3.12.2024 REGULATION ON AMENDING THE REGULATION ON THE AUTHORIZATION OF MEDICINAL PRODUCTS FOR HUMAN USE

December3,2024 TUESDAY OfficialGazette Number:32741 REGULATION FromTurkishMedicinesandMedicalDevicesAgency:
REGULATIONONAMENDINGTHEREGULATIONONTHEAUTHORIZATIONOF MEDICINALPRODUCTSFORHUMANUSE ARTICLE1-Thephrase“RegulationonClinicalTrialsofPharmaceuticalsandBiologicalProductspublishedin theOfficialGazettedated13/4/2013andnumbered28617”insubparagraph(c)ofthesecondparagraphofArticle2ofthe RegulationontheAuthorizationofMedicinal ProductsforHumanUsepublishedintheOfficialGazettedated11/12/2021 andnumbered31686hasbeenamendedtoRegulationonClinicalTrialsofMedicinalProductsforHumanUsepublished intheOfficialGazettedated27/5/2023andnumbered32203”.
ARTICLE2-Thephrase“LawNo.7223onProductSafetyandTechnicalRegulationsdated5/3/2020and numbered7223”hasbeenaddedtothefirstparagraphofArticle3ofthesameRegulationafterthephrase“Article6ofthe BloodandBloodProductsLawNo.5624dated11/4/2007”.
ARTICLE3-Thefollowingsubparagraphhasbeenaddedtothefirstparagraphof Article4ofthesame Regulation. “ll)Applicationforanobligatorycase:Anapplicationthatrequiresachangeinthefileofamedicinalproductfor humanuseduringtheauthorizationprocessofamedicinalproductforhumanuseandincludesachangethatisdeemedto
bemandatorywhenevaluatedbytheAgencybasedontherequestoftheapplicant,”
ARTICLE4-Subparagraph(c)ofthefirstparagraphofArticle8ofthesameRegulationhasbeenamendedasfollows,thephrases“telephoneandfaxnumber”insubparagraphs(ç)and(aa)havebeenamendedto“telephonenumber, e-mailaddressandfaxnumber”,thephrase“telephonenumberandfaxnumber”insubparagraph(d)hasbeenamendedto “telephonenumber,e-mailaddressandfaxnumber”,thephrase“ofthestudies”insubparagraph(m)hasbeenamendedto “ofthetrials”,thephrase“tostudies”hasbeenamendedto“totrials”,andthephrase“studies”hasbeenamendedto “trials”,thephrase“intheRegulationonClinicalTrialsofPharmaceuticalsandBiologicalProducts”hasbeenamendedto “intheRegulationonClinicalTrialsofMedicinalProductsforHumanUse”,subclause(3)ofthesameparagraphand subparagraph(u)ofthesameparagraphhavebeenamendedasfollowsandthefollowingsubparagraphhasbeenaddedto thesameparagraph. “c)Iftheapplicantisatradecompany,theTurkishTradeRegistryGazetteindicatingthedutiesandtitlesofthe responsiblepersons.” “3)Forclinicaltrialsauthorizedbyotherhealthauthoritiesotherthantheagency,theAustralianMedicines Authority(TGA),theUKMedicinesAuthority(MHRA),thefoundingorpermanentmembercompetentauthoritiesofthe InternationalHarmonizationCommittee(ICH),anauditreportissuedbythecompetentauthoritiesoftheAgency,the AustralianMedicinesAuthority(TGA),theUKMedicinesAuthority(MHRA),theInternationalCommitteefor Harmonization(ICH)whoarefoundingorpermanentmembers,fromthecentersdeterminedinaccordancewiththe guidelinepublishedbytheAgencyamongthecenterswheresuchclinicaltrialsareconducted,preferablyfortherelevant study,orifthisisnotpossible,foradifferentstudyconductedwithintwoyearspriortothedateofcompletionofthe relevantstudy,showingthattherelevantstudywascarriedoutinaccordancewiththerequirementsoftherelevant guidelineandinaccordancewithGoodClinicalPractices(GCP).” “u)Withtheexceptionoftheproductsthatareofstrategicimportanceforthesustainabilityofhealthservicesand thatareprescribedforuseinseriouspublichealthissuesthatshalladverselyaffectthenormallifeandactivitiesofthe wholeorcertainsegmentsofthesociety,especiallyincasesthatshalloccuragainstpublichealththreatsrecognizedbythe WorldHealthOrganizationortheEuropeanUnionoracceptedbytheMinistryofHealth(pandemics,biologicalthreatsand similar)andthataredeemedappropriateforapplicationbythePriorityEvaluationBoard,fortheimportedorlicensed manufacturedproductforwhichamarketingauthorization applicationhasbeenmade,alistofothercountriesforwhicha marketingauthorizationapplicationhasbeenmadeandacopyofthemarketingauthorizationorPharmaceuticalProduct Certificateapprovedbythehealthauthorityofoneofthecountriesonthelistbeforethemarketingauthorizationisissued inTurkey,orincaseswherethesedocumentsarenotissued,theinformationordocumentacceptedbytheAgencyshowing thattheproducthasbeenapprovedformarketingauthorizationbytherelevantauthority” “çç)Ifthe

