BOOSTING INNOVATION FOR NEGLECTED DISEASES

Call to governments

to provide significant and sustained support to bring essential new drugs, vaccines, and diagnostics to people suffering and dying from neglected diseases

- Every day over 35,000 people die from infectious diseases such as AIDS, malaria, tuberculosis, and most neglected diseases such as leishmaniasis, Chagas disease and sleeping sickness.
- These diseases affect hundreds of millions, yet we lack safe, affordable, effective, field-adapted vaccines, diagnostics, and drugs to tackle them.
- Between 1986 and 2001, global funding for health research rose from \$30 billion to US\$106 billion, but progress towards new health tools for the poor remains insignificant.
- Of 1,393 new medicines approved between 1975 and 1999, only 1% was developed for tropical diseases and tuberculosis.
- Basic science about infectious diseases exists and biomedicine is developing extremely fast, but without political determination this progress cannot be used to develop essential products.
- The profit-driven model of drug development is not suited to developing essential health tools for neglected diseases.
- Current regulatory practices are poorly adapted to assessing the therapeutic advances of new drugs, vaccines and diagnostics for neglected diseases.
- Higher levels of intellectual property protection have not resulted in increased drug R&D for global health needs.

In the last few years, this health challenge has spurred global awareness and some commitment from the international community. A number of developing countries have been strengthening their capacity for new health technologies, and their role will be increasingly critical. Not-for-profit entities have been established to accelerate innovation for neglected diseases. They are beginning to build a pipeline of projects in response to the real needs of neglected patients. These product development partnerships act as "virtual" laboratories, working collaboratively with public research institutes, universities, and pharmaceutical and biotechnology industries. However, the majority of these entities are mainly funded by philanthropic organisations and individual donors. The response remains insufficient with only marginal involvement by wealthier governments.

There is an urgent need to correct the fatal imbalance of the current drug development model. Governments must take responsibility for global public health.

New models and financial mechanisms must be pursued. Determined policy action is needed to direct health-needs driven R&D and harness collaborative R&D initiatives. This will ensure that initial progress is translated into improved, affordable and field-adapted drugs and diagnostics that can reach patients most in need.

We urge governments to provide

- **Political leadership** Make global health and medicines a strategic sector and set R&D priorities according to the needs of patients. Only then can the world achieve the Millennium Development Goals that envision among other things significant progress in combating HIV/AIDS, tuberculosis, malaria and other neglected diseases.
- **Sustained financial support** Governments rich and poor, as well as inter-governmental organisations should provide, on a sustainable basis, US\$ 3 billion a year needed to reach an appropriate level of health research for diseases of the poor. To secure long term success new funding mechanisms should be designed.
- New rules to stimulate essential health R&D Redirecting today's knowledge and scientific expertise to neglected needswill mean a substantial shift in the way essential health products are valued, financed and made available. A new enabling framework should include access to knowledge, chemical compounds, and research tools protected by intellectual property rights. Technology transfer and research capacity strengthening in disease-endemic countries should be at the heart of the endeavour. In addition, regulatory approval processes must be streamlined in order to rapidly deliver essential medicines to patients. The risks and benefits of each drug or vaccine must be assessed in relation to the needs of patients, the severity of the disease, and available treatments and vaccines.

Without bold, new steps, disease will continue to ravage the developing world, with global consequences. Governments should act NOW.

DND*i*

Drugs for Neglected Diseases initiative

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in association with Davy Koech, Director, Kenya Medical Research Institute, Kenya; Paolo Buss, President, Oswaldo Cruz Foundation, Brazil; Philippe Kourilsky, Director General, Institut Pasteur, France; Ismail Merican, Director General, Ministry of Health, Malaysia; Nirmal K. Ganguly, Director General, Indian Council of Medical Research, India; Rowan Gillies, President Médecins Sans Frontières International; Barbara Stocking, Director, Oxfam GB; Richard Jefferson, Director BIOS Initiative, Australia; and others...