fimea

Instructions for filling out the application for reduction of storage obligation:

1. Party subject to storage obligation	
1.1 Name of company	The name of the company on the importing or manufacturing authorisation
1.2 Name of contact person	The name of the person responsible for handling the application for reduction of the storage obligation, reachable during office hours
1.3 Name of person responsible for emergency stocks	The name of the person responsible for the company's storage obligation, if this is a different person from the one named under 1.2
1.4 Mailing address	The address to which the permit decision should be mailed
1.5 Contact person phone number	A phone number where the contact person may be reached during office hours
1.6 Contact person e-mail	An e-mail address where the contact person may be reached during office hours

2. Medicinal product subject to storage obligation	
2.1 Name of medicinal product	The name of the medicinal product to which the application for reduction of the storage obligation applies
2.2 Strength of medicinal product	The strength of the medicinal product to which the application for reduction of the storage obligation applies
2.3 Pharmaceutical form	As given in the marketing authorisation
2.4 Package size(s)	The package size(s) which the application concerns. The storage obligation is not specific to any particular package size. If there are package sizes of the same product and suitable for the same purpose available in Finland under the same marketing authorisation, these may be used to fulfil the storage obligation. Subject to Fimea approval, the storage obligation for medicinal products may be satisfied with packages labelled in a language other than Finnish, if the statutory requirements for emergency stocks are otherwise fulfilled.
2.5 ATC code	ATC code identifying the medication
2.6 Medicine group	One of the medicine groups specified in the Act on emergency stocks of pharmaceuticals, e.g. 1) antimicrobials
2.7 Pharmaceutical ingredient	A pharmaceutical ingredient specified for inclusion in emergency stocks by Government Degree, e.g. amoxicillin
2.8 Data on marketing authorisation holder	Name of the marketing authorisation holder, and name of contact person

3. Data on emergency stocks	
3.1 Location of emergency stocks in Finland	Street address of the emergency stock warehouse in Finland
3.2 Sales and consumption data determining the storage obligation	
Pharmaceutical	If a pharmaceutical manufacturer is applying for a reduction for a time period

manufacturer:	in the first half of a storage year, the domestic sales data for the medicinal product containing the pharmaceutical ingredient in question for the time period from the beginning of March to the end of August in the year before the storage year must be submitted. If a pharmaceutical manufacturer is applying for a reduction for a time period in the second half of a storage year, the domestic sales data for the medicinal product containing the pharmaceutical ingredient in question for the time period from 1 October in the year before the storage year to 31 March in the storage year must be submitted. Give the time period and enter the sales data for the relevant period.
Pharmaceutical importer:	If a pharmaceutical importer is applying for a reduction for a time period in the first half of a storage year, the domestic sales data for the medicinal product containing the pharmaceutical ingredient in question for the time period from the beginning of March to the end of August in the year before the storage year must be submitted. If a pharmaceutical importer is applying for a reduction for a time period in the second half of a storage year, the domestic sales data for the medicinal product containing the pharmaceutical ingredient in question for the time period from 1 October in the year before the storage year to 31 March in the storage year must be submitted. Give the time period and enter the sales data for the relevant period.
National Institute for Health and Welfare	If the National Institute for Health and Welfare is applying for a reduction for any time period in a storage year, data on consumption of the vaccine in question in the first half of the year before the storage year must be submitted.
3.3 The volume of the storage obligation as notified to Fimea	
3.4 Duration of reduction applied for Give the estimated beginning and end dates of the period to which the reduction applies (e.g. 1 February to 31 March 2012)	
3.5 Volume of reduction applied for Calculate the volume of reduction applied for by subtracting the lowest stock volume during the reduction period from the prescribed storage obligation volume. Give the volume of reduction as a percentage of the storage obligation volume, rounding off decimals.	
3.6 Stock volume at the time of the application Enter the current stock volume at the time of submitting the application. The party subject to a storage obligation must monitor compliance with the obligation regularly. If a reduction is required, it should be applied for as early as possible.	
3.7 Plan for and explanation of fulfilling the obligation Enter the batches delivered for storage, their volume and their delivery times	

4. Statutory grounds for the reduction permit	
4.1 Grounds: disruption of availability	'Disruption of availability' refers to temporary interruptions in the delivery of pharmaceuticals beyond the control of the party subject to a storage obligation; these may be due to a quality defect, a shortage of raw material or similar disruption in the production of the medicinal product. A disruption of availability is considered to be a long-term disruption if it lasts for a continuous period of more than three months during the storage year or if a previous reduction permit was granted earlier to the same medicinal product for the same reason. In case of a long-term disruption, the applicant must explain the reason for the disruption in the reduction application and append a written declaration on same from the manufacturer responsible for the medicinal product.
4.2 Grounds: a commodity subject to the storage obligation is in danger of deteriorating during its period of storage so as to become unsuitable for its purpose	Enter the volumes of the batches in storage at the time of application and their expiry date data. Also enter a calculation showing at what rate the storage batches will exceed their expiry dates.
5. Estimate of the impact of the reduction on security of supply Explain how a reduction permit granted will not compromise security of supply. The party subject to a storage obligation must prepare an analysis of whether the security of supply of the medicinal product in question might be compromised.	
6. Previously granted permits for reductions to the storage obligation State any reduction permits granted for the medicinal product in question during the two previous storage years. Enter the reduction volumes and beginning and end dates of any such reduction permits.	
7. Signature of the person responsible for emergency stocks Enter the place and time of signing. The application must be signed by the person who is responsible for emergency stocks.	