Bill to regulate assisted reproductive technologies on the anvil

Legislation aiming to regulate the growing number of clinics offering assisted reproductive technologies (ARTs) has been drafted and will be placed before Parliament soon. Assisted reproductive technologies have been available in India for the past 30 years, with the second test-tube baby in the world being born in Calcutta (now Kolkata) in 1978. According to WHO estimates, the number of infertile couples in India is in the range of 13–19 million. A variety of ART services are being provided both in rural and urban areas, and in the absence of a control mechanism, activists have been raising concerns about the technologies, vulnerability of women, possibility of commercial exploitation and lack of quality control.

The National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India were released in 2005, jointly by the Indian Council of Medical Research (ICMR) and the National Academy of Medical Sciences. These were to provide a framework for the accreditation, supervision and regulation of clinics offering ART services. It has been difficult to achieve compliance with and enforcement of the guidelines, and the enactment of the law will make this possible.

The Bill, called The Assisted Reproductive Technologies (Regulation) Bill, 2008, has been drafted by a 12-member committee consisting of government officials, senior clinicians and legal experts. It provides for the establishment of a national advisory board, and state boards which would meet regularly and ensure compliance with the law. This would be done through mechanisms such as clinic registrations, the formulation of policies on issues such as minimum staff requirements in the clinics, and so on. There are sections covering the duties of an ART clinic, as well as the rights and duties of patients, donors, surrogates and children. Drafts of consent forms for various procedures, as well as of contracts between the stakeholders (such as the patient and clinic), have been included.

The draft Bill is available for comment on the ICMR website (http://icmr.nic.in/art/draft_art.htm) and the authorities hope to be able to table it in Parliament soon.

Activists have criticized the bill in its current form. Commenting on behalf of SAMA, a Delhi-based NGO, N. B. Sarojini says, ‘Our advocacy efforts with various groups and organizations have led to the emergence of a strong opinion that the focus of the Draft Assisted Reproductive Technologies (Regulation) Bill and Rules, 2008 tends to promote the interest of the private sector providers of these technologies rather than regulate them … we are concerned about the Bill’s inadequacy in protecting and safeguarding the rights and health of women and children. The Bill comes across as regressive and anti-women.’

ANANT BHAN, Pune, Maharashtra

A bill to counter counterfeit drugs

On 21 October 2008, the Rajya Sabha approved the Bill seeking an amendment to the Drugs and Cosmetics Act, 1956. The Bill makes offences related to fake and counterfeit drugs non-bailable for up to 90 days, raises the punishment from a minimum of 5 years’ imprisonment to 10 years, and sets a maximum sentence of life imprisonment. The fine has been raised from Rs 10 000 to Rs 10 lakhs, or three times the value of the confiscated drugs, whichever is higher. The Bill was passed by the Lok Sabha on 23 October 2008. It now requires the assent of the President before it becomes law.

A study conducted by the International Pharmaceutical Federation for the WHO concluded that 3.1% of drugs in India were counterfeit—defined as such even if only the packing, and not just the ingredients, were fake. Most of the drugs were found to belong to the anti-infective category.

The major players in the country’s market have welcomed the penalties, but small and medium-sized manufacturers are worried by what they describe as the government’s obsolete regulatory machinery, characterized by an inadequate number of drug inspectors and obsolete testing laboratories. They have voiced concern over the possibility that the test results from these laboratories may be invalid, which could implicate even non-counterfeit drugs. Concerns have also been raised about the absence of a specific definition of a substandard drug in the Bill.

The Ministry of Health and Family Welfare has sought amendments in the new definition of counterfeit drugs, as proposed by the International Medical Products Anti-Counterfeiting Taskforce, a WHO initiative, in response to concerns that the definition may prevent access to legitimate off-patent or generic drugs. The task force defines a drug as counterfeit ‘when there is a false representation in relation to its identity, history or source. This applies to the product, its container, packaging or other labelling information.’ Counterfeit copies, which it says cover both branded and generic products, ‘may include products with correct ingredients/components, with wrong ingredients/components, without active ingredients, with incorrect amounts of active ingredients, or with fake packaging’.

PRABHA DESIKAN, Bhopal, Madhya Pradesh

Codeine in breast milk poses risk to babies—Canada issues health advisory

Health Canada issued an advisory on 8 October 2008 on the rare but serious health risk to breastfed babies posed by the use of codeine in nursing mothers. Codeine is found in prescription and non-prescription products used to relieve pain or to treat cough. This advisory was issued after a Health Canada review of a case of fatal opioid poisoning in a breastfed neonate, whose codeine-prescribed mother was a CYP2D6 ultra-rapid metabolizer. The phenotypic consequence of this genotype is enhanced formation of morphine from codeine.

