

A.L. 72 ta' l-2005

**ATT TA' L-2003 DWAR IL-MEDIĊINI
(ATT NRU. III TA' L-2003)**

**Regolamenti ta' l-2005 li jemendaw ir-Regolamenti dwar
il-Mediċini (Awtorizzazzjoni għal Tqeghid fis-Suq)**

BIS-SAHHA tas-setgħat mogħtija bl-artikolu 106 ta' l-Att dwar il-Mediċini, il-Ministru tas-Sahha, Anzjani u Kura fil-Komunità għamel ir-regolamenti li ġejjin:

1. It-titolu ta' dawn ir-regolamenti hu Regolamenti ta' l-2005 li jemendaw ir-Regolamenti dwar il-Mediċini (Awtorizzazzjoni għal Tqeghid fis-Suq), u dawn għandhom jinqraw u jiftiehmha waħda mar-Regolamenti ta' l-2004 dwar il-Mediċini (Awtorizzazzjoni għal Tqeghid fis-Suq) hawnhekk iżjed 'il quddiem imsejha "ir-regolamenti prinċipali".

Titolu.

A.L. 387 ta' l-2004.

2. Ir-regolament 2 tar-regolamenti prinċipali għandu jiġi emendat kif ġej –

Jemenda r-regolament 2 tar-regolamenti prinċipali.

(a) wara d-definizzjoni "medicini" għandha tidhol din it-tifsira li li ġejja:

““prodott mediċinali ġeneriku” tfisser prodott mediċinali li għandu l-istess kompożizzjoni kwalitattiva u kwantitattiva ta' sustanzi attivi u l-istess forma farmaċwetika bħal dik tal-prodott mediċinali ta' referenza, u li l-bioekwivalenza tiegħu mal-prodott mediċinali tista' tkun ġiet ippruvata bi studji ta' biodisponibilità adatti. Il-melħ differenti, esterj, eterj, iżomerj, taħlit ta' iżomerj, komplessi jew derivattivi ta' sustanza attiva għandhom ikunu kkunsidrati li huma l-istess sustanza attiva, sakemm ma jkunux differenti b'mod sinifikanti fil-proprietajiet tagħhom fejn għandha x'taqsam is-sigurtà u, jew l-effikaċja. F'każijiet bħal dawk, informazzjoni addizzjonali li ttiprovdi prova dwar is-sigurtà u, jew l-effikaċja tal-melħ differenti, esterj jew derivattivi ta' sustanza attiva awtorizzata għandha tkun ipprovduta mill-applikant. Il-forom farmaċewtiċi orali ta' rilaxx immedjat differenti għandhom jiġu kkunsidrati bħala forma farmaċewtika waħda u l-istess.

Ma jkunux mehtieġa studji ta' biodisponibilità minghand l-applikant jekk huwa jkun jista' juri li l-prodott mediċinali ġeneriku jkun jissodisfa l-kriterji rilevanti kif definiti fil-linji gwida dettaljati adatti;"; u

(b) wara t-tifsira ta' "Stat Membru" għandu jidhol dan li ġej:

“ “prodott mediċinali ta' referenza” tfisser prodott mediċinali awtorizzat taht ir-regolament 4(1) u skond il-provvedimenti tar-regolamenti 5 u 6;”.

Tissostitwixxi r-regolament 7 tar-regolamenti prinċipali.

3. Minflok ir-regolament 7 tar-regolamenti prinċipali għandu jidhol dan li ġej:

“ (1) B'deroga mir-regolament 5 u minghajr preġudizzju għal liġi dwar il-protezzjoni tal-proprietà industrijali u kummerċjali, l-applikanti ma jkunx mitlub li jiprovdi r-riżultati tal-provi qabel dawk kliniċi u tal-provi kliniċi jekk huwa juri li:

