FVK-KLVZ 16 TÜRKİYE İLAÇ VE TIBBİ CİHAZ KURUMU FARMAKOVİJİLANS SİSTEMİ KILAVUZU_EN

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e.Giventhefactthatadversereactionreportingmightbeassociatedwithqualitydefect, takingsamplesfromthemarketandsendingthemtoAnalysisandControlLaboratory foranalysis f.Wheneverdeemednecessary,performingsalesblockage,withdrawaloperationsonITS
2.2.4.3.ProcessesInvolvingPharmacovigilanceThroughouttheLifeCycleofaMedicinal ProductforHumanUse
Worksandtransactionsrelatedtopharmacovigilancearedeterminedinfiveprocessgroupsthat involvepharmacovigilancethroughoutthelifecycleofmedicinalproductforhumanuse(seeTable1).
1.Collection,managementandanalysis:Thisprocessgroup,whereappropriate, describesthecollection,generalmanagementandanalysisofdata,informationand documentationrelatedtoproductsafety.
2.Reviewandevaluation:Thisprocessgroupdescribesgeneralreviewandanalysis (e.g.bythemembersofcommission)ofdata,informationanddocumentationrelatedto productsafety.
3.Decisionmakingandtakingaction:Thisprocessgroupdescribesgeneral coordinationofdecisionmakingthroughscientificcommissions.
4.Communication:Thisprocessgroupdescribesgeneralcoordinationofsafety communication.
5.Monitoring:Thisprocessgroupdescribesgeneralmonitoringofimplementation andeffectofproposedcorrectiveactions.
ResponsibilitiesperProcessAreaforPharmacovigilance(throughoutproductlifecycle)
DutiesoftheAgency withregardto Pharmacovigilance Collection, Management, Analysis Reviewand Evaluation DecisionMaking andTakingAction CommunicationMonitoring Conductof pharmacovigilance system TUFAM/FRMUTUFAM/FRMU TUFAM/FRMU TUFAM/FRMUTUFAM/FRMU Adversereaction management TUFAM TUFAM TUFAM TUFAM TUFAM Document IssuedFirstOn RevisionDate RevisionNo. Page
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