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Effect of Changing Pharmaceutical Legislations on Combating Importation and Developing Domestic Drug Manufacturing in Sri Lanka

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Background: Given the complexity of the pharmaceutical industry, how far the Sri Lankan government has achieved its objectives through legislations is questionable.

Objectives: To investigate the correlation between objectives of various legislations introduced and the impact seen in terms of pharmaceutical importation and developing domestic drug manufacturing in Sri Lanka.

Methodology: This is a descriptive cross-sectional study which investigates registration data obtained from Sri Lankan Drug Index 2009/2010 and National Medicines Regulatory Authority (NMRA) public database. In addition, published documents were analyzed as sources of data and statements of policy. Analysis was done over 28 years (1991-2019) in three divided periods; up to June 1991, 1991 to 2009 and 2009 to April 2019. Data was analyzed to see patterns correlated with the legislative changes during the relevant period.

Results: The average ratio between a single drug molecule to product registrations was 1:4 in 1991 and 1:7 thereafter for 28 years. Annual growth of registrations from 1991 to 2010 was 2.8% and in 2010 - 2019 was negative 0.66%. This can be related with the introduction of NMRA act in 2015 and price ceiling in 2016. Domestic drug manufacturing was 9% (305), 3% (207) and 3.5% (227) respectively for the three periods. Domestic Parenteral product manufacturing has improved, but no sign of biological product manufacturing. Indian product dominance has been 26% (886), 40% (2778) and 59% (3836) respectively. Drugs imported from countries with strict high regulatory standards have been reduced from 34% (1172) to 4% (252). Importation from Asian countries has been increased from 33% (1126) to 81% (5210).

Conclusions: Importation of pharmaceuticals has been controlled through policies in an unfettered manner. However, government should introduce strategic policies and regulations to maintain appropriate quality of the low cost pharmaceuticals which are being increasingly imported to the country. Changing Pharmaceutical Legislations has no significant effect on domestic manufacturing.

Keywords: *Sri Lankan pharmaceutical legislations, Drug importation, Drug manufacturing, Pharmaceutical registration, Policy development*