Change of name of liposomal medicines at high risk of medication errors

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[Marketing authorisation holders](https://www.ema.europa.eu/en/glossary/marketing-authorisation-holder) of medicines containing liposomal drug delivery systems are requested to submit a [variation](https://www.ema.europa.eu/en/glossary/variation) to change the names of liposomal medicines, but only if there is a high risk of medication errors which would raise concerns regarding the safe use of the [medicinal product](https://www.ema.europa.eu/en/glossary/medicinal-product).

EMA’s human medicines committee ([CHMP](https://www.ema.europa.eu/en/glossary/chmp)) and the [Coordination Group for Mutual Recognition and Decentralised Procedures - Human](https://www.ema.europa.eu/en/glossary/coordination-group-mutual-recognition-decentralised-procedures-human) ([CMDh](https://www.ema.europa.eu/en/glossary/cmdh" \t "_blank" \o "Coordination Group for Mutual Recognition and Decentralised Procedures - Human -  the group responsible for the examination and coordination of questions relating to the marketing authorisation of human medicines in two or more Member States in accordance with the mutual recognition or decentralised procedure.   More information can be found under 'Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh)'.)) adopted these clarifications at their September 2019 meetings, following their [initial joint recommendation on liposomal medicines](https://www.ema.europa.eu/en/news/names-liposomal-medicines-be-changed-avoid-medication-errors) issued in July.

The [CHMP](https://www.ema.europa.eu/en/glossary/chmp) and the [CMDh](https://www.ema.europa.eu/en/glossary/cmdh" \t "_blank" \o "Coordination Group for Mutual Recognition and Decentralised Procedures - Human -  the group responsible for the examination and coordination of questions relating to the marketing authorisation of human medicines in two or more Member States in accordance with the mutual recognition or decentralised procedure.   More information can be found under 'Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh)'.) have now clarified that for medicines administered topically or by other routes of administration, the qualifier 'liposomal' or 'pegylated liposomal' should only be added to the [invented name](https://www.ema.europa.eu/en/glossary/invented-name) in those cases when a clear risk of medication errors has been identified. Elements such as [route of administration](https://www.ema.europa.eu/en/glossary/route-administration), medication error reporting or long established use should be taken into consideration when assessing the need for the qualifier.

In those cases where a name change is considered necessary, applicants are requested to update the name throughout the [product information](https://www.ema.europa.eu/en/glossary/product-information), including all annexes. This is an addition to the communication from July, in which they were instructed to amend only section 1 of the [summary of product characteristics](https://www.ema.europa.eu/en/glossary/summary-product-characteristics).

[Marketing authorisation holders](https://www.ema.europa.eu/en/glossary/marketing-authorisation-holder" \t "_blank" \o "The company or other legal entity that has the authorisation to market a medicine in one, several or all European Union Member States.) are requested to submit an A.2.a [variation](https://www.ema.europa.eu/en/glossary/variation) before the end of September 2019 to update the name of liposomal medicines in line with the new recommendation from the [CHMP](https://www.ema.europa.eu/en/glossary/chmp) and the [CMDh](https://www.ema.europa.eu/en/glossary/cmdh" \t "_blank" \o "Coordination Group for Mutual Recognition and Decentralised Procedures - Human -  the group responsible for the examination and coordination of questions relating to the marketing authorisation of human medicines in two or more Member States in accordance with the mutual recognition or decentralised procedure.   More information can be found under 'Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh)'.).