2.5.5.Website

İYI FARMAKOVIJILANS UYGULAMALARI (İFU) KILAVUZU MODÜL VIII – GÜVENLILIK İLETIŞIMI_EN

GuidelineonGood Pharmacovigilance Practices(GVP) ModuleVIII–Safety communication TURKISHMEDICINESANDMEDICALDEVICESAGENCY 27.04.2022

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SECTIONI
IntroductionandScope

1.1.IntroductionandScope

ThisModuleprovidesguidanceonhowtocommunicateandcoordinatesafetyinformation concerningmedicinalproducts.Communicatingsafetyinformationtopatientsandhealthcare professionalsisapublichealthresponsibilityandisessentialforachievingtheobjectivesof pharmacovigilanceintermsofpromotingtherational,safeandeffectiveuseofmedicines, preventingharmfromadversereactions,minimisingrisksandcontributingtotheprotection ofpatients'andpublichealth.

Safetycommunicationisabroadtermcoveringdifferenttypesofinformationon medicines,includingstatutoryinformationascontainedintheproductinformation(i.e.the summaryofproductcharacteristics(SmPC),packageleaflet(PL)andthelabellingofthe packaging).AlthoughsomeprinciplesinthisModule(Sections2.1.and2.2.)applytoall typesofsafetycommunication,theModuleitselffocusesonthecommunicationof'important newsafetyinformation',whichmeansnewinformationaboutapreviouslyknownor

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unknownriskofamedicinewhichhasorcouldhaveanimpactonamedicine'srisk-benefit balanceanditsconditionofuse.Unlessotherwisestated,theterm'safetycommunication'in thisModuleshouldbereadasreferringtonewsafetyinformation.
Highlevelsofpublicinterestareanticipatedwhennewsafetyconcernsariseanditis importantthatclearandconsistentmessagesareprovidedinatimelymanner.SectionIIofthis Moduledescribesprinciplesandmeansofsafetycommunicationaswellasgivingparticular considerationtodirecthealthcareprofessionalcommunications(DHPCs),andproviding specificguidanceforpreparingthem.Thisisbecauseofthelevelofcoordinationrequired betweenmarketingauthorisationholdersandtheAgencyintheirpreparation.
SECTIONII
Structuresandprocesses
2.1.Objectives
Mainobjectivesforconveyingsafetycommunicationtohealthcareprofessionalsorpublic aimsat:
providingtimely,evidence-basedinformationonthesafeandeffectiveuseofmedicines,
facilitatingchangestohealthcarepracticeswherenecessary,
changingattitudes,decisionsandbehavioursinrelationtotheuseofmedicines,
supportingriskminimisationbehaviour,
facilitatinginformeddecisionsontherationaluseofmedicines.
2.2.Principles
Thefollowingprinciplesshouldbetakenintoconsiderationwhileconveyingsafety communicationtohealthcareprofessionalsorpublic:
Safetycommunicationshoulddeliverrelevant,clear,accurateandconsistentmessages andreachtherightaudiencesattherighttimeforthemtotakeappropriateaction,
Safetycommunicationshouldbetailoredtotheappropriateaudiences(e.g.patients andhealthcareprofessionals)byusingappropriatelanguageandtakingaccountofthe differentlevelsofknowledgeandinformationneedswhilstmaintainingtheaccuracy andconsistencyoftheinformationconveyed,
Theneedforcommunicatingsafetyinformationshouldbeconsideredthroughoutthe pharmacovigilanceandriskmanagementprocess,andshouldbepartoftherisk assessmentandriskminimisationmeasures,
Thereshouldbeadequatecoordinationandcooperationbetweenthedifferentparties (e.g.theAgencyandmarketingauthorisationholders)involvedinissuingsafety communications,
Informationonrisksshouldbepresentedinthecontextofthebenefitsofthemedicine andincludeavailableandrelevantinformationontheseriousness,severity,frequency, riskfactors,timetoonset,reversibilityofpotentialadversereactionsandexpected timetorecovery,
Safetycommunicationshouldaddresstheuncertaintiesrelatedtoasafetyconcern,
Informationoncompetingriskssuchastheriskofnon-treatmentshouldbeincluded whereappropriate,
Themostappropriatequantitativemeasuresshouldbeusedwhendescribingand comparingrisks(e.g.theuseofabsoluterisksandnotjustrelativerisks);when comparingrisks,denominatorsshouldbethesameinsize(Theuseofothertoolssuch asgraphicalpresentationoftheriskand/ortherisk-benefitbalancemayalsobe considered),
Patientsandhealthcareprofessionalsshould,wherepossible,beconsultedand messagespre-testedearlyinthepreparationofsafetycommunication,particularlyon complexsafetyconcerns,
Whererelevantsafetycommunicationshouldbecomplementedatalaterstagewith follow-upcommunication(e.g.ontheresolutionofasafetyconcernorupdated

