İYI FARMAKOVIJILANS UYGULAMALARI KILAVUZU MODÜL EK I – TANIMLAR – 03.08.2022_EN (002)

GuidelineonGood Pharmacovigilance Practices ANNEXI-DEFINITIONS(revised1stedition) Dateoffirstissue 12.06.2014 Dateoftherevised1stedition 03.08.2022 TURKISHMEDICINESANDMEDICALDEVICESAGENCY 03.08.2022

1 Tableofcontents

TABLE OF CONTENTS

EUReferencedate,Unionreferencedate
Adverseevent(AE),Adverseexperience
Adversereaction,Adversedrugreaction(ADR),Suspectedadverse(drug)reaction,Adverse **effect,Undesirableeffect**
Minimumcriteriaforreporting
Unexpectedadversereaction
Individualcasesafetyreport(ICSR),Adverse(drug)reactionreport
Seriousadversereaction
Ongoingsignal
Overdose
Missinginformation
Pharmacovigilance
Pharmacovigilancesystem
Pharmacovigilancesystemmasterfile
Qualityofapharmacovigilancesystem
Qualitysystemofapharmacovigilancesystem
Companycoresafetyinformation(CCSI)
Companycoredatasheet(CCDS)
Safetyissue,Safetyconcern
Targetpopulation(treatment),Treatmenttargetpopulation
Drug(Medicinalproductforhumanuse)
Misuseofamedicinalproduct
Risksrelatedtouseofamedicinalproduct
Abuseofamedicinalproduct
Misuseofamedicinalproductforillegalpurposes
Qualityrequirements
Qualityimprovements
Qualitycontrolandassurance
Qualityplanning
Qualityadherence
Closedsignal
Crisis
Occupationalexposure
Incident
Importantidentifiedriskandimportantpotentialrisk
Periodicbenefit/riskevaluationreport(PBRER)
Potentialrisk
Referencesafetyinformation
Riskminimizationactivity,riskminimizationmeasure
Riskmanagementplan(RMP)
Riskmanagementsystem
Post-authorizationsafetystudy

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

Healthcareprofessional
Directhealthcareprofessionalcommunication(DHPC)
Signal
Signalconfirmation
Signaldetection
Signalvalidation
Signalmanagementprocess
Spontaneousreport,Spontaneousnotification
Solicitedsourcesofindividualcasesafetyreports
Identifiedclinicalstudy
Identifiedrisk
Consumer
Goodpharmacovigilancepractices(GVP)forTurkey
Internationalbirthdate
Developmentinternationalbirthdate
Validatedsignal
Datalockpoint
Benefit/riskbalance
Emergingsafetyissue
Newlyidentifiedsignal
Audit
Auditfinding(s)
Auditplan
Auditprogram
Auditrecommendation

3 EUreferencedate,Unionreferencedate
Formedicinalproductscontainingthesameactivesubstanceorthesamecombinationof activesubstances,thedateofthefirstmarketingauthorizationintheEUofamedicinal productcontainingthatactivesubstanceorthatcombinationofactivesubstances;orifthis datecannotbeascertained,theearliestoftheknowndatesofthemarketingauthorizationsfor amedicinalproductcontainingthatactivesubstanceorthatcombinationofactivesubstances.
Adverseevent(AE),Adverseexperience
Anyuntowardmedicaloccurrenceinapatientorclinicaltrialsubjectadministereda medicinalproductandwhichdoesnotnecessarilyhaveacausalrelationshipwiththis treatment. Anadverseeventcanthereforebeanyunfavorableandunintendedsign(e.g.anabnormal laboratoryfinding),symptom,ordiseasetemporallyassociatedwiththeuseofamedicinal product,whetherornotconsideredrelatedtothemedicinalproduct.
Adversereaction,Adversedrugreaction(ADR),Suspectedadverse(drug)reaction, Adverseeffect,Undesirableeffect Aresponsetoamedicinalproductwhichisnoxiousandunintended. Inthiscontext,“response”meansthatacausalrelationshipbetweenamedicinalproductand anadverseeventisatleastareasonablepossibility.
Adversereactionsmayarisefromuseoftheproductwithinoroutsidethetermsofthe marketingauthorizationorfromoccupationalexposure.Useoutsidethemarketing authorizationincludesoff-labeluse,overdose,misuse,abuseandmedicationerrors.
Ifaneventisspontaneouslyreported,eveniftherelationshipbetweentheeventandthe medicinalproductisunknownorunstatedbythebyhealthcareprofessionalorconsumeras primarysource,itmeetsthedefinitionofanadversereaction.Therefore,allspontaneous reportsnotifiedbyhealthcareprofessionalsorconsumersareconsideredsuspectedadverse reactions,sincetheyconveythesuspicionsoftheprimarysources,unlesstheprimarysource specificallystatethattheybelievetheeventtobeunrelatedorthatacausalrelationshipcanbe excluded.
Minimumcriteriaforreporting

