IDENTIFICATION AND PRE-QUALIFICATION OF SUPPLIERS OF PHARMACEUTICAL PRODUCTS IN ANGOLA

Luanda, August 2012
SUMMARY

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1 INTRODUCTION

This questionnaire is intended to identify and qualify as supplier of medication and clinical devices (manufacturers/laboratories, their representatives and importers), as well as to collect accurate, complete information regarding the quality and reliability of the service being or yet to be provided.

This questionnaire refers to the WHO's technical specifications regarding pharmaceutical preparations, as outlined under "Technical Reports" No. 823 and 863.

This questionnaire is the key element of an administrative and technical dossier for assessing pharmaceutical suppliers in Angola.

The assessment will give way to an Accreditation Certificate issued by the National Directorate for Medication and Equipment (NDME), in terms of accepting the supplier, with the ultimate purpose of obtaining a licence.

The Certificate will be valid for 3 years as of the approval date, should the conditions assessed as part of this inquiry remain the same.

In the event of any change to or modification of the current conditions, as assessed as part of the current inquiry, the supplier shall inform the NDME in order to update the dossier.

The questionnaire is presented according to the following plan:

**General information**

Geared to economic Agents operating in Angola, be they Manufacturers bearers of AIM, Bearers of AIM, Representatives or Importers of pharmaceutical products.

**Pharmaceutical information**

Broken down into three parts, concerning each of the specific activities of the economic Agents:

a) The first part concerns medication Manufacturers, bearers of AIM and their representatives;

b) The second part pertains to Manufacturers of clinical devices, medical material and diagnostic equipment;

c) The third part concerns Importers of pharmaceutical products (non-manufacturing suppliers: importers and central procurement bodies).

Suppliers must all commit to the statements they have made, under penalty of their application being rejected. The inquiry must be signed by the legal representatives of the aforementioned suppliers.

In this capacity, suppliers must complete the Pharmaceutical Information pertaining to the "Manufacturer", according to the manufactured products.

Manufacturers who market not only their own products but also pharmaceutical products that are not manufactured by them are, for this supplementary range, considered Representatives/importers. To this end, they must also complete the part pertaining to importers and comply with the provisions regarding such bodies.

Suppliers working as "importers of pharmaceutical products" shall complete the questionnaire regarding their own operations, to which they shall add, for each manufacturer, a "Manufacturer
Suppliers who label the products they market only under their name shall, from the standpoint of their pharmaceutical responsibility, be regarded as manufacturers. To this end, they are to complete the "Pharmaceutical Information" of the part pertaining to the "Manufacturer."

This questionnaire must be completed in its entirety to be accepted. The information provided will be given confidential treatment.

Certified copies of the originals must be enclosed with the questionnaire, along with the translations to Portuguese, recognized by the consular services of Angola, regarding the following essential documents issued in the Country of origin by the competent Authorities:

1 - Manufacturing Authorisation indicating the sites of production, storage and batch release;
2 - Certificate showing proof of Ownership of the Permission to manufacture the medication in a third-party country;
3 - Statement regarding the status of the exporter country's Authorization to Market;
4 - Authorization to manufacture for export;
5 - Pre-qualification Certificate in cases involving products used for major endemics (HIV/AIDS, tuberculosis, malaria, …) and for products used in reproductive health and vaccines.
6 - Inspection Certificate for the last two years;
7 - A scientific opinion on the assessment of medication intended solely for export, as issued by the Pharmaceutical Regulatory Authority;
8 - Authorization to Export.

The Service reserves the right to request any additional information or document deemed pertinent for assessing the questionnaire.

The documentation shall be organized according to the structure disclosed in this questionnaire and submitted:

a) In hard copy, in a folder labelled on its spine with the Organization's name and address;
b) In digital form (CD R), also identified.

Every page of the hard-copy dossier must be numbered, initialed and must bear the stamp used by the services of the inquired organization.

The questionnaire will be examined, taking into account the set of answers given, thereby leading to an initial assessment.

