SYKEHUSAPOTEKENE

Purchase Agreement

Agreement governing the purchase of software and equipment

The Norwegian Government's Standard Terms and Conditions for IT Procurement

SSA-K 2018

Tender for delivery of Advanced Unit Dose Packaging and Dispensing Solution

SSA-K Appendix 3 Customer Technical Platform

Case number: 2022/512

Content

1. Introduction

This appendix provides a description of the workflow and ICT structure for a future production plan for unit doses, located at Hospital Pharmacy in Ahus. This production plan will produce and distribute unit doses to Ahus hospital.

1.1. Background

Ahus has implemented an Electronic Medical Record (EMR) Metavision. To increase patient safety, one of the main objectives of this implementation is to achieve closed loop medication management (CLMM). To close the medication loop, the hospital will need electronically identifiable unit doses. Helse Sør-Øst (HSØ) has advised Sykehusapotekene HF to provide unit doses for all the hospitals throughout the region.

Hospital Pharmacy Ahus located at Nordbyhagen already has a unit dose production facility and is currently providing unit doses for Ahus hospital. The currant packaging and dispensing machine is from 2008 (Ahus hospital opening) and is starting to reach maximum capacity and life expectancy. Due to increasing demand for unit dose from Ahus, and an expected further increase in the future, todays unit dose packing and dispensing machine needs replacing. The current system is planned to be replaced within the same production facilities with an advanced unit dose packaging and dispensing machine to achieve increased capacity for packing and dispensing with the capability of patient specific orders. Patient specific orders are likely to be implemented at some stage, but this is not jet decided by Ahus Hospital.

The contractor would have to come up with suggestions how to implement new machinery in todays production facility in a way that minimises downtime and disadvantage for the hospital.

Hospital Pharmacy Ahus also has a site at Ahus, Kongsvinger (Hospital Pharmacy Ahus, Kongsvinger). It has jet to be decided if Hospital Pharmacy Kongsvinger will have a unit dose dispensing machine.

The following descriptions will focus on the tentative workflow developed for the supply chain for unit doses throughout Ahus and the ICT ecosystem for the planned solution. The non-unit dose medications follow a separate workflow and is therefore not included in this description.

Sykehusapotekene HF is planning to implement ERP system Oracle in 2023-2024. The details in integrations towards ERP is jet to be decided.

The workflow and corresponding ICT integrations are not yet established, and the Contracting Authority is open to discuss alternative solutions if the Contractor has any suggestions for improvement.

1.2. Terms and definitions

Term	**Meaning/explanation**
Helse Sør-Øst (HSØ)	South East Norway Regional Health Authority
Metavision	The Electronic Medical Record (EMR) implemented in HSØ.
Ahus production plant	The unit dose production facillity at Sykehusapoteket Ahus, Nordbyhagen is planning to replace/ establish, located at the Hospital Pharmacy in Ahus, Nordbyhagen.
Regional pharmacy	Hospital Pharmacy Ahus, Kongsvinger

Sykehusapotekene HF	The Hospital Pharmacies Health Authority - South East Norway. Also, The Contracting Authority for this tender.
UDPS	Unit dose production system
CLMM	Closed loop medication management
PTS	Pneumatic tube system
AGV	Automated guided vehicle
Ahus	Akershus Universitetssykehus

Table 1: Terms and definitions

2. Context

2.1. Tentative workflow for the offered solution

Sykehusapoteket Ahus in Sykehusapotekene HF is planning to establish an advanced production plant for unit doses with a high degree of automation and digitalization, which provides a high proportion of drugs delivered as unit doses to the hospital Ahus. The unit doses provided will contribute to achieving CLMM, and thereby increased patient safety and more efficient drug handling.

As shown in Figure 1, the production plant at Ahus will produce and store unit doses. About 90% of the produced drugs will be delivered to ward directly from the production site. The remaining 10% will be dispensed from the production facility and loaded at the hospital pharmacy Ahus, Kongsvinger. We intend to use the hospital's PTS and AGV, PTS from AeroCom and AGV from MLR System GmbH, combined with manual transport for the internal deliveries to Ahus hospital.

There is one regional hospital pharmacy that is located at Ahus, Kongsvinger where it's a possibility to have a local storage and dispensing of unit doses from the advanced UDPS.

