

B.1 Assessment of need

The establishment of a secondary chemical reference substance, calibrated against a primary reference standard substance, may be desirable for various practical reasons, e.g. the primary standard may not be available in adequate quantities to supply all local needs. Moreover, the availability of such secondary chemical reference substances (for example, on a regional basis) would reduce the cost and the delay in receiving the reference material.

The body that establishes a secondary chemical reference substance for national or regional use should be clearly defined by the appropriate regional or national drug regulatory authority. The traceability between the secondary and the primary chemical reference substance must be documented.