The absence of documents deemed essential, or any unsatisfactory answer to certain questions regarded as vital shall result in the rejection of the dossier after hearing the interested party.
GENERAL INFORMATION

1.1 Supplier Identification

Name: ………………………………………………………………………………………………………….
Complete address: …………………………………………………………………………………………….
………………………………………………………………………………………………………………….
Tel:        : ………………………………………………………………………………………………………..
Fax.       : ………………………………………………………………………………………………………..
E-mail : …………………………………………………………………………………………………………….
Tax Identification No.: ……………………………………………………………………………………...
Company Registered under No. : ……………………………………………………………………………..
(enclose a certified copy of the company Deed and of the Company Register)
Main activity as outlined in the Company Registry: ………………………………………………………….
…………………………………………………………………………………………………………………..
………………... ………………………………………………………………………………………………..

1.2 Areas of Activity and Authorization to operate in the Pharmaceutical Sector

With an x or in bold print, indicate the cases that apply
☐ Manufacturer /  ☐ Importer
☐ Bearer of AIM  ☐ Representative
☐ Of pharmaceutical specialties
☐ Of generic medication
☐ Of other medical items
☐ Of pharmaceutical specialties
☐ Of generic medication
☐ Of other medical items

Attach a list………..…………………. ……………………..……………………………..
………………………………………………                ……………………..……………………………..
…………………..........................................                ………………………..…………………..……….
../ ..…                                                                            ..…/…..

For the domestic market (exporting country)  ☐ For export

Activity Authorization No.: …………..                 Activity Authorization No.: …………..

Enclose a copy of the authorizations for the practice of your activities as a Manufacturer and/or an importer of pharmaceutical products issued by the National Regulatory Authority and that of the Country of origin.
1.3 Inspection by the Competent National Authorities

Has your company been the subject to inspection in these last three years by the national authority?

☐ Yes  ☐ No

If so, enclose a copy of the report regarding the inspection conducted in the last two years.

1.4 Inspection by International Organizations

Has your company been the subject to inspection in these last three years by international authorities or bodies?

☐ Yes  ☐ No

If so, enclose a copy of the report regarding the last inspection.

1.5 Staff List

NB: inside and/or outside the country

Total staff: .................................................................

Administrative staff: .................................................................

Technical staff: .................................................................

Number of pharmacists: .................................................................

Is the staff registered with the National Social Security Institute?

☐ Yes  ☐ No

Name of the people holding a key position, state their qualifications and tasks.

Director:

.................................................................

Other people qualified to represent or take on responsibility for the company:

.................................................................

Pharmacist in charge:

.................................................................

Assistant pharmacists and their duties.

.................................................................

Name of person in charge of exports:

.................................................................

Tel.: .................................................................

E-mail: .................................................................
### 1.6 Business Relations

State the name of at least 5 current noteworthy clients in the domestic market (state or private organizations, NGOs…)

<table>
<thead>
<tr>
<th>Client name</th>
<th>Client type</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-</td>
<td></td>
</tr>
<tr>
<td>2-</td>
<td></td>
</tr>
<tr>
<td>3-</td>
<td></td>
</tr>
<tr>
<td>4-</td>
<td></td>
</tr>
<tr>
<td>5-</td>
<td></td>
</tr>
<tr>
<td>…/…</td>
<td></td>
</tr>
</tbody>
</table>

### 1.7 Status of Inventories

a. Do you keep a permanent inventory of all of your products? □ Yes □ No

b. Do you keep a permanent inventory of part of your products? □ Yes □ No

If so, what is the percentage of the permanent inventory:

<table>
<thead>
<tr>
<th>Inventory</th>
<th>% Surface</th>
<th>% Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>All products</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Part of the products</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 1.8 Company Status and Connections

a. If the company is a subsidiary, state the name and location of the parent company:

..........................................................................................................................................................
..........................................................................................................................................................
..........................................................................................................................................................

b. If the company owns subsidiaries, draft a table stating the names and locations and attach it to the questionnaire.

