Laporan praktek kerja profesi apoteker di kementerian kesehatan republik indonesia rumah sakit umum pusat fatmawati apotek kimia farma no 282 = Apothecary internship report at kementerian kesehatan republik indonesia rumah sakit umum pusat fatmawati apotek kimia farma no 282

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Abstrak

Praktek Kerja Profesi Apoteker di Direktorat Bina Produksi Dan Distribusi Alat Kesehatan Direktorat Jenderal Bina Kefarmasian Dan Alat Kesehatan Kementerian Kesehatan Republik Indonesia bertujuan untuk mengetahui struktur organisasi, tugas, dan fungsi serta peran apoteker dalam kebijakan, pengawasan dan pengendalian alat kesehatan dan perbekalan kesehatan rumah tangga. Direktorat Bina Produksi dan Distribusi Alat Kesehatan mempunyai tugas dalam melaksanakan penyiapan perumusan dan pelaksanaan kebijakan dan penyusunan Norma, Standar, Prosedur dan Kriteria (NSPK), serta pemberian bimbingan teknis dan evaluasi di bidang produksi dan distribusi alat kesehatan serta perbekalan kesehatan rumah tangga. Tugas khusus yang diberikan berjudul pemeriksaan dan penilaian berkas permohonan izin edar produk diagnostik "Hormolisa Testosterone". Penilaian dilakukan untuk mendapatkan izin edar, dimana produk tersebut memiliki identifikasi spesifik. Identifikasi tersebut diperlukan untuk penentuan klasifikasi alat kesehatan, persyaratan dan pendaftaran kode Code of Federal Regulation (CFR) dan Harmonized Commodity Description and Coding System (HS code).
<hr>Apothecary Internship at Directorate of Production and Distribution of Medical Devices Directorate General of Pharmaceutical and Medical Devices of the Republic of Indonesia's Ministry of Health aimed to determine the organizational structure, duties, functions and role of the pharmacist in the policy, supervision and control of medical equipment and medical supplies household. Directorate of Production and Distribution of Medical Devices has a duty to carry out the preparation of the formulation and implementation of policies and preparation of Norms, Standards, Procedures and Criteria (NSPK), and providing technical guidance and evaluation in the field of production and distribution of medical equipment and medical supplies household. Given a special assignment called inspection and assessment of the marketing authorization application for beam diagnostic products "Hormolisa Testosterone". Assessment is carried out to obtain marketing authorization, where the product has a specific identification. Identification is required for the determination of the classification of medical devices, the requirements and the registration code of the Code of Federal Regulations (CFR) and the Harmonized Commodity Description and Coding System (HS code).