions as full partners in product R&D.

- Public-private partnerships.

- The increasing number of independent product R&D and other research initiatives and how they fit into the overall picture.

- Ensuring best practices (e.g., good laboratory practice, good clinical practice and bioethics).

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