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AIDS HELPLINE: 0800-0123-22 Prevention is the cure

- (iii) Evaluation of request to amend Professional Information in respect of which clinical data relating to safety and efficacy must be evaluated:
R3 300;
- (iv) Annually, in respect of the retention of the registration of a medicine, the registration of which has been approved by the Authority in terms of Section 15(3): R1 200: Provided that this provision shall come into effect one year after the date on which the registration of the said medicine was approved by the Authority in terms of Section 15(3): Provided further that the said fees payable during a particular calendar year shall be payable on or before the last working day of June that year, failing which the registration may be cancelled in terms of Section 16(4).

5 Use of unregistered medicines

- (a) In respect of the submission of an application for the **authorisation of the use of an unregistered medicine**:
 - (i) Clinical trial application (Companies): R9 900;
 - (ii) Clinical trial application (Institutions): R4 950;
 - (iii) Any other clinical trial application: R2 420;
 - (iv) Any other application except for the purpose of performing a clinical trial: R330.
- (b) In respect of **clinical trials amendments**:
 - (i) Fees in respect of an application for technical amendments:
R 2 310 per amendment;
 - (ii) Fees in respect of an application for administrative amendment:
R715 per amendment.



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In respect of licences

- (a) An application for a new licence in terms of Section 22C (1)(b) of the Act:
 - (i) Manufacture: R23 980;
 - (ii) Distribute: R14 300 [Holder of certificate of registration (HCR)];
 -  (iii) Wholesale: R14 300;
 - (iv) Import: R14 300 (Holder of certificate of registration);
 - (v) Export: R14 300 (Holder of certificate of registration).

- (b) An application for the renewal of a licence in terms of Section 22D of the Act, the licensing of which has been approved by the Authority in terms of Section 22C(1)(b) of the Act:
- (i) Manufacture: R20 900
 - (ii) Distribute: R11 990 (Holder of certificate of registration);
 - (iii) Wholesale: R11 990;
 - (iv) Import: R8 800 (Holder of certificate of registration);
 - (v) Export: R8 800 (Holder of certificate of registration).
- (c) Annually, in respect of the retention of a licence issued in terms of Section 22C(1)(b) of the Act: R4 000, and this fee is payable on or before the last working day of June that year, failing which registration may be cancelled;
- * (d) Licensing for any manufacturer, distributor, wholesale, import or export, the license of which has been approved by the Authority in terms of Section 22(1)(b) of the Act: R3 190;
- (e) Application for the amendment to an existing licence to manufacture, distribute, wholesale, import or export: R5 000.

7 Inspections to assess the quality, safety and efficacy of medicines or scheduled substances

- (a) Local manufacturing site: R715/h;
- (b) International manufacturing sites (excluding Southern Africa Development Community countries): R4 400/h
- (c) International manufacturing sites in Southern Africa Development Community countries: R2 000/h;
- * (d) Wholesale sites: R6 050;
- (e) Distributor sites, Local: R6 050;
- (f) Clinical trial site; Local: R715/h;
- (g) International clinical trial site (excluding Southern Africa Development Community countries): R4 400/h;
- (h) International clinical trial sites in Southern Africa Development Community countries: R2 000/h;
- (i) Local pharmacovigilance inspection: R715/h
- (j) International pharmacovigilance inspection (excluding Southern Africa Development Community countries): R4 400/h
- (k) International pharmacovigilance inspection in Southern Africa Development