SYKEHUSAPOTEKENE

SYKEHUSAPOTEKENE I MIDT-NORGE

SJUKEHUSAPOTEKA VEST

SYKEHUSAPOTEK NORD
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The Hospital Pharmacies in Norway

Description

The purpose of this document is to provide an overall description of the hospital pharmacies' guidelines for collaboration in clinical trials. The document has been prepared by the National Group for Clinical Trials at the four hospital pharmacy enterprises in Norway (N-KLUT).
This document is also available in a Norwegian version.

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1. Organisation of the Hospital Pharmacies in Norway

The hospital pharmacies are part of Norway's specialist health care service. The hospital pharmacies are non-commercial pharmacies and are defined in the Norwegian Pharmacy Act (*Lov om apotek)* as "pharmacies co-located with a public hospital or a private hospital that is included in public health plans, and for which the primary task is the supply of medicinal products to the hospital".

The hospital pharmacies are organized under the Ministry of Health and Care Services (*Helse- og omsorgsdepartmentet, HOD).* HOD owns the four Regional Health Authorities (RHAs): South-Eastern Norway Regional Health Authority (HSØ), Western Norway Regional Health Authority (HV), Central Norway Regional Health Authority (HMN), and Northern Norway Regional Health Authority (HN). These Regional Health Authorities are responsible for the specialist health care services in their respective health regions.

In Norway, there are four Regional Hospital Pharmacy Trusts affiliated with the Regional Health Authorities: Sykehusapotekene HF (South-Estern Norway), Sjukehusapoteka Vest HF (Western Norway), Sykehusapotekene i Midt-Norge HF (Central Norway), and Sykehusapotek Nord HF (Northern Norway). These Trusts are owned by their respective Regional Health Authoritiy and are responsible for the supply of medicinal products within their regions. The Regional Health Authorities ("the hospitals") and the Hospital Pharmacy Trusts ("the hospital pharmacies") are not the same legal entity and have different organisation numbers.

The Hospital Pharmacy Trusts owns the hospital pharmacies. There are 37 hospital pharmacies in Norway, distributed across the four health regions, with the majority located in the South-Eastern region. Several hospital pharmacies may provide services to the same hospital trust. Which services the pharmacies are to provide in the individual study will be assessed at the time of contract negotiations. In Oslo, there are five hospital pharmacies that provide services within clinical trials: Hospital Pharmacy Oslo, Radiumhospitalet; Hospital Pharmacy Oslo, Ullevål; Hospital Pharmacy Oslo, Rikshospitalet; Hospital Pharmacy Oslo, Diakonhjemmet; and Hospital Pharmacy Oslo, Lovisenberg. These pharmacies fall under the collective designation of Hospital Pharmacies Oslo (SAO).

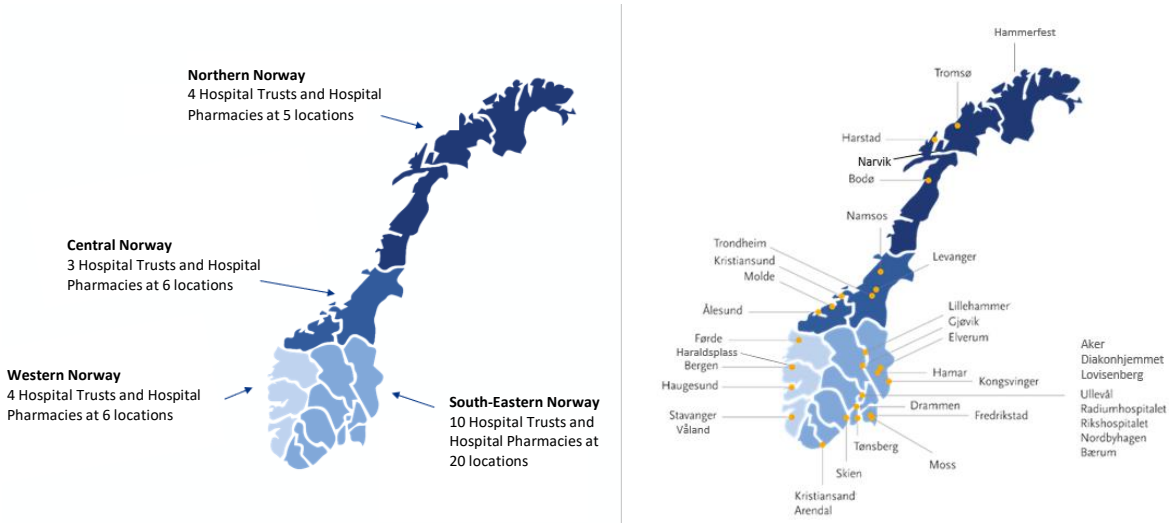

Figure 1. Overview of Hospital Trusts and Hospital Pharmacies in Norway

a. Regulatory Framework

Hospital pharmacies comply with applicable legislation, which includes, among others:

- Lov om apotek (apotekloven)
- Lov om legemidler m.v. (legemiddelloven)
- Lov om helsepersonell m.v. (helsepersonelloven)
- Forskrift om apotek (apotekforskriften)
- Forskrift om klinisk utprøving av legemidler til mennesker
- Forskrift om rekvirering og utlevering av legemidler m.m.
- Forskrift om tilvirkning og import av legemidler
- Forskrift om tilvirkning av legemidler i apotek
- Forskrift om grossistvirksomhet med legemidler
- Europaparlaments-og rådsforordning (EU) nr. 536/2014 om kliniske studier med legemidler til mennesker
- EudraLex - Volume 4 - Public Health - European Commission

All handling of investigational medicinal products (IMP), including receipt, storage, and dispensing, is performed in accordance with Good Clinical Practice (GCP).
The hospital pharmacies are subject to regular inspections by the Norwegian medicines authorities, the Norwegian Medical Products Agency (DMP).
Copies of operating licences may be provided upon request to the chief pharmacist at the relevant hospital pharmacy. Manufacturing authorisations pursuant to the Medicinal Products Act are available in Eudra GMDP.

b. Personell

Employees of the hospital pharmacies are primarily licensed pharmacists and pharmacy technicians. Personnel with responsibilities and tasks related to clinical trials receive general and study-specific training if they are to perform tasks in accordance with a pharmacy agreement. Curricula vitae (CVs) and documentation of completed GCP training for hospital pharmacy personnel are provided upon request.
Hospital pharmacy personnel may undergo study-specific training from/with the sponsor if this is required. This typically applies to those who have overall responsibility for the study. Training of other personnel is conducted internally and documented in accordance with the quality system of the individual hospital pharmacy.
As the Hospital Pharmacies are owned by a governmental institution, all employees of the hospital pharmacies are considered to be “public officials” under the Financial Disclosure regulations. The hospital pharmacies do not disclose any financial information about customers.
Chief pharmacists sign confidentiality agreements from sponsors if required. All employees of the hospital pharmacies have signed confidentiality declarations that cover the enterprise’s customers and collaboration partners; therefore, individual employees working with clinical trials do not sign separate confidentiality agreements.
Furthermore, it is not permitted to collect, store, or distribute personal data relating to employees of the hospital pharmacies beyond necessary contact information and CVs required to conduct the study.

2. Quality System

The hospital pharmacies have electronic quality systems that ensure that all activities are performed in compliance with applicable legislation.

The systems ensure that governing documents are in place for the handling of clinical trials. The electronic system provides versioning, traceability of changes, regular review of documents, and implementation of relevant documents for employees. The content of relevant procedures may be shared with sponsors.
The hospital pharmacies have validated temperature monitoring systems that ensure continuous temperature monitoring. Calibration certificates are made available to the sponsor upon request.
The hospital pharmacies have a deviation management system used for follow-up of deviations related to clinical trials; however, the hospital pharmacies also adhere to the sponsor's deviation procedures when applicable.

3. Services

The hospital pharmacies offer a range of services in connection with clinical trials. The most common services are listed below.

- Manual ordering of IMP and other comparator products, rescue medication, premedication, etc.
- Import of IMP into Norway
- Receipt and verification of IMP
- Storage of IMP
- Temperature monitoring – automated with alarm system
- Return of transport packaging
- Formulating and design of prescription forms (in collaboration with the investigational site)
- IRT (Interactive Response Technology)-related tasks, such as receipt of IMP
- Drug accountability
- Shipment of IMP
- Preparation of IMP
  (including registration and maintenance of IMP in the production support system)
- Manufacturing of IMP
- Dispensing of IMP
- Additional labelling at each dispensing to the individual patient
- Handling of IMPs returned to the hospital pharmacy
- Destruction of IMP
- Participation during GCP audits and GCP inspections
- Facilitation of monitoring
- Relabelling with new expiry date*

* Requires authorisation from the Directorate for Medical Products (DMP)

