Frequently Asked Questions on the

Undesirable Medical Advertisements Ordinance

scope of the Undesirable Medical Advertisements **Q1** What is the **Ordinance?** A.1 The Undesirable Medical Advertisements Ordinance (UMAO), Cap. 231, aims to protect public health through prohibiting or restricting advertisements which may induce the seeking of improper management of certain health conditions. According to the UMAO, publication of advertisements likely to lead to the use of any medicine^{*}, surgical appliance or treatment for the purpose of treating human beings for, or preventing them from contracting diseases or conditions specified in column 1 of Schedule 1 (except for purposes specified in column 2) and for treating human beings for purposes specified in Schedule 2 of the UMAO as well as advertisements relating to abortion are not allowed. Effective from 1 June 2012, the UMAO also prohibits/ restricts advertising of six groups of claims specified in Schedule 4 for all orally consumed products*. *As defined in the UMAO – "Medicine" – includes any kind of medicament or other curative or preventive substance, and whether a proprietary medicine, a patent medicine, a Chinese herbal medicine, a proprietary Chinese medicine, or purported natural remedy; "Orally Consumed Product" -(a) means a product (whether or not it is a medicine) for human consumption which is intended to be taken orally and is in any of the following forms -(i) pill; (ii) capsule; (iii) tablet; (iv) granule; (v) powder; (vi) semi-solid; (vii) liquid; or (viii) a form similar to any of the forms mentioned in subparagraphs (i), (ii), (iii), (iv), (v), (vi) and (vii); and

	(b) does not include a product which is customarily consumed only as food or drink (that is to say, to provide energy, nourishment or hydration) or to satisfy a desire for taste, texture or flavour.
	For more details, please refer to the UMAO and the guidelines on the UMAO on our website. (<u>http://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/other_useful_infor mation/umao.html</u>).
Q.2	What is considered as an "advertisement" under the UMAO?
A.2	According to the UMAO, "advertisement" includes any notice, poster, circular, label, wrapper or document, and any announcement made orally or by any means of producing or transmitting light or sound.
	In other words, it covers advertisement published in the newspapers and magazines, leaflets, signboards, radios, televisions, internet as well as the labels on the container or package of a product.
Q.3	Whether product external package or product inserts is considered as an advertisement?
A.3	According to the UMAO, the sale or supply, or offer or exposure for sale or supply, of any medicine, orally consumed product, surgical appliance, or treatment in a labelled container or package shall constitute the publication of an advertisement. However, the supply, inside any container or package containing any medicine, orally consumed product, surgical appliance or treatment, of information relating to that or any other medicine, product, surgical appliance or treatment shall not constitute publication of advertisement.
	Therefore, the external package of the product is considered as a form of advertisement whereas the product insert does not constitute an advertisement.
Q.4	Is verbal promotion considered as a publication of advertisement?
A.4	According to the UMAO, advertisement includes any announcement made orally or by any means of producing or transmitting light or sound. Therefore, verbal

	treatment is generally considered as an advertisement (such as health talk and verbal promotion by salesmen). In considering whether an individual case contravenes the UMAO, the content of the advertisement will be considered as a whole, including the wording and the message it advertised.
Q.5	Are registered pharmaceutical products or proprietary Chinese medicines subject to the control of UMAO?
A.5	Registered pharmaceutical products or proprietary Chinese medicines fall within the definition of "medicine" under the UMAO and are hence subject to the regulation of Schedules 1 and 2 of the UMAO. If they also fall within the meaning of "orally consumed products", their advertisements containing claims specified under column 1 of Schedule 4 of the UMAO (except allowed by column 2) will also be regulated by section 3B of the UMAO.
Q.6	Can I publish an advertisement or label a registered pharmaceutical product or a proprietary Chinese medicine based on information contained in its product insert, given that the insert has been vetted by the Department of Health before the product is granted registration?
A.6	Under the UMAO, the sale or supply, or offer or exposure for sale or supply of a medicine or an orally consumed product in a labelled container or package constitutes the publication of an advertisement. Since the label of a product is a form of advertisement, any claims that are prohibited from publication by the UMAO should not appear on the label of the product irrespective of whether these claims had been approved to be specified in the product insert during the product registration. Traders should comply with the requirements of UMAO in developing the label or any other kinds of advertisement for their products.
Q.7	If an advertisement includes a scientific report or scholar's interview as reference to promote a product, will it contravene the UMAO?
A.7	When determining whether an advertisement is contravening the UMAO, the contents of the advertisement will be considered as a whole with reference to the legal requirements under the UMAO. Reliance on scientific report or scholar's interview is not by itself a defence.
	Traders should seek legal advice when there are questions concerning