Some form of patient specific deliveries is a part of a future solution in Helse Sør-Øst, and the offered solution must have functionality for patient specific deliveries implemented.

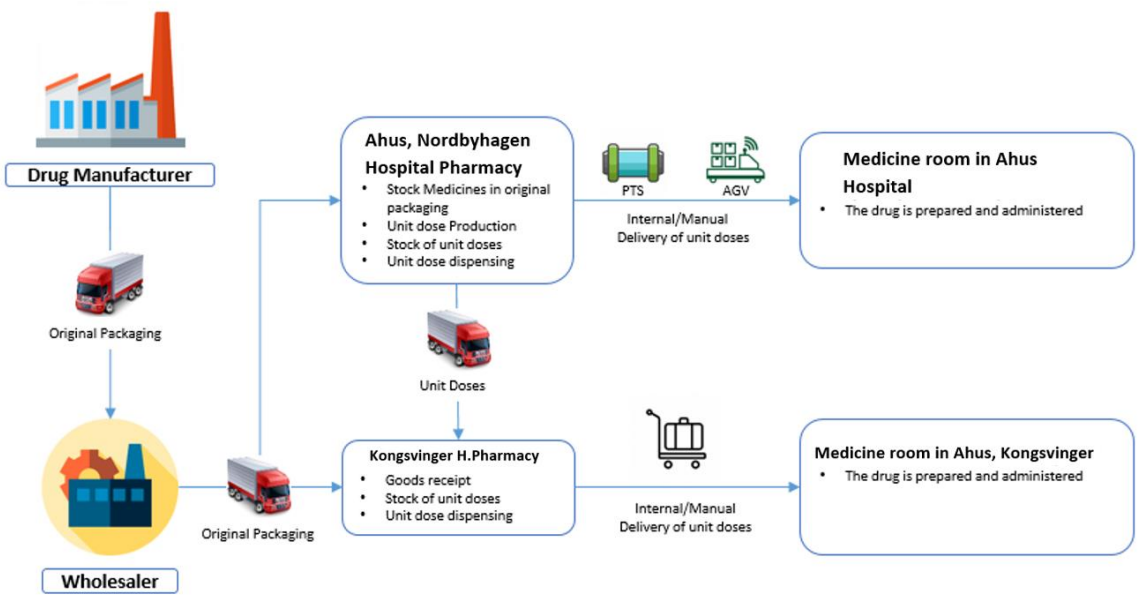

Figure 1: Overview of the centralized solution for unit doses.

The preferred solution is the one that will provide the lowest operating and investment costs in addition to offering the most optimal logistics solution with the least possible environmental footprint.

2.2. Production plant at Ahus

The offered solution for the production plant must provide a complete system for drug preparation, unit dose production, unit dose storage and unit dose dispensing, according to the requirements stated in K Appendix 1. Handling of all drug packages intended for unit dose production (raw materials) is yet to be decided, they may be stored in an automated storage solution, e.g., BD Rowa or similar. Table 2 gives an overview of the activities at the production plant.

Activity	**Description**
Goods receipt and Stock Raw Material	Pharmacy employee receives drugs in original packaging from the wholesaler/vendor. All drug packages intended for unit dose production are to be stored in an automated pack dispensing system which registers the drugs into the Contracting Authority's ERP system (Oracle). The offered solution must be integrated with the Contracting Authority's ERP system for information about stock level of drugs intended for unit dose production.
Drug Preparation	Pharmacy employee prepares the drugs for unit dose production in conformance with national and internal guidelines, and according to the offered solutions requirements for drug preparation. Find the Contracting Authority's requirements regarding the drug preparation process in K Appendix 1, Chapter 2 "Drug preparation".
Production	The unit dose production system produces unit doses from the prepared drugs according to the Contracting Authority's design requirements. Find the Contracting Authority's requirements regarding the unit dose production process in K Appendix 1, Chapter 3 "Unit dose production".
Stock Unit Dose	The offered solution must include an automated storage solution for the unit doses. Find the Contracting Authority's requirements regarding the storage solution for unit doses in K Appendix 1, Chapter 4 "Unit Dose Storage".
Dispense and Group Unit Doses	The unit doses are dispensed and grouped according to orders from the Contracting Authority's ERP system. The offered solution must be integrated with the Contracting Authority's ERP system to receive and confirm/send orders of unit doses to the Contracting Authority's customers. Find the Contracting Authority's requirements regarding the Dispensing process in K Appendix 1, Chapter 5 "Unit dose dispensing".

