

A.L. 22 ta' l-2004**ATT TA' L-2003 DWAR IL-MEDIĊINI
(ATT NRU. III TA' L-2003)****Regolamenti ta' l-2004 dwar il-Farmakoviġilanza**

Bis-sahha tas-setgħat mogħtija bl-artikolu 106 ta' l-Att ta' l-2003 dwar il-Mediċini, il-Ministru tas-Sahha għamel dawn ir-regolamenti li ġejjin:-

1. (1) It-titolu ta' dawn ir-regolamenti hu Regolamenti ta' l-2004 dwar il-Farmakoviġilanza. Titolu u bidu fis-sehh.

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

2. Dawn ir-regolamenti għandhom japplikaw għal prodotti mediċinali awtorizzati għall-użu mill-bniedem u għal kull attività ta' farmakoviġilanza konnessa ma' dan. Skop.

3. Għall-finijiet ta' dawn ir-regolamenti - Tifsir.

“abbuż minn prodotti mediċinali” tfisser użu eċċessiv intenzjonali, persistenti jew sporadiku, ta' prodotti mediċinali li jkun akkumpanjat minn effetti fiżiċi jew psikoloġiċi li jagħmlu hsara;

“l-Att” tfisser l-Att ta' l-2003 dwar il-Mediċini;

“il-Kummissjoni” tfisser il-Kummissjoni skond id-Deciżjoni tal-Kunsill 1999/468/EC tat-28 ta' Ġunju 1999;

“il-Komunità” tfisser Komunità Ewropea u ż-Zona Ekonomika Ewropea;

“l-Aġenzija” tfisser l-Aġenzija Ewropea għall-Evalwazzjoni ta' Prodotti Mediċinali stabbilita minn Regolament (EEC) Numru 2309/93;

“l-Awtorità” tfisser l-Awtorità dwar il-Liċenzjar mwaqqfa skond l-artikolu 3 ta’ l-Att;

“Rapport Perjodiku Aġġornat dwar is-Sigurtà” tirreferi ghar-rapporti perjodiċi li jkun fihom id-dokumenti msemmija fir-regolament 6 ta’ dawn ir-regolamenti;

“reazzjoni hażina” tirreferi ghal rispons ghal prodott mediċinali li hu noċiv u mhux intenzjonat u li jokkorri meta tinghata doża normalment użata fil-bniedem għall-prolassi, dijanjosi jew terapija ta’ mard jew għar-restawr, korrezzjoni jew modifika ta’ funzjoni fiżjoloġika;

“reazzjoni hażina mhux mistennija” tirreferi ghal reazzjoni hażina, li n-natura, severità jew riżultat tagħha ma jkunux konsistenti mas-sommarju tal-karatteristiċi tal-prodott;

“reazzjoni hażina gravi” tirreferi ghal reazzjoni hażina li tirriżulta f’ mewt jew li tkun thedded il-hajja, jew li minhabba fiha persuna jkollha tiddaħhal l-isptar bħala pazjent jew li jittawwal iz-zmien ta’ pazjent fl-isptar, jew li tirriżulta f’ diżabilità jew inkapaċità sinifikanti, jew li tkun anomalija kongenita jew difett mit-twelid;

“Stat Membru” tfisser Stat li jkun membru ta’ l-Unjoni Ewropea u jinkludi wkoll l-Iżlanda, in-Norveġja u Lichenstein;

“studju dwar is-sigurtà wara awtorizzazzjoni” tfisser studju farmakoepidemjoloġiku jew prova klinika magħmula skond ma jkun fiha l-awtorizzazzjoni biex isir il-bejgħ, li jsiru bl-iskop li jidentifikaw jew jikkwantifikaw periklu għas-sigurtà relatat ma’ prodott mediċinali awtorizzat;

Twaqqif ta’ sistema ta’ farmakoviġilanza.