	interpretation of the UMAO.
Q.8	Can I advertise products with claims which are proven to be effective?
A.8	The UMAO aims to protect public health through prohibiting or restricting advertisements which may induce the seeking of improper management of certain health conditions, but not to regulate the truthfulness of claims contained in the advertisements. Therefore, any claims that are prohibited to be published by the UMAO should not appear in the advertisement, even those claims are proven to be effective.
	Whether the content of an advertisement is truthful or misleading is subject to the control of other legislation, such as the Trade Descriptions Ordinance (TDO), Cap. 362, which is enforced by the Customs and Excise Department. For enquiries on the TDO, please contact the Customs and Excise Department.
Q.9	Are there any defence provisions under the UMAO?
A.9	In any proceedings for a contravention of section 3, 3B or 4 of the UMAO, it shall be a defence to prove that the advertisement to which the proceedings relate was made only in a publication of a technical character intended for circulation mainly amongst persons of the following classes, or of one or some of them –
	 (a) medical practitioners registered under the Medical Registration Ordinance (Cap 161), or persons deemed to be medical practitioners under section 29 thereof;
	(b) pharmacists registered under the Pharmacy and Poisons Ordinance (Cap 138);
	(c) the medical and para-medical staff of –
	 (i) any hospital or maternity home to which the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165) applies;
	 (ii) any clinic to which the Medical Clinics Ordinance (Cap. 343) applies;
	(iii) any hospital, maternity home or clinic maintained by theGovernment, the Chinese University of Hong Kong or the

	University of Hong Kong; (iv) any hospital, maternity home or clinic managed or controlled by the Hospital Authority established under the Hospital Authority Ordinance (Cap. 113);
	(d) Chinese medicine practitioners registered or listed under the Chinese Medicine Ordinance (Cap 549)
Q.10	Are the advertisements (including product label) for products imported from overseas regulated by the UMAO?
A.10	The UMAO is one of the Laws of Hong Kong. Any advertisements published in Hong Kong making claims for medicines, orally consumed products, surgical appliances or treatment should comply with the provisions of the UMAO. Importers or distributors have the responsibility to ensure that products sold in Hong Kong and their advertisements (including product label) published in Hong Kong comply with the UMAO.
Q.11	Does the Department of Health provide a pre-approval service for traders?
A.11	The Department of Health currently does not have a pre-approval system, and will not comment on any individual examples or cases.
	To facilitate the trade in understanding the UMAO, in addition to these FAQs, the Department of Health has prepared bilingual guidelines on the UMAO which are available on the website of the Drug Office. Traders are advised to refer to the UMAO and guidelines on the UMAO at http://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/other_useful_infor mation/umao.html. Traders should seek legal advice when there are questions concerning interpretation of the UMAO.
Q.12	What are the prohibited claims for orally consumed products?
A.12	Schedule 4 of the UMAO is to prohibit/ restrict advertisements on 6 groups of claims related to orally consumed products. The claims are listed below:

	Clair	ns	Restriction imposed
	(i)	Prevention, elimination or treatment of breast lumps	
	(ii)	Regulation of function of genitourinary system	The advertising of these three claims is not allowed under any circumstances.
	(iii)	Regulation of endocrine system	
	(iv)	Regulation of body sugar or glucose	For these items, only 4 prescribed claims are permissible as specified for
	(v)	Regulation of blood pressure	each type of claim in column 2 of Schedule 4 (e.g. " <i>The product is</i>
	(vi)	Regulation of blood lipids or cholesterol	suitable for people concerned about blood sugar"). However, for products not registered under the Chinese Medicine Ordinance (CMO) or the Pharmacy and Poisons Ordinance (PPO), a specified disclaimer must be clearly put in the advertisement to inform consumers that they are not products registered under the CMO or the PPO.
0.13	mation	/www.drugoffice.gov.hk/eps/do/er n/umao.html). are the "similar claims"?	n/pharmaceutical_trade/other_useful_infor
A.13	UMA to the circum	O are not conclusive. All claims like effect as those specified c	ccified in column 1 of Schedule 4 of the s that can reasonably be understood to be laims, with reference to all the relevant milar claims" and the publication of these ed by the UMAO.
Q.14	What	are the examples of orally consu	med products?
A.14	for or cordyo within	al use such as chitosan tablets, she ceps extract powder, lactobacillus the definition of the orally cor	y Chinese medicines, and health products hark cartilage capsules, fish oils capsules, capsules and agaricus granule etc. all fall hsumed products. For further examples, ementary Guidelines on Regulation of Six