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activeingredientissupplieddomestically,thesupplycontractandinvoicesignedbetweentheactive ingredientsupplierandthemarketingauthorizationapplicant,andifitissuppliedfromabroad,theletterofconformity issuedinaccordancewiththerelevantguidelinespublishedbytheAgency.” ARTICLE5-Thephrase“inlinewiththerelevantguidelines”hasbeenaddedtothefirstparagraphofArticle12 ofthesameRegulationafterthephrase“inmonthsof”.

ARTICLE6-Thephrase“returnedtoitsholder;”inthefirstparagraphofArticle13ofthesameRegulationhasbeenamendedto“revoked:”andthesecond,thirdandfourthparagraphsofthesameArticlehavebeenamendedasfollows andthefollowingparagraphhasbeenaddedtothesameArticle. “(2)Theinformationanddocumentstobesubmittedtothe Agencymustbedeemedappropriatebytheagencyin termsofcurrent scientificrequirementsandthedatesubmittedfortheaforementionedinformationanddocumentspursuant tosubparagraph(c)ofthefirstparagraphmustnotexceedthreeyears.TheAgencymaymakeanexceptiontothisissuefor conditionalauthorizationapplicationsmadewithinthescopeofArticle33.

(3)Incaseare-authorizationapplicationismadeformedicinalproductsforhumanusewhoseapplicationwas rejectedundersubparagraph(c)ofthefirstparagraph,prioritydecisionsintheauthorizationorinspectionprocessesgiven bythePriorityEvaluationBoard,ifany,fortheproductsinquestion,authorizationprocessesofrelatedproductsare initiateddirectly. (4)Incaseare-authorizationapplicationismadeformedicinalproductsforhumanusewhoseapplicationwas rejectedwithinthescopeofsubparagraph(c)ofthefirstparagraph,theupdatedfileinwhichtheamendmentsapprovedor requestedbytheAgencyareincludedandthecommitmentforsuchinclusionaresubmittedforthefile.If,despitethis commitment,itisdeterminedthatthechangesapprovedandrequestedbytheAgencyarenotreflectedinthecurrentfile, thefileshallberejectedagainandthepriritydecisionsmadebythePriorityEvaluationBoardfortheproductinquestion intheauthorizationorinspectionprocessesshallbecanceled.” “(5)Inmarketingauthorizationapplicationsforjointlymarketedproducts,theapplicationshallberejectedifthe marketingauthorizationrenewalofthemedicinalproductforhumanusereferredtohasnotbeencompletedwithinthe scopeofArticle21.”

