SöğütözüMahallesi,2176.SokakNo:506520Çankaya/Ankara

11.05.2023 SÖZLEŞMELI FARMAKOVIJILANS HIZMET KURULUŞLARININ ÇALIŞMA USUL VE ESASLARI HAKKINDA KILAVUZ_EN

Telephone:(0312)2183000Fax:(0312)2183460 E-mail:tufam@titck.gov.tr Web:https://www.titck.gov.tr/ TurkishMinistryofHealth TurkishMedicinesandMedicalDevicesAgency

TABLE OF CONTENTS

Purpose
Scope
Basis
Definitions
Minimumcriteriathatmustbemetby CPSPs
Pharmacovigilanceresponsibilitiesofmarketingauthorizationholdersthatmaybedelegatedto **CPSPs**
Considerationsfordelegationofpharmacovigilanceobligationsofmarketingauthorization **holders**
RoleofCPSPinconductingcontrolledaccessprograms
TransferofpharmacovigilanceactivitiesbetweenCPSPs
Effectiveness
Enforcement

Purpose

ARTICLE1–(1)ThisGuidelinesetsforththeoperatingprinciplesandproceduresand responsibilitiesofContractPharmacovigilanceServiceProviders(CPSPs)toensurethat pharmacovigilanceservicesareconductedinlinewiththeapplicableregulations.

Scope

ARTICLE2–(1)UndertheRegulationonSafetyofMedicinalProducts,marketingauthorization holdersmaydelegateallorsomeoftheirpharmacovigilanceresponsibilitiestoaCPSP,withthe marketingauthorizationholderretainingultimateresponsibilityforfullandaccuratefunctioningofthe pharmacovigilancesystem.Thisguidelineappliestomarketingauthorizationholdersand CPSPs. Marketingauthorizationholderswhofilltheirpharmacovigilanceobligationsinternallyarealso expectedtomeettheminimumcriteriarequiredofCPSPs.

Basis

ARTICLE3–(1)ThisGuidelineisissuedbasedontheRegulationonSafetyofMedicinalProducts, publishedinOfficialGazette#28973ofApril15,2014,Law#6698onProtectionofPersonalData, publishedinOfficialGazette#29677ofApril07,2016,andtheRegulationonPersonalHealthData, publishedinOfficialGazette#30808ofJune21,2019.

Definitions

ARTICLE4–(1)Forthepurposesofthis Guideline:
a)AdverseReactionorAdverseDrugReaction(ADR)meansaresponsetoamedicinalproduct whichisnoxiousandunintended;
b)QualifiedPersonforPharmacovigilancemeansaphysicianorpharmacistemployedbythe marketingauthorizationholderoracontractpharmacovigilanceserviceprovidertofulfill requirementsoftheRegulationonSafetyofMedicinalProducts;
c)ControlledAccessProgrammeansaprogramconducted,conditionalonfulfillmentofasetof patientaccesscriteria,toallowaccesstomedicinalproducts,whichhaveprovenbenefitsbut

sion published by the Turkish Medicines and Medical Devices Agency (TİTCK), imported from the AIFD Legislation Portal archive. In the event of any discrepancy, the Turkish original text (mevzuat.g

