

A.L. 400 ta' l-2003**ATT TA' l-2003 DWAR MEDICINI
(ATT NRU. III ta' l-2003)****Regolamenti ta' l-2003 dwar Prodotti Medicinali (Riklamar)**

BIS-SAHHA tas-setghat mogħtija mill-artikoli 31 u 106 ta' l-Att ta' l-2002 dwar Medicini, il-Ministru tas-Sahha għamel ir-regolamenti li ġejjin:-

1. (1) It-titolu ta' dawn ir-regolamenti hu Regolamenti ta' l-2003 dwar Prodotti Medicinali (Riklamar). Isem u bidu fis-sehh

(2) Dawn ir-regolamenti għandhom jidhlu fis-sehh fl-1 ta' Mejju, 2004.

2. F'dawn ir-regolamenti, sakemm ir-rabta tal-kliem ma teħtieġx Interpretazzjoni. mod ieħor:

“l-Att” tfisser l-Att dwar il-Medicini;

“il-kumitat għar-riklamar” ifisser il-kumitat għar-riklamar għal prodotti medicinali li jopera fl-Awtorità;

“l-Awtorità” tfisser l-Awtorità għall-Medicini mwaqqfa taħt l-artikolu 4 ta' l-Att;

“prodotti medicinali” tfisser medicinali għall-użu uman;

“starter pack” tfisser pakki żgħar li dwarhom ingħatat awtorizzazzjoni biex jitqiegħdu fis-suq, iddisinjati biex jipprovdu medicina biżżejjed lil min jippreskrivihom biex jibda kura f'dawk iċ-ċirkustanzi meta jista' jkun hemm dewmien mhux mixtieq jew li ma jistax ikun evitat biex tingħata l-medicina skond riċetta, meta bidu ta' kura immedjata hu meħtieġ, jew meta min jippreskrivi jhoss li l-użu ta' dan il-pakk hu indikat fl-interess tal-pazjent;

Riklamar.

3. (1) Riklamar ta' prodotti mediċinali għandu jinkludi kull forma ta' informazzjoni mogħtija bieb bieb, attività ta' kanvassjar jew thajjir maħsuba biex tippromwovi b'kull mezz li jkun il-preskrizzjoni, forniture, bejgħ jew konsum ta' prodotti mediċinali.

(2) Dan ir-rikamar għandu, b'mod partikolari, jinkludi:

(a) r-rikamar ta' prodotti mediċinali lill-pubbliku ġenerali;

(b) r-rikamar ta' prodotti mediċinali lil persuni kwalifikati biex jippreskrivuhom jew ifornuhom;

(c) żjajjar minn pjazzisti ta' mediċini lil persuni kwalifikati biex jippreskrivu jew ifornu prodotti mediċinali;

(d) l-forniture ta' kampjuni;

(e) l-provvediment ta' thajjir biex wiehed jippreskrivi jew iforni prodotti mediċinali bl-ghoti ta' rigali, offerti jew wegħdiet ta' xi benefiċċju jew bonus, kemm fi flus kemm f'oġġetti, hliet meta l-valur intirnsiku tagħhom hu minimu;

(f) sponsorjar ta' laqgħat promozzjonali li jattendu għalihom persuni kwalifikati biex jippreskrivu jew ifornu prodotti mediċinali; u

(g) sponsorjar ta' kongressi xjentifiċi li jattendu għalihom persuni kwalifikati biex jippreskrivu jew ifornu prodotti mediċinali u b'mod partikolari l-hlas ta' l-ispejjeż ta' u akkomodazzjoni tagħhom f'konnessjoni ma' dawn il-kongressi.

(3) Id-disposizzjonijiet tas-subregolament (1) ta' dan ir-regolament ma għandux jinkludi:

(a) t-tikkettjar u l-volantini li jkunu mal-pakkett, li huma soġġetti għad-dispożizzjonijiet ta' l-Att jew xi regolamenti magħmulin tahtu;

(b) korrispondenza, li possibilment ikollha magħha materjal ta' natura mhux promozzjonali, meħtieġa biex wiehed iwieġeb mistoqsija speċifika dwar prodott mediċinali partikolari;

(c) thabbiriet informattivi fattwali u materjal referenzjali li għandu x'jaqsam ma' materji bħal bdil ta' pakki, twissijiet ta' reazzjonijiet hżiena bhala parti minn prekawzjonijiet ġenerali

kontra d-droga, katologi kummerċjali u listi ta' prezzijiet, sakemm dawn ma jinkludux pretensjonijiet dwar il-prodott;

(d) dikjarazzjonijiet li ghandhom x'jaqsmu ma' sahha jew sahha umana, sakemm ma jkun hemm ebda referenza, kemm diretta kemm indiretta, ghal prodotti mediċinali.