ARTICLE7-ThefirstparagraphofArticle14ofthesameRegulationhasbeenamendedasfollows. "(1)TheAgencyshallreviewthemarketingauthorizationapplicationsinaccordancewiththeauthorizationcriteria duringthepreliminaryevaluation,andsendanofficialnotificationtotheapplicantwhethertheapplicationisacceptedor rejected.Thenotificationsentforapplicationapprovalshallnotbeconsideredasthestart oftheauthorizationprocess.The startoftheauthorizationperiodoftheapplicationwhoseevaluationprocessiscompletedandacceptedshallbenotifiedto theauthorizationholderseparatelybytheAgency.The dateofthisnotificationshallbeconsideredasthestartofthe authorizationperiod.Theauthorizationprocessshallbefinalizedinthefollowingtwohundredandtendays.Inaddition, theperiodforevaluationsbyexternalorganizations,theperiodforofficialholidays,excludingweekends,andtheperiod forstatesofemergencyshallnotbeincludedintheauthorizationperiod.”

ARTICLE8-Paragraph(b)ofthefirstparagraphofArticle17ofthesameRegulationhasbeenrepealed. ARTICLE9-ThefirstparagraphofArticle18ofthesameRegulationhasbeenrepealed,thephrase“righttothree writtenandtwooralreplies”inthesecondparagraphhasbeenamendedto“righttofivereplies(righttotwoorepliescanbe

usedorally)”andsubparagraphs(c)and(d)ofthesameparagraphhavebeenamendedasfollows.

“c)Inadequacyornon-complianceofbioavailabilityor,whereapplicable,”

“d)Inadequacyornon-complianceofthequalitativeandquantitativeformulaordataonitsquality,”

ARTICLE10-ThefifthparagraphofArticle22ofthesameRegulationhasbeenamendedasfollows. (5)Iftheproductswhosemarketingauthorizationhavebeensuspendedforthereasonsspecifiedinsubparagraphs (i)or(j)ofthefirstparagraphare wishedtobereleasedtothemarketagain,anapplicationismadetotheAgencywitha commitmenttoplacetheproductonthemarketwithineighteenmonthsatthelatest.Ifdeemedappropriatebythe Agency, thesuspensionofthemarketingauthorizationislifted.Fortheproductsnotreleasedtothemarketwithintheagreedperiod, theprocessisstartedinaccordancewithArticle23."

ARTICLE11-Subclause(2)ofparagraph(b)ofthefirstparagraphofArticle26ofthesameRegulationand subparagraphs(ç)and(d)havebeenamendedasfollows,thephrase“tobemanufactured”insubparagraph(e)ofthesame paragraphhasbeenamendedto“manufactured”,thefollowingsubparagraphhasbeenad