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recommendations),
Theeffectivenessofsafetycommunicationshouldbeevaluatedwhereappropriateand possible(see2.6),
Safetycommunicationsshouldcomplywithrelevantrequirementsrelatingtoindividual dataprotectionandconfidentiality.
2.3.Targetaudiences
Theprimarytargetaudiencesforsafetycommunicationissuedbytheagencyand marketingauthorisationholdersshouldbepatients,carersandhealthcareprofessionals. Healthcareprofessionalsplayanessentialroleinensuringthatmedicinesareusedas effectivelyandsafelyaspossible.Effectivesafetycommunicationenablesthemtotake adequateactionstominimiserisksandtogiveclearandusefulinformationtotheirpatients. Thisultimatelypromotespatientsafetyandconfidenceintheregulatorysystem.Both healthcareprofessionalsinclinicalpracticeandthoseinvolvedinclinicaltrialsshouldbe providedwithappropriateinformationonanysafetyconcernatthesametime. Patient,consumerandhealthcareprofessionalorganisationscanplayaroleas multipliersastheycandisseminateimportantsafetyinformationtotargetaudiences. Themediaisalsoatargetaudienceforsafetycommunication.Thecapacityofthemedia toreachouttopatients,healthcareprofessionalsandthegeneralpublicisacriticalelementfor amplifyingnewandimportantinformationonmedicines.Thewaysafetyinformationis communicatedthroughthemediawillinfluencethepublicperceptionanditistherefore importantthatthemediareceivessafetyinformationdirectlyfromtheAgencyinadditionto theinformationtheyreceivefromothersources.
2.4.Contentofsafetycommunication
Theinformationinthesafetycommunicationshallnotbemisleadingandshallbe presentedobjectively[Article22(12)oftheRegulationontheSafetyofMedicinalProducts]. Safetyinformationshouldnotincludeanymaterialorstatementwhichmightconstitute advertising.
Therefore,takingintoaccounttheprinciplesin2.2.,safetycommunicationshouldcontain: importantnewinformationonanyauthorisedmedicinalproductwhichhasanimpact onthemedicine'srisk-benefitbalanceunderanyconditionsofuse, thereasonforinitiatingsafetycommunicationclearlyexplainedtothetargetaudience, anyrecommendationstohealthcareprofessionalsandpatientsonhowtodealwitha safetyconcern,
whenapplicable,astatementontheagreementbetweenthemarketingauthorisation holderandtheAgencyonthesafetyinformationprovided,
informationonanyproposedchangetotheproductinformation(e.g.SmPCorPL), anyadditionalinformationabouttheuseofthemedicineorotherdatathatmaybe relevantfortailoringthemessagetothetargetedaudience,
alistofliteraturereferences,whenrelevantorareferencetowheremoredetailed informationcanbefound,
whererelevant,areminderoftheneedtoreportsuspectedadversereactionstoTurkish PharmacovigilanceCenter(TÜFAM).
2.5.Meansofsafetycommunication
Communicationtoolsandchannelshavebecomemorenumerousandvariedovertime, offeringthepublicmoreinformationthanwaspreviouslypossible.Relevantcommunication toolsandchannelsshouldbeconsideredwhenissuingasafetycommunicationinorderto reachthetargetaudiencesandmeettheirgrowingexpectations.Differentcommunication toolsandchannelsarediscussedinSections2.5.1.to2.5.10.
2.5.1.Directhealthcareprofessionalcommunication(DHPC)(DearHealthcare ProfessionalCommunicationLetters)
DearHealthcareProfessionalCommunicationLetterisacommunicationinterventionby