whichcarrysignificantrisks,priortobeingprescribedorplacedonthemarkettoensuretheir safeuseandthattherisksinvolvedareminimized;
ç)AgencymeansTurkishMedicinesandMedicalDevicesAgency;
d)MedDRAmeansamedicaldictionaryforregulatoryactivities,createdbytheInternational CouncilforHarmonization;
e)MedDRAMaintenanceandSupportServicesOrganization(MSSO)meansaservice organizationestablishedtomaintain,distributeandsupportMedDRAforusersunder supervisionoftheICHMedDRAManagementCommittee;
f)Periodicbenefit/riskassessmentreport(PBRAR)meansareportcompiledbymarketing authorizationholdersatdefinedpost-authorizationtimepointsinaspecificformattoevaluate thebalanceofbenefitsvsrisksofamedicinalproduct;
g)RiskManagementPlan(RMP)meansadetaileddescriptionoftheriskmanagementsystem;
ğ)MarketingAuthorizationHoldermeansanaturalorlegalpersonwhoholdsmarketing authorizationforahumanmedicinalproduct;
h)ContractPharmacovigilanceServiceProvider(CPSP)meansanorganizationmeetingthe criterialaiddownintheguidelineconcernedandauditedandaccreditedbytheAgency,which employsatleastonepersonincapacityofQualifiedPersonforPharmacovigilanceandatleast onepersonastheirdeputy,andtowhichamarketingauthorizationholderhasdelegatedallor someofitspharmacovigilanceobligationsonawrittencontract;and
ı)Auditmeansasystematic,disciplined,independentanddocumentedprocessforobtaining auditevidenceandevaluatingitobjectivelytodeterminetheextenttowhichtheauditcriteria arefulfilled.

MinimumcriteriathatmustbemetbyCPSPs
ARTICLE5–(1)Marketingauthorizationholdersmayfulfilltheirpharmacovigilanceobligations undertheRegulationonSafetyofMedicinalProductsandotherapplicableguidelinesthroughaCPSP onthebasisoftheprinciplesdescribedbelow.Insuchcases,anotarizedresponsibilitysharing document,describingspecificpharmacovigilanceservicesthatwillbeperformedthroughtheCPSP, mustbesubmittedtotheAgency.
(2)ACPSPdelegatedbyamarketingauthorizationholdertoperformallorsomeofthe pharmacovigilanceobligationsmustmeetthefollowingcriteria:
a)Properequipmentandasufficientnumberofpersonnel:
CPSPsareobligatedtohaveasufficientnumberofemployees,proportionaltotheirworkload, andtoexpanditsstaffandequipmenttoreflectgrowingworkloadwhichmayresultfromincreased numberofclientsormedicinalproductsforwhichtheyareresponsible.
ThekeypersonnelataCPSParethequalifiedpersonforpharmacovigilanceandtheirdeputy.
Itmustbeensuredthatthepersonnelemployedinthoserolesreceiveappropriatetrainingandhave sufficientexperience,andtheyaremaintainedinthoseroles.
i)Mandatorytrainingforqualifiedpersonforpharmacovigilanceandtheirdeputy:
Aftertheirappointmentintheseroles,thequalifiedpersonforpharmacovigilanceand theirdeputymustundergoandsuccessfullycompleteaninitialtrainingprogram providedbytheAgency.Participantswhofailtoattendsessionswithoutanexcuse acceptabletotheAgencymaynotcontinueintheirrolenormaytheyassumetherole ofqualifiedpersonforpharmacovigilanceoradeputyatanothercompany.
TheymustcompletethebasicMedDRAcodingtrainingofferedbyMedDRAMSSO (CodingwithMedDRa,SafetyDataAnalysisandSMQs)withinsixmonthsafter startingintheirrole.Theymustattend,receiveanddocumentthattheyhavereceived alltheotherface-to-faceoronlinesessionsorganizedbyMedDRAMSSO.
Theymustattend,receiveanddocumentthattheyhavereceivedsuchotherface-to-faceoronlinetrainingrelevanttotheirotherroles(e.g.reportingadversereactions, preparingPBRARsandRMPs).
Intheeventofsignificantamendmentstopharmacovigilanceregulations(e.g.a

sion published by the Turkish Medicines and Medical Devices Agency (TİTCK), imported from the AIFD Legislation Portal archive. In the event of any discrepancy, the Turkish original text (mevzuat.g

