Laporan praktek kerja profesi apoteker di Badan Pengawas Obat dan Makanan Jl. Percetakan Negara No. 23 Jakarta periode 1-24 April 2014 = Apothecary profession internship report at food and drug regulatory Jl. Percetakan Negara No. 23 Jakarta on the period of April 1th to April 28th 2014

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Abstrak

Profesi Apoteker memegang beragam peranan penting di Badan Pengawas Obat dan Makanan (POM) sebagai salah satu lembaga pemerintah melalui implementasi ilmu kefarmasian dan non-kefarmasian yang dimiliki dalam rangka pengembangan kompetensi yang harus dimiliki oleh profesi Apoteker. Kajian pengawasan obat dan makanan merupakan suatu proses pengawasan yang menyeluruh dari proses hulu hingga proses hilir, yang mencakup pengawasan premarket dan post market yang seluruhnya ditujukan untuk melindungi masyarakat dari peredaran produk yang sub-standar. Direktorat Standardisasi Produk Terapetik (PT) dan Perbekalan Kesehatan Rumah Tangga (PKRT) berperan dalam pengawasan pre-market yakni melalui pemberian layanan bimbingan industri farmasi, penyusunan standar, pedoman, dan regulasi terkait produk terapetik dan PKRT, serta penilaian dan evaluasi laporan dan protokol uji Bioekivalensi (BE) terhadap produk obat tertentu sebagai bagian persyaratan registrasi obat.

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Pharmacist hold a variety of important roles in Indonesia Food and Drug Regulatory Agency Badan POM as one of the government agencies through the implementation of the science of pharmacy and non pharmacy owned in order to develop competencies that should be possessed by the pharmacist profession Study of drug and food control is a process of thorough scrutiny of the upstream and downstream processes which includes pre market monitoring and post market surveillance which are all aimed to protect public from sub standard products Standardization Directorate of Threapeutics Products and Household Health plays a role in pre market monitoring through the provision of guidance to pharmaceutical industry preparation of standards guidelines and regulations related to therapeutic products and household health as well as assessment and evaluation reports and bioequivalence test protocols against certain drug products as part of drug registration requirements.