4. Ir-riklamar ta' prodott mediċinali:

Kwalità ta' riklamar.

(a) ghandu jinkoraġġixxi l-użu razzjonali tal-prodott mediċinali, billi jipprezentah oggettivament u bla ma jesagera l-propjetajiet tiegħu;

(b) ghandu jikkonforma mad-dettalji mnizzlin fil-ġabra tal-karatteristiċi tal-prodott mediċinali;

(ċ) ma ghandux ikun qarrieqi.

5. (1) Hadd ma jista' jirriklama prodott mediċinali li ma nghatatilhomx awtorizzazzjoni li jistgħu jinbiegħu; Kriterji ta' riklamar.

(2) (a) Hadd ma jista' jirriklama prodott mediċinali li huma aċċessibbli biss b'ricetta medika, skond il-Klassifika ta' Prodotti mediċinali kif imfissra fl-Att jew xi regolamenti magħmulin tahtu; jew Kap. 101.

(b) fihom drogi narkotiċi jew sustanzi psikotropiċi, kif definiti taht l-Ewwel Skeda ta' l-Ordinanza dwar il-Medicini Perikolużi u t-Tielet Skeda ta' l-Ordinanza dwar il-Professjoniji Medika u l-Professjonijiet li ghandhom x'jaqsmu magħha. Kap. 31.

(3) Hadd ma jista' jsemmi fir-riklamar għall-pubbliku generali indikazzjonijiet terapewtiċi bħalma huma:

- (a) tuberkułożi;
- (b) mard trasmess sesswalment;
- (c) mard iehor serju li jittiehed;
- (d) kanċer u mard iehor tat-tumuri;
- (e) insomnja kronika;
- (f) dijabete u mard iehor metaboliku.

(4) Ebda prodott mediċinali ma jista' jitqassam direttament lill-pubbliku mill-industrija għal skopijiet promozzjonali sakemm din id-distribuzzjoni ma hix awtorizzata mill-Awtorita dawr il-Licenzjar f'kazijiet speċjali u għal skopijiet speċifiċi:

Iżda d-disposizzjonijiet tas-subregolamenti (1) u (2) ma ghandhomx japplikaw ghal kampanji ta' tilqim meta dawn isiru mill-industrija wara li tkun gabet l-approvazzjoni ta' l-Awtorita dwar il-Licenzjar.

(5) Prodotti mediċinali jistghu jkunu riklamati lill-pubbliku ġenerali li, bis-saħħa tal-kompożizzjoni u skop tagħhom, huma maħsubin u disinjati biex jintużaw bla intervent ta' tabib għal skopijiet ta' dijanjosi jew għal preskrizzjoni jew kontrollar kontinwu ta' kura, bil-parir ta' l-ispjżjar jekk ikun hemm bżonn;

Metodu ta' riklamar.

6. Bla preġudizzju għar-regolament 5 ta' dawn ir-regolamenti, ir-riklamar kollu lill-pubbliku ġenerali ta' prodott mediċinali għandu:

(a) jkun imfassal b'mod li jkun ċar li l-messaġġ hu riklam u li l-prodott hu identifikat ċar bħala prodott mediċinali;

(b) jinkludi għall-inqas l-informazzjoni li ġejja:

(i) isem il-prodott mediċinali, u wkoll l-isem komuni jekk il-prodott mediċinali jkun fih sustanza attiva wahda biss;

(ii) l-informazzjoni meħtieġa għall-użu korrett tal-prodott mediċinali; u

(iii) stedina legibbli espressa biex wiehed jaqra tajjeb l-istruzzjonijiet fuq il-volantin tal-pakkett jew fuq l-ippakkjar ta' barra, skond il-każ.

Materjal eskluż fir-riklamar.

