# FEES FOR MARKETING AUTHORISATION

**FEES PAYABLE IRRESPECTIVE OF AREA IN ZAMBIAN KWACHA**

**1. Pharmaceutical License**

| No | Description of Fees | Fee units | Amount 30Ngwee/feeunit |
|---|---|---|---|
| **(a) Complete Manufacture** | | | |
| (i) | Application for grant of pharmaceutical license | 64,533 | 19,360.00 |
| (ii) | Re-inspection of premises for pharmaceutical license – manufacture of medicine | 47,867 | 14,360.00 |
| (iii) | Re-locating to new premises | 64,533 | 19,360.00 |
| (iv). | Inspection of Additional production line | 25,400 | 7,620.00 |
| (v) | Inspection of Additional production block | 47,867 | 14,360.00 |
| (vi) | Renewal for pharmaceutical license – manufacture | 47,867 | 14,360.00 |
| **(b) Primary Repackage of Medicine** | | | |
| (i) | Application for grant of pharmaceutical license | 35,400 | 10,620.00 |
| (ii) | Re-inspection of premises for pharmaceutical license – repackage of medicine | 24,400 | 7,320.00 |
| (iii) | Re-locating to new premises | 35,400 | 10,620.00 |
| (iv). | Inspection of Additional /Modification of production line | 12,200 | 3,660.00 |
| (v) | Inspection of Additional /Modification of production block | 25,400 | 7,620.00 |
| (vi) | Renewal for pharmaceutical license – repackage of medicine | 25,400 | 7,620.00 |
| **(c) Secondary Repackage of Medicine** | | | |
| (i) | Application for grant of pharmaceutical license | 17,700 | 5,310.00 |
| (ii) | Re-inspection of premises for pharmaceutical license – repackage of medicine | 12,200 | 3,660.00 |
| (iii) | Inspection of Additional /Modification of production line | 7,000 | 2,100.00 |
| (iv). | Inspection of Additional /Modification of production block | 12,200 | 3,660.00 |
| (v) | Renewal for pharmaceutical license – repackage of medicine | 12,200 | 3,660.00 |
| **(d) Local Manufacture of Natural Remedies** | | | |
| (i) | Application for grant of pharmaceutical license | 35,400 | 10,620.00 |
| (ii) | Re-inspection of premises for pharmaceutical license – repackage of medicine | 24,400 | 7,320.00 |
| (iii) | Inspection of Additional /Modification of production line | 25,400 | 7,620.00 |
| (iv). | Inspection of Additional /Modification of production block | 25,400 | 7,620.00 |
| (v) | Renewal for pharmaceutical license – repackage of medicine | 25,400 | 7,620.00 |
| (vi) | Re-location or export permit | 25,400 | 7,620.00 |

**2. Marketing Authorisation of Locally Manufactured or packaged medicines or allied substances)**

| | | | |
|---|---|---|---|
| **a** | **Locally Manufactured Medicines** | | |
| (i) | Human Medicines | 16,667 | 5, 000.00 |
| (ii) | Veterinary Medicines | 16,667 | 5, 000.00 |
| | | | |
| **b** | **Locally Packaged Medicines** | | |
| (i) | Human Medicines | 36,667 | 13,328.00 |
| (ii) | Veterinary Medicines | 25,867 | 7,760.00 |
| **c** | Allied Substances | 5,000 | 1,500.00 |
| **d** | Evaluating Additional Information for an Application of a Locally Manufactured Product supplied with Inadequate Technical Information (quality safety or efficacy) | 5,667 | 1,700.00 |
| **e** | Annual Retention Fees for Locally Manufactured Medicines and Allied Substances | | |
| (i) | Human Medicines | 8,333 | 2,500.00 |

| | | | |
|---|---|---|---|
| (ii) | Veterinary Medicines | 8,333 | 2,500.00 |
| (iii) | Allied Substances | 3,333 | 1,000.00 |
| **f** | Renewal of Marketing Authorisation for locally manufactured Medicines or Allied Substances | | |
| (i) | Human Medicines | 11,667 | 3,500.00 |
| (ii) | Veterinary Medicines | 10,000 | 3,000.00 |
| (iii) | Allied Substances | 4,000 | 1,200.00 |
| **g** | Amendment Fees for Medicines and Allied Locally Manufactured Products | | |
| (i) | Minor amendment | 1,333 | 400.00 |
| (ii) | Major amendment | 6,500 | 1,950.00 |

