

《危害药品目录》中国专家共识

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摘要 目的 制定我国《危害药品目录》,为国内各级医疗机构规范危害药品管理、防控职业暴露风险提供科学依据。方法 由中国药学会静脉用药调配管理专业委员会、国家药事管理专业医疗质量控制中心组织制定,基于文献研究和国外危害药品清单及制定程序,采用专家组研讨会和专家问卷调查法(德尔菲法)确定危害药品品种遴选范围、遴选原则及证据确认标准,筛选在我国上市且符合遴选原则的化学药品、生物制品及中成药品种,形成《〈危害药品目录〉中国专家共识》。结果 确立了5项危害药品遴选原则(说明书有防护标注、致癌性、生殖毒性、遗传毒性和低剂量器官毒性)及相应的证据确认标准,形成了包含210种药品的《危害药品目录》,涵盖抗肿瘤药、内分泌系统用药、神经系统用药、免疫调节药、抗感染药物、心血管系统用药、血液系统用药、泌尿系统用药、妇产科用药、皮肤科用药及其他类;与国外危害药品清单相比,该目录新纳入了25种危害药品,包括15种抗肿瘤药、6种中成药和4种生物制品。另外,本《共识》将可能具有潜在职业暴露风险的88种中成药列入附表供医疗机构管理参考。结论 本共识的制定紧密贴合我国临床用药实际情况,方法科学、严谨,可为各级医疗机构规范管理危害药品、防控职业暴露风险提供参考。**关键词** 危害药品;目录制定;职业防护;中成药;国产创新药

Chinese expert consensus on the Hazardous Drug List

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ABSTRACT **OBJECTIVE** To formulate the *Hazardous Drug List* in China, and provide a scientific basis for standardizing the management of hazardous drugs, preventing and controlling occupational exposure risks in medical institutions at all levels in China. **METHODS** Under the joint organization of the Intravenous Medication Admixture Management Professional Committee of the Chinese Pharmaceutical Association and the National Medical Quality Control Center for Pharmaceutical Management, based on literature research and international hazardous drug lists and their development procedures, the scope of hazardous drug selection, selection principles, and evidence confirmation criteria were determined through expert panel seminars and expert questionnaire survey method (Delphi method). Chemical drugs, biological agents, and Chinese patent medicines marketed in China that met the selection principles were screened to form the *Chinese Expert Consensus on the Hazardous Drug List*. **RESULTS** Five principles for selecting hazardous drugs were established (including protective labeling in package inserts, carcinogenicity, reproductive toxicity, genotoxicity, and organ toxicity at low doses), along with the corresponding evidence confirmation criteria. The *Hazardous Drug List* containing 210 drugs was formulated, covering anti-tumor drugs, endocrine system drugs, nervous system drugs, immunomodulators, anti-infective drugs, cardiovascular system drugs, hematological system drugs, urinary system drugs, obstetrics and gynecology drugs, dermatological drugs and other categories. Compared with international hazardous drug lists, 25 newly included hazardous drugs were added, including 15 anti-tumor drugs, 6 Chinese patent medicines and 4 biological agents. In addition, 88 Chinese patent medicines that may have potential occupational exposure risks are listed in the appendix for reference by medical institutions in management. **CONCLUSIONS** The development of this consensus closely aligns with the actual clinical drug use in China, with a scientific and rigorous methodology, and can serve as a reference for medical

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