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Can the MAH of an 'originator' product apply for a generic of its own product

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QUESTION

Can the Marketing Authorisation Holder (MAH) of an 'originator' product apply for a generic of its own product?

If the answer is No, what is the legal base for this?

Is this handled in the same way by all MSs?

ANSWER

There is nothing in the pharmaceutical legislation preventing an originator company from filing a generic application using as reference a product of that same company. The generic application would of course have to comply with the requirements of the legislation concerning that type of application. This includes the rules regarding data protection where the required period of data exclusivity must have elapsed regardless of who holds the marketing authorisation for the reference product.

The conclusion above would apply to the various regulatory possibilities available: where the company intends to obtain marketing authorisation for the generic product in a Member State where a marketing authorisation for the reference product exists; where the generic application is submitted in a Member State where the reference product is not authorised; and where the generic application refers to a reference product which is no longer authorised.