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## Pharmaceutical labels will soon have to include brand name in additional languages

**Government/policy**

**Israel - Gilat, Bareket & Co., Reinhold Cohn Group**

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Amendments 17 and 20 to the Pharmacists Ordinance, which will come into effect on August 1 2012, will require that pharmaceutical labelling indicate certain particulars, including the brand name of the product, not only in Hebrew and English, but also in Arabic and Russian.

A revised practice guideline of the Ministry of Health, which would set forth the specific guidelines for labelling pharmaceuticals, is forthcoming, but no specific date has been announced for its publication.

In light of the new labelling requirements, it is advisable to apply for trademark registration for the product name in each of the four languages in order to ensure optimal protection for the brand.

At present, only non-prescription pharmaceuticals which are permitted for general sale (ie, which are not sold in a pharmacy or by a pharmacist) must, under the applicable administrative regulations, be labelled with the product's brand name in Hebrew, English, Arabic and Russian (see the Pharmacists Regulations (Sale of a Non-prescription Preparation other than in a Pharmacy or other than by a Pharmacist (5765/2004), Regulation 13(b), implemented in the Ministry of Health Practice Guideline 54/2004, Section 3.2.2). So far, other pharmaceuticals - namely, any pharmaceuticals dispensed in a pharmacy or by a pharmacist, either with or without a prescription - had to be labelled with the brand name only in Hebrew and in English (see the Pharmacists Regulations (Preparations) (5746/1986), Regulation 20; see also Regulation 22, implemented by the Ministry of Health Practice Guideline 43/2007, Section 3.2.1.1).

The Pharmacists Ordinance [New Version] 5741/1981 (an act of primary legislation governing the marketing, labelling and dispensation of pharmaceuticals in Israel) was recently amended (through the enactment, in 2010 and 2011, of Amendments 17 and 20 to the Pharmacists Ordinance) to require that the brand name of a preparation be indicated in all four languages on the label. This issue was previously partially regulated by administrative regulations. As of August 1 2012, the labels of both prescription and over-the-counter pharmaceuticals will have to include several important details, including the brand name of a preparation, in Hebrew, Arabic, English and Russian.

Section 30 of the Pharmacists Ordinance, as amended, will read as follows (informal translation):

> " *(a) Any dispensed medicine and medicinal drug shall be delivered in bottles or packages adequately sealed and labelled with a label that indicates the name of the pharmacy, the serial number of the prescription as recorded in the register of prescriptions, the name of the patient and usage instructions; the label shall also indicate in Hebrew, Arabic, English and Russian the name of the preparation and, in respect of a preparation for which a consumer information leaflet is included, the words 'Please see the consumer information leaflet before use'.*
>
> *(a1) The packaging of a non-prescription preparation, other than a non-prescription preparation sold in accordance with Section 42, shall also be marked in a clear and legible manner with the following:*
>
> > *(1) In Hebrew - the name of the preparation; the intended use; cautionary labels as defined in the Pharmacists Order (Classification and Handling of Poisons) 5733/1972; the words 'Please see the consumer insert before use'; any other marking prescribed by the director;*
> >
> > *(2) In Arabic, English and Russian - the name of the preparation; the words 'Please see the consumer information leaflet before use';*
> >
> > *(3) The active ingredient.*
>
> *(b) Medicines for external use shall also be labelled with an orange label bearing the words 'For external use' in Hebrew, Arabic, English and Russian.*"

Section 42 provides in the relevant part (informal translation):

> "*(b) Retail of a non-prescription preparation other than in a pharmacy or other than by a pharmacist shall be permitted when it is made in accordance with the provisions prescribed by the Minister of Health under Subsection (c).*
>
> *(c) For the purpose of protecting public health, the Minister of Health shall prescribe, with the*

> *approval of the Labour, Welfare and Health Committee of the Knesset, provisions regarding the retail of a non-prescription preparation other than in a pharmacy or other than by a pharmacist, in the following matters:*
>
> *…*
>
> > *(2) conditions of packaging, including the quantity of preparations in each package;*
> >
> > *(3) conditions of possession, storage and labelling; ...*"

Regulation 13(b) of the Pharmacists Regulations, enacted under Section 42(c) of the Pharmacists Ordinance, provides in the relevant part (informal translation):

> "*(b) Notwithstanding the provisions of Subsection (a), the name of the preparation, the intended use and the referral to the consumer information leaflet shall be also indicated in the Arabic, English and Russian languages…*"

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