Health Canada is currently working with drug manufacturers so that the labelling for codeine-containing prescription products is revised to include information that better identifies the risk to breastfed babies whose mothers are ultra-rapid metabolizers of codeine. The guidelines for the labelling of non-prescription products containing codeine are also being revised to provide more information about this risk.
In order to minimize the exposure of breastfed babies to the risk of morphine, Health Canada recommends that nursing mothers should: (i) consult a physician before taking any codeine-containing products; (ii) read the ingredient list of all over-the-counter medications, especially cough or pain medications, to see if they contain codeine; (iii) use the lowest effective dose for the shortest period of time if treatment with codeine is necessary; (iv) monitor the child carefully if the mother experiences extreme sleepiness, confusion or shallow breathing; and (v) contact a doctor immediately if the breastfed baby is sleepier than usual or has trouble breastfeeding or breathing.

MEENAKSHI KASHYAP, Canada

Virus hunters awarded Nobel Prize...and counterfeit drug discovery wins IgNobel!

The Nobel Prize for medicine or physiology for 2008 has been awarded to virus hunters Harald zur Hausen (German Cancer Research Centre, Heidelberg, Germany), Françoise Barré-Sinoussi (Pasteur Institute, Paris, France) and Luc Montaigner (World Foundation for AIDS Research and Prevention, Paris). Zur Hausen will get one-half of the 10 million Swedish Kroner (US$ 1.4 million), while the French researchers will share the other half of the prize money.

Zur Hausen fought existing dogma in the 1970s and 1980s to hypothesize, and then prove, that HPV (human papillomavirus) was a carcinogenic virus responsible for causing cervical carcinoma. His discoveries improved our understanding of the disease and helped shape screening programmes for the detection of cervical cancer. In addition, the development of Gardasil, the vaccine against cervical cancer, is a direct result of his research work.

Barré (as she was then) and Montagnier had detected in 1983 that the puzzling new disease that seemed to affect homosexuals and haemophiliacs was caused by a lentivirus which contained reverse transcriptase and was a retrovirus. They detected this in a culture of the affected lymph nodes of a patient who had what we now recognize as AIDS. They showed that the retrovirus infected and killed T lymphocytes, thus leading to decreased immunity. The group named the virus LAV (lymphadenopathy-associated virus), a name later changed to HIV by the WHO.

The Nobel committee ignored the contributions of Robert Gallo. There had been an intense controversy in the 1980s about who should get priority with regard to discovery of the virus. It is now generally accepted that the French team discovered the virus, whereas Gallo made the causal connection between the virus and the disease. However, according to the rules governing the prize, only three people can share the prize; perhaps this contributed to Gallo being left out.

Ravi V. (Professor of Neurovirology, NIMHANS, Bangalore) says: ‘The ... very significant discoveries ... showed that viruses can cause diseases both by immortalizing cells or killing cells. It’s interesting that Zur Hausen’s work showed that HPV can immortalize cells and cause cervical cancer. In contrast, Barré–Sinoussi and Montagnier discovered a virus (HIV) that kills cells to cause disease (AIDS). These two great discoveries seem to say that there are two sides to everything in science as well.’

Meanwhile, the 2008 IgNobel prize was awarded to Dan Ariely (Duke University, USA), Rebecca Waber (MIT, USA), Baba Shiv (Stanford University, USA) and Ziv Carmon (INSEAD, Singapore) for their discovery (JAMA 2008;299:1016–17) that more expensive counterfeit drugs were more effective than low-priced counterfeit medicines!

SANJAY A. PAI, Bangalore, Karnataka

Phase 1 drug trials to be initiated in India

The recent announcement by the Drugs Controller General of India (DCGI) that India will soon permit phase 1 trials of drugs being developed abroad has been met with dismay by those familiar with the drug trial industry in India. Phase 1 trials for safety are the first to be conducted in human beings and the complications cannot be predicted. These trials are almost always conducted on healthy people, who opt for them because they receive large payments.

The DCGI’s announcement is the latest in a number of steps that the government has taken to promote India as a site for the trial of international drugs, just as it has done for medical tourism. Clinical trials in India cost less than half of what they do in the West, and India has the medical infrastructure, the trained human power and a large number of potential participants.

Earlier, a ‘phase lag’ requirement prevented trials from being conducted at the same phase in India as they were abroad. However, in January 2005, amendments in the Drugs and Cosmetics Act enabled concurrent phase trials of foreign drugs to be conducted in India. Yet, the amended Act did not permit phase 1 trials under normal circumstances. However, in the past few months, the DCGI has held consultations with various stakeholders, including non-governmental organizations (NGOs) and lawyers, to gauge the possibility of introducing phase 1 trials. A bill to enable this has reportedly been drafted by the Central Drugs Standard Control Organization. The DCGI has announced that new staff would be hired and a series of other infrastructure and training measures taken to prepare for the situation.

Critics of this move have pointed out that the infrastructure for monitoring and ethics review is grossly inadequate for the number of ongoing clinical trials. The potential participants are economically vulnerable and may not be in a position to give informed consent. It is feared that India will become a destination for foreign companies eager to test new drugs by exploiting this vulnerability, exposing the participants to serious risks, something that might not be possible in their own countries.