世界卫生组织技术报告丛书
961

世界卫生组织药品标准专家委员会第45次技术报告

世界卫生组织 编
金少鸿 宁保明 主译

医药科技出版社 世界卫生组织

报告汇集了国际专家组的观点
并不代表世界卫生组织的决定和主张的政策

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序

1948年第一次世界卫生大会批准建立了统一药典的专家委员会（Expert Committee on the Unification of Pharmacopoeias），1951年更名为国际药典专家委员会（Expert Committee on the International Pharmacopoeia），1959年再次更名为药品标准专家委员会（Expert Committee on Specifications for Pharmaceutical Preparations），该委员会最初的作用是起草和编纂国际药典。随着世界卫生组织在全球疾病控制和预防方面的协调能力和影响力的不断增强，尤其是在艾滋病、SARS、禽流感、结核、疟疾等严重威胁人类健康和安全的全球性疾病方面，WHO更是发挥了不可替代的作用。作为成立最早的委员会之一，药品标准专家委员会的工作范围也不断扩大，涉及药品生产质量管理规范（GMP）、药品管理方面的法规性指导文件（比如药品的可互换性、固定剂量复方制剂和药品稳定性研究）、假药和劣药的处理。另外，该专家委员会还制定了大量的有关质量控制和质量保证体系方面的专门指导意见。

本人于1996当选为WHO药品专家委员会委员，作为该委员会的现任中国籍委员，参加了2001年以来的历次专家委员会会议，从2003年起WHO药品标准专家委员会每年举行一次会议并出版技术报告。

从2006年起，我和我的同事们已经连续翻译出版了第39～44次WHO药品标准专家委员会技术报告。其中关于药品生产的GMP、药品预认证、化学对照品指导原则、仿制药品质量评价等技术文件对国内相关工作的开展具有很好的参考价值，受到大家的广泛好评。

特别感谢中国食品药品检定研究院李云龙、李波、何兰等同事对技术报告翻译工作的大力支持。

衷心感谢给予支持和帮助的湖北省、浙江省、福建省药品检验机构的领导和同事们。

本报告供国内药品研发、质量控制和质量保证、药品检验、药品注册和监督人员参考。

金少鸿

2015年9月

世界卫生组织药品标准专家委员会
日内瓦，2010 年 10 月 18～22 日

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利益申明

Members and temporary advisers of the WHO Expert Committee on Specifi cations forPharmaceutical Preparations reported the following:

Dr Nilka Guerrero Rivas: Her Institute at the University Octavio Méndez Pereira in Panama performs, as part of its public health mandate, as reference laboratory for quality control of pharmaceutical products, fixedfee quality control services for local manufacturers, including Laboratorios Prieto, S. A. /Panamá, LAFSA/Panamá, Medipán/Panamá and Laboratorios Rigar/Panamá.

Professor Henning Kristensen: His wife is a former employee of Novo Nordisk and holds approximately US $ 20, 000 in stocks in this company. The WHO Expert Committee on Specifi cations for

Pharmaceutical Preparations does not consider any of the products manufactured by Novo Nordisk.

Professor I. Addae – Mensah, Professor S. Bawazir, Mr E. Wondemagegnehu Biwota, Dr L. Cargill, Mr J. – M. Caudron, Mr A. C. da Costa Bezerra, Professor T. G. Dekker, Professor J. Hoogmartens, Dr T. Kawanishi, Dr K. Keller, Dr G. N. Mahlangu, Dr J. A. Molzon, Professor T. L. Paúl, Dr L. Paleshnuik, Ms M. –L. Rabouhans, Dr J. –L. Robert, Dr S. Singh and Mr D. Smith reported no conflict of interest.

目录