7. Ir-riklamar ta' prodott mediċinali lill-pubbliku ġenerali ma għandu jkollu ebda materjal li:

(a) jagħti l-impresjoni li konsultazzjoni medika jew operazzjoni kirurġika m'hix meħtieġa, b'mod partikolari billi joffri dijanjosi jew billi jissuġġerixxi kura bil-posta, internet jew xi mezz ieħor;

(b) jissuġġerixxi li l-effetti tat-tehid tal-mediċina huma garantiti, ma jistghux iġibu reazzjonijiet hżiena jew huma aħjar minn, jew ekwivalenti għal, dawġ ta' kura jew prodott mediċinali ohra;

(c) jissuġġerixxi li s-saħħa tal-persuna tista' titjeb bit-tehid tal-mediċina;

(d) jissuġġerixxi li s-sahha tal-persuna tista' tintlaqat jekk ma jihux il-mediċina. Izda dan ma japplikax għall-kampanji ta' tilqim imsemmija fis-subregolamenti (1) u (2) tar-regolament 5 ta' hawnhekk;

(e) hu dirett esklussivament jew prinċipalment għat-tfal;

(f) jirreferi għal rakkomandazzjoni minn xjenzjati, nies jew persuni professjonisti tas-sahha li m'huma xejn minn dan iżda li, minhabba ċ-ċelebrità tagħhom, jistgħu jinkoraġġixxu l-konsum ta' prodotti mediċinali;

(g) jissuġġerixxi li l-prodott mediċinali hu oġġett ta' l-ikel, kosmetiku jew prodott iehor tal-konsumatur;

(h) jissuġġerixxi li s-sigurtà jew l-effikaċja tal-prodott mediċinali ġejja mill-fatt li hu naturali;

(i) jista', b'deskrizzjoni jew rappreżentazzjoni dettaljata ta' l-istorja tal-każ, iwassal għal awtodijanjosi żbaljata;

(j) jirreferi, bi kliem mhux adatt, allarmanti jew qarrieq, għal pretesjonijiet ta' fejqan;

(k) juża, bi kliem mhux adatt, allarmanti jew qarrieq, rappreżentazzjonijiet bi stampi ta' kambjament fil-ġisem tal-bniedem ikkaġunati minn mard jew leżjoni, jew ta' l-azzjoni ta' prodott mediċinali fuq il-ġisem tal-bniedem jew fuq partijiet minnu;

(l) isemmi li l-prodott mediċinali jkun ingħata awtorizzazzjoni biex jinbiegh.

8. Kull riklamar ta' prodott mediċinali lil persuni kwalifikati biex jippreskrivu jew ifornu dawn il-prodotti għandu jinkludi:

Materjal ta' riklamar lil persuni kwalifikati biex jippreskrivu.

(a) informazzjoni essenzjali kompatibbli mal-ġabra ta' karatteristiċi li għandha tinkludi -

- i) l-isem kummerċjali
- ii) lista ta' ingredjenti attivi;
- iii) għamla farmaċewtika
- iv) indikazzjoni maġġuri kif jintuża;
- v) id-dożaġġ u metodu kif jintuża;
- vi) effetti sekondarji, twissijiet, prekawzjonijiet u kontro-indikazzjonijiet;

vii) l-isem u l-indirizz tad-detentur ta' l-awtorizzazzjoni għall-bejgħ; u

(b) il-klassifika ta' forniment tal-prodott mediċinali.

Informazzjoni
minima fuq
dokumenti.

9. (1) Kull dokumentazzjoni li għandha x'taqsam ma' prodott mediċinali li hu trasmess bhala parti mill-promozzjoni ta' dak il-prodott lil persuni kwalifikati biex jippreskrivuh jew ifornuh għandha tinkludi, bhala minimu, id-dettalji mnizzlin fir-regolament 8 ta' hawnhekk u għandha tagħti d-data li fiha saret jew kienet riveduta l-ahhar darba.

(2) Kull informazzjoni li tkun fid-dokumentazzjoni msemmija fis-subregolament (1) ta' dan ir-regolament għandha tkun eżatta, aġġornata, verifikabbli u kompleta biżżejjed biex min jirċeviha jkun jista' jifhem il-valur terapewtiku tal-prodott mediċinali involut.

(3) Kwotazzjonijiet u wkoll tabelli jew materjal illustrattiv iehor mehud minn perjodiċi mediċi jew xoghlijiet xjentifiċi ohra biex jintużaw fid-dokumentazzjoni msemmija fis-subregolament (1) ta' dawn ir-regolamenti għandha tkun riprodotta fedelment u s-sors preċiża għandha tkun indikata.