**3. Advertising and Promotion of Medicines and Allied Substances**

| | | | |
|---|---|---|---|
| a | Advertising medicines to the general public | 16,667 | 5,000.00 |
| b | Promotional medicines to the health care professional fees | 3,333 | 1,000.00 |
| c | Exhibition of medicines at a public event fees | 6,667 | 2,000.00 |

**4. Clinical Trials Involving a Locally Manufactured Investigational Product**

| | | | |
|---|---|---|---|
| a | Clinical Trial Certificate involving Investigational Products without Marketing Authorisation | | |
| (i) | Human | 48,333 | 14,500.00 |
| (ii) | Veterinary | 34,333 | 10,300.00 |
| b | Clinical Trial Certificate involving Investigational Products with Marketing Authorisation | | |
| (i) | Human | 46,667 | 14,000.00 |
| (ii) | Veterinary | 32,667 | 9,800.00 |

**5. Good Clinical Practice Inspection for Local Sites**

| | | | |
|---|---|---|---|
| (i) | GCP inspection local sites | 50,000 | 15,000.00 |

**6. Other fees**

| | | | |
|---|---|---|---|
| a | Preclearance Fees for Quality Assurance (QA) of imports for commercial consignments, Government ministries departments, Programs projects and similar institutions | | 1.5% of FOB invoice value |
| b | Preclearance Fees for Quality Assurance (QA) of imports for unregistered medicines and Allied substance for commercial consignments, Government Ministries Departments, Programs projects and Similar institutions | | 5% of FOB invoice value |
| c | Preclearance Fees for Quality Assurance (QA) of imports for Donations | | 1% of FOB invoice value |
| d | Preclearance Fees for Quality Assurance (QA) of imports for Active Pharmaceutical Ingredients (API), Bulk finished products and intermediates | | 1% of FOB invoice value |
| e | Amendment to licences, certificates and permits | 1,500 | 450.00 |
| f | Loss of licences, certificates and permits | 1,500 | 450.00 |
| g | Transfer of licences, certificates and permits | 1,500 | 450.00 |
| h | Issue of Certificate of a Pharmaceutical Product(CPP) | 333 | 100.00 |
| i | Application for import of Narcotic drugs and psychotropic substances | 333 | 100.00 |
| j | Inspection of premises for issue of a GMP certificate (local Manufacture) | 20,000 | 6,000.00 |
| k | Inspection and supervision for disposal of expired products | 3,333 | 1,000.00 |
| l | Fast track fees | | Double the applicable MA applicable fee |
| m | Restoration of Marketing Authorisation Medicines | | |
| (i) | Medicines | 20,000 | 6,000.00 |
| (ii) | Allied Substances | 4,000 | 1,200.00 |
| n | Inspection of Register | 167 | 50.00 |
| o | Late submission of application for renewal of marketing authorisation in respect of locally manufactured medicines and allied substances | 33 per day application is late | 10.00 |

**FEES PAYABLE IN US DOLLARS**

**1. Application for Marketing Authorisation of Human Medicines Imported as Finished Products**

| | Description of Fees | Fee units | Amount 30Ngwee/feeunit |
|---|---|---|---|
| a | Generics | | US$ 2,000.00 |
| b | New Chemical Entities | | US$ 2,800.00 |
| c | Biologicals | | US$ 2,800.00 |
| d | Abridged Applications | | US$ 1,700.00 |

**2. Application for Marketing Authorisation of Veterinary Medicines Imported as Finished Products**

| | | | |
|---|---|---|---|
| a | Generics | | US$ 1,750.00 |
| b | New Chemical Entities | | US$ 2,100.00 |
| c | Biologicals | | US$ 2,100.00 |
| d | Abridged applications | | US$ 1,550.00 |

**3. Application for Marketing Authorisation Allied Substances Imported as Finished Products**

| | | | |
|---|---|---|---|
| a | Allied Substances | | US$ 500.00 |

**4. Evaluating Additional Information for an Application Imported as Finished Products**

| | | | |
|---|---|---|---|
| a | Inadequate Technical Information (quality safety or efficacy | | US$ 400.00 |