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dedtothesameparagraph,the phrase“sixmonths”insubparagraph(c)ofthesecondparagraphofthesameArticlehasbeenamendedto“oneyear”and thefollowingparagraphhasbeenaddedtothesameArticle.
“2)Incaseofatradecompany,theTurkishTradeRegistryGazetteindicatingthedutiesandtitlesofthe responsiblepersons,” adocumentissuedbythelicensingcompanyindicatingthattherealpersonortrade companymakingtheimportis thesolerepresentativeauthorizedfortheimport,licensingandsaleofthep roductinquestioninTurkey,andinthecaseof jointmarketing,thedocumentindicatingthatthejointmark etingauthorizationhasbeengrantedtotherealpersonortrade companyotherthanthesolerepresentati veauthorizedinTurkey,andthejointmarketingagreementcontainingthewritten approvalsoftherealpe rsonsortradecompaniesforjointmarketingandthetraderegistrycertificationoftheparties, d)Incasethe medicinalproductforhumanuseismanufacturedunderlicense,adocumentissuedbythelicensing comp anyindicatingthattherealpersonortradecompanyengagedintheproductionisthesolerepresentativea uthorized forthelicensing,productionandsaleoftheproductinTurkey,andincaseofjointmarketing,ado cumentindicatingthat therealpersonortradecompanyotherthanthesolerepresentativeauthorizedin Turkeyisauthorizedforjointmarketing, andajointmarketingagreementcontainingthewrittenconsent oftherealpersonsortradecompaniesforjointmarketing andthetraderegistrycertificationoftheparties,” “f)Intheeventthatamedicinalproductforhumanusem anufacturedinTurkeyissubjecttojointmarketing,the jointmarketingagreementcontainingthewritten consentofthenaturalpersonsortradecompaniesthatshallconductjoint marketingandthetraderegistrycertificateoftheparties.”
“(6)Notransferprocessshallbeestablishedformedicinalproductsforhumanuseforwhichthemarketing authorizationhasnotbeenrenewed.”
ARTICLE12-Thefollowingadditionalarticleshavebeenaddedtothesame Regulation. “Exceptionalcases ADDITIONALARTICLE1-(1)TheAgencymayauthorizetheplacingonthemarketofalicensedmedicinal pr oductforhumanuseinlimitedquantitiesforalimitedperiodoftimeupontherequestofthemarketingauth orization holderinordertoensurethesustainabilityofhealthcareservicesbytheMinistryinserioussuppl yproblemsthatshall adverselyaffectthenormallifeandactivitiesofthewholeorcertainsegmentsofthes ociety,providedthatitislimitedto individualcases,therelevantsituationdoesnotprejudicethesafetyoft heproductandisdeemedappropriatebythe PriorityAssessmentBoard.
Diversificationapplicationsformedicinalproductsforhumanusecontaininganintegratedmedica ldevice
ADDITIONALARTICLE2-(1)Intheeventthatamedicinalproductforhumanuseforwhichavariation applic ationismadewithinthescopeoftheRegulationonVariationsinAuthorizedMedicinalProductsforHuman Use containsanintegratedmedicaldevice,iftheapplicantdeclaresthatthereisnochange/addition/subt ractionintheintegrated medicaldeviceofthecurrentlyauthorizedmedicinalproductforhumanuseorac hangethatshallaffecttheperformanceof thedevice,CEcertificateornotifiedbodyopinionisnotrequired fortheintegratedmedicaldeviceofthemedicinalproduct forhumanuseforwhichavariationapplicationismade.” ARTICLE13-Thephrases"31/12/2024"inthefirst paragraphoftheprovisionalArticle6ofthesameRegulation havebeenamendedto"1/1/2026". ARTICLE14-Thephrase“until31/12/2028”inthefirstparagraphoftheprovisionalArticle8ofthesame Re gulationhasbeenamendedto“inaccordancewiththedatesspecifiedinsubclauses(1)and(2)ofsubparag raph(b)of thefifthparagraphoftheprovisionalArticle1oftheMedicalDeviceRegulationpublishedinthe OfficialGazettedated 2/6/2021andrepeatingnumbered31499”. ARTICLE15-Thephrase"1/1/2025"in thefirstparagraphoftheprovisionalArticle10ofthesameRegulation hasbeenamendedto"1/1/2026". ARTICLE16-Thefollowingprovisionalarticleshavebeenaddedtothesame Regulation.
“Productswithongoingauthorizationprocess PROVISIONALARTICLE13-(1)Themarketingauthorizatio nprocessesofmedicinalproductsforhumanusefor whichthemarketingauthorizationprocessisongoin gasof1/3/2024andforwhichtheresultsoftheanalysisformarketing authorizationarenotfoundtobeapp ropriateshallnotbecompleteduntiltheanalysisisfoundtobeappropriate.For medicinalproductsforhu manuseinthemarketingauthorizationapplicationprocessforwhichthefirstanalysisresultis foundtobei nappropriate,theanalysisisrepeatedbyrequestinganimprovedsamplefromthecompany.Ifanon- com

