

Application for Reimbursement for Specialty care high-cost medicine (SCHCM) – Biosimilar or Generic drugs

- **Part I:** Marketing authorization holder/applicant should fill in each field on the form. Application is not considered valid unless all the fields have been filled in. If there is not an approved reimbursement for a similar indication of an original drug, application must be sent on the form „*Application for reimbursement for SCHCM – New indication.*”
- **Part II:** Assessment by Drug and Therapeutics Committee (DTC) at The National University Hospital (NUH) of Iceland

Part I. – Basic Information

1. Please fill in the following basic information:	
Marketing authorization holder	
Local representative	
Contact name	
Address	
Phone number	
Email address	

2. Trade name and active pharmaceutical ingredient.

3. What is the new pharmaceutical form?

4. What is the new strength?

5. Insert link to SmPC.

6. ATC code.

7. Which indications for reference medicinal product have been approved for reimbursement? https://www.lyfjastofnun.is/verd-og-greidsluthattaka/akvardanir-verd-greidsluthattoku/	Mark with an X to the indications that is being applied for biosimilar or generic drug

8. Is public procurement finalised or ongoing?

9. Other aspects for consideration?

Part II. – Assessment by Drug and Therapeutics Committee (DTC) of the National University Hospital (NUH)

1. Full assessment:

2. Summary of clinical and economical:

3. Date of summary/by: