

UAE Registration Requirements for General Sale List (GSL) Products

In the United Arab Emirates (UAE), the General Sale List (GSL) includes Dietary Supplements, Medicated Cosmetics, Antiseptic and Disinfectants and Miscellaneous products which contains pharmaceutical ingredients and/or a medical claim and cannot be classified as medicines.

The application can be made in English or Arabic. Marketing authorization for GSL products in the United Arab Emirates (UAE) can only be given to companies (Manufacturer) who are registered in the UAE ministry of health. Below is a list of the GSL product registration requirements followed by the requirements for registering a company in the UAE ministry of health. Applicants in the UAE should have Medical stores licensed by the Ministry of Health.

Registration of the GSL Product requires:

1. Application and document receiving form for the Registration of new GSL product (typed). Available from the Technical Affairs Section.
2. Certificate of Pharmaceutical Product (CPP) as per the WHO Certification Scheme or Free Sale Certificate (FSC) for the product.
To be issued by Competent Authorities in Country of Origin, it must be authenticated by the foreign affairs section of the UAE or any GCC embassy in the country of origin.

▶ The CPP must contain:

- ✓ Trade Name of the Product.
If the Trade Name of the product intended for registration in UAE is different from that in the Country of Origin, difference should be explained clearly in the CPP/FSC and both Trade Names should be mentioned with confirmation of similarity in composition and other specifications.
 - ✓ Composition of the product in details (Active and inactive ingredients with their quantities).
 - ✓ Name of the Manufacturer/Marketing Authorization Holder/ Manufacturing Site(s)/ Contract Manufacturer(s) with address.
 - ✓ Shelf-life of the product with Storage conditions.
 - ✓ Declaration that the product is freely sold in country of Origin for less than 2 years.
3. Package Insert for the product authenticated from Competent Authorities (if applicable).
 4. Three (3) samples of the product in its final package.
 5. Certificate of Analysis of the same batch of the samples submitted for registration.

The following information must be submitted on company letterhead with logo, signature and stamp:

6. Statement issued from the Principal Company showing that the product is devoid from hormones, heavy metals, antibiotics, steroids, derivatives of pork and any natural and chemical ingredients having harmful effects on human biological and behavioural functions. If the product contains an ingredient from animal source, the kind of animal and part extracted from it must be specified percentage of alcohol if any must be mentioned together with reasons thereof.

Adopted from MOH Circular No. 20 for 2001 issued by the Director of Drug Control Department

7. Halal certificate issued by recognizable organizations and authorities.
8. Authenticated contract between MAH & agent mentioning the products for which the agent is going to be responsible for.
9. The applicant should have a medical store licensed by the Ministry of Health. (as per the Circular No. 1 for year 2006)
10. valid company registration certificate issued by UAE / MOH drug control department
11. Submit BSE / TSE free certificate from competent authority in Country of origin (*wherever applicable*)
12. outer label, inner label and insert of the product on stamped company letterhead.
13. CD of artwork (outer, inner label and insert) of the product in JPEG format.

If the product marketing authorization holder (MAH) & manufacturer has not been registered in the UAE ministry of health, then this must be done before a product can be submitted for registration.

Documents required for GSL Company registration

Application is collected from Technical Affairs Section Secretary or downloaded from the MOH website, the forms are **PART ONE** (for MAH) & **PART TWO** (for manufacturing site), at the end of each form there is a list of required documents to be attached along with the form, applications are to be filled and stamped by the MAH & manufacturer, documents are to be attached along with each form.

N.B.: The GSL registration committee may request QCL analysis of the submitted products and the applicant will have to provide necessary samples and other analysis requirements requested by the drug control laboratory.

N.B:- All forms and complete copy of guidelines for company and product registration can be requested from the technical affairs section secretary, telephone 02- 6117325 or downloaded from the MOH website at the following link:

http://www.moh.gov.ae/moh_site/phar_med/moh_p_m.htm