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plianceisidentifiedagainthesecondanalysis,theanalysismethodofthenewsampleisdefinedandthea nalysisis carriedoutbyconductinganevaluationmeetingwiththerepresentativesofthecompanyaboutt heanalysismethod.Ifin thethirdanalysisthereisanon-complianceagain,thefinalevaluationmeetingish eldwiththecompanyrepresentatives, thenon-complianceoftheanalysisisdescribedandthenewanalys ismethodisdefinedandthefinalanalysisisconducted. Incaseswhereitisdeterminedthatthequalitative orquantitativeformulaofthemedicinalproductforhumanuseisnotin complianceorthedeclaredspecifi cationsofthemedicinalproductforhumanuseareoutsidetheacceptablelimits,even thoughthespecifie danalysisstepshavebeencompleted,themarketingauthorizationapplicationshallberejected. (2)Asof1 /3/2024,inordertocompletethemarketingauthorizationprocessesofmedicinalproductsforhumanuse forwhichtheanalysisproceduresformarketingauthorizationarestillinprogress,theparametersforwhic htheanalysisis stillinprogressmustbeconcludedaccordingly.Iftheanalysisresultisfoundtobeinappropr iate,theproceduresshallbe carriedoutinaccordancewiththefirstparagraph. Productsclassifiedfromtraditionalherbalmedicinalproductstomedicinalproductsforhumanuse PROVISIONALARTICLE14-(1)Forproductstransferredfromtraditionalherbalmedicinalproductsto med icinalproductsforhumanuse,itismandatorytoapplyformarketingauthorizationwithinoneyearfromth edateof officialnotificationofthetransitiondecisiontotheapplicantandtocompletethemarketingauth orizationapplication withinfiveyears.Thetraditionalherbalmedicinalproductauthorizationsofproduc tsthatfailtoapplyforandobtainan authorizationwithinthisperiodareinvalid. Acceptanceoftransferap plicationsformedicinalproductsforhumanuseforwhichauthorizationhasnotbeen renewed PROVISIONALARTICLE15-(1)ThesixthparagraphofArticle26shallnotbeapplieduntil1/7/2025.” ARTICLE17-TheninthparagraphoftheIntroductionandGeneralPrinciplessectioninAnnex-1ofthesame Regulationhasbeenamendedasfollows. “(9)AllclinicaltrialsconductedinTurkeyshallfullycomplywitht herequirementsoftheRegulationonClinical TrialsofMedicinalProductsforHumanUsepublishedinthe OfficialGazettedated27/5/2023andnumbered32203. Duringtheevaluationofanapplication,clinicaltr ialsofmedicinalproductsforhumanuseconductedoutsideTurkeyand intendedforuseinTurkeymustbe designed,implementedandreportedonthebasisofgoodclinicalpracticesandethical principlesestablishedinaccordancewiththeprinciplessetoutintherelevantRegulation.” ARTICLE18-Thefirstparagraphofthesubsection1.2.ApplicationFormoftheSection1.MODULE1: ADMI NISTRATIVEINFORMATIONinPARTIofAnnex-1ofthesameRegulationhasbeenamendedasfollowsand thesubsection1.8.InformationonClinicalStudiesofthesamesectionhasbeenamendedasfollows. “The applicantshallsubmitadiplomaoranotarizedcopyofthediplomaoftheprofessionsspecifiedinArticle7 o fthisRegulationoragraduationcertificateobtainedfromtheCouncilofHigherEducation,acertifieddocu mentshowing thathe/sheisauthorizedtomaketheapplication,andincaseofatradecompany,theTurkis hTradeRegistryGazette indicatingthecompany'sestablishmentpurposesandthedutiesandtitlesoftheresponsiblepersons.” “1.8.InformationonClinicalTrials Iftheclinicaltrialsareconductedoutside Turkey,astatementfromthea pplicantmustbesubmitted,includinga statementthattheapplicantmeetstheethicalrequirementsseto utintheRegulationonClinicalTrialsofMedicinal ProductsforHumanUse.Thedeclarationmustincludeth estatement“ClinicaltrialsconductedoutsideTurkeymeetthe ethicalrequirementsoftheRegulationon ClinicalTrialsofMedicinalProductsforHumanUse”andmustbeaccompanied byalistofalltrials(protocolnumber)andthecountriesinvolved.”

