D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

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Prior to the launch of Dzuveo in each Member State (MS), the Marketing Authorisation Holder (MAH) must agree about the content and format of the educational materials, including communication media, distribution modalities, and any other aspects of the programme, with the National Competent Authority (NCA).
The MAH shall ensure that in each MS where Dzuveo is marketed, all HCPs (i.e. physicians, hospital pharmacists, and nurses) who are expected to prescribe / administer the product are provided with a Healthcare Professional Guide, outlining critical information for the safe and effective use of Dzuveo, including:

The method of use of the device;
• The minimum dosing interval of one sublingual tablet per hour, in order to prevent / minimise the important identified risk of respiratory depression and the important potential risk of overdose;
• The key message to convey during patients counselling, about possible respiratory depression / overdose;
• Detailed instruction on how to handle overdose / respiratory depression