

EAHP POSITION PAPER ON SMPC AND DENSITY INFORMATION

The summary of product characteristics (SmPC) of a medicinal product, submitted by a marketing authorisation holder at the time of marketing authorisation application, forms a crucial basis of information for healthcare professionals on how to use the medicinal product safely and effectively.

This position paper sets out a formal request from the 34 member country associations of the European Association of Hospital Pharmacists (EAHP) for improvement to the standard requirements of information included in an SmPC.

In particular, it requests a new requirement that the SmPC contain data specifying the density of a drug solution.

Background to the request

Across Europe, hospital pharmacies are increasingly adopting a gravimetric approach to compounding intravenous medications. The gravimetric approach utilises automated systems or integrated computer assisted gravimetric software programmes, to guide the operator through the different steps of the compounding process. This combination offers several advantages in relation to the standard volumetric method of preparation that has traditionally been used in institutions.

- The gravimetric method verifies the dosing accuracy of the additive syringe in a reliable, objective and reproducible manner.
- The alternative, volumetric approach to dosing accuracy is reliant on a visual inspection of the syringe and thereby depends on the accuracy of the observer's sight. This is a subjective measurement with considerable inter/intra observer variability.
- The gravimetric method collects process data in "real time" creating a reliable and comprehensive audit log for the whole compounding process.
- Conversely, documentation of volumetric preparations is usually completed manually before or after the individual process steps are completed.
- The accuracy of a calibrated balance is greater than the dosing accuracy of a disposable syringe.
- The dosing accuracy of a 5 ml disposable syringe is only required to be within $\pm 5\%$ of the intended volume (DS/EN ISO 7886-1).
- The combination of the gravimetric preparation method and an integrated software program incorporates a variety of quality control check points during the compounding process. These check points assist in verifying the use of the correct drug/dilutant and the dosing accuracy of the final product¹. Large volumetric errors (e.g. double additions) are more easily recognised and the products can be rejected.

¹ With further assistance provided by barcode scan recognition. See EAHP position paper on single unit barcoding for more information. <http://www.eahp.eu/practice-and-policy/advocacy>.

However, the accuracy of the gravimetric method depends on an accurate determination of the density of the drug solution being used. **Unfortunately the summary of product characteristics (SmPC) rarely includes this data, forcing hospital pharmacies to contact the manufacturers directly. This approach is often time consuming and the quality of the data received can vary considerably.**

The inclusion of data specifying the density of a drug solution in the SmPC will increase patient safety, by providing widespread access to quality assured data throughout the European Union.

EAHP and its membership therefore call on the European Medicines Agency, the European Commission, and national medicines agencies to bring about a change to SmPC requirements; **that marketing authorisation holders and applicants provide information within the SmPC specifying the density of a drug solution.**