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whichimportantsafetyinformationisdeliveredirectlytoindividualhealthcareprofessionals byamarketingauthorisationholderortheAgency,toinformthemoftheneedtotakecertain actionsoradapttheirpracticesinrelationtoamedicinalproduct.
The"Dearhealthcareprofessionalcommunicationletter"shouldnotcontainanymaterial orstatementthatcanbeconsideredaspromotionalorgivetheimpressionthatitisfor commercialpurposes.Directcommunicationwithhealthcareprofessionalsregardingquality errorsofdrugsisoutofthescopeofpharmacovigilance.
DHPCshouldnotbeusedforsafetyinformationthatdoesnotrequireimmediate communicationandfordisseminatinginformationthatisnotimportanttobecommunicated tohealthcareprofessionalsindividually,suchasSmPCchangesthatdonotaffectthe appropriateuseofthedrug.
DuringtheprocessofpreparingtheDHPC,themarketingauthorisationholderandthe Agencyshouldcooperate.PriortotheissuanceoftheDHPCbythemarketingauthorisation holder,anagreementmustbereachedbetweenthepartiesinquestion.Thisagreementshall coverboththecontentoftheinformation(see2.4)aswellasthecommunicationplan includingtheintendedrecipientsandthepublicationscheduleoftheDHPC.Whilepreparing theDHPC,therelevanttemplate(seeAnnexIandAnnexII)andthedirectionsgiveninthe noteswithinthetemplateshouldbeappliedasnecessary.
Wherethereareseveralmarketingauthorisationholdersofthesameactivesubstance and/oraclassofproductsforwhichaDHPCistobeissued,asingleconsistentmessage shouldbedelivered.
Wheneverpossibleandappropriate,itisadvisedthathealthcareprofessionals' organisationsareinvolvedduringthepreparationofDHPCstoensurethattheinformation deliveredbytheDHPCsisusefulandadaptedtothetargetaudience.
ADHPCshouldbecomplementedbyothercommunicationtoolsandchannelsandthe principleofprovidingconsistentinformationshouldapply.
ADHPCshouldbeincludedasanadditionalriskminimisationmeasureaspartofarisk managementplan(seeGVPModuleVI).
ADHPCshouldbedisseminatedinthefollowingsituationswhenthereisaneedtotake immediateactionorchangecurrentpracticeinrelationtoamedicinalproduct:
suspensionorrevocationofamarketingauthorisationforsafetyreasons,
animportantchangetotheuseofamedicineduetotherestrictionofanindication,
anewcontraindication,orachangeintherecommendeddoseduetosafety reasons,
newmajorwarningsorprecautionsforuseintheproductinformation,
newdataidentifyingapreviouslyunknownriskorachangeinthefrequencyor severityofaknownrisk,
newevidencethatthemedicinalproductisnotaseffectiveaspreviously considered,
newrecommendationsforpreventingortreatingadversereactionsortoavoid misuseormedicationerrorswiththemedicinalproduct,
ongoingassessmentofanimportantpotentialrisk,forwhichdataavailableata particularpointintimeareinsufficienttotakeregulatoryaction(inthiscase,the DHPCshouldencourageclosemonitoringofthesafetyconcerninclinical practiceandencouragereporting,andpossiblyprovideinformationonhowto minimisethepotentialrisk).
TheAgencymaydisseminateorrequestthemarketingauthorisationholderto disseminateaDHPCinanysituationwherethecompetentauthorityconsidersitnecessaryfor thecontinuedsafeandeffectiveuseofamedicinalproduct.
Theproposeddateandtimefordisseminationshouldbecarefullycalculated;ideally,a DHPCisdisseminatedatthebeginningoftheweek;however,thedisseminationofurgent

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informationshouldnotbedelayedjustforthisreason(detailsonthedisseminationofletters aredescribedinAnnexesIandII).