Ebda rigali jew
vantagġ monetarju
jew benefiċċji
f'forma ta' oġġetti.

10. (1) Meta prodotti mediċinali jkunu qed jiġu promossi lil persuni kwalifikati biex jippreskrivuhom jew ifornuhom, ebda rigali, vantagġi monetarji jew benefiċċji f'forma ta' oġġetti ma jistgħu jkunu fornuti, offruti jew imwiegħda sakemm ma jkunux irħas u rilevanti għall-prattika tal-mediċina jew farmaċija.

(2) Ospitalità fil-promozzjoni tal-bejgħ u ospitalità li tiġi offruta f'okkażjonijiet purament professjonali u xjentifiċi għandha dejjem tkun f'livell raġonevoli u sekondarja għall-iskop ewlieni tal-laqgħa u ma tistax tkun estiza għal nies li m'humiex professjonisti tas-saħħa.

(3) Persuni kwalifikati biex jippreskrivu jew ifornu prodotti mediċinali ma għandhomx iħajjru jew jaċċettaw xi taħjir ipprojbit mis-subregolament (1) jew li jmur kontra s-subregolament (2) ta' dan ir-regolament:

Iżda l-mizuri jew prattiċi eżistenti dwar prezzijiet, margini ta' qligħ u skonti ma għandhomx jintlaqtu.

Kampjuni b'xejn.

11. (1) Kampjuni b'xejn għandhom ikunu pprovduti fuq bażi eċċezzjonali lil persuni biss li huma kwalifikati biex jippreskrivuhom u bil-kondizzjonijiet li ġejjin:

- (a) in-numru ta' kampjuni għal kull prodott mediċinali kull sena li jingħata b'ricetta għandu jkun limitat;
- (b) kull forniture ta' kampjuni għandha ssir bi tweġiba għal talba bil-miktub li trid tkun iffirmata u ddatata mill-aġent li jkun qed jippreskrivi;
- (c) persuni li jfornu kampjuni għandhom iżommu sistema adegwata ta' kontroll u kontabilità;
- (d) kull kampjun għandu jkun identiku ma' l-iċken preżentazzjoni fis-suq;
- (e) kull kampjun għandu jkun immarkat "kampjun mediku b'xejn - m'hux għall-bejgħ" jew għandu juri xi kliem ieħor li għandu l-istess tifsira. Dan għandu jkun legibbli u ma jithassarx.
- (f) kull kampjun għandu jkollu miegħu kopja tal-ġabra tal-karatteristiċi tal-prodott;
- (g) ebda kampjun ta' prodotti mediċinali li fihom sustanzi psikotropiċi jew narkotiċi fis-sens tat-tifsira ta' konvenzjonijiet internazzjonali, kif definiti taht l- Ewwel Skeda ta' l-Ordinanza dwar il-Medicini Perikolużi u t-Tielet Skeda ta' l-Ordinanza dwar il- Professjoniji Medika u l-Professjonijiet li għandhom x'jaqsmu magħha, ma jista' jkun fornut.

(2) Bla preġudizzju għas-subregolament (1) ta' dan ir-regolament, kampjuni ta' prodotti mediċinali kklassifikati skond l-artikolu 29(2) ta' l-Att li huma prodotti mediċinali li jistgħu jkunu preskritti biss minn klassi speċifika ta' preskriventi għandhom ikunu distribwiti biss lil din il-klassi ta' preskriventi.

(3) Starter packs ma għandhomx jitqiesu bħala kampjuni u ma għandhomx ikunu ttikkettjati bħala tali.

12. (1) Pjazzisti mediċi għandhom jingħataw taħriġ adegwat mid-ditta li timpjegahom u għandu jkollhom għarfien biżżejjed biex ikunu jistgħu jagħtu informazzjoni li hi preċiża u kemm jista' jkun kompleta dwar il-prodotti mediċinali li huma jippromwovu. ^{Pjazzisti.}

(2) Waqt kull żjara, pjazzisti mediċi għandhom jagħtu lil persuni lil jżuru, jew ikollhom lesti għalihom, ġabriet tal-karatteristiċi ta' kull prodott mediċinali li jipprezentaw, flimkien ma' dettalji tal-prezz.

(3) Pjazzisti mediċi għandhom jittrasmettu lis-servizz xjentifiku msemmi fir-regolament 13 ta' dan ir-regolament kull informazzjoni fuq l-użu tal-prodotti mediċinali li huma jirriklamaw, b'referenza partikolari għal xi reazzjonijiet hżiena rrapportati lilhom mill-persuni li huma jżuru.

