

4. Name, class, quantity of drug(s)

Note 1: Must be signed or countersigned by head of medical institution or firm conducting actual testing.

Note 2: For convenience, this application is often submitted attached to a new drug application. See page 19 above.

Fee schedule

1. All drugs not listed below Rs. 1,000 (US\$20)
2. Drugs listed in Schedule X Rs. 1,000 (US\$20)
3. Drugs imported in small quantities for personal use --
4. Drugs imported in small quantities by a public hospital Rs. 100 (US\$2)
5. Drugs for examination, testing, or analysis Rs. 100 (US\$2)

Multiple drugs can be registered with the same import license application. The fee for the first drug in the application is Rs. 1,000, and each additional drug costs Rs. 100. For later import licenses, if the drug is from the same manufacturing site as before, the first drug also costs Rs. 100. However, drugs in Schedule X cannot be mixed with other drugs on the same import license application.

E. Adverse Event Reporting

Legally, any firm applying for new drug registration undertakes to provide the DCGI with postmarketing safety reports. This reporting should be in the form of a Periodic Safety Update Report (PSUR). The PSUR is submitted twice a year for the first two years of marketing and one a year during the third and fourth years. It should include all new data received from postmarket surveillance, any regulatory changes in other countries, and a recommendation on any necessary changes to the product. If any new studies are commissioned, these should also be concluded.

Besides the PSUR, all serious unexpected adverse events in India known to the licenseholder should be reported within 15 days.

However, from the point of view of establishing a modern system of monitoring drug safety, it is publicly recognized as inadequate to collect data only from recent new drugs. In 2004, India formed a national adverse event reporting body, the National Pharmacovigilance Center, which is housed in the All India Institute for Medical Sciences. 33 regional and local reporting bodies have also been established under it. These centers take in safety reports from hospitals and medical professionals. A 16-member National Pharmacovigilance Advisory Committee periodically evaluates the data and may recommend regulatory responses.

India is still at an early stage in adverse event reporting. At this stage, an important goal of these pharmacovigilance bodies is simply to encourage doctors and patients to develop