4. (a) L-Awtorità għandha twaqqaf sistema ta’ farmakoviġilanza li tintuża biex tiġbor informazzjoni utli fis-sorveljanza ta’ prodotti mediċinali, b’referenza partikolari għal reazzjonijiet hżiena fi bnedmin, tevalwa din l-informazzjoni xjentifikament u tqis kull informazzjoni aċċessibbli fuq l-użu hażin u abbuż minn prodotti mediċinali li jista’ jkollhom impatt fuq l-evalwazzjoni tal-benefiċċji u r-riskji tagħhom. (b) Għandu jkun id-dmir tat-tobba u ta’ professjonisti tas-saħħa ohrajn li jirrappurtaw lill-Awtorità kull reazzjoni hażina sospetta, kemm gravi kemm mhux mistennija, għal xi prodott mediċinali. (ċ) Din l-informazzjoni għandha tingabar u titqabbel ma’ tagħrif fuq il-konsum ta’ prodotti mediċinali.

5. (1) Ikun id-dmir tad-detentur ta' awtorizzazzjoni għall-bejgh li jkollu permanentement u kontinwament għad-disposizzjoni tiegħu persuna debitament kwalifikata responsabbli għall-farmakoviġilanza.

Dmir tad-detentur ta' awtorizzazzjoni għall-bejgh.

(2) Din il-persuna kwalifikata tkun responsabbli:

(a) għat-twaqqif u l-manutenzjoni ta' sistema ta' farmakoviġilanza li tiżgura li kull informazzjoni dwar ir-reazzjonijiet hżiena suspettati li tkun giet rappurtata lill-persunal tal-kumpannija u lil rappreżentanti mediċi, tkun miġbura u tinzamm biex tkun disponibbli għall-Awtorità;

(b) għall-preparazzjoni tar-rapporti neċessarji skond Volum 9 tar-Regoli li Jrieġu Prodotti Mediċinali fil-Komunità Ewropea;

(ċ) biex twieġeb b'mod shih u mill-ewwel għal kull talba magħmula mill-Awtorità, inkluż l-għoti ta' informazzjoni fuq il-volum ta' bejgh jew hrug ta' ricetti tal-prodotti mediċinali involuti;

(d) biex tipprovdi kull informazzjoni lill-Awtorità relatata ma' l-evalwazzjoni tal-benefiċċji u r-riskji li jkun fih prodott mediċinali, inkluża informazzjoni xierqa fuq studji dwar sigurtà wara l-awtorizzazzjoni.

6. (1) Id-detentur ta' l-awtorizzazzjoni għall-bejgh għandu jżomm dokumenti dettaljati fuq kull reazzjoni hażina suspettata għal kull prodott mediċinali mibjugħ minnu.

Dokumenti dettaljati.

(2) (a) Id-detentur ta' l-awtorizzazzjoni għall-bejgh għandu wkoll minnufih jiddokumenta u jirrapporta r-reazzjonijiet hżiena suspettati kollha li jsiru f'Malta lill-Awtorità u f'kull każ mhux aktar tard minn 15-il ġurnata kalendarja minn meta jirċievi l-informazzjoni.

(b) Id-detentur ta' l-awtorizzazzjoni għall-bejgh għandu wkoll minnufih jiddokumenta u jirrapporta r-reazzjonijiet hżiena suspettati kollha li jsiru fit-territorju ta' Stati Membri ohra lill-Awtorità kompetenti ta' l-Istat Membru li fit-territorju tiegħu tkun saret ir-reazzjoni hażina u f'kull każ mhux aktar tard minn 15-il ġurnata kalendarja minn meta jirċievi l-informazzjoni.

(ċ) Id-detentur ta' l-awtorizzazzjoni għall-bejgh għandu wkoll minnufih jiddokumenta u jirrapporta r-reazzjonijiet hżiena kollha suspettati serji u mhux mistennija li jsiru fit-territorju ta' pajjiż terz lill-Awtorità u f'kull każ mhux aktar tard minn 15-il ġurnata kalendarja minn meta jirċievi l-informazzjoni..

(3) Fil-każ ta' prodotti mediċinali li jkunu bbenefikaw mill-proċeduri ta' rikonoxximent reċiproku, id-detentur ta' l-awtorizzazzjoni għall-bejgħ għandu jinforma lill-Istat Membru ta' referenza b'kull reazzjoni hażina gravi suspettata li tkun saret fil-Komunità.