regulationmodifyingthecurrentpractices,guidelineupdates,newGVPguidelines), theymustattendsubsequenttrainingsessionsorganizedbytheAgencytoupdatetheir trainingcertificate. ii)Experience Theymusthavenotlessthan3yearsofdocumentedexperienceworkingina pharmacovigilanceroletobeeligiblefortheroleofqualifiedpersonfor pharmacovigilance. iii)Workload Aqualifiedpersonforpharmacovigilancemayassumeresponsibilityof pharmacovigilanceactivitiesfornotmorethan100activesubstances.Forexample,where threeindividualcompanieswhosepharmacovigilanceobligationshavebeenassumed, haveintotal100activesubstancesorless,onequalifiedpersonforpharmacovigilance employedbytheCPSPmayassumeresponsibilityforsuchthreecompanies.Inanother example,whereasinglemarketingauthorizationholderhas290activesubstances,three separatequalifiedpersonsforpharmacovigilancemustbeassignedtosuchmarketing authorizationholder,andtheactivesubstancesforwhicheachqualifiedpersonfor pharmacovigilancewillberesponsibleshouldbedesignatedandproposedtotheAgency. Itisrecommendedtoallocatetherolesbasedonrespectivetherapyareasofthemedicinal products.Wheremultiplemarketingauthorizationholderclientsarereservedforthesame activesubstance,theseshouldberegardedasdifferentactivesubstancesandaccount towardthequotaof100activesubstances.

Moreover,apersonwhoactsasqualifiedpersonforpharmacovigilanceforamarketing authorizationholdermaynotdeputizeforthequalifiedpersonforpharmacovigilanceof anothercompany. Adeputyqualifiedpersonforpharmacovigilancemaydeputizeforuptotwoqualified personsforpharmacovigilance. iv)Recognitionandreachability Toraiseawarenessforimprovingreportingofadversereactionsandensurereportsare submittedappropriatelyandwithintheprescribedtimelines,thequalifiedpersonfor pharmacovigilanceandtheirdeputyshouldbeknownto,andrecognizedandreachableby everyoneatthecompanyforwhichtheyassumeresponsibilityofpharmacovigilance obligations,includingcallcenterstaff,securitypersonnelandmanufacturingteams.

b)Suitableworkingenvironment

Itisessentialthatasuitablelocation,andsufficienttechnicalmeansandequipment(e.g. informationtechnology(IT)systems,(electronic)archives)areavailabletocarryout pharmacovigilanceactivities.Additionally,theremustbeaISO9001QualityManagementCertificate, issuedbyaconformityassessmentorganization,accreditedbyTURKAKforISO9001Quality ManagementAccreditation.

TheCPSPshouldhaveaphysicalarchivefacility,sufficientlylargetoaccommodatethe numberofpharmacovigilanceclientsservedbyit.Thearchiveshouldbeequippedwithstainlesssteel cabinetskeptunderlockandkey,assignedtoeachclient.Accesstothearchiveshouldberestrictedto authorizedpersonnel.Accesstothearchivefacilityshouldbeloggedusingafingerprintscanning system.Thetemperatureandhumidityofthephysicalarchivefacilityshouldbeloggedand compatiblewithonlinetransmission.

Documentsmaybestoredinanelectronicformat,providedthattheelectronicsystemis properlyvalidatedandappropriateprecautionsareinplacetoensuresystemsecurity,accessand backup.Wherethedocumentsareconvertedtoanelectronicformatfromhardcopy,theconversion processusedshouldensurethatallinformationfromtheoriginaldocumentarelegiblypreservedand themediumusedforstorageremainsreadableovertime. c)Safetydatabase

ThesafetydatabaseshouldbeE2B(R3)-compatibleandfullyvalidated.Itmustbeensuredthat databelongingtoindividualclientsarestoredinfullysegregateddatabasesandprivacyofthedata storedthereinisensured.