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

Forthepurposeofreportingcasesofsuspectedadversereactions,theminimumdataelements foracaseare:anidentifiablereporter,anidentifiablepatient,anadversereactionanda suspectmedicinalproduct. Unexpectedadversereaction Anadversereaction,thenature,severityoroutcomeofwhichisnotconsistentwiththe summaryofproductcharacteristicsofthemedicinalproduct. Thisincludesclass-relatedreactionswhicharementionedinthesummaryofproduct characteristics(SmPC)butwhicharenotspecificallydescribedasoccurringwiththisproduct. Individualcasesafetyreport(ICSR),Adverse(drug)reactionreport Thereportwithaspecificformatandcontentforthereportingofoneorseveralsuspected adversereactionstoamedicinalproductthatoccurinasinglepatientataspecificpointof time. 4 Seriousadversereaction Seriousadversereactionsareadversereactionswhichresultindeath,arelife-threatening, requirein-patienthospitalizationorprolongationofexistinghospitalization,resultin persistentorsignificantdisabilityorincapacity,orresultinacongenitalanomaly/birthdefect. Life-threateninginthiscontextreferstoareactioninwhichthepatientwasatriskofdeathat thetimeofthereaction;itdoesnotrefertoareactionthathypotheticallymighthavecaused deathifmoresevere. Medicalandscientificjudgementshouldbeexercisedindecidingwhetherothersituations shouldbeconsideredserious.Medicalandscientificjudgementshouldbeexercisedin decidingwhetherothersituationssuchasimportantmedicaleventsthatmightnotbe immediatelylife-threateningorresultindeathorhospitalizationbutmightjeopardizethe patientormightrequireinterventiontopreventoneoftheotheroutcomeslistedinthe definitionaboveshouldbeconsideredserious.Examplesofsucheventsareintensive treatmentinanemergencyroomorathomeforallergicbronchospasm,blooddyscrasiasor convulsionsthatdonotresultinhospitalizationordevelopmentofdependencyorabuse. Anysuspectedtransmissionviaamedicinalproductofaninfectiousagentisalsoconsidereda seriousadversereaction. Ongoingsignal Inperiodicbenefit/riskevaluationreports,asignalthatremainsunderevaluationatthedata lockpoint. Thisdefinitionisalsoapplicabletoperiodicsafetyupdatereports. Overdose Administrationofaquantityofamedicinalproductgivenperadministrationorcumulatively whichisabovethemaximumrecommendeddoseaccordingtotheSmPCapprovedbythe Agency.Clinicaljudgementshouldalwaysbeappliedinunderstandingwhetheritisan overdose. Missinginformation Gapsinknowledgeaboutamedicinalproduct,relatedtosafetyoruseinparticularpatient populations,whichcouldbeclinicallysignificant. Importantmissinginformationisdefinedascriticalgapsinknowledgeforspecificsafety issuesorpopulationsthatusethemarketedproduct[InternationalCouncilofHarmonization (ICH)]. Pharmacovigilance Scienceandactivitiesrelatingtothedetection,assessment,understandingandpreventionof adversereactionsoranyothermedicine-relatedproblem. Inlinewiththisgeneraldefinition,mainobjectivesofpharmacovigilanceactivitiesin accordancewiththerelevantregulationsare: Preventingharmfromadversereactionsarisingfromtheuseofauthorizedmedicinal productswithinoroutsidethetermsofmarketingauthorizationorfromoccupational exposure. 5 Promotingthesafeandeffectiveuseofmedicinalproducts,inparticularthrough providingtimelyinformationaboutthesafetyofmedicinalproductstopatients, healthcareprofessionalsandthepublic. Pharmacovigilanceisthereforeanactivitycontributingtotheprotectionofpatients’and publichealth. Pharmacovigilancesystem Asystemusedbythemarketingauthorizationholderandapplicants,theAgencyandother organizationstofulfilthetasksandresponsibilitieslistedinRegulationonSafetyofDrugs