Detentur ta' awtorizzazzjoni għall-bejgħ.

13. (1) Id-detentur ta' awtorizzazzjoni għall-bejgħ għandu jistabbilixxi, fl-azjenda tiegħu, servizz xjentifiku inkarigat mill-informazzjoni dwar il-prodotti mediċinali li hu jqiegħed fis-suq.

(2) Id-detentur ta' awtorizzazzjoni għall-bejgħ għandu:

(a) jzomm aċċessibbli għall-kumitat għar-riklamar ta' prodotti mediċinali, jew jikkomunikalu, kampjun ta' kull riklam li johroġ mill-azjenda tiegħu flimkien ma' dikjarazzjoni li tindika l-persuni li lilhom hija indirizzata, il-metodu ta' disseminazzjoni u d-data ta' l-ewwel disseminazzjoni;

(b) jiżgura li r-riklamar tal-prodotti mediċinali mill-azjenda tiegħu jikkonforma mal-htigiet ta' dawn ir-regolamenti;

(ċ) jivverifika li l-pjazzisti mediċi impjegati mill-azjenda tiegħu ngħataw tahriġ adegwat u li huma jaqdu l-obbligi imposti fuqhom mir-regolament 12 ta' dawn ir-regolamenti;

(d) ifornu lill-kumitat għar-riklamar l-informazzjoni u għajnuna li jehtieg biex jaqdi r-responsabbiltajiet tiegħu;

(e) jiżgura li d-deċiżjonijiet mehudin u l-kondizzjonijiet imposti mill-kumitat għar-riklamar jitharsu immedjatament u kompletament.

Kumitat għar-riklamar.

14. (1) Għandu jitwaqqaf fl-Awtorità kumitat għar-riklamar magħmul minn persuni kwalifikati kif imiss skond kif stabbilit mill-Ufficial Ezekuttiv Ewlieni ta' l-Awtorità.

(2) Il-kumitat għar-riklamar għandu jkun responsabbli għal materji ta' riklamar li jinkludu:

(a) l-offerta ta' pariri u informazzjoni fuq materji ta' riklamar;

(b) il-hruġ ta' kondizzjonijiet u linji ta' gwida fuq riklamar;

(ċ) il-kontroll kontinwu ta' riklami ta' prodott mediċinali;

(d) l-investigazzjoni ta' każijiet ta' ksur ta' dawn ir-regolamenti jew xi linji ta' gwida li jistgħu jinharġu mill-Awtorità, inklużi lmenti mressqin mill-pubbliku.

L.N. 400 of 2003

**MEDICINES ACT, 2003
(ACT NO. III of 2003)**

Medicinal Products (Advertising) Regulations, 2003

IN exercise of the powers conferred by articles 31 and 106 of the Medicines Act, 2003, the Minister of Health, has made the following regulations:-

1. (1) The title of these regulations is the Medicinal Products (Advertising) Regulations, 2003. Citation and commencement

(2) These regulations shall come into force on the 1st May, 2004.

2. In these regulations, unless the context otherwise requires: Interpretation.

“the Act” means the Medicines Act;

“the advertising committee” means the advertising committee for medicinal products working within the Authority;

“the Authority” means the Medicines Authority established under article 4 of the Act;

“medicinal products” means medicinals for human use;

“starter packs” means small packs for which a market authorisation has been granted, designed to provide sufficient medicine for a prescriber to initiate treatment in such circumstances where there might be undesirable or unavoidable delay in having a prescription dispensed, where immediate commencement of treatment is necessary, or where the prescriber feels that the use of such presentation is indicated in the interests of the patient;

3. (1) Advertising of medicinal products shall include any form of door-to-door information, canvassing activity or inducement designed to promote through any means or media the prescription, supply, sale or consumption of medicinal products.

(2) Such advertising shall in particular include:

(a) the advertising of medicinal products to the general public;

(b) advertising of medicinal products to persons qualified to prescribe or supply them;

(c) visits by medical sales representatives to persons qualified to prescribe or supply medicinal products;

(d) the supply of samples;

(e) the provision of inducements to prescribe or supply medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in kind, except when their intrinsic value is minimal;

(f) sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products; and

(g) sponsorship of scientific congresses attended by persons qualified to prescribe or supply medicinal products and in particular payment of their travelling and accommodation expenses in connection therewith.