ThedatabaseshouldincorporatethelatestversionofMedDRAandWHODrugDictionary andExtendedEudraVigilanceMedicinalProductDictionary(XEVMPD).Thedatabasesthatmaybe

sion published by the Turkish Medicines and Medical Devices Agency (TİTCK), imported from the AIFD Legislation Portal archive. In the event of any discrepancy, the Turkish original text (mevzuat.g

usedincludeArgusSafety(Oracly),ARISg/LifeSphereSafety,ArisGlobalIRT,PVWorks(Ennov Group,PvEdge(Sarjen),SafetyEasy(ABCube),VaultSafety(Veeva),SafetyBaseInterchangeand,if properlyvalidatedandequippedwithappropriatesystemsecurity,accessandbackupfeatures,anin-housedatabasedevelopedbythecompany. ç)InformationSecurityandCyberSecurity Informationsecurityencompassesabroadspectrumoftopics,rangingfromphysicaland peripheralsecuritytohumanresourcessecurity,securityofcommunicationsandcorrespondence security,andinformationsystemssecurity.
Allinformationstoredinhardcopyandelectronicdevicesmustbemanagedinlinewiththe principlesofconfidentiality(ensuringdataispreventedfromaccessbyunauthorizedpersonneland protectedagainstunauthorizedaccess),integrity(preventingmodificationofdatabyunauthorized personnel)andaccessibility(ensuringdataremainsavailableandaccessibletoauthorizedpersonnel whenneeded).

Toensuretheforegoingrequirementismet,companiesmustmeetinformationsecurity standards,complywithallapplicableregulatoryrequirements,identifyandmanagerisksto informationassets,undertakecontinualreviewoftheinformationsecuritysystemandtakeactionas appropriate,andinformusers(i.e.everyonewhohasaccesstoinformation,includingpersonnelof marketingauthorizationholders,CPSPsandthirdpartiesconductingcontrolledaccessprograms, employeesofbusinesspartners,andcompanysupportpersonnel).
Toensurethesecurityofinformationsystems,documentationshouldbeinplaceaccordingto TSISO/IEC27001InformationSecurityManagementSystemStandardandTSISO/TEC20000 InformationTechnologyServiceStandard,andtherequirementsandprocedureslaiddowntherein shouldbecompliedwith.SomeparticularlysignificantaspectsoftheİSO27001standardare specificallyhighlightedbelow: InformationSecurityOfficersoftheOrganization: Anumberofproceduresandcontrolsmustbeperformedpriortohiring,duringemployment, atrolechangeandseveranceofallpersonnel(e.g.full-timeandpart-timecontractedemployees, employeesofcontractors,businesspartnersandsupportcompanies)whohaveaccesstothe informationprocessingfacilities.
Allpartiesshouldbemadeawarethatapersonaland/orcorporateconfidentialityagreement willbeexecutedwithallpersonnelandcontractorspriortohiring.Thecontentoftheagreementand theobligationsofpartieslaiddownthereinshouldbeexplainedindetail.Theagreementshould clearlyspecifyinformationsecurityresponsibilitiesofindividualsandthemanagement.
Individualswillbeobligatedtomaintainconfidentialityofdatalearnedbythemduringtheir employmentandrefrainfromdisclosingthesamewithoutauthorizationinanymannerwhatsoever evenafterchangeofroleorseverance.Theconfidentialityobligationremainsinforceindefinitely.It mustbeensuredthattheseveranceprocedureofpersonnelwholeavetheorganizationorareassigned toadifferentrolearecconductedimpeccablyfromaninformationsecurityviewpoint.
Datatransferisacriticalprocess,whichmayhavelegalramificationsandgiveriseto administrativeorcriminalpenaltiesifperformedincorrectlyorwithoutauthorization.Theprecautions laiddowninKVKKDecree#2018/10mustbeinplaceforanytransmissionofspecialpersonaldata (healthdata).
WherethedataaretobetransferredtoanotherCPSP,theformercontractserviceproviderof themarketingauthorizationholderwillperform“secureerasure”ofallpharmacovigilancedataafter thetransferhasbeencompleted,andemployanappropriateproceduretodestroytheharddrivesthat wereusedforstoringthedata.Alldocumentsinhardcopymustbedeliveredtothemarketing authorizationholderonaformalreport,withoutmodificationorduplication.
Ifacloudserviceisused,theCPSPmustnotifythemarketingauthorizationholderandobtain theirconsent.Ifthemarketingauthorizationholderconsentstotheirdatabeingstoredoncloud,the pharmacovigilancedatamustbeencryptedusingcryptographictechniques.
Ariskmanagementapproachshouldbeemployedforsecuringinformationassetsonthebasis