ARTICLE19-Thephrase“RegulationonClinicalTrialsofPharmaceuticalsandBiologicalProducts”in the subsection“5.2.Contents:BasicPrinciplesandRequirements”oftheSection5.MODULE5:CLINICALS TUDY REPORTSinthePARTIoftheAnnex-1ofthesameRegulationhasbeenamendedto“RegulationonCli nicalTrialsof MedicinalProductsforHumanUse”. ARTICLE20-Thephrase“RegulationonClinicalTrialsof PharmaceuticalsandBiologicalProducts”inthesub- section1.1MedicinalProductsforHumanUseDeriv edfromPlasmaofSection1BIOLOGICALMEDICALPRODUCTS inPARTIIIofAnnex-1ofthesameRegulatio nhasbeenamendedto“RegulationonClinicalTrialsofMedicinalProducts forHumanUse”,thephrase“Re gulationonChangesinAuthorizedorAuthorization-PendingMedicinalProductsfor HumanUse,publish edintheOfficialGazettedated23/5/2005andnumbered25823”hasbeenamendedto“Regulationon Va riationsinAuthorizedMedicinalProductsforHumanUse",andthephrase“RegulationonVariationsinAut

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horizedor Authorization-PendingMedicinalProductsforHumanUse”insub-section1.2.Vaccinesofthes amesectionhasbeen
amendedto“RegulationonVariationsinAuthorizedMedicinalProductsforHumanUse”.
ARTICLE21-Thephrase“naturalandlegalpersons”inthefirstparagraphofArticle2ofthesameRegulation havebeenamendedto“naturalpersonsandtradecompanies”,subclauses(1)and(2)ofparagraph(u)ofth efirstparagraph ofArticle4andthephrases“naturalorlegalperson”insubparagraph(ee)havebeename ndedto“naturalpersonortrade company”,thephrases“naturalorlegalpersons”inthefirstparagraphof Article6andthefirstparagraphofArticle8have beenamendedto“naturalpersonsortradecompanies”,t hephrase“legalentities”insubparagraph(b)ofthefirstparagraph ofArticle7hasbeenamendedto“trade companies”,thephrases“ofthenaturalorlegalperson”insubparagraphs(n)and (o)ofthefirstparagraph ofArticle8havebeenamendedto“ofthenaturalpersonortradecompany”andthephrases“to thenatural orlegalperson”havebeenamendedto“tothenaturalpersonortradecompany”,thephrase“ofthenatura lor legalpersons”insubparagraph(ö)ofthesameparagraphhavebeenamendedto“ofthenaturalperson sortrade companies”,thephrase“tothenaturalorlegalperson”inthesecondparagraphofArticle20hasb eenamendedto“tothe naturalpersonortradecompany”,andinthethirdparagraphofthesameArticle,t hephrase“naturalorlegalperson”has beenamendedto“naturalpersonortradecompany”,thephrase“t othenaturalorlegalpersons”inthefifthparagraphof Article23havebeenamendedto“tothenaturalpers onsortradecompanies”,thephrase“ofthenaturalorlegalpersons”in subparagraph(2)ofparagraph(a)o fthefirstparagraphofArticle26hasbeenamendedto“ofthenaturalpersonsortrade companies”,thephr ase“naturalorlegalperson”inthethirdparagraphofthesamearticlehasbeenamendedto“natural perso nortradecompany”,thephrase“naturalorlegalperson”inthefirstparagraphofArticle27hasbeenamen dedto “naturalpersonortradecompany”,andthephrase“toanaturalorlegalperson”hasbeenamended to“toanaturalperson oratradecompany”andthephrase“toitsownprivateorlegalentity”inthesecondp aragraphofArticle28hasbeen amendedto“toitself”.
ARTICLE22-ThisRegulationshallbecomeeffectiveonthedateofitsissuance.
ARTICLE23-ThisRegulationisenforcedbytheHeadofTurkishMedicinesandMedicalDevicesAgency.

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