<table>
<thead>
<tr>
<th>Subsidiary</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td></td>
</tr>
<tr>
<td>3…/…</td>
<td></td>
</tr>
</tbody>
</table>

c. State the companies with which your company has forged joint-venture agreements, as well as the object of these agreements:

<table>
<thead>
<tr>
<th>Company</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td></td>
</tr>
<tr>
<td>3…/…</td>
<td></td>
</tr>
</tbody>
</table>
d. Draft a table stating the companies with which your company has forged permanent service provision agreements for specific manufacturing operations, and attach it to the questionnaire, with the following specifications:

<table>
<thead>
<tr>
<th>Company</th>
<th>Product</th>
<th>Since when</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3…/…</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1.9 Shipment Organization

a. Normally, what are your shipping conditions:

☐ FIM
☐ FOB
☐ DDP

b. From which terminal are your deliveries shipped:

☐ Airport/ Africa
☐ Airport/ China
☐ Airport/ Europe
☐ Airport/ India
☐ Seaport/ Africa
☐ Seaport/ China
☐ Seaport/ Europe
☐ Seaport/ India
☐ North Road Port
☐ South Road Port
☐ East Road Port
☐ Rail Port
c. State the name of the freight carrier ordinarily dealing with the air transport:

Company: ...........................................................................................................................................
Address: .........................................................................................................................................
Contact person: ............................................................................................................................... 
Fax: ................................................................................................................................................
E-mail: ...............................................................................................................................................
d. State the name of the freight carrier ordinarily dealing with the maritime transport:

Company: ...........................................................................................................................................
Address: .........................................................................................................................................
Contact person: ............................................................................................................................... 
Fax: ................................................................................................................................................
E-mail: .............................................................................................................................................
e. State the name of the local official handling agent:

Body:

Address:
Tel:
Contact person:
Fax:
E-mail:

f. State the name of the Insurance Company which services you normally turn to:


g. What Organization inspects the goods at the shipping point?


Does the aforementioned Organization have representation in  □ Yes  □ No  Angola?

Name of Organization:
Address:
Tel:
Fax:
E-mail:
PHARMACEUTICAL INFORMATION

MEDICATION MANUFACTURER / BEARERS OF AIM / REPRESENTATIVES

PRODUCTION RANGE AND OFFICIAL DOCUMENTS

1.10. Production Range

In the list below, indicate the cases corresponding to your production range and, regarding each product form, state your production capability (in number of units per year).

Oral presentations:
- Tablets
- Lozenges
- Capsules/Gel Capsules
- Drinkable solutions
- Syrups
- Powders for oral suspensão
- Others: attach list to questionnaire

Injectable presentations:
- Liquid presentations (ampoules or vials)
- Powders for injectable preparations
- Solutions for perfusion
- Others: attach list to questionnaire

Other medication presentations:
- Creams and ointments
- Suppositories
- "Ovules"
- Ophthalmic pharmaceutical products
- Optical pharmaceutical products
- Nasal solutions
- Solutions and emulsions for external use
- Others: attach list to questionnaire

1.11 WHO System for Certifying the Quality of Products Entering the International Market


☐ Yes  ☐ No
1.12 Record of Products in the Country of the Manufacturer

Which products are recorded in the Country of the manufacturer? □ Yes □ No

Attach: the "Statement regarding the Status of the Authorization for Introduction of pharmaceutical products in the Market", as per the model provided for by the WHO System for Quality Certification of pharmaceutical products entering the International market (WHO Technical Reports no. 823 and 863), certified document as well as the respective translation to Portuguese.

<table>
<thead>
<tr>
<th>Product</th>
<th>Pharmaceutical presentation</th>
<th>Active Substance</th>
<th>Authorization for Introduction in the Market (AIM)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Name</td>
<td>Number</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Quantity /per-unit dose</td>
<td></td>
</tr>
<tr>
<td>…/…</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Attach to the questionnaire the list of your products registered for export.

1.13 Certificate of Good Practices in Manufacturing (GPM)

For each manufacturing site, attach the copies of the Certificates of Good Practices in Manufacturing (GPM) as well as the translation to Portuguese.