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

anddesignedtomonitorthesafetyofmedicinalproductsanddetectanychangetotheir risk/benefitbalance.
Ingeneral,apharmacovigilancesystemisasystemusedbyanorganizationtofulfilitslegal tasksandresponsibilitiesinrelationtopharmacovigilanceanddesignedtomonitorthesafety ofauthorizedmedicinalproductsanddetectanychangetotheirrisk/benefitbalance.
Pharmacovigilancesystemmasterfile
Adetaileddescriptionofthepharmacovigilancesystemusedbythemarketingauthorization holderwithrespecttooneormoreauthorizedmedicinalproducts. Qualityofapharmacovigilancesystem
Allelementsofthepharmacovigilancesystemwhichareconsideredtoproduce,accordingto estimatedlikelihoods,outcomesrelevanttotheobjectivesofpharmacovigilance.
Qualitysystemofapharmacovigilancesystem
Theorganizationalstructure,responsibilities,procedures,processesandresourcesofthe pharmacovigilancesystemaswellasresourcemanagement,compliancemanagementand recordmanagement. Thequalitysystemispartofthepharmacovigilancesystem.
Companycoresafetyinformation(CCSI)
Formedicinalproducts,allrelevantsafetyinformationcontainedinthecompanycoredata sheetpreparedbythemarketingauthorizationholderandwhichthemarketingauthorization holderrequirestobelistedinallcountrieswherethecompanymarketstheproduct,except whenthelocalregulatoryauthorityspecificallyrequiresamodification.
Itisthereferenceinformationbywhich“listed”and“unlisted”aredeterminedforthe purposesofperiodicreportingformarketedproducts,butnotbywhich“expected”and “unexpected”aredeterminedforexpeditedreporting Companycoredatasheet(CCDS)
Adocumentpreparedbythemarketingauthorizationholdercontaining,inadditiontosafety information,materialrelatedtoindications,dosing,pharmacologyandotherinformation concerningtheproduct. Safetyissue,Safetyconcern
Animportantidentifiedrisk,importantpotentialriskormissinginformation.
6 TheICHdefinitionofsafetyconcernis:Animportantidentifiedrisk,importantpotentialrisk orimportantmissinginformation,i.e.includesthequalifier“important”inrelationtomissing information(seeICH-E2C(R2)Guideline). Targetpopulation(treatment),Treatmenttargetpopulation
Thepatientswhomightbetreatedwiththemedicinalproductinaccordancewiththe indication(s)andcontraindicationsintheauthorizedproductinformation.
Drug(Medicinalproductforhumanuse):
1)Anysubstanceorcombinationofsubstancespresentedashavingpropertiesfortreatingor preventingdiseaseinhumanbeings;orusedinoradministeredtohumanbeingseitherwitha viewtorestoring,correctingormodifyingphysiologicalfunctionsbyexertinga pharmacological,immunologicalormetabolicaction,ortomakingamedicaldiagnosis.
Misuseofamedicinalproduct
Situationswhereamedicinalproductisintentionallyandinappropriatelyusednotin accordancewiththetermsoftheauthorizedproductinformation.
Risksrelatedtouseofamedicinalproduct
Anyriskrelatingtothequality,safetyorefficacyofthemedicinalproductasregardspatients’ healthorpublichealthandanyriskofundesirableeffectsontheenvironment.
Abuseofamedicinalproduct
Persistentorsporadic,intentionalexcessiveuseofmedicinalproductswhichisaccompanied byharmfulphysicalorpsychologicaleffects. Misuseofamedicinalproductforillegalpurposes
Misuseforillegalpurposesismisusewiththeadditionalconnotationofanintentionof misusingthemedicinalproducttocauseaneffectinanotherperson.Thisincludes,amongst others:thesale,tootherpeople,ofmedicinesforrecreationalpurposesanduseofamedicinal producttofacilitateassault. Qualityrequirements
Thosecharacteristicsofasystemthatarelikelytoproducethedesiredoutcome,orquality objectives.
Qualityimprovements

