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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 for improvement to the standard requirements of information included in an SmPC. EAHP and its membership 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.

EAHP's position paper on SmPC and density information is available HERE [1].

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Links

[1]

https://www.eahp.eu/sites/default/files/eahp_position_paper_on_smpc_and_drug_density_information.pdf