- Export of IMP (see Chapter 11)**

** Hospital pharmacies must apply for authorisation from the DMP for each export

4. Agreements

The sponsor enters into an agreement with the hospital (CTA). As the hospital pharmacies and the hospitals are separate legal entities, a separate pharmacy agreement must also be concluded.
The hospital pharmacies enter into agreements with both commercial sponsors (e.g. pharmaceutical companies or CROs (Clinical Research Organisations)). The hospital pharmacies may also enter into agreements with hospitals, as well as other academic and health institutions.
An agreement shall be negotiated for each study per hospital pharmacy. The agreement is

negotiated with the hospital pharmacy that will provide the service(s). For commercial studies, the agreement consists of a legal component and a pharmacy component (Exhibit A/Work Order), the latter describing contact information and services with pricing.
For commercial studies, the four Hospital Pharmacy Trusts have entered into a joint agreement with Inven2, which negotiates the legal component of the agreement on behalf of all hospital pharmacies. Sponsors may enter into either a Master Pharmacy Agreement (framework agreement) or a Pharmacy Agreement (single-study agreement). If a framework agreement is established, the negotiated legal component will apply to all studies for which sponsor requests services from the hospital pharmacy(-ies), and only a pharmacy component is negotiated for each study. If a single-study agreement is entered into, both the legal component and the pharmacy component are negotiated, and in order to maintain efficiency it is important that the legal component and the pharmacy component are negotiated in parallel. There are regional adaptations of the templates for the pharmacy component. Regionally adapted templates may be requested from the relevant hospital pharmacy. After the study has been notified to Inven2 via the notification form on their website, Inven2 forwards the notification form and initiates contract negotiations with the respective Hospital Pharmacy Trust.
For academic studies, the hospital and other health and academic institutions contact the relevant hospital pharmacy directly.

5. Requirements for the Sponsor and the Investigator

Hospital pharmacies should be involved at an early stage in the planning and initiation process of a clinical drug trial.
In order for the hospital pharmacies to provide a reliable and satisfactory service, certain requirements must be fulfilled by the sponsor and the investigator. These requirements concern the availability of necessary documentation and access to pharmacy-relevant information.
The sponsor and the investigator shall familiarize themselves with and comply with national regulations.
The following documents will be requested and must be submitted to the relevant hospital pharmacy in connection with the negotiation and conclusion of the pharmacy agreement:

- Protocol, current version
- Pharmacy manual/procedure for drug handling / Summary of Product Characteristics (SmPC) or a corresponding detailed description of the handling of the IMP
- Investigator's Brochure (if available)
- Approved labelling of the IMP
- Regulatory approvals (previous approvals from the Regional Committees for Medical and Health Research Ethics (REK) and the Directorate for Medical Products (DMP)).
  If not available at the present time, the hospital pharmacy may retrieve approvals from the CTIS portal.

The hospital pharmacy also needs to receive the following information:

- Who will be the Importer of Record (IoR) of the IMP into Norway (name and address). See Chapter 6.
- Which company is the exporter of the IMP (name and address)
- Which company is the supplier of the IMP (name and address)
- Who issues the Batch Certificate/QP Release (name and address)
- Name of the study nurse and/or study coordinator

- Estimated study start / Site Initiation Visit (SIV)

Please note that it is the responsibility of the sponsor/investigator to ensure that the hospital pharmacies always have updated documentation and information throughout the duration of the study. The hospital pharmacies recommend that the documents be submitted electronically.
For IMP where the hospital pharmacy uses authorised medicinal products from its own stock, monitoring of changes to the SmPC is included in the pharmacy's standard procedures. The specific manufacturer/supplier depends on the current tender period and may be provided upon request.
The sponsor and the investigator shall comply with the agreements that have been concluded.

6. Import and Distribution Route

Norway is part of the EEA and the EU internal market but is not part of the EU Customs Union. This means that goods must be custom-cleared, and that information such as the importer must be specified. This, together with the authorities' requirements that hospital pharmacies shall qualify and control their suppliers, forms the basis for requesting information for supplier qualification.

Who may import medicinal products for clinical trials into Norway?
Both the sponsor and the hospital pharmacy may import medicinal products provided that the necessary authorisation is in place. Entities holding such authorisation may be a wholesaler, a pharmacy, or a manufacturer.
Norwegian Medical Products Agency (DMP) provides general guidance on who is permitted to import medicinal products for clinical trials into Norway on its website.
Norsk: Innførsel/import av legemidler til kliniske studier i Norge - Direktoratet for medisinske produkter
English: Import of medicinal products for clinical studies in Norway - Norwegian Medical Products Agency

Sponsor as importer
The sponsor must deliver the medicinal products via an entity holding either a wholesale or manufacturing authorisation for the medicinal products. The medicinal products must be released within the EU/EEA.