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

Correctingandimprovingthestructuresandprocesseswherenecessary.Thisdefinitionis applicableinthecontextoffulfillingqualityrequirements. Qualitycontrolandassurance Monitoringandevaluatinghoweffectivelythestructuresandprocesseshavebeenestablished andhoweffectivelytheprocessesarebeingcarriedout.
Thisdefinitionisapplicableinthecontextoffulfillingqualityrequirements. Qualityplanning Establishingstructures,andplanningintegratedandconsistentprocesses.
Thisdefinitionisapplicableinthecontextoffulfillingqualityrequirements.

7 Qualityadherence Carryingouttasksandresponsibilitiesinaccordancewithqualityrequirements. Closedsignal Inperiodicbenefit/riskevaluationreports,asignalforwhichanevaluationwascompleted duringthereportinginterval.
Asafetysignalcanbeclosedeitherbecauseitisrefutedorbecauseitisdeterminedtobea potentialoridentifiedriskfollowingevaluation.
Thisdefinitionisalsoapplicabletoperiodicsafetyupdatereports. Crisis Inthecontextofthisguideline,acrisisisdefinedasasituationwhere,afterassessmentofthe associatedrisks,urgentandcoordinatedactionandcontrolbetweentheAgencyandthe marketingauthorizationholderarerequired. Occupationalexposure Anexposuretoamedicinalproductasaresultofone'sprofessionalornon-professional occupation. Itdoesnotincludetheexposuretooneoftheingredientsduringthemanufacturingprocess beforethereleaseasfinishedproduct. Incident Asituationwhereaneventoccursornewinformationarises,irrespectivewhetherthisisin thepublicdomainornot,inrelationto(an)authorizedmedicinalproduct(s)whichcouldhave aseriousimpactonpublichealth.
Theincidentmayberelatedtoquality,efficacyorsafetyconcerns,butmostlikelytosafety and/orquality(andpossiblysubsequentsupplyshortages).Inaddition,situationsthatdonot seematafirstglancetohaveaseriousimpactonpublichealth,butareinthepublicdomain-subjectofmediaattentionornot-andmayleadtoseriouspublicconcernsabouttheproduct, mayalsoneedtobeconsideredasincidents.Likewise,othersituationswhichmighthavea negativeimpactontheappropriateuseofamedicinalproducts(e.g.resultinginpatientsstop takingtheirmedicine)mayfallwithinthedefinitionofanincident.
Importantidentifiedriskandimportantpotentialrisk
Anidentifiedriskorpotentialriskthatcouldhaveanimpactontherisk/benefitbalanceofthe productorhaveimplicationsforpublichealth.
Whatconstitutesanimportantriskwilldependuponseveralfactors,includingtheimpacton theindividual,theseriousnessoftheriskandtheimpactonpublichealth.Normally,anyrisk thatislikelytobeincludedinthecontraindicationsorwarningsandprecautionssectionofthe productinformationshouldbeconsideredimportant. Periodicbenefit/riskevaluationreport(PBRER) Areportprovidinganevaluationoftherisk/benefitbalanceofamedicinalproductfor submissionbythemarketingauthorizationholderatdefinedtimepointsduringthepost-authorizationphase.