1.14 Production

1. Name and Qualification of the Officer in Charge of Production

Name: ………………………………………………………………………………………………………………………………

Qualification: □ Pharmacist □ Other: specify……………………………………………………………………………………

2. Production Lines by manufacturing site

Provide a short description of your internal production lines by manufacturing site:
………………………………………………………………………………………………………………………………………
………………………………………………………………………………………………………………………………………
………………………………………………………………………………………………………………………………………
………………………………………………………………………………………………………………………………………

3. Subcontracting

Do you turn to subcontracting for all or part of your manufacturing operations? □ Yes □ No

If so, provide a table with the name of the body or bodies, the locations and the reasons for subcontracting and attach it to the questionnaire:

<table>
<thead>
<tr>
<th>Name of subcontracted company</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>…/…</td>
<td></td>
</tr>
</tbody>
</table>
What are some of the subcontracted operations: (if appropriate)

- Manufacture of the pharmaceutical presentation specify the operations
- Storage of the finished pharmaceutical presentation
- Labelling of the finished pharmaceutical presentation
- Release of the batch

Are the finished products, manufactured under a subcontracting system, physically received at your facility before being distributed?  □ Yes □ No

Are the finished products, manufactured under a subcontracting system, controlled by you before being distributed?  □ Yes □ No

Explain the applied protocol: ………………………………………………………………………………………
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1.15 Quality Assurance

1. Name and qualification of the person in charge of releasing the batches

Name: ……………………………………………………………………………………………………………………………

Qualification:  □ Pharmacist
□ Other: specify…………………………………………

2. Name and qualification of the person in charge of quality assurance

Name: ……………………………………………………………………………………………………………………………

Qualification:  □ Pharmacist
□ Other: specify…………………………………………

3. Name and qualification of the person in charge Quality Control (Laboratory)

Name: ……………………………………………………………………………………………………………………………

Qualification:  □ Pharmacist
□ Other: specify…………………………………………

4. Quality Control Operations
Quality control is carried out on: (indicate, as appropriate)

☐ Active raw materials  ☑ Non-active raw materials (excipients)  ☐ Storage items  ☐ Intermediate products  ☐ Wholesale pharmaceutical products  ☐ Finished products  ☐ Products manufactured and/or stored under a system of subcontracting.

5. Subcontracting Quality Control

Do you turn to subcontracting for all or part of your quality control operations?  ☑ Yes  ☐ No

If so, state the name of the body or bodies you turn to, which operations are subcontracted and the reasons for subcontracting. Enclose, with the questionnaire, a chart with the specifications given below.

<table>
<thead>
<tr>
<th>Name and address of the subcontracted party</th>
<th>Subcontracted tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>.../...</td>
<td></td>
</tr>
</tbody>
</table>

6. Approval of Raw materials

1. Do you hold a European Certificate of Product Compliance (ECP) or a Drug Master File (DMF) for the raw materials used?  ☑ Yes  ☐ No

With the questionnaire, enclose the list of the corresponding raw materials, with the ECP or DMF references.

2. Can you confidentially provide your clients with your sources for the supply of raw materials?  ☑ Yes  ☐ No

If not, explain why:

....................................................................................................................................................
....................................................................................................................................................
....................................................................................................................................................
....................................................................................................................................................

3. Is the active raw material (active substance) controlled?  ☑ Yes  ☐ No

Explain your sampling procedure:

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....................................................................................................................................................

4. Is the non-active raw material (excipients) controlled?  ☑ Yes  ☐ No

Explain your sampling procedure:

....................................................................................................................................................
....................................................................................................................................................
....................................................................................................................................................
....................................................................................................................................................
7. Batch Dossier

Is a manufacturing dossier kept for each batch of product? □ Yes □ No

If so, point out the constituent elements of the aforementioned dossier:

□ The batch numbers of the raw materials used
□ The results of tests on raw materials
□ Manufacturing stages and dates
□ The name of those in charge of the aforementioned stages
□ Identification of the material used in the manufacturing
□ The results of intermediate controls carried out during the manufacturing
□ The results of environmental controls
□ Comments regarding production-related incidents
□ Comments regarding the non-observance of the standard manufacturing formula
□ The comparative balance of production
□ The batch number of stored items
□ The results of the quality control of wholesale products
□ The results of the quality control of finished products