sion published by the Turkish Medicines and Medical Devices Agency (TİTCK), imported from the AIFD Legislation Portal archive. In the event of any discrepancy, the Turkish original text (mevzuat.g

ofISO/IEC27005andTSISO31000standards.
Logsofalltransactionswithdatashouldbesecurelymaintainedonaseparatemediumfornot lessthantwoyearsandremainavailableduringaudits,andremoteaccesstodata,ifapplicable,should bebasedonnotlessthantwo-factorauthenticationandarrangementsfordatabackupmustbeinplace. FortransfersofpersonalhealthdatawithinTürkiyeandabroad,therequirementsofArticle8 and9,respectively,ofLaw#6698mustbesatisfied. InformationSecurityObligationsofPersonnel: a)IfCPSPpersonnelpersonallybreachesinformationsecurity,theywillbeliableforany resultingdamagetotheiremployer,themarketingauthorizationholderorthirdparties.

b)Personnelwillusethedataentrustedtothemortowhichtheyhavebeengrantedaccessby theiremployersolelyinconnectionwiththeirassignedtasks.Theywillprotectthedataas theirownandnotshareitwithanyunauthorizedparties,andeventhenonaneed-to-know basis.
c)Personnelmaynotsharedatawithanyunauthorizedparties,includingofficersofclients, unlessspecificallyauthorizedtodoso.
ç)Personnelmaynotusetheinformationtheyhaveacquiredtoservetheinterestsofany individual,group,institutionororganization.
d)Personnelisunderobligationtomaintainconfidentialityofandrefrainfromdisclosingto thirdpartiesanyconfidentialinformationlearnedbythem,whetherornotrelatedtotheir assignment.Thisobligationsremainsinforceafterthepersonnelleavestheiremployer.
e)Personnelmaynotunlawfullyacquire,alter,attempttoerase,transferorduplicatethe softwareapplications,dataorotheritemsstored/usedininformationsystems.
f)Personnelmaynotengageinanybehaviorthatmayresultindestruction,alteration, erasureoftheinformationprocessingsystemsusedbythemandthedatastoredtherein, partiallyorcompletely,normaytheyattempttoobstructsystemfunctionalityorcause systemmalfunction,whethertoharmothersortoderiveabenefitforthemselvesorothers, orfornospecificreason.
g)Personnelmaynotwithoutdueauthorizationandforanypurposewhatsoeveruse, duplicate,moveortransferdataacquiredbytheminthecontextoftheirroleorarestored ininformationprocessingsystemsinanyform(e.g.printed,magneticmedium).
d)QualityManagementSystem
Qualityoperationsmustbeconductedbyaunitproperlytrainedinqualityprocedures.CPSPs, aswithmarketingauthorizationholders,areobligatedtomeettherequirementslaiddowninthe GuidelineonGoodPharmacovigilancePractice(GVP),ModuleIV–PharmacovigilanceQuality System. ThequalitymanagementsystememployedbytheCPSPmustmeetthefollowingminimum criteria: Qualitypolicy Humanresourcesmanagement oMonitoringpersonnelrolesandcompetencies Roledefinitions Individualroleandcompetencycards Competencymonitoringandassessment Trainingrecordforms Informationsecuritymanagement oInformationsecuritydocuments oAccesscontrol/mobiledevicesandremoteworking oInformationclassification(andprocessing) oPhysicalandperipheralsecurity oAcceptableuseofassets/cleandeskandclearscreen oInformationtransfer,communicationsecurity oRestrictiononsoftwareinstallationanduse oBack-up oMalwareprotection oEmploymentofcryptographiccontrols