- When using a manufacturing authorisation within the EU/EEA, registration in the Brønnøysund Register Centre (holding a Norwegian organisation number) and notification of the company to the Norwegian Medical Products Agency (DMP) are required. The manufacturer must release the medicinal product (issuing a batch certificate).
- When using a wholesale authorisation within the EU/EEA, only registration in the Brønnøysund Register Centre (holding a Norwegian organisation number) is required.

Both wholesalers and manufacturers must be able to present valid authorisation (Wholesale Distributor Authorisation (WDA) or Manufacturing/Importation Authorisation (MIA)) and certificates (Good Distribution Practice (GDP) or Good Manufacturing Practice (GMP)).
Hospital Pharmacy as importer
Hospital pharmacies may import medicinal products from approved EEA wholesalers without specific authorisation (in accordance with the Regulation on the Manufacturing and Import of Medicinal Products, §3.1 (*Forskrift om tilvirkning og import av legemidler)*). Approved EEA wholesalers include manufacturers acting as wholesalers for their own manufactured medicinal

products and must therefore be the issuer of the batch certificate. IMP shall be addressed and shipped to the hospital pharmacy (not to the hospital) as agreed.

Who may not import into Norway?
Individual hospitals in Norway **are not authorised** to import medicinal products.
Approval from the Norwegian Medical Products Agency (DMP) for the conduct of a clinical trial does **not include authorisation for the manufacturing and/or import/introduction of medicinal products**. Importation of medicinal products for clinical trials in Norway may only be carried out by an entity holding the necessary authorisation. For direct delivery of IMP to the investigational site, a Norwegian wholesale authorisation is required with wholesale activity 2.5 Direct distribution to professional end users *(2.5 Direktedistribusjon til profesjonelle sluttbrukere)* included in the authorisation.

Import from third countries
Medicinal products may **not** be shipped directly from third countries, i.e. countries outside the EU/EEA, to the hospital pharmacy. This applies regardless of whether the sponsor or the hospital pharmacy is the importer.

Supplier qualification
Hospital pharmacies must ensure that medicinal products are supplied by entities holding valid authorisations.
The following documentation is required:

- When the sponsor is the importer: WDA from the importer into Norway (responsibility from the Norwegian border to the hospital pharmacy)
- MIA/WDA from the physical sender
- MIA/WDA from the exporter (responsibility from the physical sender to the Norwegian border)
- MIA from the manufacturer issuing the batch certificate

Documents that must accompany the shipment are described in Chapter 6.

7. Receipt of IMP and equipment

IMP and other relevant equipment shall only be shipped upon prior agreement and must be sent directly to the address specified in the pharmacy agreement with the relevant hospital pharmacy. Shipments must be addressed to the hospital pharmacy, not to the individual hospital.
Each shipment shall comply with GDP requirements, and documentation necessary for receipt and import control must be available to the hospital pharmacy.
The following must be available to the hospital pharmacy upon receipt of the IMP:

- Pro forma customs invoice
- Packing list
- Temperature monitoring
- Batch certificate (if not already provided)

If the sponsor requires return of transport boxes, temperature loggers, or other equipment, it is the sponsor's responsibility to organise and pay for the return. This must be specified in the pharmacy agreement, and it is the sponsor's responsibility to provide the necessary documents and return labels.
IMP will be placed in quarantine if required documentation is missing or if receipt of the IMP is not in accordance with the order.

8. Preparation of IMP

Reconstitution and Preparation

All hospital pharmacies may perform simple reconstitution/preparation in accordance with the Regulation on the Manufacturing and Import of Medicinal Products, such as addition of water to oral liquids and reconstiuting of medicinal products for infusion/injection. However, hospital pharmacies that perform aseptic preparation of infusion bags and syringes must hold a manufacturing authorisation from the Norwegian Medical Products Agency (DMP).

Packaging/Labelling and Manufacturing

Labelling, packaging, and blinding of IMP, including relabeling with a new expiry date, are considered manufacturing activities. This requires additional manufacturing authorisation, and not all pharmacies hold such authorisation. The required manufacturing authorisation depends on the status of the medicinal product to be labelled/packaged/blinded and the activities necessary to obtain a finished IMP. It is recommended to contact the relevant hospital pharmacy for a specific assessment of each study.