8. Procedure for Releasing Batches

Explain your process for releasing batches:

1. In the case of internal production (with no subcontracting):

   …………………………………………………………………………………………………………………
   …………………………………………………………………………………………………………………
   …………………………………………………………………………………………………………………
   …………………………………………………………………………………………………………………
   …………………………………………………………………………………………………………………

2. In the event of subcontracting all or part of what is manufactured:

   …………………………………………………………………………………………………………………
   …………………………………………………………………………………………………………………
   …………………………………………………………………………………………………………………
   …………………………………………………………………………………………………………………
   …………………………………………………………………………………………………………………

9. Determining the Best Before Date and the Expiry Date of the Manufactured Products

How do you determine the best before date and the expiry date of the products you manufacture? Are tropical conditions taken into account?

□ Yes □ No

Briefly describe the method used (time, temperature and relative humidity):

………………………………………………………………………………………………………………
………………………………………………………………………………………………………………
10. Determining Bioavailability (Generic Drugs)

How do you show the products' therapeutic equivalence?

1. Through bioequivalence studies? □ Yes □ No

If so, for what type of products, with which Reference product, in what countries and how many volunteers?

With the questionnaire, enclose a chart with the specifications given below.

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Reference Product</th>
<th>Country</th>
<th>Number of Volunteers</th>
</tr>
</thead>
<tbody>
<tr>
<td>…</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. Through dissolving tests compared "in vitro"? □ Yes □ No

If so, for which product type, and with which Reference product?

With the questionnaire, enclose a chart with the specifications given below.

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Reference Product</th>
</tr>
</thead>
<tbody>
<tr>
<td>…</td>
<td></td>
</tr>
</tbody>
</table>

3. In the absence of one of the aforementioned methods, how do you provide evidence of product bioavailability:

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…………………………………………………………………………………………………………………
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……………………………………………………………………………………………………………….

11. Sample Storage
Do you store the samples of each manufactured batch? □ Yes □ No

If so, under what conditions?
At what temperature?
…………………………………………………………………………………………………………
For how long? ……………………………………………………………………………………
What kind of storage (sales-related, other: specify)? ………………………………………
…………………………………………………………………………………………………………
…………………………………………………………………………………………………………
…………………………………………………………………………………………………………

Yes □ No
12. Sampling Procedure

How is the sampling carried out? Briefly explain:

………………………………………………………………………………………………………………
………………………………………………………………………………………………………………
………………………………………………………………………………………………………………
………………………………………………………………………………………………………………
………………………………………………………………………………………………………………
………………………………………………………………………………………………………………

13. Batch Monitoring

1. Do you ensure the monitoring of every batch delivered to the client? □ Yes □ No

Explain:

………………………………………………………………………………………………………………
………………………………………………………………………………………………………………
………………………………………………………………………………………………………………
………………………………………………………………………………………………………………
………………………………………………………………………………………………………………
………………………………………………………………………………………………………………
………………………………………………………………………………………………………………

2. Do you gather the conditions for quickly organizing a batch-recall procedure, in the event of a problem? □ Yes □ No

Briefly describe the procedure:

………………………………………………………………………………………………………………
………………………………………………………………………………………………………………
………………………………………………………………………………………………………………
………………………………………………………………………………………………………………
………………………………………………………………………………………………………………
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………………………………………………………………………………………………………………
………………………………………………………………………………………………………………
………………………………………………………………………………………………………………
COMMITMENT STATEMENT

We, the undersigned,

Mr./Ms. ……………………………………………………………………………..…… ……., Director General

Mr./Ms. ……………………………………………………………………………., Pharmacist Officer in Charge

Mr./Ms. ……………………………………………………………………………., Officer in charge of releasing the batches

Mr./Ms. ……………………………………………………………………………., Officer in Charge of Quality Assurance

We hereby certify that the information provided in this questionnaire is correct.

Prepared in, …………………….on…………………………………………………………………….

Signature of the Director General: …………………………………………………………….

Signature of the Pharmaceutical Officer in charge: ……………………………………………

Signature of the Officer in charge of releasing the batches:…………………………………….

