# Update on the Classification of Pharmaceutical Products in Bahrain

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NHRA's scope includes regulating healthcare professionals, facilities, equipment, and pharmaceutical products, in addition to setting related guidelines in line with international standards.

According to Decree No. 9 of 2016 in relation to Classifying Pharmaceutical Products and Health Products ('Decree 9 of 2016'), a pharmaceutical product is classified as either a health product or a medicine, based on the Pharmaceutical Product Classification Guideline annexed to the decree ('PPC Guidelines'). Health products include: herbal products; products containing vitamins; products containing minerals; and other products that contain specific substances such as amino acids, charcoal lipids such as omega 3 and certain antiseptics ('Health Products').

The PPC Guidelines attempt to provide clear definitions for what are considered Medicines (as defined herein) and Health Products, in addition to providing detailed information to be used as a basis for pharmaceutical products classification.

The basis used by NHRA for classification, as explained by the PPC Guidelines, includes a number of factors, mainly: the composition of a product; medical claims made in relation to a product; its concentration; its method of consumption; and the potential for any medical interference (e.g. adverse interactions with other medicines).

**Composition**

The PPC Guidelines provides a list of more than one hundred substances and preparation techniques of such substances, which cannot be included in an herbal product. Any product containing any of these substances, or which uses certain preparation techniques, will be classified as a medicine ('Medicine'). Some examples of herbal products considered to be a Medicine are: Aconitum napellus L, Berberis aristata and Ginkgo biloba L. Products may also be classified as Health Products if they include substances produced by or obtained from bees (including royal jelly, bee pollen and propolis), natural enzyme products, crude or refined coal tars, and certain antiseptics.

**Concentration**

Whether vitamins and mineral-containing products will be classified as a Health Product or Medicine depends on the concentration amount of the vitamins and minerals in the given product.

The PPC Guidelines provides a table for lower and upper concentration limits for vitamins and minerals.

**Method of Consumption and Medical Interference**

Generally, pharmaceutical products which state any of the following characteristics are classified as a Medicines and cannot be classified as a Health Product: ‘be sterile’, ‘be administered by injection’, ‘be subject to a medical prescription’, and ‘necessitate the intervention of a licensed healthcare professional’.

**Medical claims**

The classification methodology for Health Products described above will only apply if no medical claims are made in association with the product, as the inclusion of a medical claim would likely cause the product to be classified as a Medicine.

The PPC Guidelines provides examples of words or phrases, either used together or on their own that could be considered as making medical claims in relation to a product and whether they are considered as medicinal/medical. These include: ‘alleviates’, ‘avoids’, ‘boosts immune system’, ‘burns fat’, ‘calms’, ‘can benefit those who suffer from’, ‘clears’, ‘clinical trials evidence suggests’, ‘clinical trials suggest’, ’clinically proven to’, ‘combats’, ‘controls’, ‘counteracts’, ‘cures’, ‘eliminates’, ‘fights’, ‘maintains a normal . . . e.g. water balance, mood, etc.’, ‘helps’, ‘lowers cholesterol’, ‘protects against’, and ‘strengthens the immune system’.

The foregoing is not exhaustive and each statement or the use of certain words in combination or on their own needs to be considered carefully in its context and in relation to the product. The use of limited generic terms are less likely to be considered as making medical claims although it is recommended that the use of any of the mentioned terms of phrases are considered carefully or are avoided in relation to Health Products.

There is, however, an exception for medical claims or indications that are made in relation to products classified as Health Products (not Medicines), if such claims or indications are suitable for self-diagnosis and self-treatment, do not require the intervention of a licensed healthcare professional, and if these claims are consistent with supporting evidence regarding the safety and traditional use of those products.

**Other Considerations**

When classifying a new product, NHRA takes into consideration previous classifications to ensure that closely related products will be similarly classified.

If any product contains a substance with a known pharmacological affect, it will be classified as a Medicine by NHRA, irrespective of the presence or absence of any claims contained in the product packaging or literature.

Any product containing two or more regulated components that are physically, chemically, or otherwise combined or mixed and produced as a single product will be regulated in accordance with the highest regulatory standards, e.g. a product containing both a steroid and herbal substance would be regulated as a Medicine and not as a Health Product.

**Official Fees**

A new decree was published in the official gazette of 18 August 2016 under Law No. 17 of 2016, introducing new official fees for licences granted by NHRA.

The decree also confirmed that the licence renewal must be submitted at least one month before the expiration of the licence.

In relation to the point of sale of certain products, all products requiring a prescription can only be sold in pharmacies. The classification of a product as a Medicine or a Health Product as well as its composition, concentration, and medical use will determine if a prescription is needed for that product. Another function of NHRA is to determine the prices of Medicines and provide a formal list of such prices. NHRA does not,

however, determine the prices of Health Products.

**Summary**

Decree 9 of 2016 has helped to clarify the classification of Health Products and Medicines in Bahrain and attempts to bring these into line with international standards. The classification and registration regime implemented by NHRA has made matters clearer for importers and manufacturers but challenges will no doubt arise in relation to new products that enter the Bahrain market. It is suggested that before the sale or importation of any Health Products or Medicines in Bahrain, clear regulatory advice is obtained.