IncaseswhereahealthauthorityoutsideofTurkeywantsaDHPCtobepublishedin

theircountryregardingalicenseddruginTurkey,thelicenseholdermustinformtheAgency. Thisactionformspartofthelegalrequirementformarketingauthorisationholderstonotify competentauthoritiesofnewinformationthatmayaffectthebenefit/riskbalanceofadrug.

2.5.2.CommunicationmaterialsfromtheAgencytargetedathealthcare professionals

TheAgencycanissuesafetycommunicationstargetinghealthcareprofessionalsdirectly. Theseareusuallypublishedonthewebsiteofthecompetentauthority.Thesecommunications containtheAgency'srecommendationsandadviceforriskminimisationforhealthcare professionals,andproviderelevantbackgroundinformation.

SafetycommunicationsfromtheAgencyshouldfollowtheprinciplesidentifiedabove (see2.2)andshouldbeissuedwhenthereisaneedtotakeimmediateactionorchangecurrent practiceinrelationtoamedicinalproductbyconsideringexistingpublicinterest.

6 TheAgencyshouldmakeuseofthemostappropriatetoolsandchannelsdescribedinthis Sectiontomaximisedisseminationandaccessibilityofrelevantinformation.

2.5.3.Documentsinlaylanguagetopatientsandthegeneralpublic

Communicationmaterialinlaylanguage(e.g.usingaquestions&answersformat)helps patientsandthegeneralpublictounderstandthescientificevidenceandregulatoryactions relatingtoasafetyconcern.LaylanguagedocumentsshouldcontaintheAgency's recommendationsandadviceforriskminimisationforpatients,andshouldbeaccompanied byrelevantbackgroundinformation.

Laylanguagedocumentsshouldbeusefultomembersofthepublicwhohaveaninterest inthesubjectbutdonothaveascientificorregulatorybackground.Referenceshouldbe madetoothercommunicationmaterialsonthetopictodirectreaderstowheretheycanfind furtherinformation.

Laylanguagedocumentsarepublishedontheofficialinternetportalsof theAgency,and mayalsobedistributedtorelevantpartiessuchaspatientandhealthcareprofessional associations.

Wheneverpossibleandappropriate,itisadvisedthatpatientsareinvolvedduringthe preparationoflaylanguagedocumentstoensurethattheinformationtheydeliverisuseful andadaptedtothetargetaudience. 2.5.4.Presscommunication

Presscommunicationincludespressreleasesandpressbriefingswhichareprimarily intendedforjournalists.

Competentauthoritiesmaysendpressreleasesdirectlytojournalistsinadditionto publishingthemontheirwebsites.Thisensuresthatjournalists,inadditiontoobtaining informationfromothersources,receiveinformationthatisconsistentwiththeauthority's scientificassessment.Interactionwiththemediaisanimportantwaytoreachouttoawider audienceaswellastobuildtrustintheregulatorysystem.

Pressreleasesmayalsobepreparedandpublishedbymarketingauthorisationholders. However,wheninformationonpharmacovigilanceconcernsregardingtheuseofdrugswill bemadepublic,theAgencyisinformedinadvanceorsimultaneously.Themarketing authorisationholderwarrantsthatthisinformationiscorrectandnotmisleading.Press releasesofmarketingauthorisationholdersshouldrefertoadministrativemeasuresthatthe Agencymayhaveinitiatedandrelevantinvestigationsinprogress.