8 Periodicbenefit/riskevaluationreportsshouldfollowtheformatdescribedinModuleIII. Potentialrisk Anuntowardoccurrenceforwhichthereissomebasisforsuspicionofanassociationwiththe medicinalproductofinterestbutwherethisassociationhasnotbeenconfirmed. Examplesinclude: Non-clinicaltoxicologicalfindingsthathavenotbeenobservedorresolvedinclinical studies. Adverseeventsobservedinclinicaltrialsorepidemiologicalstudiesforwhichthe magnitudeofthedifference,comparedwiththecomparatorgroup,ontheparameterof interestraisesasuspicionof,butisnotlargeenoughtosuggest,acausalrelationship.
Asignalarisingfromaspontaneousadversereactionreportingsystem.
Eventsknowntobeassociatedwithotheractivesubstanceswithinthesameclassor whichcouldbeexpectedtooccurbasedonthepropertiesofthemedicinalproduct.
Referencesafetyinformation

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

Inperiodicbenefit-riskevaluationreportsformedicinalproducts,allrelevantsafety informationcontainedinthereferenceproductinformation(e.g.thecompanycoredatasheet) preparedbythemarketingauthorizationholderandwhichthemarketingauthorizationholder requirestobelistedinallcountrieswhereitmarketstheproduct,exceptwhenthelocal regulatoryauthorityspecificallyrequiresamodification.
Itisasubsetofinformationcontainedwithinthemarketingauthorizationholder'sreference productinformationfortheperiodicbenefit-riskevaluationreport.Wherethereference productinformationisthecompanycoredatasheet,thereferencesafetyinformationisthe companycoresafetyinformation. Riskminimizationactivity,riskminimizationmeasure Publichealthinterventionsintendedtopreventtheoccurrenceofadversereactionsassociated withtheexposuretoamedicine,reducethelikelihoodofoccurrence,ortoreducetheir severityshouldadversereactionsoccur.
Theseactivitiesmayconsistofroutineriskminimizationmeasures(e.g.SmPC,thepackage leaflet,thepacksize,thelegalstatusoftheproduct,anditsformulation)oradditionalrisk minimizationmeasures(e.g.educationalprograms,controlledaccessprograms,other additionalriskminimizationmeasures). Riskmanagementplan(RMP) Adetaileddescriptionoftheriskmanagementsystem.
Theriskmanagementplanestablishedbythemarketingauthorizationholdershallcontainthe followingelements:
(a)anidentificationorcharacterizationofthesafetyprofileoftheconcernedmedicinal product
(b)anindicationofhowtocharacterizefurtherthesafetyprofileoftheconcernedmedicinal product
(c)adocumentationofmeasurestopreventorminimizetherisksassociatedwiththe medicinalproduct,includinganassessmentoftheeffectivenessofthoseinterventions
(d)adocumentationofpost-authorizationobligationsthathavebeenimposedasacondition ofthemarketingauthorization
9 Riskmanagementsystem
Asetofpharmacovigilanceactivitiesandinterventionsdesignedtoidentify,characterize, preventorminimizerisksrelatingtoamedicinalproduct,includingtheassessmentofthe effectivenessofthoseinterventions Post-authorizationsafetystudy
Anystudyrelatingtoanauthorizedmedicinalproductconductedwiththeaimofidentifying, characterizingorquantifyingasafetyhazard,confirmingthesafetyprofileofthemedicinal product,orofmeasuringtheeffectivenessofriskmanagementmeasures.
Apost-authorizationsafetystudymaybeaninterventionalclinicaltrialormayfollowan observational,non-interventionalstudydesign. Healthcareprofessional
Forthepurposesofreportingsuspectedadversereactions,itmeansphysicians,pharmacists, dentists,nursesandmidwives. Directhealthcareprofessionalcommunication(DHPC)
Acommunicationdelivereddirectlytohealthcareprofessionalsbyamarketingauthorization holderorAgency,toinformthemoftheneedtotakecertainactionsandadapttheirpractices inrelationtoamedicinalproduct. DHPCsarenotrepliestoenquiriesfromhealthcareprofessionals.
Signal Informationarisingfromoneormultiplesources,includingobservationsandexperiments, whichsuggestsanewcausalassociation,oranewaspectofaknownassociationbetweenan interventionandaneventorsetofrelatedevents,eitheradverseorbeneficial,thatrequires verificatoryaction.
Newaspectsofaknownassociationmayincludechangesinthefrequency,duration,severity oroutcomeoftheadversereaction. Signalconfirmation
Evaluationanddiscussionofavalidatedsignalbytheadministrativeauthority. Signaldetection
Theprocessoflookingforand/oridentifyingsignalsusingdatafromanysource. Signalvalidation
Processofevaluatingthedatasupportingthedetectedsignalinordertoverifythatthe availabledocumentationcontainssufficientevidencedemonstratingtheexistenceofanew potentiallycausalassociation,oranewaspectofaknownassociation,andthereforejustifies furtheranalysisofthesignal.Thisevaluationshouldtakeintoaccountthestrengthofthe

