**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**

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

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| 2. Trade name and active pharmaceutical ingredient. |
|  |
| 3. What is the new pharmaceutical form? |
|  |
| 4. What is the new strength? |
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| 5. Insert link to SmPC. |

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| 6. ATC code. |

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| --- | --- |
| 7. Which indications for reference medicinal product have been approved for reimbursement? <https://www.lyfjastofnun.is/verd-og-greidsluthatttaka/akvardanir-verd-greidsluthatttoku/> | Mark with an X to the indications that is beeing applied for biosimilar or generic drug |
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| 8. Is public procurement finalised or ongoing? | |

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| 9. Other aspects for consideration? |

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

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| 1. Full assessment: |

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| 2. Summary of clinical and economical: |

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| 3. Date of summary/by: |