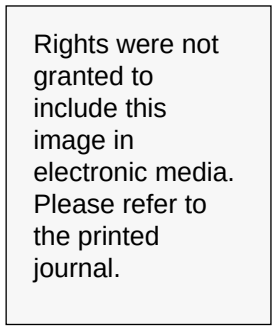
AIDS activists force attention to fluconazole in South Africa

South African AIDS activists last week applied to the drug regulatory authority for special exemption to allow the use of a generic version of flucanozole as a matter of urgency, although it is not registered in the country (see p 1541). Diflucan (fluconazole), used to treat cryptococcal meningitis and fungal infections associated with HIV, is protected by patent in South Africa, so generic manufacturing is not allowed and the company Pfizer is able to set its own price.



Guidelines criticised

The so-called Section 21 application follows the Treatment Action Campaign's (TAC) high-profile smuggling into the country of 3000 tablets of "generic" fluconazole (Biozole; Biolab Company, Thailand) from Thailand. TAC chairman, Zackie Achmat, said the illegal importation of the drug was part of the defiance campaign against "patent abuse and AIDS profiteering" by multinational pharmaceutical companies.

Achmat, who is living with HIV and who has refused antiretroviral treatment in protest against government's decision not to make AIDS drugs available in the public-health service, bought Biozole in Thailand for R1·78 per 200 mg tablet. The state pays Pfizer R28·57 per tablet for diflucan and the private sector pays R80·24.

The Western Cape attorney general is deciding whether to proceed with criminal charges against Achmat for illegally importing the drugs. Achmat faces a R40 000 fine or 10 years in jail.

On Oct 20, Achmat handed himself over to narcotics police and agreed to give the Biozole tablets to the Medicines Control Council (MCC) for testing to see if they are up to standard. Achmat says he has the results of biological equivalence studies done in Thailand, which, he says, show it to be as effective as Diflucan. The MCC has yet to make a decision on the registration of Biozole but a spokesman confirmed that Section 21 applications are often granted.

Meanwhile, Health Minister Manto Tshabalala-Msimang last week released the country's first published guidelines on the treatment of HIV and AIDS for health-care workers. Considered long overdue, the guidelines range from ethical considerations involving HIV/AIDS to managing occupational exposure to the virus.

The guidelines have already drawn criticism for failing to mention antiretroviral treatment for mother-to-child transmission (MTCT) of the HIV. Instead, the advice on MTCT includes giving HIV-positive pregnant women vitamin supplements, treating their sexually transmitted diseases, and use of vaginal cleansing to prevent transmission.

Morna Cornell, director of the AIDS Consortium questioned whether the government was refusing to consider us of a range of available antiretroviral therapies that could prevent up to 50% of mother-to-child infections. Tshabalala-Msimang said the South African government had at no time said it would never give antiretrovirals to pregnant women, but she "condemned the narrow view" that antiretrovirals are "the only way" to prevent MTCT.

Adele Baleta

Concern expressed over delay in French patients' bill of rights

A coalition of more than 20 patients' organisations has publicly demanded that the French government speed up its planned legislation on a bill of rights for patients. The promise of comprehensive legislation on patients' rights was made 18 months ago by then Health Secretary, Bernard Kouchner, who organised nationwide consultations on the subject.

The government had agreed to propose legislation in three domains, one on patients' rights, one on quality of health care, and one on compensation payment for damages sustained through medical interventions.

On July 5 this year, Health Secretary Dominique Gillot presented a first draft of the law to all parties involved. "The first part, especially, constitutes a major step forward", says Laure Albertini, a lobbyist with AIDES, France's national organisation for people with AIDS. "Under the proposed law patients have the right to access their own medical notes; under the present system they are completely dependent upon their doctor to provide them with the necessary information", he said.

The proposed law also requires that the treating physician inform the patient about all aspects of the planned medical intervention, including benefits, risks, and, the possible consequences of non-compliance. In case of litigation the burden of proof of whether the information was provided lies with the doctor. The second part of the proposed legislation relates to quality of care and will oblige doctors to take part in a certain amount of postgraduate training.

According to Albertini, all consulted parties agreed on these two parts. The present political problem lies within part three of the proposal, as this describes financial compensation for damages sustained through medical interventions. "The possibly enormous financial consequences may have made the government reluctant to proceed", says Albertini, "which is a pity since we now run the risk that a broadly welcomed patients' bill of rights will be abandoned".

Wim Weber

Dutch doctors denounce prescription law

The Dutch Health Minister, Els Borst, is proposing legislation requiring doctors to state diagnoses on prescriptions for drugs, in a bid to enhance transparency and accountability. Presently, this is forbidden under a law protecting a patient's privacy. The new law would give pharmacists the opportunity to check the appropriateness of the prescription. In addition, health insurers may monitor prescriptions. Both pharmacists and patients' interest groups have welcomed the initiative. But physicians' organisations have denounced the law, questioning pharmacists' ability to judge the adequacy of drug prescriptions. They have called the proposal "a serious breach of the confidentiality of the patient–doctor relationship".