

PREAMBLE

This document provides information and instructions on how to present the required information when communicating the 2020 SEP adjustment (SEPA) for medicines prices adjusted in terms of Section 22G of Medicines and Related Substances Act (101 of 1965) as amended, and Regulation 8 of the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances. The applicants are required to comply with all the requirements and instructions in this document, failure to do so will result in the submission being considered incomplete. Incomplete submissions shall be regarded as ineligible for processing on the basis of non-compliance with the requirements of these guidelines. These guidelines must be read together with the relevant sections of the Medicines Pricing regulations.