NEWS IN BRIEF

Generic trade deal agreed at last

After almost two years of discussions, the World Trade Organization (WTO) has finally agreed on a breakthrough deal to allow poorer countries access to cheaper generic medicines. Current WTO rules established at the Doha meeting in November 2001 give countries facing public health crises the right to override patents on vital drugs and order generic alternatives, but only from domestic producers, because countries such as the United States feared that generics could be smuggled back into richer countries, and wanted to set limits on which drugs are seen as essential and which countries are 'poor'. But in an emotional plea, African negotiators overcame last-minute hitches in talks by stressing that 2.2 million Africans had died of AIDS and other epidemics during an eight-month deadlock in the process and 8,400 people in the final 24 hours of the talks. The new agreement allows poorer countries to import generic drugs when necessary, but lists a number of rich countries that will refrain from importing generics and less-rich countries that will import them only in circumstances of extreme urgency.

Report addresses ethical issues in pharmacogenetics

A new report from the Nuffield Council on Bioethics states that if the potential benefits of pharmacogenetics are to be realised, ethical, legal and regulatory concerns need to be addressed. The report, entitled *Pharmacogenetics: ethical issues*, makes a number of recommendations to ensure that the introduction of pharmacogenetic testing and treatments is as straightforward as possible. These include the promotion of the appropriate use of pharmacogenetic analysis in clinical trials; incentives to encourage companies to develop medicines that will provide benefit to small subpopulations of patients; the reconsideration of the definition of an orphan medicine, with reference to the implications of genetic stratification of both patients and disease; and guidances from regulatory bodies as to the circumstances in which pharmacogenetic tests will be incorporated into the licence conditions of a medicine.

FDA releases guidances for Good Manufacturing Practices

As part of a two-year strategy started a year ago, the US FDA outlined new steps in its initiative to modernize the regulation of pharmaceutical manufacturing and product quality, by issuing five new guidances (http://www.fda.gov/cder/gmp/index.htm). The FDA also outlined how it has collaborated with academia, industry and other government organizations to promote innovative approaches to drug development and regulation, and how it has taken steps to streamline and improve its internal processes.

Diabetes warning for atypical antipsychotics

The US FDA has requested that six atypical antipsychotics for schizophrenia and other psychotic disorders carry labels warning of an increased risk of hyperglycaemia and diabetes. The drugs concerned are olanzapine (Zyprexa; Eli Lilly), risperidone (Risperdal; Johnson & Johnson), Clozapine (Clozaril; Novartis), aripiprazole (Abilify; Bristol-Myers Squibb), quetiapine fumarate (Seroquel; AstraZeneca) and ziprasidone (Geodon; Pfizer). The request follows results in August from a long-awaited US study in around 20,000 schizophrenia patients that linked quetiapine fumarate, risperidone and olanzapine to an increased incidence of diabetes. The FDA's decision could erase much of the stigma from olanzapine, which has been the focus of attention in this diabetes debate because it tends to cause more weight gain among patients than other atypical antipsychotics.

Deals means smiles

Two big licensing deals have helped to boost optimism in the biotech industry, and shown how much large companies are willing to pay to fill their pipelines. Aventis said it had bought the rights to Regeneron's anti-angiogenesis compound, vascular endothelial growth factor (VEGF) Trap, in a deal that could pay Regeneron up to US $510 million. The treatment — a fusion between two distinct receptor components and the stem or constant (Fc) region of an antibody, which inhibits the formation of VEGF in tumours — is in Phase I trials for solid tumours and non-Hodgkin's lymphomas. In addition, Amgen agreed to pay up to US $612 million to the Swedish-based company Biovitrum for the rights to its small-molecule inhibitors of 11β-hydroxysteroid dehydrogenase type 1 (11βHSD1) for the treatment of metabolic diseases. The most advanced compound is BVT.3498, which is in the early stages of Phase II trials.

Wanted: radiation drugs

As part of moves to provide protection against increased threats of terrorism, the US FDA announced that it is trying to encourage production of treatments for contamination by radioactive plutonium, americium or curium, which could be found in 'dirty bombs'. The agency said it had determined from medical reports and published literature that two drugs, pentetate calcium trisodium (Ca-DTPA) and pentetate zinc trisodium (Zn-DTPA), if produced under specific conditions, could be safe and effective treatments for removing these radioactive elements. The treatments bind to the radioactive element and the complex is excreted in the urine. The FDA is calling for manufacturers to submit New Drug Applications for Ca-DTPA and Zn-DTPA products.