

Medicinal Product Names: New Guidance Document

Overview on the Requirements by Swissmedic



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I. Introduction

On 1 January 2020, Swissmedic issued a document giving new guidance on the lawfulness of medicinal product names (the Guidance Document HMV4¹). In this document, Swissmedic summarizes its practice of examining product names during the application process of medicinal products for market authorization. The Guidance Document HMV4 is based on, and derived from, the Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (Swiss Therapeutic Product Act, TPA²) and its ordinances.³

It is the purpose of the underlying TPA, amongst others, to protect consumers of therapeutic products against fraud (article 1 para. 2 letter a TPA). To that end, Swissmedic, as the competent authority for the marketing authorization of medicinal products,...

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