**5. Annual Retention Fees for Medicines or Allied Substances Imported as Finished Products**

| | | | |
|---|---|---|---|
| a | Human Medicines Generics | | US$ 800.00 |
| b | Human Medicines NCEs | | US$ 800.00 |
| c | Biologicals | | US$ 800.00 |
| d | Veterinary Medicines | | US$ 700.00 |
| e | Allied Substances | | US$ 200.00 |

**6. Renewal of Marketing Authorisation for Medicines or Allied Substances Imported as Finished Products**

| | | | |
|---|---|---|---|
| a | Human Medicines Generics | | US$ 1,200.00 |
| b | Human Medicines NCEs | | US$ 1,200.00 |
| c | Biologicals | | US$ 1,200.00 |
| d | Veterinary Medicines | | US$ 1,000.00 |
| e | Allied Substances | | US$ 350.00 |
| f | Late submission of application for renewal of marketing Authorisation in respect of imported medicines or allied substances ( Fee for each day) | | 5.00 |

**7. Amendment Fees for Medicines and Allied Substances Imported as Finished Products**

| | | | |
|---|---|---|---|
| a | Minor amendment | | US$ 100.00 |
| b | Major amendment | | US$ 500.00 |

**8. Good Manufacturing Practices Inspection for Foreign-Based Manufacturers in Support of Applications for Marketing**

| | | | |
|---|---|---|---|
| a | Full site: Southern Africa | | US$ 3,500.00 |
| b | Full site: Rest of Africa | | US$ 5,000.00 |
| c | Full site: Far East/Asia | | US$ 6,500.00 |

| | | | |
|---|---|---|---|
| d | Full site: Europe, America and Australia | | US$ 7,500.00 |
| e | Additional production line | | US$ 1,500.00 |
| f | Fees for GMP documents evaluation (desk Audits) per manufacturing site | | US$ 3,500.00 |

**9. Good Manufacturing Practices Inspection for Foreign-Based Manufacturers in Support of Applications for Marketing**

| | | | |
|---|---|---|---|
| a | Each additional site such as warehousing for raw materials, final packaging, quality control and final release | | US$ 1,500.00 |

**10. Clinical Trials Involving Imported Investigational Products**

| | | | |
|---|---|---|---|
| a | Human Clinical Trial Certificate involving Investigational Products without Marketing Authorisation | | US$ 3,000.00 |
| b | Human Clinical Trial Certificate involving Investigational Products with Marketing Authorisation | | US$ 2,500.00 |
| c | Veterinary Clinical Trial Certificate involving Investigational Products without Marketing Authorisation | | US$ 2,100.00 |
| d | Veterinary Clinical Trial Certificate involving Investigational Products with Marketing Authorisation | | US$ 2,000.00 |
| e | Amendment of clinical trial certificate involving an imported investigational product | | |
| (i) | Minor amendment | | 100.00 |
| (ii) | Major amendment | | 500.00 |

**11. Good Clinical Practice Inspection Foreign based Bioequivalence Sites (Part VI, Section 52)**

| | | | |
|---|---|---|---|
| a | Full site: Southern Africa | | US$ 3,500.00 |
| b | Full site: Rest of Africa | | US$ 5,000.00 |
| c | Full site: Far East/Asia | | US$ 6,500.00 |
| d | Full site: Europe, America and Australia | | US$ 7,500.00 |

**THE AMOUNTS DUE MUST BE REMMITTED TO THE FOLLOWING ACCOUNT:**

ZAMBIA MEDICINES REGULATORY AUTHORIY
STANDARD CHARTERED, MAIN BRANCH, CAIRO ROAD, LUSAKA
USD ACCOUNT:8700211468100

STANDARD CHARTERED, NORTHEND BRANCH, CAIRO ROAD, LUSAKA
ZMW ACCOUNT:0100122033800

Swift code: SCBLZMLX

As you make payments please ensure to pay all bank charges as well. Please notify the Authority of the Bank transaction and list of retained products on the following email
pharmacy@zamra.co.zm