(3) The provisions of sub-regulation (1) hereof shall not include:

(a) the labelling and the accompanying package leaflets, which are subject to the provisions of the Act or any regulations made thereunder;

(b) correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product;

(c) factual, informative announcements and reference material relating to such matters as pack changes, adverse-reaction warnings as part of general drug precautions, trade catalogues and price lists, provided they include no product claims;

(d) statements relating to human health or diseases, provided there is no reference, either direct or indirect, to medicinal products.

4. The advertising of a medicinal product:

Advertising quality.

(a) shall encourage the rational use of the medicinal product, by presenting it objectively and without exaggerating its properties;

(b) shall comply with the particulars listed in the summary of product characteristics of the medicinal product;

(c) shall not be misleading.

5. (1) It shall not be lawful to advertise medicinal products for which no marketing authorisation has been granted;

Advertising criteria

(2) (a) It shall not be lawful to advertise to the general public medicinal products which are available on medical prescription only, in accordance with the Classification of Medicinal Products as defined in the Act or any regulations made thereunder; or

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(b) contain narcotic drugs or psychotropic substances, as defined under the First Schedule of the Dangerous Drugs Ordinance and the Third Schedule of the Medical and Kindred Professions Ordinance.

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(3) It shall not be lawful to mention in advertising to the general public therapeutic indications such as:

- (a) tuberculosis;
- (b) sexually transmitted diseases;
- (c) other serious infectious diseases;
- (d) cancer and other tumoral diseases;
- (e) chronic insommmnia;
- (f) diabetes and other metabolic diseases.

(4) No medicinal products may be distributed directly to the public by the industry for promotional purposes unless such distribution is authorised by the Licensing Authority in special cases and for specific purposes:

Provided that the provisions of sub-regulations (1) and (2) shall not apply to vaccination campaigns when these are carried out by industry after having obtained the approval of the Licensing Authority.

(5) Medicinal products may be advertised to the general public which, by virtue of their composition and purpose, are intended and designed for use without the intervention of a medical practitioner for diagnostic purposes or for the prescription or monitoring of treatment, with the advice of the pharmacist, if necessary.

Method of advertising.

6. Without prejudice to regulation 5 of these regulations, all advertising to the general public of a medicinal product shall:

(a) be set out in such a way to be clear that the message is an advertisement and that the product is clearly identified as a medicinal product;

(b) include the following minimum information:

(i) the name of the medicinal product, as well as the common name if the medicinal product contains only one active substance;

(ii) the information necessary for the correct use of the medicinal product; and

(iii) an express, legible invitation to read carefully the instructions on the package leaflet or on the outer packaging, as the case may be.

Excluded material in advertising.

7. The advertising of a medicinal product to the general public shall not contain any material which:

(a) gives the impression that a medical consultation or surgical operation is unnecessary, in particular by offering a diagnosis or by suggesting treatment by mail, internet or any other means;

(b) suggests that the effects of taking the medicine are guaranteed, are unaccompanied by adverse reactions or are better than, or equivalent to, those of another treatment or medicinal product;

(c) suggests that the health of the subject can be enhanced by taking the medicine;

(d) suggests that the health of the subject could be affected by not taking the medicine provided that this shall not apply to the vaccination campaigns referred to in sub-regulations (1) and (2) of regulation 5 hereof;

(e) is directed exclusively or principally at children;

(f) refers to a recommendation by scientists, health professionals or persons who are neither of the foregoing but who,

because of their celebrity, could encourage the consumption of medicinal products;

(g) suggests that the medicinal product is a foodstuff, cosmetic or other consumer product;

(h) suggests that the safety or efficacy of the medicinal product is due to the fact that it is natural;

(i) could, by a description or detailed representation of a case history, lead to erroneous self-diagnosis;

(j) refers, in improper, alarming or misleading terms, to claims of recovery;

(k) uses, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of a medicinal product on the human body or parts thereof;

(l) mentions that the medicinal product has been granted a marketing authorisation.

8. Any advertising of a medicinal product to persons qualified to prescribe or supply such products shall include: Advertising material to persons qualified to prescribe

(a) essential information compatible with the summary of product characteristics which shall include -

- i) the trade name
- ii) a list of active ingredients;
- iii) a pharmaceutical form;
- iv) major indications for use;
- v) the dosage and method of use;
- vi) side effects, warnings, precautions and contraindications;
- vii) the name and address of the market authorisation holder; and

(b) the supply classification of the medicinal product.