oManagementoftechnicalgaps oPrivacyandprotectionofpersonallyidentifyinginformation oSupplierrelations oNewhireinitiationform(includingissuanceofpersonnelaccesscard,authorization toaccessbuildings/facilities,accountcreationforaccesstoinformationsystemsand authorizations,informationsecurityawarenesstraining,orientation,executionof confidentialityagreement). oSeveranceform. Procedures oStandardoperatingproceduredraftingandimplementationprocedure oAppointmentprocedureofqualifiedpersonforpharmacovigilance

sion published by the Turkish Medicines and Medical Devices Agency (TİTCK), imported from the AIFD Legislation Portal archive. In the event of any discrepancy, the Turkish original text (mevzuat.g

oAppointmentprocedureofdeputyqualifiedpersonforpharmacovigilance
oManagementandreportingprocedureofadversedrugreactionreports
oCausalityassessmentprocedureofadversereactions oLiteraturereportsmanagementprocedure
oManagementprocedureofmedicinessubjecttoadditionalmonitoring
oSafetyalertmanagementprocedure oSignalmanagementprocedure
oCPSPinternalandexternalcommunicationprocedure
oProcedurefordirecthealthcareprofessionalcommunications
oProcedureforpreparingperiodicbenefit/riskassessmentreports
oProcedureforpreparingriskmanagementplans
oProcedureforpreparinganddisseminatingtrainingmaterials
oProcedureforpreparingthePharmacovigilanceSystemMasterFile
oBenefit/riskassessmentprocedure oTrainingprocedure: CPSPpersonneltrainingprocedure
Orientationprogram Six-monthon-the-jobtrainingplan Annualon-the-jobtrainingplan
Trainingassessmentform Newhireinitiationandroleadjustmentcontrolform
Trainingneedanalysisform Trainingassessmentform Personneltrainingregistrationform
Trainingassessmentreport Trainingprocedureforpharmacovigilanceserviceproviders
Orientationprogram Trainingassessmentform Six-monthon-the-jobtrainingplan
Annualon-the-jobtrainingplan Trainingneedanalysisform Personneltrainingregistrationform
Trainingassessmentreport oCorrectiveandpreventiveactionsprocedure
oPhysical/electronicarchiving Procedureforretrievingfilesfromthearchive

Procedurefordeliveringfilesforarchiving
Temperatureandhumiditytrackingdiagram oAuditprocedure oRiskmonitoringprocedure
oPharmacovigilancecrisismanagementprocedure oProcedureforcheckingconflictofinterest
oProcedureforpreparingandfollowinguponagreementswithcounterparties
oProcedureforprotectingpersonaldatainthecontextofpharmacovigilance Formsused
Recordmanagement
Pharmacovigilanceresponsibilitiesofmarketingauthorizationholdersthatmaybedelegatedto CPSPs
ARTICLE6–(1)Marketingauthorizationholdersmaydelegateto CPSPssomeoralloftheir
followingpharmacovigilanceobligationsunderthe“RegulationonSafetyofMedicinalProducts”and
otherapplicableguidelines: a)Managementofadversereactionreports
oGuidelineonGoodPharmacovigilancePractice(GVP)ModuleI–
ManagementandReportingofAdverseDrugReactions
oGuidelineonProtectionofPersonalDatainPharmacovigilanceActivities
oGVPModuleIV–PharmacovigilanceQualitySystem oAnnexI–Definitions b)Literaturescreening
oGVPModuleI–ManagementandReportingofAdverseDrugReactions
oGVPModuleIV–PharmacovigilanceQualitySystem c)PreparingPBRARs
oGVPModuleIII–PeriodicBenefit/RiskAssessmentReport
oGVPModuleIV–PharmacovigilanceQualitySystem ç)PreparingPharmacovigilanceSystemMasterFile
oGVPModuleV–PharmacovigilanceSystemMasterFile
oGVPModuleIV–PharmacovigilanceQualitySystem d)PreparingRMPs
oGVPModuleVI–RiskManagementSystems
oGVPModuleVIAnnex1–BasicRequirementsforRiskManagementPlans forCOVID-19Vaccines
oGVPModuleIV–PharmacovigilanceQualitySystem
oGVPModuleIX–SelectionofRiskMinimizationMeasuresandTools
oGVPModuleIX–Annex1–TrainingMaterials e)Signaldetectionandassessment
oGVPModuleVII–SignalManagement oGVPModuleIV–PharmacovigilanceQualitySystem
f)Benefit/riskassessment oGVPModuleX–Pre-MarketingBenefit/RiskAssessment
oGVPModuleXI–Post-MarketingBenefit/RiskAssessment
oGVPModuleIV–PharmacovigilanceQualitySystem g)Pharmacovigilancetraining
CPSPsmustprovideappropriateperiodictrainingtopersonnelwhomayaffectthe