Althoughaimedatjournalists,pressreleaseswillbereadbyotheraudiencessuchas healthcareprofessionals,patientsandthegeneralpublic.Referenceshouldthereforebemade torelatedcommunicationmaterialsonthetopic.IncaseswhereaDHPCand/ora communicationisalsoprepared,healthcareprofessionalsshouldideallyreceiveitpriortoor aroundthesametimeofthepublicationordistributionofapressreleasesothattheyarebetter preparedtorespondtopatients.

PressbriefingswithjournalistsshouldbeconsideredbytheAgencyforsafetyconcernsor

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othermattersrelatingtothesafetyofmedicinalproductsthatareofhighmediainterestor whencomplexorpublic-health-sensitivemessagesneedtobeconveyed. 2.5.5.Website Awebsiteisakeytoolformembersofthepublic(includingpatientsandhealthcare professionals)activelysearchingtheinternetforspecificinformationonmedicinalproducts. TheAgencyandmarketingauthorisationholdersshouldensurethatimportantsafety informationpublishedonwebsitesundertheircontroliseasilyaccessibleandunderstandable bythepublic.Informationonwebsitesshouldbekeptup-to-date,withanyinformationthatis out-of-datemarkedassuchorremoved.

2.5.6.Socialmediaandotheronlinecommunications Onlinesafetyinformationmayalsobedisseminatedviasocialmediaandotherwebtools. Whenusingnewer,morerapidcommunicationchannels,specialattentionshouldbepaidto ensurethattheaccuracyoftheinformationreleasedisnotcompromised. 2.5.7.Bulletinsandnewsletters Pharmaceuticalsafetybulletinsensurethatnewinformationonthesafetyandefficacyof drugsisregularlyreleasedandwidelyaccessible.Bulletinsallowforcollectiveremindersof drugsafetyissuesthathavebeenpreviouslyannouncedinvariousways. TheAgencycanreachalargeaudiencewiththesetoolsbyusingweb-basedandother availablemeans. 2.5.8.Inter-authoritycommunication WhentheAgencymakesitsowndecisionsortakesanewregulatoryactiononaspecific safetyconcern,itmayalsotakeintoaccounttheevaluationsmadebyotherhealthauthorities orregionalorinternationalorganizationswithcomparablestandardsandmayshare informationwhenrequested. 2.5.9.Respondingtoenquiriesfromthepublic TheAgencyandmarketingauthorisationholdersshouldhavesystemsinplacefor respondingtoenquiriesaboutmedicinesfromindividualmembersofthepublic.Responses shouldtakeintoaccounttheinformationwhichisinthepublicdomainandshouldbebased onthedruginformationapprovedbytheAgency.Wherequestionsrelatetoindividual treatmentadvice,thepatientshouldbeadvisedtospeakwithahealthcareprofessional. Inthisregard,marketingauthorisationholderssubjecttotheprovisionsofthe "RegulationonPromotionalActivitiesofMedicinalProductsforHumanUse". 2.5.10.Othermeansofcommunication Inadditiontothosediscussedabove,thereareothertoolsandchannelssuchas publicationsinscientificjournalsandjournalsofprofessionalbodies. Sometoolsandchannelsmaybeusedinthecontextofriskmanagement.Inadditionto theproductinformation,othercommunicationtoolscanbeusedtodisseminateinformation abouttheproduct.Theseareconsideredasadditionalriskminimisationmeasuresandmay includepatientalertcardsoreducationalmaterials.TheseareoutsidethescopeofthisModule andaredescribedinmoredetailinGVPModuleVI. 2.6.Effectivenessofsafetycommunication Safetycommunicationisconsideredeffectivewhenthemessagetransmittedisreceived andunderstoodbythetargetaudienceinthewayitwasintended,andappropriateactionis takenbythetargetaudience.Wherepossible,mechanismsshouldbeintroducedinorderto measuretheeffectivenessofthecommunication.Aresearch-basedapproachwillnormallybe appropriateinordertoestablishthatsafetycommunicationshavemetthestandardof2.2.This approachmaymeasuredifferentoutcomes,includingbehaviour,attitudes,andknowledge. Whenevaluatingtheeffectivenessofsafetycommunication,thescopeoftheevaluationmay bebroadenedtoincludefactorsotherthantheperformanceoftheindividualtoolsusedinthe safetycommunication.Properimplementationoftheriskcommunicationplanstepsiscritical totheeffectivenessofsafetycommunication(seeAppendixIII). InthecaseofDHPCs,marketingauthorisationholdersshouldinformtheAgencyabout anydifficultyidentifiedduringthedisseminationoftheDHPCs(e.g.problemsrelatedtothe listofrecipientsorthetimingandmechanismofdissemination).Appropriateactionshouldbe takenasneededtocorrectthesituationorpreventsimilarproblemsinthefuture.