Prepare delivery to Ahus hospital	Pharmacy employee prepares the order for Ahus hospital. The order is composed of unit doses and drugs in original packaging. The drugs in original packaging are handled via the Contracting Authority's ERP system and this activity is not included in this tender.
Prepare delivery to Ahus, Kongsvinger	Pharmacy employee prepares the order for the hospital pharmacy Ahus, Kongsvinger. The order is exclusively composed of unit doses from the advanced UDPS. The offered solution must include a solution to facilitate the handling, storing and dispensing of unit doses at the hospital pharmacy Ahus, Kongsvinger. Find the Contracting Authority's requirements regarding the transportation and handling of unit doses for regional pharmacies in K Appendix 1, Chapter 6 "Regional pharmacies".)

Table 2: Overview of activities in the production plant at Ahus and the requirements connected to these activities.

2.3. Hospital Pharmacy Ahus, Kongsvinger

The Contracting Authority will need a solution to prepare and register unit doses for transportation to the Hospital Pharmacy Ahus, Kongsvinger, and a goods receipt, storage and dispensing solution for unit doses at the Hospital Pharmacy Ahus, Kongsvinger. The solutions for the Hospital Pharmacy Ahus, Kongsvinger are included in the customer requirement section of this tender (K Appendix 1, Chapter 6 "Regional pharmacies"), and the Contractors are encouraged to offer solutions for the regional pharmacies with a high degree of digitalization and automation.

The Contracting Authority will prefer a modular storage solution that can be adapted to fit the various locations and might be extended if needed.

3. Production volume and users

3.1. Production volume and prognosis

The total need for unit doses in Ahus is estimated to 4,3 million unit doses in 2025, with a high degree of uncertainty. As described in chapter 2.2, the total volume of unit doses to be delivered in Ahus will consist of unit doses from the advanced UDPS.

The estimated volume needed from the advanced UDPS will reach approximately 5,3 million unit doses in 2035. The offered solution must be able to deliver the necessary amount of unit doses needed to reach the yearly estimate within 100 operating hours per week or less. Experience shows a variation in deliveries to the hospital throughout the year. Seasonal variation is ± 15% from mean. This variation must be taken into account when designing capacity of the system.

Table 3 gives the estimated production volume in millions of unit doses from 2025 to 2035.

Ahus	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035
Advanced UDPS	4,33	4,42	4,50	4,59	4,69	4,78	4,88	4,97	5,07	5,17	5,28

Table 3: Estimated production volume in million unit doses. These numbers have a significant degree of uncertainty.

3.2. Regional distribution

As shown in Figure 2, the sites of Ahus have different needs for unit doses. The numbers given in the figure are estimated number of unit doses from advanced UDPS per hospital in 2025. These numbers have a significant degree of uncertainty.

