

Market-approved medicines

Serial number:

Date of receipt:

The ATMP council is tasked with preparing all new treatments at Sahlgrenska University Hospital that include medicines for advanced therapies (Advanced Therapy Medicinal Products, ATMP). Dates for when the ATMP Council meets, which are scheduled once a month, are announced on the ATMP Centre's website. The ATMP Council's activities are covered by the confidentiality rules set out in the Publicity and Confidentiality Act (2009:400).

The document, "Market-approved drugs" can be completed electronically and is limited to a maximum of 9 pages including help text and signature page. To be able to make an assessment of resources, the product summary for the therapy in question must be attached to this document.

The document must be signed by the operations manager (VC) at the treating clinic and sent together with attachments via email to su.atmpcenter@vgregion.se

The opinions of the ATMP council are communicated via the ATMP center to the person or persons who signed the document.

Table of contents

Market-approved medicines	1
Section 1. Information about the clinic	3
Section 2. Information about treatment	5
Section 3. Information om financing	7
Section 4. Justify the introduction of treatment at Sahlgrenska University Hospital	7
Section 5. Information till biosäkerhetskommittén	8
Section 6. Other information	8
Section 7. Signatures	9

Section 1. Information about the treating clinic/pharmaceutical company

1.1 Treating/responsible doctor

Name:
Title:
Company/University/college:
Health care affiliation:
Address:
Email:
Phone:

1.2 Treating clinic and operations manager

1.2.1 State your wishes at which clinic(s) the treatments will take place as well as the name and contact details of the operations manager, if any.

Wishes for a clinic:
Address:
Business manager name:
Email:
Phone:

1.3 Pharmaceutical company

Contact person:
Title:
Email:
Phone:

1.4 Agreement

1.4.1 Has an agreement been drawn up between responsible clinical operations and manufacturing operations?

- Yes. If yes, please attach the agreement
 No
 Not current

1.4.2 Has an agreement been drawn up between the responsible clinical activity and the hospital pharmacy function?

- Yes. If yes, please attach the agreement
- No
- Not current

1.4.3 Has an agreement been drawn up between the Västra Götaland region and pharmaceutical companies?

- Yes. If yes, please attach the agreement
- No
- Not current

14.4 Has an agreement been drawn up between the responsible clinical activity and other activities?

- Yes. If yes, please attach the agreement
- No
- Not current

Other information

Section 2. Information about treatment

2.1 Drug (name, indication, type of treatment, patient group, patient background, how many patients to be treated per year, etc.)

2.2 Need for resources

Describe the resource needs for treatment within SU/Sahlgrenska University Hospital. Eg resources for disposal, manufacturing, shipping, preparation, treatment, or legal resources. *Ex resources at: Salvage apheresis will take place at XXX. Medicines are manufactured at supplier xxx alternatively. Receipt of medication will be done by xxx (for klp it can be done at a clinic with a routine determined by a pharmacist) alternatively by the hospital pharmacy. Dispensing of medicines is done by Sjukhusapotek. Preparation will be carried out by the Preparation unit VO Medicines/preparation in the department*

2.3 Ange tillhörande ATMP-undergrupp

- Cell therapy drugs
- Gene therapy drugs
- Tissue engineering product
- Combined, describe how

2.4 Process description – Manufacturing (scale/capacity, validation status, quality control), storage, packaging.

	Yes	No
Apheresis	<input type="checkbox"/>	<input type="checkbox"/>
Manufacturing	<input type="checkbox"/>	<input type="checkbox"/>
Preparation (preparation)	<input type="checkbox"/>	<input type="checkbox"/>
Storage, specify the type of freezer/other	<input type="checkbox"/>	<input type="checkbox"/>
Repacking required	<input type="checkbox"/>	<input type="checkbox"/>
Transport between hospitals	<input type="checkbox"/>	<input type="checkbox"/>
Administration, special instructions, environmental aspects	<input type="checkbox"/>	<input type="checkbox"/>

Section 3. Information on financing

3.1 Describe how the treatment is financed? (treating clinic, preparation, manufacturing, drug cost)

Section 4. Justify the introduction of treatment at Sahlgrenska University Hospital

4.1 Describe why Sahlgrenska University Hospital should make this treatment available in its operations.

Section 5. Information to the Biosafety Committee

5.1 Describe biosafety issues such as environment, work environment and waste management as well as risks when handling the product

Section 6. Other information

Section 7. Signature

Responsible attending physician

Date

Text name

Business manager

Date

Text name