	Groups of Health Claims of Orally Consumed Products at http://www.drugoffice.gov.hk/eps/do/en/doc/guidelines_forms/umao_Annex_B_S http://www.drugoffice.gov.hk/eps/do/en/doc/guidelines_forms/umao_Annex_B_S http://www.drugoffice.gov.hk/eps/do/en/doc/guidelines_forms/umao_Annex_B_S http://www.drugoffice.gov.hk/eps/do/en/doc/guidelines_forms/umao_Annex_B_S http://www.drugoffice.gov.hk/eps/do/en/doc/guidelines_forms/umao_Annex_B_S http://www.drugoffice.gov . Any advertisements published in Hong Kong
	making claims for an orally consumed product have to comply with the provisions of the UMAO.
Q.15	Can advertisements of orally consumed products publish claims which are prohibited/ restricted under Schedule 1 and 2 of the UMAO?
A.15	According to the UMAO, "medicine" includes any kind of medicament or other curative or preventive substance, and whether a proprietary medicine, a patent medicine, a Chinese herbal medicine, a proprietary Chinese medicine, or purported natural remedy. If an orally consumed product falls within the meaning of a "medicine" under the UMAO, its advertisements are subject to the regulation of Schedules 1 and 2 in addition to Schedule 4.
Q.16	My product is not an "orally consumed product". Will it be regulated by the UMAO?
A.16	Schedule 4 of the UMAO only applies to advertisements of "orally consumed products", However, if the product concerned belongs to medicine as defined in the UMAO, surgical appliance or treatment, its advertisements would then be subject to the regulation of Schedules 1 and 2 of the UMAO.
Q.17	Would the health claims in advertisements of registered proprietary Chinese medicines and pharmaceutical products in form of orally consumed products be regulated in the same way as other orally consumed products?
A.17	Under the UMAO, claims made for all orally consumed products in advertisements would be regulated in the same way, regardless of whether the product is a registered proprietary Chinese medicine/ pharmaceutical product or not.
	The only difference is when claims relating to the regulation of body sugar or glucose, regulation of blood pressure and regulation of blood lipids or cholesterol are made as allowed by column 2 of Schedule 4 of the UMAO, those products which are not registered under the Pharmacy and Poisons Ordinance (Cap. 138) or the Chinese Medicine Ordinance (Cap. 549), publication of these permissible claims must also be accompanied by the disclaimer specified in column 2 of

	Schedule 4 of the UMAO.
Q.18	Is there any language requirement in publishing the permissible claims and disclaimer as specified in Schedule 4 of the UMAO in an advertisement?
A.18	The permissible claims and disclaimer as specified in column 2 of Schedule 4 should be published in Chinese or in both Chinese and English in advertisements wholly or mainly in Chinese whereas the claims and disclaimer should be published in English or in both Chinese and English for advertisements wholly or mainly in English.
Q.19	Can I use claims similar to those permissible claims specified in column 2 of Schedule 4?
A.19	No. The exact wording of the permissible claims as specified in column 2 of Schedule 4 should be used in the advertisement if claims are related to the regulation of body sugar or glucose, the regulation of blood pressure and the regulation of blood lipids or cholesterol.
Q.20	Who would be held liable for contravening the UMAO?
A.20	Under section 3(1) of UMAO, the person who published, and caused to be published, any advertisement likely to lead to the use of any medicine, surgical appliance or treatment for treating human beings for, or preventing human beings from any disease or condition specified in column 1 of Schedule 1, or for treating human beings for any purpose specified in Schedule 2 would be held liable.
	Under section 3B(1), the person who published, and caused to be published, an advertisement for an orally consumed product which makes for the product a claim specified in column 1 of Schedule 4, or any similar claim, which is not allowed by column 2 of that Schedule, would be held liable.
	Under section 4, the person who in any manner wrote, printed, or published and caused to be written, printed or published any advertisement relating to abortion would be held liable.
	In an advertisement published in contravention of the above sections, the person named in that advertisement is held out –

	(a) as being a manufacturer or supplier of medicine, product or surgical appliances; or
	(b) as being able to provide any treatment,
	that person would be presumed, until the contrary is proved, to have
	caused the advertisement to be published.
	If an advertisement published in contravention of the above sections gives the
	name, address or telephone number of, or indicates some other means of contacting,
	a person, and that person –
	(a) manufactures or supplies medicine, product or surgical appliances; or
	(b) provides any treatment,
	that person would be presumed, until the contrary is proved, to have
	caused the advertisement to be published.
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Q.21	What is the penalty of contravening the UMAO?
A.21	Any person who contravenes the provisions of section 3, 3B or 4 of the UMAO
	shall be guilty of an offence and shall be liable upon a first conviction to a fine at
	level 5 and imprisonment for 6 months and upon a second or subsequent
	conviction for an offence under the same section to a fine at level 6 and
	imprisonment for 1 year. Please refer to Schedule 8 of the Criminal Procedure
	Ordinance (Cap. 221) at Hong Kong e-Legislation (http://www.elegislation.gov.hk)
	which shows the prevailing amounts on the level of fines for offences.

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