9. Storage of IMP and study documentation

The hospital pharmacy performs storage of IMP in accordance with the agreement with the sponsor/investigator, regulatory requirements, and Good Clinical Practice (GCP). IMP are stored in a designated and labelled storage area, separate from the hospital pharmacy's other medicinal products.

IMP and study documentation are stored to be inaccessible to unauthorised people. The hospital pharmacies have procedures for quarantine in case of deviations in storage conditions, sales suspension, or other notifications from the sponsor.

10. Dispensing and distribution of IMP

Dispensing and distribution of IMP from the Hospital pharmacies may be carried out in several ways, and the services offered may vary between hospital pharmacies. The pharmacy agreement entered with each individual pharmacy describes how these tasks may be performed.

When shipping IMP, the hospital pharmacies follow their own applicable Standard Operating Procedures (SOPs), which describe how shipments shall be carried out.

Some hospital pharmacies are located separately from the investigational site, which will entail transportation of IMP between locations.

11. Return and destruction of IMP

Hospital pharmacies may assist with the return and destruction of IMP, at the sponsor's request and as described in the pharmacy agreement.

For health, safety, and environmental reasons (HSE), used vials/ampoules are not stored after preparation of IMP. The hospital pharmacy does not accept used infusion bags and syringes; these are destroyed in accordance with the hospital's internal procedures.

Destruction may be carried out in various ways, including:

- **Locally at the hospital pharmacy in accordance with the pharmacy's procedures** – no destruction certificate is issued; however, it may be agreed that the hospital pharmacy completes a destruction log or destruction form, which is signed and dated to ensure documentation of the destruction.
- **Sent for incineration via a contracted wholesaler** – a destruction certificate may be issued.
- **Export from the hospital pharmacy** – the hospital pharmacies do not hold a general export authorisation; an export authorisation must be applied for from the Norwegian Medical Products Agency (DMP) for each shipment in each individual clinical trial. The sponsor is responsible for documentation, labelling, and customs declaration in connection with export.

12. Monitoring, audit og inspections

Monitoring

Monitors may visit the hospital pharmacy to conduct monitoring of a clinical study, provided that the visit has been agreed with the hospital pharmacy in advance. Monitors will be asked to sign a confidentiality agreement prior to or during the first visit.

The hospital pharmacy facilitates office workspace and provides access to a copier and/or scanner as needed during the period in which monitoring of the relevant clinical study is conducted. Beyond this, the monitor must bring any necessary equipment, including their own computer, if required to perform the monitoring visit.

During the monitoring visit, the monitor will meet with study personnel at the hospital pharmacy and will thereby be granted access to agreed study documentation and relevant information regarding the IMP in the relevant clinical study. The monitor will not be granted access to the hospital pharmacy's electronic production system and will not have access to production areas; however, access to storage areas may be granted by agreement and accompanied by hospital pharmacy study personnel.

Audit and inspection

Sponsor shall inform the hospital pharmacy of audits, and the hospital pharmacy shall have the opportunity to participate in the opening meeting.

The investigation site shall inform the hospital pharmacy upon notification of a GCP inspection, and the hospital pharmacy shall have the opportunity to participate in the opening meeting.

For both audits and GCP inspections, the hospital pharmacy shall ensure the availability of necessary documentation and/or personnel to facilitate the conduct of the audit or inspection. Following audits and GCP inspections, the hospital pharmacy must receive the final report and/or information in cases where there are findings related to the hospital pharmacy. The investigational

site coordinates responses to any findings with the hospital pharmacy and is responsible for submission of responses to the authorities.

13. Archiving

The hospital pharmacy provides all documentation related to its services to the sponsor for archiving after the sponsor/CRO has carried out the final monitoring of the documents at the hospital pharmacy. The hospital pharmacy will retain a copy of the documentation if deemed necessary to meet internal documentation requirements.
Study documentation is archived in accordance with Regulation (EU) No 536/2014 and the ICH E6 (R3) Guideline for Good Clinical Practice.

14. Appendices

Contact list for the regions – Hospital Pharmacy Trusts, Appendix 1

15. Revision History

Date	Version	Change
20.04.2026	1.0	Final, New document

Appendix 1

Contact list for the regions – Hospital Pharmacy Trusts

Last updated: April 2026

Region	E-mail
South-Eastern Norway	clinical.trial.SAHF@sahf.no
Western Norway	ClinicalTrials_SiB@sav.no
Central Norway	kliniskestudier@sykehusapoteket.no
Northern Norway	kliniske.studier@sykehusapotek-nord.no