Signature of the Officer in Charge of Quality Assurance:…………………………………….
IMPORTERS

1.16 Status related to the manufacturers of the products they import

1. Manufacturer Consent

Are they recognized by the Manufacturers Bearers of the AIM/ Bearers of the AIM/ Representatives of the products imported?

☐ Yes ☐ No

2. Suppliers

Are you normally supplied by supplying organizations not belonging to the preceding group?

☐ Yes ☐ No

Specify the aforementioned organizations, by which you are recognized and/or supplied, by completing a chart, according to the model below and enclose a copy of the license or of the letter of consent from each organization (according to the model below).

<table>
<thead>
<tr>
<th>Manufacturer bearer/Bearer/Representative</th>
<th>COMPLETE ADDRESS / CONTACTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Another Supplier</td>
<td></td>
</tr>
<tr>
<td>.../...</td>
<td></td>
</tr>
</tbody>
</table>

1.17 Quality assurance system

1. Name and qualification of the person in charge of quality

1. Number of people in charge of quality assurance: ...............................................................

Name of the person in charge of quality assurance: ...............................................................

Qualification

☐ Pharmacist
☐ Other: specify........................................

Enclose certified copy of the diploma

Name of the deputy-officer in charge: ...............................................................

Qualification

☐ Pharmacist
☐ Other: specify........................................

Enclose certified copy of the diploma

2. Quality assurance system

1. Storage Procedures

Do you have a Good Practices Manual regarding Storage?
2. Distribution Procedures

Do you have a Good Practices Manual regarding Distribution (GPD)?

Briefly describe the Quality Assurance System (Enclose a summary of the Quality Assurance Manual)

3. Supplier Selection

Describe the criteria/procedure for selecting your suppliers:

3. Monitoring batches (recording/sampling)

1. Do you record and keep samples of every batch that you receive and distribute to your clients?

4. WHO System for Certifying the Quality of Pharmaceutical Products Entering International Trade

COMMITMENT STATEMENT

We, the undersigned,

Mr./Ms. …………………………………………………………………………………………………………., Director General

Mr./Ms. ………………………………………………………………………………………………………… Pharmaceutical officer in charge / Technical Director

Mr./Ms. ………………………………………………………………………………………………………… Officer in charge of the Quality Assurance System)

( if other than the Technical Director )

We hereby certify that the information given in this questionnaire is correct.

Prepared on ……………………………., on:……./……../………..

Signature of the Director General:

………………………………………………………………………………………………………

Signature of the Pharmaceutical officer in charge / Technical Director

………………………………………………………………………………………………………

Officer in charge of the Quality Assurance:

………………………………………………………………………………………………………
LETTER OF CONSENT
FROM THE MANUFACTURER / BEARER OF AIM / REPRESENTATIVE

(Model)

MANUFACTURER IDENTIFICATION

Name: …………………………………………………………………………………………………………………
Tel.: …………………………………………………………………………………………………………………
Fax. …………………………………………………………………………………………………………………
E-mail: …………………………………………………………………………………………………………………
Legal status: …………………………………………………………………………………………………………………
Company Registered under No. : ……………………………………………………………………………………,
Legally set up and duly authorized in : ……………………………………………………………………….
Which main place of business is: …………………………………………………………………………………
…………………………………………………………………………………………………………………..
hereby appoint and accredit ……………………… (name of Representative/Importer) …………..
……………………………………………………………………………………………………………………………,
legally constituted and licensed in Angola, practising its main business in………………..
……………………………………………………………………………………………………………………………,
In witness whereof, the following hereby set their hands unto this document:…………………..(date).

• For the representative/importer ……………………………………………………. (name of representative/importer)

(name of officer in charge)                       (Category of officer in charge)                       (Signature)

• For the Bearer of AIM or Manufacturer………………………………………… (name of bearer or manufacturer)

(name of officer in charge)                       (Category of officer in charge)                       (Signature)

• For the Representative……………………………………………………….(name of representative)

(name of officer in charge)                       (Category of officer in charge)                       (Signature)