9. (1) Any documentation relating to a medicinal product which is transmitted as part of the promotion of that product to persons qualified to prescribe or supply it shall include, as a minimum, the particulars listed in regulation 8 hereof and shall state the date on which it was drawn up or last revised. Minimum information on documents.

(2) All the information contained in the documentation referred to in sub-regulation (1) of this regulation, shall be accurate, up-to-date, verifiable and sufficiently complete to enable the recipient to understand the therapeutic value of the medicinal product concerned.

(3) Quotations as well as tables and other illustrative matter taken from medical journals or other scientific works for use in the documentation referred to in sub-regulation (1) of these regulations, shall be faithfully reproduced and the precise sources indicated.

No gifts, or pecuniary advantages or benefits in kind.

10. (1) Where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy.

(2) Hospitality at sales promotion and hospitality being offered at events for purely professional and scientific purposes, shall always be reasonable in level and secondary to the main purpose of the meeting and must not be extended to other than health professionals.

(3) Persons qualified to prescribe or supply medicinal products shall not solicit or accept any inducement prohibited under sub-regulation (1) or contrary to sub-regulation (2) of this regulation:

Provided that existing measures or trade practices relating to prices, profit margins and discounts shall not be affected.

Free samples.

11. (1) Free samples shall be provided on an exceptional basis only to persons qualified to prescribe them and on the following conditions:

(a) the number of samples for each medicinal product each year on prescription shall be limited;

(b) any supply of samples shall be in response to a written request, to be signed and dated, from the prescribing agent;

(c) persons supplying samples shall maintain an adequate system of control and accountability;

(d) each sample shall be identical with the smallest presentation on the market;

(e) each sample shall be marked "free medical sample - not for sale" or shall show some other wording having the same meaning. Such marking shall be legible and indelible;

(f) each sample shall be accompanied by a copy of the summary of product characteristics;

(g) no samples of medicinal products containing psychotropic or narcotic substances as defined under the First Schedule of the Dangerous Drugs Ordinance and the Third Schedule of the Medical and Kindred Professions Ordinance, may be supplied.

(2) Without prejudice to sub-regulation (1) of this regulation, samples of medicinal products classified in terms of article 29(2) of the Act as being medicinal products that can only be prescribed by a specific class of prescriber shall only be distributed to such class of prescribers.

(3) Starter packs shall not be regarded as samples and shall not be labelled as such.

12. (1) Medical sales representatives shall be given adequate training by the firm which employs them and shall have sufficient scientific knowledge to be able to provide information which is precise and as complete as possible about the medicinal products which they promote. Sales representatives.

(2) During each visit, medical sales representatives shall give the persons visited, or have available for them, summaries of the product characteristics of each medicinal product they present together with details of the price .

(3) Medical sales representatives shall transmit to the scientific service referred to in regulation 13 hereof any information about the use of the medicinal products they advertise, with particular reference to any adverse reactions reported to them by the persons they visit.

13. (1) The marketing authorisation holder shall establish, within his undertaking, a scientific service in charge of information about the medicinal products, which he places on the market. Detentur ta' awtorizzazzjoni għall-bejgh.

(2) The marketing authorisation holder shall:

(a) keep available for, or communicate to, the advertising committee for medicinal products, a sample of all advertisements emanating from his undertaking together with a statement indicating the persons to whom it is addressed, the method of dissemination and the date of first dissemination,

(b) ensure that advertising of medicinal products by his undertaking conforms to the requirements of these regulations,

(c) verify that medical sales representatives employed by his undertaking have been adequately trained and that they fulfill the obligations imposed upon them by regulation 12 hereof,

(d) supply the advertising committee with the information and assistance it requires to carry out its responsibilities,

(e) ensure that the decisions taken and conditions imposed by the advertising committee are immediately and fully complied with.

Advertising
committee.

14. (1) There shall be established within the Authority an advertising committee made up of appropriately qualified staff as determined by the Chief Executive Officer of the Authority.

(2) The advertising committee shall be responsible for advertising issues which include:

(a) the offering of advice and information on advertising issues;

(b) the issuing of conditions and guidelines on advertising;

(c) the monitoring of advertisements of medicinal products;

(d) the investigation of cases suspected of breaching these regulations or any guidelines as may be issued by the Authority, including complaints made by the public.