

# Recent Publications and Sources of Information

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## Emergency contraception

Emergency contraception will only have an impact on reducing unwanted pregnancies if women are provided with information and access to the methods available before they are needed. *Emergency Contraception: A Guide for Service Delivery* sets out to propose how emergency contraception can be integrated into the community and family planning care facilities through service outlets as a first contact point. Emergency contraception is considered to be one component of the long-term strategy to improve overall reproductive health care.

In spite of the effectiveness of modern contraceptives, unwanted pregnancies occur in large numbers throughout the world and many women seek termination. It is estimated that 40 to 60 million abortions are performed each year; approximately 20 million of which are carried out under unsafe and dangerous conditions. If emergency contraceptive methods were easily available, millions of unwanted pregnancies and abortions could be averted. These methods include increased doses of combined oral contraceptives, high doses of progestogen-only pills containing levonorgestrel and copper-releasing intrauterine devices.

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*Emergency Contraception: A Guide for Service Delivery. Family and Reproductive Health, World Health Organization, Geneva, WHO/FRH/FPP 98.19.*

## UN Consolidated List: restrictions in use and availability

An update of the pharmaceutical section of the Sixth Issue of the United Nations *Consolidated List of Products whose Consumption and/or Sale have been Banned, Withdrawn, Severely Restricted or Not Approved by Governments* has now been compiled.

The document *Pharmaceuticals: restrictions in use and availability* presents information on new national regulatory decisions and voluntary withdrawal of products by manufacturers on grounds of safety.

This information has been reported between 1993–1999. Criteria for inclusion of the products in the UN Consolidated List were developed in 1985 and revised subsequently. Although interpretation of the criteria continues to vary widely, leading to disharmony in reporting, the list is still useful to drug regulatory authorities and the pharmaceutical industry to give an indication of the status of products. More detailed information on action taken by the regulatory authorities or the manufacturers should be confirmed directly at source.

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*Pharmaceuticals: restrictions in use and availability. Essential Drugs and Medicines, World Health Organization, Geneva, WHO/EDM/QSM/99.2.*

## New antituberculosis drug development

Only one new antituberculosis drug has come to the market in the last 28 years despite nearly 2 million deaths from the disease occurring each year. A new report from the UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR) — Incentives and Disincentives for New Antituberculosis Drug Development — looks at the reasons for the lack of interest in antituberculosis drugs by the pharmaceutical industry and how to stimulate research and development of new drugs. The report contains a brief description of the current situation and major findings of the evaluation. Lack of interest by pharmaceutical companies is attributed to:

- The cost of drug development: which varies between US \$300 to 500 million, and company concern that the commercial return would be insufficient from patients in developing countries.
- Risk of patent violations.
- The perception that new drugs would not be responding to an unmet medical need given the cost-effectiveness of the directly-observed short-course treatment (DOTS) regimen for TB which is currently available. This would also tend to force down the price of any new drugs.

In conclusion, the report proposes broad recommendations which include the need for public sector efforts to build relationships with industry and other stakeholders, provide discussion and drive forward the process of antituberculosis drug development by helping to build, define and protect markets for new drugs. Governments should also be encouraged to strengthen their health infrastructure, lower the barriers to development and build financing mechanisms for the private sector.

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*Incentives and Disincentives for New Antituberculosis Drug Development. World Health Organization, Geneva, WHO/TDR/PRD/TB/00.1 (2000) or <http://www.who.tdr/publications/antituberculosis.htm>*

### **Carcinogenic risks from antiviral and antineoplastic drugs**

The Seventy-Sixth volume of the International Agency for Research on Cancer (IARC) Monographs comprises evaluations of pharmaceutical agents which include antivirals (aciclovir, zidovudine, zalcitabine and didanosine), some DNA topoisomerase II inhibitors (teniposide, etoposide, mitoxantrone and amsacrine) and others (hydroxyurea, phenolphthalein and vitamin K substances) which have not been reviewed previously. The evaluations of carcinogenic risk are made by international working groups of independent scientists and are qualitative in nature. No recommendation is given for regulation or legislation.

The term carcinogenic risk in the IARC Monograph series is taken to mean the probability that exposure to an agent will lead to cancer in humans. Inclusion of an agent in the Monographs does not imply that it is a carcinogen, only that published data have been examined. Equally, the fact that an agent has not yet been evaluated in a monograph does not mean that it is not carcinogenic.

Two chemicals were tested for carcinogenicity in genetically engineered mice which are particularly susceptible to induction of tumours at certain sites through specific mechanisms. Some of these transgenic, knockout, models can be considered the laboratory counterparts of certain rare human genetic syndromes, and the models may be particularly useful for testing drugs to be administered to individuals with such syndromes.

*IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. Some antiviral and Antineoplastic Drugs, and Other Pharmaceutical Agents. Volume 76, International Agency for Research on Cancer. World Health Organization, Geneva, ISBN 92 832 1276 2*

### **HIV preventive vaccine research: ethical considerations**

The HIV pandemic is characterized by unique biological, social and geographical factors that affect the balance of risks and benefits for individuals and communities who participate in HIV vaccine development activities. These factors may require that additional efforts are needed to address the protection and welfare of participating individuals and communities in order to fulfil their rights as full and equal participants.

The need for an HIV vaccine is becoming more urgent, and over twenty vaccine candidates are at various stages of development. The successful development of effective HIV preventive vaccines is likely to require studies in different populations around the world involving the collaboration of various partners in government, agencies, research institutions and industry.

The UNAIDS secretariat has developed a guidance document on the ethical considerations in HIV preventive vaccine research which is directed to use by research participants, investigators, community members, governments, pharmaceutical companies, and ethical and scientific review committees. It suggests standards, but can equally be used as a frame of reference from which to conduct discussion and reach decisions. Consultation has taken place among lawyers, activists, social scientists, ethicists, research scientists, epidemiologists, nongovernmental organizations and public health officials and has included people from 33 countries.

The guidance document sets out to highlight some of the critical elements to be considered in ensuring availability, capacity building, development of research protocols, identification of study populations, community participation, ethical review and monitoring.

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*Ethical Considerations in HIV Preventive Vaccine Research. UNAIDS Guidance Document 00/07E/2000. UNAIDS, Geneva, Switzerland. <http://www.unaids.org>*