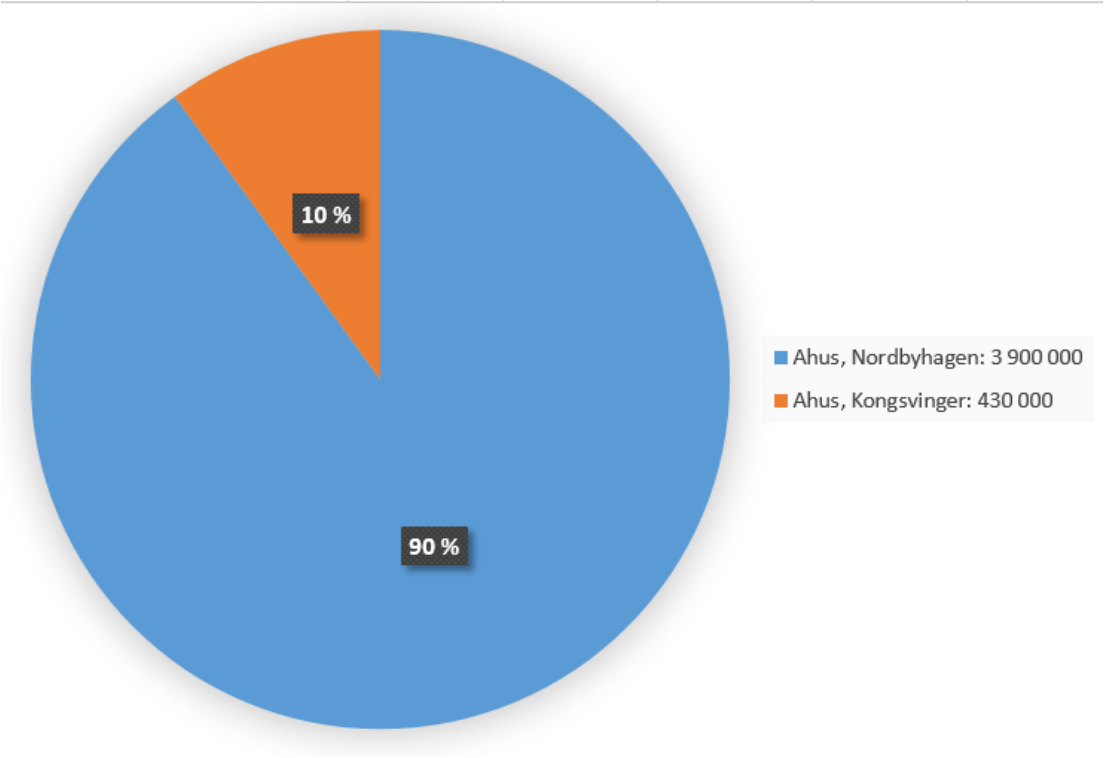

Figure 2: Approximate distribution of the unit dose needs for the different sites at Ahus

3.3. Users

The number of users is a result of the solution offered, and consequently will have to be decided in cooperation with the Contractor. The Contractor must specify in K Appendix 7 the cost of each client or licence needed for each user and specify if there are differences according to access level.

4. Facility

4.1. Delivery address

Akershus Universitets Sykehus (Ahus), Sykehusveien 25, 1474 Nordbyhagen.

4.2. Location and area for the offered solution

4.2.1. Production plant at Ahus, Nordbyhagen

The existing area used for unitdose production at Ahus, Nordbyhagen is shown in Figure 3:

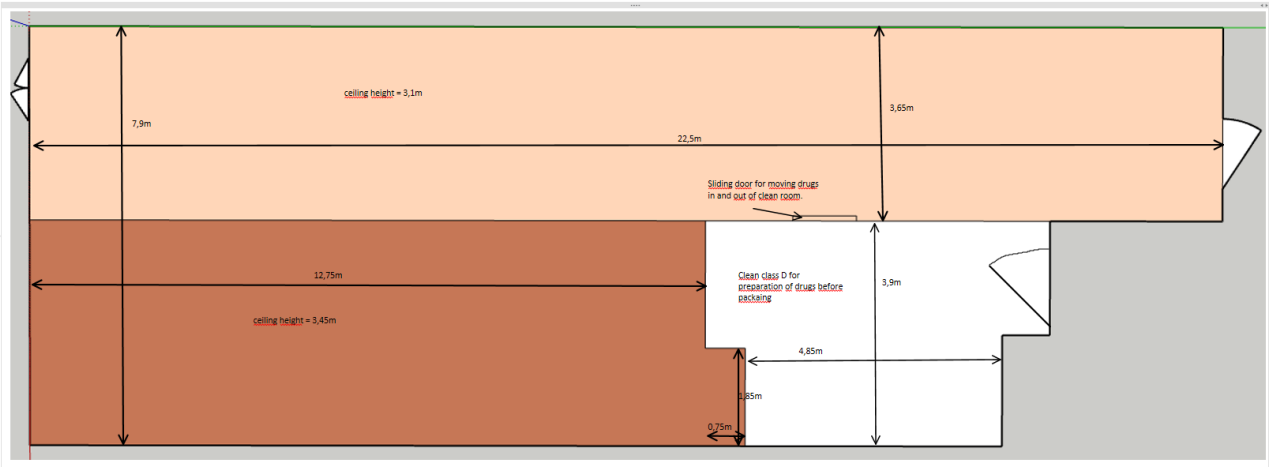

Figure 3: Drawing of the locals for unit dose production at Ahus.