(4) Kemm-il darba ma jkunx intalab mod iehor mill-awtorizzazzjoni għall-bejgħ, jew ma jkunx gie indikat mir-Regoli li Jriegħu Prodotti Mediċinali fil-Komunità Ewropea, dokumenti tar-reazzjonijiet hżiena kollha, inkluża evalwazzjoni xjentifika tal-benefiċċji u r-riskji pprezentati mill-prodotti mediċinali, għandhom jigu pprezentati lill-Awtorità fl-għamla ta' rapport ta' sigurtà li jkun aġġornat perjodikament, jew minnufih malli dan jigi mitlub jew perjodikament wara l-ghoti ta' l-awtorizzazzjoni għall-bejgħ kif ġej:

- (a) kull sitt xhur għall-ewwel sentejn,
- (b) kull sena fis-sentejn ta' wara,
- (c) fi żmien l-ewwel tiġdid.

(5) Wara l-perjodi msemmija fis-subartikolu (4) ta/ dan ir-regolament, Rapport Perjodiku Aġġornat dwar is-Sigurtà għandhom jigu pprezentati ta' kull hames snin flimkien ma' applikazzjoni għat-tiġdid ta' l-awtorizzazzjoni. Izda d-detentur ta' awtorizzazzjoni għall-bejgħ jista' jitlob li jkun hemm bidla fil-perjodi hawn qabel imsemmija.

Rapport li jsir mill-Awtorità

7. L-Awtorità għandha tizgura li r-rapporti ta' reazzjonijiet hżiena gravi suspettati li jkunu graw fuq it-territorju tagħha jkunu minnifuh disponibbli għad-detentur ta' awtorizzazzjoni għall-bejgħ, għall-Kummissjoni, għall-Agenzija u għall-Istati Membri fi żmien 15-il gurnata kalendarja min-notifika tagħhom.

Sospensjoni,irtirar,bdil.

8. (1) L-Awtorità għandha tissospendi, tirtira jew tibdel awtorizzazzjoni għall-bejgħ kull meta azzjoni bħal dik tirrizulta mehtiega wara li ssir valutazzjoni tat-tagħrif dwar il-farmakovigilanza. Dik id-decizjoni għandha titwassal lill-Agenzija, lill-Istati Membri u lid-detentur ta' awtorizzazzjoni għall-bejgħ. (2) F'każ ta' urgenza, l-Awtorità tista' tissospendi l-awtorizzazzjoni għall-bejgħ ta' prodott mediċinali, sakemm l-Agenzija, il-Kummissjoni u l-Istati Membri jigu mgharrfa l-aktar tard sal-gurnata tax-xogħol li tkun taħbat minnufih wara.

L.N. 22 of 2004

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

Pharmacovigilance Regulations, 2004

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

1. (1) The title of these regulations is the Pharmacovigilance Regulations, 2004. Title and commencement.

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

2. These regulations shall apply to authorised medicinal products for human use and any pharmacovigilance activity connected therewith. Scope.

3. For the purposes of these regulations - Interpretation.

“abuse of medicinal products” means a persistent or sporadic, intentional excessive use of medicinal products which is accompanied by harmful physical or psychological effects;

“the Act” means the Medicines Act, 2003;

“adverse reaction” refers to a response to a medicinal product which is noxious and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of a physiological function;

“the Agency” means the European Agency for the Evaluation of Medicinal Products established by Regulation (EEC) No 2309/93;

“the Authority” means the Licensing Authority set up in terms of article 3 of the Act;

“the Commission” means the Commission in accordance with Council Decision 1999/468/EC of the 28th June, 1999;

“the Community” means the European Community and the European Economic Area;

“Member State” means a State which is a member of the European Union and shall also include Iceland, Norway and Lichenstein;

“serious adverse reaction” refers to an adverse reaction which results in death or is life-threatening, or requires in-patient hospitalisation or the prolongation of existing hospitalisation, or which results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect;

“Periodic Safety Update Report” refers to the periodical reports containing the records referred to in regulation 6 of these regulations;

“post-authorisation safety study” means a pharmacoepidemiological study or a clinical trial carried out in accordance with the terms of the marketing authorisation, conducted with the aim of identifying or quantifying a safety hazard relating to an authorised medicinal product.