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8 2.7.Qualitysystemrequirementsforsafetycommunication Inaccordancewiththequalitysystemrequirementsin GVP Module IV PharmacovigilanceQualitySystem,proceduresshouldbeinplacetoensurethatsafety communicationscomplywiththeprinciplesin2.2.asappropriate. Inparticular,safetycommunicationsshouldbesubjecttoqualitycontrolstoensuretheir accuracyandclarity.Forthispurposereviewprocedureswithallocatedresponsibilitiesshould befollowedanddocumented. SECTIONIII Conductofsafetycommunication 3.1.Coordinationofsafetycommunication TheAgencyprovidesinformationtohealthcareprofessionalsondrugsafetyissues throughitsofficialwebsite.Announcementsaboutdrugsafetymadeonthewebsiteofthe Agency andtherelevantdepartmentsarelistedinthetablebelow. Subject TheRelevantDepartment Currentannouncements Importantannouncements Alldepartments PhysicianCommunicationLetter DepartmentofPharmacovigilanceandControlledSubstances ListofDrugsSubjecttoAdditional Monitoring DepartmentofPharmacovigilanceandControlledSubstances DrugsUsedwithDrugSafety MonitoringForms DepartmentofPharmacovigilanceandControlledSubstances RiskManagementMaterials DepartmentofPharmacovigilanceandControlledSubstances Union,association,company announcements DrugRegulatoryDepartment DepartmentofPharmacovigilanceandControlledSubstances SmPC/PIL DrugRegulatoryDepartment Blockingandrecallannouncements DrugAuditingDepartment

9 AnnexI–DHPCtemplate <Date> <Activesubstance,nameofmedicinalproductandmainmessage (e.g.introductionofawarningoracontraindication)> Note:Ifthedrugisinadditionalmonitoring,theblac kequilateralinvertedtriangleshouldbeaddedtothetitle beforethedrugnameoractivesubstance.Thed eclarationtextregardingtheadditionalmonitoringshouldbe addedtotheendoftheletter. DearHealthcareProfessional, Thepurposeofthisletteristoinformyouof.....Thisletterhasbeenpreparedinagreement withtheMinistryofHealth,TurkishMedicinesandMedicalDevicesAgency,Departmentof PharmacovigilanceandControlledSubstances.Thisletterisalsoavailableatwww.titck.gov.tr. Summary Guidance:Thissectionshouldbeinbold/largerfontsizethantheothersectionsoftheDHPC andpreferablyinbulletpoints. <Briefdescriptionofthesafetyconcerninthecontextofthetherapeuticindication, recommendationsforriskminimisation(e.g.contraindications,warnings, precautionsofuse)and,ifapplicable,switchtoalternativetreatment> <Recallinformation,ifapplicable,includinglevel(pharmacyorpatient)anddateof recall> Backgroundonthesafetyconcern Guidance:Thissectionmayincludethefollowinginformation: <Briefdescriptionofthetherapeuticindicationofthemedicinalproduct> <Importantdetailsaboutthesafetyconcern(adversereaction,seriousness,statementonthe suspectedcausalrelationship,and,ifknown,thepharmacodynamicmechanism,temporal relationship,positivere-challengeorde-challenge,riskfactors)> <Anestimationofthefrequencyoftheadversereactionorreportingrateswithestimated patientexposure> <Astatementindicatinganyassociationbetweentheadversereactionandoff-labeluse,if applicable> <Ifapplicable,detailsontherecommendationsforriskminimisation> <Astatementiftheproductinformationistobeorhasbeenrevised,includingadescriptionof thechangesmadeorproposed> <Placeoftheriskinthecontextofthebenefit> <ThereasonfordisseminatingtheDHPCatthispointintime> <Anyevidencesupportingtherecommendation(e.g.includecitation(s)ofkeystudy/ies)>