White area is a class-D clean room for preparation of drugs for unit dose production. Brown and light brown area is one area but with different sealing heights, dedicated for unit dose production and delivering. There must also be a storage solution for prepared drugs for unit dose production in this area.

Main part of the delivery of unit doses will be automatically delivered by PTS.

The door in right side of the drawing in figure 3 is for incoming goods. The door in left side is for outgoing goods delivered manually. There will also be drugs passing through this room that will be delivered manually to the ward stocks.

4.2.2. Regional pharmacies' storage solutions

Estimated storage capacity needed for Hospital Pharmacy Ahus, Kongsvinger is shown in table 4. The number of unit doses is estimated from the approximate number of unit doses from advanced UDPS needed in 2035 (table 3 and figure 2), and are based on storage capacity for two weeks average unit dose need:

	Storage capacity needed
Hospital Pharmacy Ahus, Kongsvinger	21 000

Table 4: estimated storage capacity needed

The Contractor should describe how their storage solution could be adapted to fit different size areas and different storage capacities, and elaborate on the relationship between size and storage capacities.

4.3. Load capacity of the production floor

Load capacity on production floor is limited to 8 kN/m², which is 800 kilograms per square meter.

4.4. Transportation path

We will need to use the existing transportation paths. The locals are in the same floor as the stock goods reception. It's needed to pass several doors/gateways. The dimensions of the smallest door is: height 205cm x 120cm width.

If bigger openings are needed, it can be discussed with the hospital.

4.5. Ventilation system, Vacuum and Air supply

The existing facility are supplied with ventilation and compressed air from the hospital.

4.5.1. Ventilation

The offered solution will be installed in a designated production room. There is also a continues flow of HEPA filtered air to the old packaging machines this may be used also in the new system. (Any necessary adaptations of the production area must be explicitly specified.) The ventilation unit providing air for the production room is also providing clean air for the D-class room for preparation of the drugs for the unit dose production.

4.5.2. Vacuum

There is no vacuum provided in the area. Contractor must include a setup for creating the needed vacuum. It's possible to install the vacuum pumps in an adjacent room.

4.5.3. Air supply

Technical compressed air are available.
Working pressure: about 8bar
Medical quality is maintained and regularly measured.

4.6. Power connections and electric supply

The system will be installed in an existing building with existing power supply. Needed supply for power will be delivered on demand. Existing system is using 230v 1.phase.

Existing system is supplied with emergency power, partly from UPS(Uninterruptible power supply) and partly from emergency power generator. Same setup can be used for the new machines. Suggested needs for UPS and emergency power supply may be described in K Appendix 1 (Requirement 13).

4.7. Network

It's several network connections in the rooms today. New network connections will be created on demand.

5. ICT ecosystem and integration

This section gives an overview of assumed "TO-BE". The "TO-BE" section is foremost a proposal that can be challenged by the contractor during the procurement process. ERP system Oracle is planned implemented during 2023-2024, therefore integrations towards ERP can't be agreed in the procurement process. Contractor should present standard integrations towards ERP. Final solution for integrations must be decided at the time the option is put into effect.

5.1. ICT Context

5.1.1. Application Ecosystem

The application ecosystem illustrates the applications and their interactions in a "TO-BE" context composed of a Production Plant Ahus, Nordbyhagen and Hospital pharmacy Ahus, Kongsvinger.

Figure 4 shows the existing integrations, represented by arrows and highlights the potential integrations by yellow, orange, blue areas. Each area represents integrations to different equipment. Whitened applications and their related areas/integrations are not part of the present procurement scope and therefore not described in this document.

The contractor's solution may interact with one or several of the following applications:

- Delta: IT system for stock management of ward stocks for medicines in all the hospitals in the region. Today pharmacists, handles all orders for medicines to ward stocks through this system. "AS-IS" are orders sent to dispensing system, this may change in the new setup.
- Oracle: it is the "TO-BE" enterprise solution for all hospital pharmacies in the south-east region regarding economy and logistics. The system handles all sales orders for the hospital pharmacies and will also handle all purchase of medicines from external vendors (Wholesaler).
- EIK: Entrance point to the medicines verification system (FMD registry) and national material registry.
- Metavision: Hospitals in the south-east region is using the EMR Metavision. New integrations for the EMR Metavision will be needed, but is not in the scope at this stage. This system is not included in the Figure 4. Principles regarding how patient specific orders are created, handled is not defined. Patient specific orders are likely to implemented at some stage.
- Production Plant (Application System): Represents applications used by the different equipment composing the future Production Plant. Section 2 details the suggested integration between Oracle and the different applications.
- Unit Dose Dispensing System: Represents a proprietary application used by the dispensing system.

