Overview of changes requiring an inspection in the GDP area

Version 1, 21.11.2025

This document provides general guidance on changes, including those that do not necessarily require an update of the company authorisation. For guidance on changes to the wholesale distribution authorisation itself, please refer to this page: Application for wholesale distribution of medicines within the EU/EEA

Companies must notify the Danish Medicines Agency of changes in due time (at least 90 days before implementation) by sending an email to GMDP-krav@dkma.dk. The email must describe the relevant change in detail, outlining the activities (e.g. risk assessment, temperature mapping, internal audit) to be performed in connection with the change. This will give the Danish Medicines Agency the best basis for deciding if the change requires an inspection before implementation or if the review can wait for the next routine inspection. This is determined on a case-by-case basis. If the company needs to notify several changes, they may be submitted together.

We expect companies to inform us of any major changes and the associated change control documentation at the next inspection so that the inspectors can determine whether the changes require special focus during the inspection. This applies equally to changes notified to the Danish Medicines Agency and other major changes.

The examples in the list below are not exhaustive. If in doubt, please contact us at GMDP-krav@dkma.dk.

Example of change	**Must GMDP-krav@dkma.dk be notified of the change?**	**Does the change require an inspection?**
Quality system		
Significant changes to the quality system (e.g. in connection with an acquisition or merger)	Yes	Assessed by the Danish Medicines Agency
Change of document management systems, e.g. switching to an electronic system for handling of deviations	No	No
Change of responsible person	No	No
Storage facilities		
New storage building	Yes	Assessed by the Danish Medicines Agency
Inclusion of additional rooms for storage in the existing storage building	Yes	Assessed by the Danish Medicines Agency
Restructuring/sectioning of storage room	No	No
Planned use of temporary storage facility	Yes	Assessed by the Danish Medicines Agency
Activities		
Implementation of AI (artificial intelligence/machine learning)	Yes	Assessed by the Danish Medicines Agency
Update of implemented AI (e.g. new algorithms)	No	No
Discontinuation of wholesale distribution authorisation (thus discontinuing activities)	Yes	Assessed by the Danish Medicines Agency

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Date	Version	Change
21.11.2025	1	New document