10 <AstatementonanypreviousDHPCsrelatedtothecurrentsafetyconcernthathaverecently beendisseminated> <Anyscheduleforfollow-upaction(s)bythemarketingauthorisationholder/Agency,if applicable> Callforreporting <AreminderofrequirementsforreportingadversereactionstotheTurkish

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PharmacovigilanceCenter(TÜFAM)and/ortherelevantcompany'squalifiedperson responsibleforpharmacovigilance,includingthedetails(e.g.name,postaladdress,fax number,websiteaddress)onhowtoreport>
<Forbiologicalmedicinalproducts,alsoincludearemindertoreporttheproductnameand batchdetails>
<Mentionifproductissubjecttoadditionalmonitoringandthereasonwhy>
Qualifiedpersonresponsibleforpharmacovigilance
<Detailsofqualifiedpersonresponsibleforpharmacovigilanceforaccesstofurther information,includingrelevantwebsiteaddress(es),telephonenumbersandapostaladdress>
Annexes(ifapplicable) <RelevantrevisedpartsoftheProductInformationtext(withanychangesvisible)>
<Additionalscientificinformation,ifapplicable> <Listofliteraturereferences,ifapplicable>

11 EkII–DHPCdisseminationschema

Disseminationaremadetophysiciansprescribingdrugs,hospitalchiefphysicians, relevantspecialtyassociations,anddeansoffacultiesofpharmacyandmedicineof universities. Disseminationcanbedoneviacargo/productpromotionrepresentative/e-mail(incase ofpandemic,cargoore-mailispreferred).
TheclosingreportoftheletterdistributionissubmittedtotheDepartmentof PharmacovigilanceandControlledSubstanceswithin15workingdays.
Intheclosingreport,ageneralevaluationofthedistributionisprovided(the disseminationroute,onwhichwebsites,ifany,theannouncementwasmade), informationonthedatewhenthedisseminationprocessstartedandwithinhowmany days,statisticaldataonthedelivery(suchasthedeliverypercentageofthe disseminations,thenumberoftargetedaudiences,thepercentageoffaileddeliveries), ifany,problemsencounteredduringtheprocessarepresented.Ifthedistributionwill bemadeviae-mail,thee-mailreceiptandreadinginformationofthee-mailsending reportsareaddedtotheclosingreport. Identifyingtheneedfora letter Thesubjectconcerns morethanone drugproduct Preparationofcorporate letterhead Disseminationbya marketing authorisation holderassignedby theAgency Preparationofclosing reportandsubmissionto theAgency Preparationofmarketing authorisationletterhead, signedanddisseminatedby theresponsiblepersonfor pharmacovigilanceofthe marketingauthorisation holder,orhis/herchief. Thesubjectconcerns onlyonedrugproduct Preparationofclosing reportandsubmission totheAgency

12 AnnexIII–RiskCommunicationPlan 1.Identificationand assessmentofrisk Riskcommunicationsteps 7.Measuring whetherthegoals andobjectives havebeen achievedafter communication ornot 2.Identifying communication needsandgoals 6.Contactingthe targetpopulation 5.Selectionof communication toolsandcreationof communication program 4.Determiningthe messagetobe transmitted 3.Determining thetarget population

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