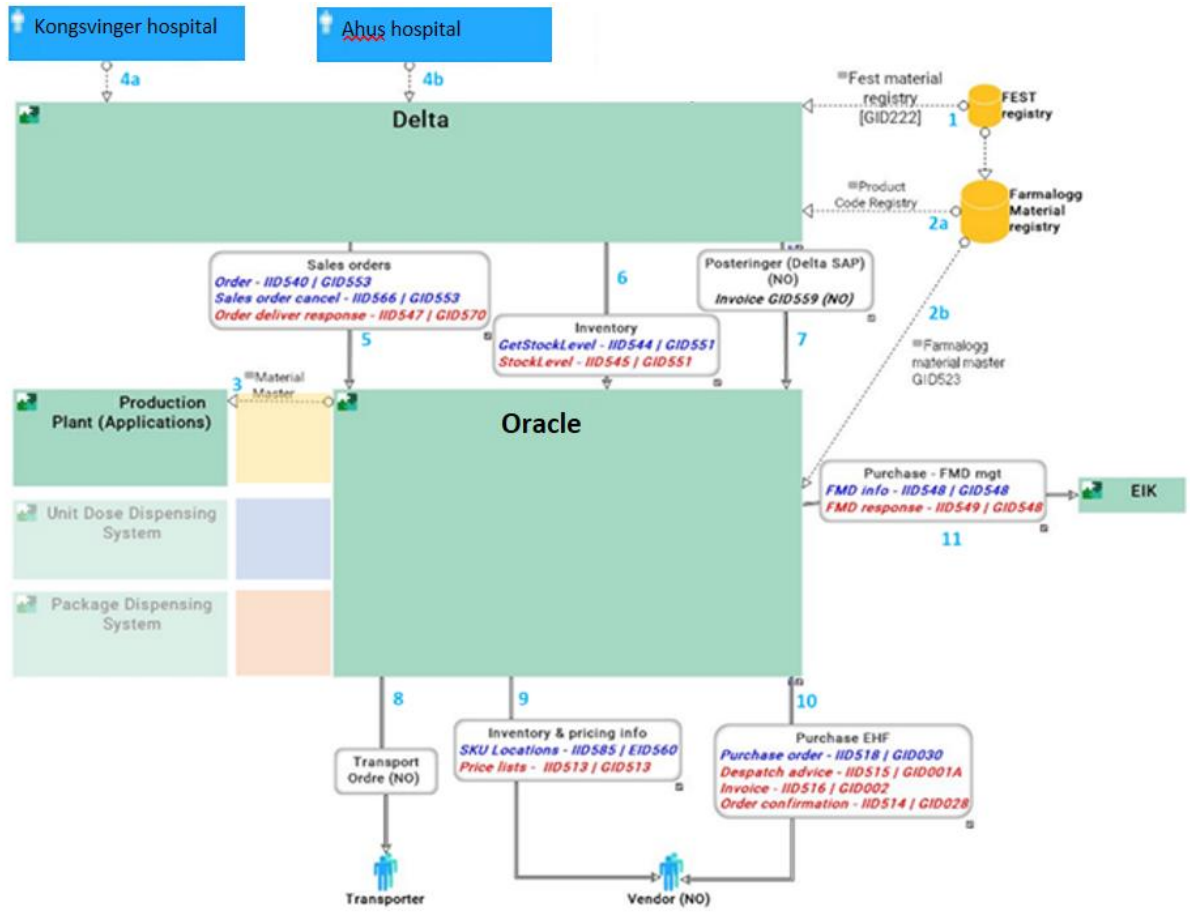

Figure 4: Illustration of the application ecosystem (Whitened area are out of procurement scope) in proposed "TO-BE"

Table 5 gives a description of the information in Figure 4.

