Clinical Trials (Licence and Fees) Regulations 2011

GN No. 168 of 2011

THE CLINICAL TRIALS ACT 2011

Regulations made by the Minister under section 35 of the Clinical Trials Act 2011

1. These regulations may be cited as the **Clinical Trials (Licence and Fees) Regulations 2011**.

2. In these regulations -

"Act" means the Clinical Trials Act 2011;

"licensee" means the holder of a trial licence;

"Phase I", "Phase II", "Phase III" or "Phase IV", in relation to a clinical trial, has the same meaning as in the International Conference Harmonisation document "General Considerations for Clinical Trials" (ICH E8), approved by the European Medicines Agency Committee for Proprietary Medicinal Products (now known as the European Medicines Agency Committee for Medicinal Products for Human Use), in September 1997 and issued with reference CPMP/ICH/291/95.

3. For the purposes of section 12(2) and 15 of the Act, the application fee shall be the application fee specified in the Schedule.

4. For the purposes of section 13(3) of the Act, the licence fee shall be the licence fee specified in the Schedule.

5. (1) An application for the amendment of a trial licence under section 15 of the Act shall be accompanied by such information as the Council may require to process the application.

(2) For the purposes of section 15(4) of the Act, the fee shall be the fee for the issue of an amended trial licence specified in the Schedule.

6. (1) Every licensee shall pay the annual service fee specified in the Schedule to the Council on the date of issue of the trial licence and thereafter not later than 15 days before the anniversary date of the licence.

(2) The annual service fee referred to in paragraph (1) shall be paid on the issue of the trial licence, notwithstanding the fact that the duration of the clinical trial is for a period of less than 12 months from the issue of the trial licence.

(3) Where the licensee fails to pay the annual service fee within the time specified in paragraph (1), he shall, in addition to the amount due, pay a surcharge of 50 per cent.

Made by the Minister on 23 September 2011.

SCHEDULE

[Regulations 3, 4, 5 and 6]

Fees

	(Rs)
Application fee	10,000
Fee payable for the issue of an amended trial licence	20,000
Licence fee –	
Clinical trial (Phase I) licence fee	100,000
Clinical trial (Phase II with a known product) licence fee	150,000
Clinical trial (Phase II with an unknown product) licence fee	200,000
Clinical trial (Phase III with a known product) licence fee	150,000
Clinical trial (Phase III with an unknown product) licence fee	200,000
Clinical trial (Phase IV) licence fee	20,000
Annual service fee	20,000