“unexpected adverse reaction” refers to an adverse reaction, the nature, severity or outcome of which is not consistent with the summary of product characteristics.

Setting up of
pharmacovigilance
system.

4. (a) The Authority shall set up a pharmacovigilance system which shall be used to collect information which is useful in the surveillance of medicinal products, with particular reference to adverse reactions in human beings, to evaluate scientifically such information and to take into account any available information on the misuse and the abuse of medicinal products which may have an impact on the evaluation of their benefits and risks.

(b) It shall be the duty of doctors and other healthcare professionals to report to the Authority any suspected serious or unexpected adverse reaction to a medicinal product.

(c) Such information shall be collated together with data on the consumption of medicinal products.

Duty of the
marketing
authorisation
holder.

5. (1) It shall be the duty of the marketing authorisation holder to have permanently and continuously at his disposal an appropriately qualified person responsible for pharmacovigilance.

(2) Such qualified person shall be responsible:

(a) for the establishment and maintenance of a pharmacovigilance system to ensure that any information about suspected adverse reactions which has been reported to the personnel of the company and to medical representatives, is collected and collated to be made available to the Authority;

(b) for the drawing up of the necessary reports in accordance with Volume 9 of the Rules Governing Medicinal Products in the European Community;

(c) to reply fully and promptly to any request made by the Authority, including the provision of information about the volume of sales or prescriptions of the medicinal product concerned;

(d) to provide any information to the Authority in relation to the evaluation of the benefits and risks afforded by a medicinal product, including appropriate information on post-authorisation safety studies.

6. (1) The marketing authorisation holder shall maintain detailed records of any suspected adverse reaction to any medicinal product marketed by him. Detailed documents.

(2) (a) The marketing authorisation holder shall also immediately record and report to the Authority all suspected adverse reactions occurring in Malta and in no case later than 15 calendar days from receiving the information.

(b) The marketing authorisation holder shall also immediately record and report all suspected serious adverse reactions occurring in the territory of other Member States to the competent authority of the Member State in whose territory the adverse reaction occurred and in no case later than 15 calendar days from receiving the information.

(c) The marketing authorisation holder shall also immediately record and report all suspected serious and unexpected adverse reactions occurring in the territory of a third country to the Authority and in no case later than 15 calendar days from receiving the information.

(3) In the case of medicinal products which have benefited from the procedures of mutual recognition, the marketing authorisation holder shall inform the reference member state of any suspected serious adverse reactions which have occurred within the Community.

(4) Unless otherwise required by the marketing authorisation, or indicated by the The Rules Governing Medicinal Products in the European Community, records of all adverse reactions, including a scientific evaluation of the benefit and risks afforded by the medicinal products, shall be submitted to the Authority in the form of a periodic safety update report, either immediately upon request or periodically after the granting of the marketing authorisation as follows:

- (a) six monthly for the first two years,
- (b) annually for the subsequent two years,
- (c) at the time of the first renewal

(5) After the periods mentioned in sub-regulation (4) hereof, the Periodic Safety Update Reports shall be submitted at five-yearly intervals together with an application for the renewal of the authorisation:

Provided that the marketing authorisation holder may request a change in the periods above mentioned.

Report by the Authority.

7. The Authority shall ensure that reports of suspected serious adverse reactions that have taken place on its territory are immediately made available to the marketing authorisation holder, the Commission, the Agency and Member States within 15 calendar days of their notification.

Suspension, withdrawal, variation.

8. (1) The Authority shall suspend, withdraw or vary a marketing authorisation whenever such action results necessary following an evaluation of pharmacovigilance data. Such decision shall be communicated to the Agency, to the Member States and to the marketing authorisation holder.

(2) In any case of urgency, the Authority may suspend the marketing authorisation of a medicinal product, provided that the Agency, the Commission and the Member States are informed thereof at the latest on the following working day.