

Question & Answer N. 92/2011

Inclusion of non-VMP devices in the packaging

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QUESTION

Is the inclusion of a device, which is strictly not related to the functioning of the medicinal product, nor mandatory for its administration, in the packaging of the VMP acceptable? If so, is reference to be made in the SPC and leaflet?

ANSWER

Additional devices which are not related to the functioning of a VMP, nor mandatory for its administration should not be part of the marketing authorisation. Therefore, there should be no inclusion of non-VMP devices in the packaging of a VMP and no mention of the non-VMP device in the product literature.

The rationale is that inclusion of non-VMP devices in the packaging of a VMP is not directly related to the use of the VMP and is promotional in nature.