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

evidence,theclinicalrelevanceandthepreviousinformationwithrespecttotheassociation.

10 Signalmanagementprocess

Asetofactivitiesperformedtodeterminewhether,basedonanexaminationofICSR, aggregateddatafromactivesurveillancesystemsorstudies,scientificliteratureinformation orotherdatasources,therearenewrisksassociatedwithanactivesubstanceoramedicinal productorwhetherknownriskshavechanged,aswellasanyrelatedrecommendations, decisions,communicationsandtracking.

Thesignalmanagementprocess,fromthedetectionofthesignaltorecommendationsfor action,shallincludethefollowingsteps: Signaldetection Signalvalidation Signalconfirmation Signalanalysisandprioritization Signalassessment Recommendationforaction

Spontaneousnotification,Spontaneousreport

Anunsolicitedcommunicationbyahealthcareprofessionalorconsumertotheagencyor marketingauthorizationholderthatdescribesoneormoreadversereactionsinapatientwho wasgivenoneormoremedicinalproductsandthatdoesnotderivefromastudyorany organizeddatacollectionscheme.

Inthiscontext,anadversereactionreferstoasuspectedadversereaction.Stimulated reportingcanoccurincertainsituations,suchasafteradirecthealthcareprofessional communication,apublicationinthepressorquestioningofhealthcareprofessionalsby companyrepresentatives,andadversereactionreportsarisingfromthesesituationsare consideredspontaneousreports,providedthereportmeetsthedefinitionabove.Reportingcan alsobestimulatedbyinvitationfrompatients'orconsumers'organizationstotheirmembers.

Solicitedsourcesofindividualcasesafetyreports

Organizeddatacollectionsystems,whichincludeclinicaltrials,non-interventionalstudies, registries,off-labeluseoruseforindividualtreatment,compassionateaccessprograms,other patientsupportanddiseasemanagementprograms,surveysofpatientsorhealthcare professionalsorinformationgatheringonefficacyorpatientcompliance.Forthepurposeof safetyreporting,solicitedreportsshouldnotbeconsideredspontaneousbutclassifiedas individualcasesafetyreportsfromstudiesandthereforeshouldhaveanappropriatecausality assessmentbythemarketingauthorizationholderorahealthcareprofessional. Completedclinicaltrial Studyforwhichaclinicaltrialreportisavailable. Identifiedrisk

Anuntowardoccurrenceforwhichthereisadequateevidenceofanassociationwiththe medicinalproductofinterest.Examplesinclude:

Adversereactionsadequatelydemonstratedinnon-clinicalstudiesandconfirmedby clinicaldata, Adversereactionsobservedinwell-designedclinicaltrialsorepidemiologicalstudies forwhichthemagnitudeofthedifference,comparedwiththecomparatorgroupona parameterofinterest,suggestsacausalrelationship,

11 Anadversereactionsuggestedbyanumberofwell-documentedspontaneousreports wherecausalityisstronglysupportedbytemporalrelationshipandbiological plausibility,suchasanaphylacticreactionsorapplicationsitereactions

Adversereactionsincludedinsection4.8oftheSmPCarealsoconsideredidentifiedrisks. Unlesstheyareclass-relatedreactionswhicharementionedintheSmPCbutwhicharenot specificallydescribedasoccurringwiththisproduct(thesewouldnormallybeconsideredasa potentialrisk). Consumer

Forthepurposeofreportingcasesofsuspectedadversereactions,apersonwhoisnota healthcareprofessionalsuchasapatientorlawyer,friendorrelative/parent/childofapatient.