(a) il-prodott mediċinali huwa essenzjalment simili għal iehor li huwa diġà awtorizzat f'Malta, u li d-detentur ta' l-awtorizzazzjoni għal tqeghid fis-suq ta' dak il-prodott simili jkun ta l-kunsens tiegħu għar-referenzi tossikoloġiċi, farmakoloġiċi u, jew kliniċi li jkunu jinsabu fid-*dossier* ta' dak il-prodott li jkun qed jintuza għall fini ta' l-eżami ta' l-applikazzjoni msemmija; jew

(b) il-kostitwent jew kostitwenti tal-prodott mediċinali għandhom użu mediku stabbilit kif imiss, b'effikaċja rikonoxxuta u b'livell ta' sigurta aċċettabbli permezz ta' biblijografija xjentifika dettaljata; jew

(ċ) il-prodott mediċinali huwa wiehed ġeneriku ta' prodott mediċinali ta' referenza li huwa jew kien awtorizzat taht regolament 4(1) ta' dawn ir-regolamenti għal mhux anqas minn sitt snin fi Stat Membru jew fil-Komunità:

Iżda:—

(i) subregolament (ċ) (i) japplika wkoll jekk il-prodott mediċinali ta' referenza ma kienx awtorizzat skond regolament 4(1) ta' dawn ir-regolamenti, f'liema każ, l-applikant għandu jindika fil-formola ta' l-applikazzjoni l-isem ta' l-Istat Membru fejn jiġi jew ikun ġie awtorizzat il-prodott mediċinali ta' referenza;

(ii) prodott mediċinali ġeneriku awtorizzat konformement ma' din id- dispozizzjoni ma għandux jittqiegħed fis-suq kemm-il darba l-perjodu stabbilit għall-esklużività ta' data ma jkunx għadda mill-awtorizzazzjoni inizjali tal-prodott ta' referenza.

(iii) fil-każijiet fejn il-prodott mediċinali ma jkunx jirrikwarda fid-definizzjoni ta' prodott mediċinali ġeneriku jew fejn il-bioekwivalenza ma tistax tiġi murija permezz ta' studji ta' biodisponibilità jew fil-każ ta' bdil f'xi sustanza attiva, indikazzjonijiet terapewtiċi, għandhom jiġu pprovduti is-sahha, il-forma farmaċewtika jew ir-rotta ta' amministrazzjoni, għar-rigward tal-prodott mediċinali ta' referenza, r-riżultati tal-provi qabel dawk kliniċi jew tal-provi kliniċi.

(iv) meta prodott mediċinali bijoloġiku li jkun simili għal prodott bijoloġiku ta' referenza ma jkunx jissodisfa l-kondizzjonijiet fit-tifsir ta' prodotti mediċinali ġeneriċi, minhabba, b'mod partikolari, differenzi relatati mal- materja prima jew ma' differenzi fil-proċessi ta' manifattura tal-prodott mediċinali bijoloġiku u l-prodott mediċinali bijoloġiku ta' referenza, għandhom jiġu pprovduti r-riżultati ta' provi adatti qabel dawk kliniċi jew tal-provi kliniċi relatati ma' dawk il-kundizzjonijiet. It-tip u l-kwantità ta' informazzjoni supplimentari li għandha tiġi pprovduta għandha tkun konformi ma' l-kriterji rilevanti msemmija fl-Anness I mad-Direttiva 2003/63 KE u l-linji ta' gwida dettaljati relatati. Ir-riżultati ta' testijiet u provi ohra mid-*dossier* tal-prodott mediċinali ta' referenza ma għandhomx jiġu provduti.

(2) Fil-każ ta' prodotti mediċinali godda li jkun fihom kostitwenti magħrufin sa dak inhar mhux mhallta flimkien għal finijiet terapewtiċi, għandhom jiġu provduti r-riżultati ta' testijiet tossikoloġiku u farmakoloġiċi u ta' provi kliniċi relatati ma' dik it-taħlita, iżda ma jkunx neċessarju li jiġu provduti riferenzi relatati ma kull kostitwent individwali:

Izda t-tmexxija ta' l-istudji u provi neċessarji sabiex jiġu applikati s-subregolament(1) u (2) u r-rekwiżiti prattiċi konsegwenzjali ma għandhomx jiġu meqjusa li jmorru kontra d-drittijiet li johorgu minn xi privata jew kontra xi ċertifikati ta' protezzjoni supplimentari għal prodotti mediċinali.”.

