India introduces regulations for making traditional medicines

Rohit Sharma *Mumbai*

The Indian government has drawn up regulations for good manufacturing practice for traditional Indian systems of medicine such as ayurveda, sidha, and unani, so that the industry can compete in international markets.

The lack of regulation was "a serious shortcoming which has now been overcome," said Shailaja Chandra, secretary of the Indian government's department of Indian systems of medicine. Her department had identified drug standardisation and quality control as the most important changes affecting the future of the Indian systems of medicines.

The new manufacturing reg-

ulations are calculated to improve the quality and standards of medicines being manufactured in some 9000 licensed pharmacies. The manufacturing rules prescribe essential infrastructure, staffing, and quality control requirements such as standard manufacturing processes and the use of authentic raw materials free from contamination.

A transition period of two years has been given to existing registered units to comply with the new rules by improving infrastructure and quality. Registered practitioners of the Indian systems of medicine, called vaidyas, hakims, and sidhas, and teaching institutions have been

exempted from the regulations.

The Indian government is also planning to install and strengthen laboratories for testing traditional medicines, says Ms Chandra. She believes that this step will promote traditional medicines in national and international markets.

Nationally, state dispensaries will be able to stock certified medicines, and the demand will grow. "Anybody abroad who buys our medicines, whether as food supplements or as medicines, would like to be assured that we as a country have certified the safety of these products," says Ms Chandra.

If the medicines have been tested in government approved laboratories, anybody who buys medicines could look for the good manufacturing practice certificate and be satisfied that some element of checking at a government level has taken place, she says. □

Germany reorganises its transplant services

Annette Tuffs *Heidelberg*

Germany is reorganising its transplant services to separate the organisations that obtain organs from those that distribute and those that transplant them. The new system is designed to increase transparency, and therefore the trust of the medical community and the German population, in regard to organ donation.

The services' structures were laid down in the transplant law of 1997, but it has taken more than two years to agree on the detailed arrangements which come into force this week.

Since 1984, transplant coordinators belonging to the Deutsche Stiftung Organtransplantation (the German foundation for organ transplantation) have been based in transplant centres and have been active in both procuring and distributing organs. In future, the organisation will concentrate mainly on procuring organs.

It is being given a contract as the independent nationwide organ procurement agency. It has central headquarters near Frankfurt and seven offices responsible for the regional organisation of organ procurement in close cooperation with donor hospitals and transplant centres.

Under the new arrangements, the role of Germany's 50 transplant centres, defined by the law, will be to concentrate on waiting lists, transplantation, and provision of aftercare.

Two agreements that come into force this weekend will put these changes into effect. The agreements have been drawn up between the Deutsche Stiftung Organtransplantation and the Dutch Eurotransplant foundation on one side and the German medical association, the German hospital association, and the health insurers on the other side.

The German transplant law obliges hospitals to report potential donors, but it is likely that many are still not reported. □

In vitro fertilisation is preferable to fertility drugs

Scott Gottlieb *New York*

Authors of a new study into high order multiple pregnancies have recommended that doctors treating infertility due to failure to ovulate in future rely exclusively on in vitro fertilisation (*N Engl J Med* 2000;343:2-7).

They argue that because inducing ovulation to treat infertility carries a considerable risk of producing unwanted multiple births, and giving lower doses of the ovary stimulating drugs decreases the chance of producing a baby, the answer lies in in vitro fertilisation.

The researchers examined ovulation induction, which involves giving women gonadotrophins to induce the release of eggs, in the treatment of 1494 women at the Center for Human Reproduction in Chicago, Illinois. The treatments resulted in 314 single babies, 88 sets of twins, 22 triplets, 10 quadruplets, five quintuplets, and two sextuplets.

Doctors conducted the study with an eye on controlling the number of follicles stimulated to

Mandy Allwood, whose infertility treatment led to a multiple birth, follows the coffins of her babies. All eight babies died in 1994

release eggs and on the serum concentration of oestradiol. They found that the more follicles that are stimulated and the higher the oestradiol concentration, the more likely it was that women would become pregnant with multiple fetuses. They found that the risk of high order pregnancy was significantly increased in women with a peak serum oestradiol concentration of 1385 pg/ml or greater.

Doctors typically attempt to reduce the chances of so called high order multiple gestation—three or more fetuses—by viewing the woman's ovaries with ultrasound to search for large

follicles and measuring serum oestradiol, which is released by the eggs as they are maturing. If it looks as if too many eggs are maturing, the woman is advised to skip the next injection and wait for another cycle. In the current study, researchers concluded that ultrasound scans were essentially worthless.

In the study, cutting back on gonadotrophins reduced the chances of multiple births but was also associated with a lower success rate.

The researchers instead recommended that doctors rely exclusively on in vitro fertilisation. □