sion published by the Turkish Medicines and Medical Devices Agency (TİTCK), imported from the AIFD Legislation Portal archive. In the event of any discrepancy, the Turkish original text (mevzuat.g

pharmacovigilancesystemorconductofpharmacovigilanceactivities,includingpersonnelliaising betweentheCPSPandmarketingauthorizationholder.Thetrainingprovidedshouldcover,without limitation,productpromotionassociates,andpersonnelwhohavearoleinclinicaltrials,handling technicalproductcomplaints,medicalinquiries,salesandmarketing,regulatoryaffairs,public relations,legalandauditingprocedures.

Thetrainingsessionsshouldbenolessthanone-hourlong,andrepeatednotlessthanfour timesannuallyonaquarterlybasis.Thefirstofthesetrainingsessionsshouldcoverbasictraining,and theothersasrefreshertraining,andutmostcaremustbetakentoensureclosemonitoringofadverse drugreactions.Thetrainingprovidedshouldbelogged,andinitialandfinaltestsshouldbeusedto ensuretraininghasbeensuccessful.

Considerationsfordelegationofpharmacovigilanceobligationsofmarketingauthorization holders

ARTICLE7–(1)Whereamarketingauthorizationholderhasdelegatedallofitsresponsibilitiestoa CPSP,theymaybeexemptedfromtherequirementtointernallyemployaqualifiedpersonfor pharmacovigilance.However,incaseswhereonlysomeofthepharmacovigilanceobligationshave beendelegatedtoaCPSP,aqualifiedpersonforpharmacovigilancemustbeemployedonafull-time basis[RegulationonSafetyofMedicinalProducts,Articles(5)and(6)].

(2)Beforedecidingonselectionofa CPSPtoworkwith,marketingauthorizationholders shouldtakeaccountofthefollowing: Duediligencemustbeperformed. Evenifpharmacovigilanceobligationshavebeencompletelydelegatedtoa CPSP,the marketingauthorizationholderremainsultimatelyresponsibleandthereforeitis advisabletoconductanauditpriortodelegationofobligations.

Iftherearean ypost-auditobservations,asetofcorrectiveandpreventiveactions addressingthesameshouldbeidentified,andtheCPSPshouldbecontractedonly aftertheidentifiedactionshavebeencompleted.

Thecontractbetweenthemarketingauthorizationholderand theCPSPshould unambiguouslyprovideeveryrelevantaspectoftheagreement,includingaclear descriptionofallrolesandresponsibilitiesthathavebeendelegated,leavingnogrey areas.Thecontractshouldbereviewedandapprovedbylegalcounselsofbothparties.

Anemployeeofthemarketingauthorizationholdershouldbeappointedaspointof contact.Thispersonnel: omustbeinformedabouteverycorrespondence,and othecontractmustlaydowntheresponsibilitiesofthecontactperson.