	Source	Target	Description
1	FEST Registry	Delta	FEST is a national registry owned by the Norwegian Medicines Agency. The database provides to doctors, pharmacies and truss maker ("bandagist"), updated information about everything you can get on prescription in Norway. FEST is integrated to Farmalogg Material Registry.
2a,2b	Farmalogg Material Registry (EIK)	Delta Oracle	Farmalogg is a national registry owned by the Pharmacy Association. The database contains information about the goods sold in pharmacy (ex: Package codes, Product Code, handling information).
3	Oracle	Production Plant (Applications)	Oracle is the to-be regional material master for all the hospital pharmacies. An integration will populate and update the contractor's solution with material information. The material master is a compilation of data contained in the registry FEST and Farmalogg. The material registry also contains information locally managed in the region outside the national registries.
4a,4b	Pharmacist	Delta	Pharmacist manages the ward stock orders in the application Delta. Pharmacist selects the LMR code and has the option to order per unit or per package. Delta has an overview of available medicines in the pharmacies, if they are available as unit dose or packages.
5	Delta	Oracle	Delta sends Hospital sales order to Oracle
6	Delta	Oracle	Delta request stock levels for all materials in the pharmacies from Oracle at a given frequency.

7	Delta	Oracle	Delta sends element for Invoicing to Oracle when ward stocks do internal transfers between stocks.
8	Oracle	Transporter	Production Plant manages the transport of finished product (Unit Dose) to local pharmacy and local hospital (Ahus) through the application Oracle.
9	Oracle	Vendor	Production plant manage the purchase orders to vendor (wholesale) with the application Oracle.
10	Oracle	Vendor	
11	Oracle	EIK	Today, an integration is existing between Oracle and the FMD Registry (through EIK). Oracle sends package information to FMD Registry when a package is dispensed. For packages used in unit dose production the dispense is sent during goods receive.

Table 5: Information flow between applications

5.1.2. Data Structure

The section describes the existing information model and the terms used today by the Contracting Authority. The information model of Oracle may change during the procurement process to comply with the project ambitions.

Table 6 lists the terms used in the document.

Terms	Description		Example	Source	ID
ERX	Medicine Active Substance	Active substance, drug form, strength	paracetamol 500 mg	Not available with current registries	
LMR	Medicine Branded Product	Active substance, drug form, strength, brand	Paracet pill 500 mg Panodil pill 500 mg	FEST/ Farmalogg Registry	LMR ID
Package Code (Material)	Medicine Package Branded Product	Active substance, drug form, strength, brand, package size	Panodil pill 500 mg, 96 pills Panodil pill 500 mg, 300 pills	FEST / Farmalogg Registry	VNR ID
Product Code		Unique identifier, assigned to each finished/ manufactured product which is ready, to be marketed or for sale.		FEST/ Farmalogg Registry	Produktkode ID
Batch information		Batch (or "lot") information is a unique identifier assigned to a group of materials allowing the access to history of its production and control.			
Expiration Date		Final day that the manufacturer guarantees the full potency and safety of a medication.			
Serial number (Serie-nummer)		Unique identifier of the manufactured package or unit dose.			SNR_P SNR_UN

Table 6: Terms

5.2. Integration

Contractor must describe standard integrations towards ERP for raw material handling, and integrations towards ERP for ward stocks orders and return from ward stocks.

Contractor must describe standard integrations for patient specific orders including return of drugs not used. Contractor needs to describe how patient specific data (name, ID number ect.) may be handled without patient specific data being stored in the dispensing system to ensure GDPR.

All integrations must be agreed at the time the option is put into effect.

5.3. Master Data

The Contracting Authority differentiates between master data from Material Registry/FEST (Drug Master), referring to the data sourced from national registries, and other master data, corresponding to data which are not provided by national registries but that are important to deliver the required functionalities.

The Contracting Authority will assess the capability to deliver the general drug data (ex: names, product code) from Oracle. Master data not provided by Oracle, needed to ensure a smooth operation, in conformance with the expected functionalities, must be maintained by the offered solution.

The contractor shall describe its information model and the expected data formatting to ensure a smooth operation in conformance with the expected functionalities (K Appendix 1a - ICT Requirements).