L.N. 72 of 2005

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

**Medicines (Marketing Authorisation) (Amendment) Regulations,
2005**

IN exercise of the powers conferred conferred by article 106 of the Medicine's Act, 2003, the Minister of Health, the Elderly and Community Care, has made the following regulations:-

Citation.

L.N. 387 of 2004.

Amends regulation 2 of the principal regulations.

1. The title of these regulations is the Medicines (Marketing Authorisation) (Amendment) Regulations, 2005 and they shall be read and construed as one with the Medicines (Marketing Authorisation) Regulations, 2004, hereinafter referred to as "the principal regulations".

2. Regulation 2 of the principal regulations, shall be amended as follows –

(a) after the definition "the Authority", there shall be inserted the following new definition:-

““generic medicinal product” means a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and, or efficacy. In such cases, additional information providing proof of the safety and, or efficacy of the various salts, esters or derivatives of an authorised active substance must be supplied by the applicant. The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form. Bioavailability studies need not be required of the applicant if he can demonstrate that the generic medicinal product meets the relevant criteria as defined in the appropriate detailed guidelines;” and

(b) after the definition "Member State" there shall be inserted the following: -

“reference medicinal product” means a medicinal product authorised under regulation 4(1) and in accordance with the provisions of regulations 5 and 6;”.

3. For regulation 7 of the principal regulations there shall be substituted the following:

Substitutes regulation 7 of the principal regulations.

“ (1) By way of derogation from regulation 5 and without prejudice to the law relating to the protection of industrial and commercial property, the applicant shall not be required to provide the results of pre-clinical tests and of clinical trials if he can demonstrate that:

(a) the medicinal product is essentially similar to another already authorised in Malta, and that the holder of the marketing authorisation of such similar product has consented to the toxicological, pharmacological and, or clinical references contained in the file of such product being used for the purpose of examining the application in question; or

(b) the constituent or constituents of the medicinal product have a well-established medicinal use, with recognised efficacy and an acceptable level of safety by means of a detailed scientific bibliography; or

(c) the medicinal product is a generic of a reference medicinal product which is or has been authorized under regulation 4(1) of these regulations for not less than six years in a Member State or in the Community:

Provided that –

(i) subregulation (c)(i) shall also apply if the reference medicinal product was not authorised in accordance with articles 4(1) of these regulations, in which case the applicant shall indicate in the application form the name of the Member State in which the reference medicinal product is or has been authorised;

(ii) a generic medicinal product authorised pursuant to this provision shall not be placed on the market until the established period for data exclusivity has elapsed from the initial authorisation of the reference product;

(iii) in cases where the medicinal product does not fall within the definition of a generic medicinal product or where the bioequivalence cannot be demonstrated through bioavailability studies or in case of changes in any active substance, therapeutic indications, strength, pharmaceutical form or route of administration, vis-à-vis the reference medicinal product, the results of the appropriate pre-clinical tests or clinical trials shall be provided;

(iv) where a biological medicinal product which is similar to a reference biological product does not meet the conditions in the definition of generic medicinal products owing to, in particular, differences relating to raw materials or differences in manufacturing processes of the biological medicinal product and the reference biological medicinal product, the results of appropriate pre-clinical tests or clinical trials relating to these conditions must be provided. The type and quantity of supplementary data to be provided must comply with the relevant criteria stated in Annex I of EU directive 2003/63 and the related detailed guidelines. The results of other tests and trials from the reference medicinal product's dossier shall not be provided.

(2) In the case of new medicinal products containing known constituents not hitherto used in combination for therapeutic purposes, the results of toxicological and pharmacological tests and of clinical trials relating to that combination must be provided, but it shall not be necessary to provide references relating to each individual constituent:

Provided that conducting the necessary studies and trials with a view to the application of subregulation (1) and (2) and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products.”.