IMPLEMENTASI KEBIJAKAN *ASEAN MEDICAL DEVICE DIRECTIVE* DALAM RANGKA MENINGKATKAN KUALITAS ALAT KESEHATAN DALAM NEGERI GUNA MENINGKATKAN POTENSI EKSPOR

TESIS

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Abstrak

Kualitas alat kesehatan menentukan keputusan medis yang tepat. Upaya untuk memfasilitasi akses terhadap alat kesehatan yang berkualitas, Indonesia bersama negara ASEAN membuat suatu kesepakatan yaitu *ASEAN Medical Device Directive*. Penelitian ini bertujuan untuk mengetahui bagaimana pelaksanaan kebijakan AMDD dilihat dari aspek: ukuran dan tujuan kebijakan, sumberdaya, komunikasi antar organisasi, sikap pelaksana, karakteristik badan pelaksana dan lingkungan. Penelitian ini dilakukan dengan menggunakan metode penelitian kualitatif dengan teknik pengumpulan data berupa wawancara mendalam dan telaah dokumen. Informan dalam penelitian ini meliputi: Kementerian Kesehatan, Kementerian Perdagangan, Asosiasi Produsen Alat Kesehatan Indonesia, PT. ABC, PT. XYZ, Badan Standardisasi Nasional, Komite Akreditasi Nasional, Badan Pengkajian dan Penerapan Teknologi dan PT. S-SBU Laboratorium. Ukuran dan tujuan kebijakan implementasi AMDD belum tercapai untuk meningkatkan kualitas dan ekspor alat kesehatan dalam negeri; ketersediaan SDM dan sumberdaya finansial sudah optimal, ketersediaan sumberdaya fasilitas belum mencukupi dalam hal standar acuan dan lembaga penilaian kesesuaian; karakteristik badan pelaksana sudah berjalan dengan baik dalam hal pembagian tanggung jawab dan penerapan *Standard Operating Procedure* (SOP); komunikasi antar organisasi sudah terlaksana tapi belum menyasar semua industri; sikap badan pelaksana sudah berkomitmen untuk melaksanakan kebijakan AMDD dan pemberian insentif mempengaruhi sikap pelaksana; lingkungan ekonomi dan politik tidak berpengaruh terhadap kebijakan AMDD.

Kata kunci : Kualitas, Alat Kesehatan, Ekspor, *ASEAN Medical Device Directive*
Bahan bacaan : 62 (2001 – 2020)

THE IMPLEMENTATION OF THE *ASEAN MEDICAL DEVICE DIRECTIVE* POLICY TO IMPROVE THE QUALITY OF DOMESTIC MEDICAL DEVICES TO INCREASE EXPORT POTENTIAL

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Abstract

The quality of medical devices determines the right medical decision. Carrying out effort to facilitate access towards quality medical devices, Indonesia and ASEAN countries made an agreement, the ASEAN Medical Device Directive. This study is aimed to determine how the implementation of AMDD policies in terms of aspects: size and policy objectives, resources, communication between organizations, attitudes of executors, characteristics of implementing agencies and the environment. This research was conducted using qualitative research methods with data collection techniques in the form of in-depth interviews and document review. Informants in this study are Ministry of Health, Ministry of Trade, Association of Indonesian Medical Device Manufacturers, PT. ABC, PT. XYZ, National Standardization Agency for Indonesia, National Accreditation Committee, Agency for the Assessment and Application of Technology and PT. S-SBU Laboratory. The size and objectives of the AMDD implementation policy have not been achieved to improve the quality and export of domestic medical devices; availability of human resources and financial resources has been optimal, availability of facility resources is not sufficient in terms of reference standards and conformity assessment agencies; the characteristics of the implementing agency have been already running well in terms of the division of responsibilities and implementation of Standard Operating Procedures (SOP); communication between organizations has been carried out but has not targeted all industries; the attitude of the implementing agency has committed to implement AMDD policies and the provision of incentives has affected the attitude of the implementers; the economic and political environment has no effect on AMDD policy.

Keywords : Quality, Medical Device, Export, *ASEAN Medical Device Directive*,
Refferences : 62 (2001 – 2020)