AftercontractingaCPSP,themarketingauthorizationholdershouldcommunicatethis, andthecontactdetailsofthepersonappointedaspointofcontact,totheAgencybya formalletter.

Themarketingauthorizationholdershouldmeetbeforehandwiththequalifiedperson forpharmacovigilanceandtheirdeputyattheCPSPwhowillcarryout pharmacovigilanceactivitiesonitsbehalf. Activitiesperformedshouldbedetailedinmonthlyreports.

TheCPSPshouldinformthemarketingauthorizationholderifandwhentheyundergo anexternalaudit.

RoleofCPSPinconductingcontrolledaccessprograms

ARTICLE8–(1)Theresponsibilityforconductingcontrolledaccessprogramsliewiththe marketingauthorizationholder,whoisalsoresponsibletoensureappropriatemeasuresareinplaceto assuresuccessfulconductoftheprogram.

(2)Inacontrolledaccessprogram,themarketingauthorizationholdercontractsa pharmaceuticalwholesalertowhichitshipstheproduct.Thecontractshouldcoverthefollowing aspects:

a)Therisksofthemedicinalproductandanypotentialimplicationsifitisreceivedbypatients whohavenotbeenprescribedtheproduct.

b)Therulesforreceivingoftheproductbythepharmaceuticalwholesalerandreshipmentto thepharmacywhoreceivedtheoriginalorder. c)Penaltiesforbreachingtherules.

sion published by the Turkish Medicines and Medical Devices Agency (TİTCK), imported from the AIFD Legislation Portal archive. In the event of any discrepancy, the Turkish original text (mevzuat.g

ç)Planning,executingandreportingjointactionstoimprovetheoperation.
Appropriatetrainingshouldbeprovidedtoensurethatthisinformationisknowntothe pharmaceuticalwholesaler'spersonnel,includingitsqualifiedperson,operationsmanagerandbranch manager. (3)Acontrolledaccessprogrammaybeconductedbya CPSP,orthroughathirdparty.Where thewholeofthepharmacovigilanceobligationshavebeendelegatedtoa CPSP,controlledaccess programactivitiesmaynotbeconductedbythesameCPSPoradifferentdepartmentofitdueto privacyofpersonaldata.
(4)Intheeventofterminationofcontractwiththemarketingauthorizationholderortransfer ofconductofthecontrolledaccessprogramtoanotherprovider,theCPSPorthethirdpartyconcerned mustdeliverallinformation,bothelectronicandinhardcopy,initspossessiontothenewservice providercontractedbythemarketingauthorizationholder,andgiveformalassurancethatnodata remainsinitspossession.Thisinformationmaynotunderanycircumstancesbedeliveredtothe marketingauthorizationholderorthirdparties.Anybreachoftheforegoingrequirementwillbe subjecttoapplicableprovisionsofLaw#6698onProtectionofPersonalData.
TransferofpharmacovigilanceactivitiesbetweenCPSPs
ARTICLE9–(1)Afterexpirationoftheircontractwitha CPSP,marketingauthorizationholders maycontractanotherCPSPormaymutuallyterminatetheircontract.Inthatcase,the pharmacovigilancedatamustbefullyandaccuratelytransferredtothenewly-contracted CPSP,and theoriginalCPSPmustensurethatallofthedatahavebeensecurelyerased.
(2)Alldocumentsinhardcopymustbealsodeliveredtothemarketingauthorizationholder withaformalreceipt,withoutanymodificationorduplicationofthedocuments. Effectiveness
ARTICLE10–(1)Thisguidelinewillenterintoforcefrom01.01.2024. Enforcement
ARTICLE11–(1)ThePresidentofTurkishMedicinesandMedicalDevicesAgencywillenforce thisGuideline.

sion published by the Turkish Medicines and Medical Devices Agency (TİTCK), imported from the AIFD Legislation Portal archive. In the event of any discrepancy, the Turkish original text (mevzuat.g