Goodpharmacovigilancepractices(GVP)forTurkey

Bodyofrulesthatapplytomarketingauthorizationholders,contractpharmacovigilance serviceorganizationsandtheAgencywithrespecttotheconductofpharmacovigilance activitiesinourcountry. Internationalbirthdate

Thedateofthefirstmarketingauthorizationforanyproductcontainingtheactivesubstance grantedtoanycompanyinanycountryintheworld.

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

Ifamarketingauthorizationholderhasnoinformationontheactualinternationalbirthdate foraproduct,itshouldfirstrefertolistingsofbirthdatesthatsomeregionsdevelopandmake publiclyavailable.Iftheproductisnotincludedinanylisting,itshouldproposetothe TİTCKabirthdatethatisbasedontheearliestknownmarketingauthorizationofthe substanceandthenobtaintheAgency'sapproval. Developmentinternationalbirthdate Dateoffirstapproval(orauthorization)forconductinganinterventionalclinicaltrialinany country. Validatedsignal Asignalforwhichthesignalvalidationprocess,wherethedatasupportingtheidentified signalisevaluated,hasverifiedthattheavailabledocumentationcontainssufficientevidence demonstratingtheexistenceofanewpotentiallycausalassociation,oranewaspectofa knownassociation,andthereforejustifiesfurtheranalysisofthesignal. Datalockpoint Foraperiodicsafetyupdatereport(PSUR),thedatedesignatedasthecut-offdatefordatato beincludedinaPSUR.
ForaPeriodicBenefit/RiskEvaluationReport(PBRER),thedatedesignatedasthecut-off datefordatatobeincludedinaPBRER,basedontheinternationalbirthdate.
Datealsoincludesdayandmonth. Benefit/riskbalance Anevaluationofthepositivetherapeuticeffectsofthemedicinalproductinrelationtothe risks,i.e.anyriskrelatingtothequality,safetyorefficacyofthemedicinalproductasregards patients'healthorpublichealth.

12 Emergingsafetyissue Asafetyalertconsideredbyamarketingauthorizationholder,withrespecttoitsauthorized medicinalproducts,torequireurgentmeasuresbecauseofthepotentialmajorimpactonthe risk/benefitbalanceofthemedicinalproductand/or onpublichealthandthepotentialneedforpromptregulatoryactionandcommunicationto patientsandhealthcareprofessionals. Newlyidentifiedsignal Inperiodicbenefit/riskevaluationreports,asignalfirstidentifiedduringthereportinginterval, promptingfurthermeasuresorevaluation.
Thisdefinitioncouldalsoapplytoapreviouslyclosedsignalforwhichnewinformation becomesavailableinthereportingintervalpromptingfurtheractionorevaluation.
Thesamedefinitionisalsoapplicabletoperiodicsafetyupdatereports. Audit Asystematic,disciplined,independentanddocumentedprocessforobtainingauditevidence andevaluatingtheevidenceobjectivelytodeterminetheextenttowhichtheauditcriteriaare fulfilled. Benchmarking,reviewsofqualifications,riskassessmentquestionnaires,surveysorother activitiesinwhichevidenceoffulfilmentofpharmacovigilancerequirementsisnot independentlyobtainedandevaluated,wouldnotberegardedasanaudit. Auditfindings Resultsoftheevaluationofthecollectedauditevidenceagainstauditcriteria.Auditevidence isnecessarytosupporttheauditor'sresultsoftheevaluation;itiscumulativeinnatureandis primarilyobtainedfromauditproceduresperformedduringthecourseoftheaudit. Auditplan Descriptionofplansandactivitiesforanindividualaudit. Auditprogram Setofoneormoreauditsplannedforaspecifictimeframeanddirectedtowardsaspecific purpose. Auditrecommendation
Describesthecourseofactionmanagementrequiredtorectifyconditionsthathavegoneawry, andtomitigateweaknessesinsystemsofmanagementcontrol.
Auditrecommendationsshouldbepositiveandasspecificaspossible.These recommendationsshouldalsoidentifythepersonswhowilltakethenecessaryactions.

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