
GUIDE TO DAILY COOPERATION IN
CONNECTION WITH THE SUPPLY OF
PHARMACEUTICALS TO THE HOSPITAL
PHARMACIES IN DENMARK AND AMGROS

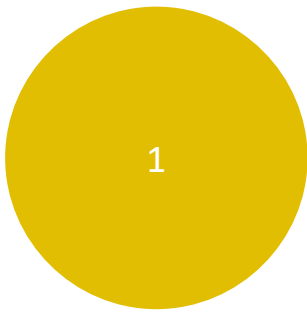


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Guidance on the framework agreement

Amgros has prepared this guide for the daily cooperation between suppliers, distributors / wholesalers, hospital pharmacies, and Amgros.

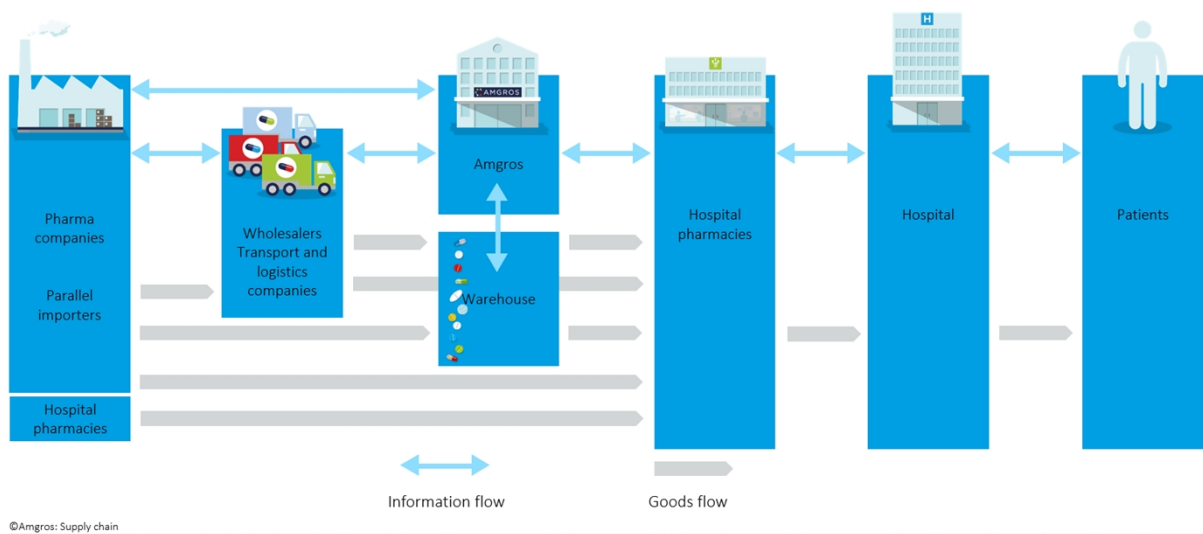
In case of doubt or discrepancy between the framework agreement entered into and this guide, it is the provisions of the framework agreement that apply.

2. Purchase of pharmaceuticals

Amgros conducts tenders on an ongoing basis and enters into agreements, including framework agreements, for the supply of the expected need for pharmaceuticals to all public hospitals in Denmark in accordance with the procurement regulations for public procurement.

Suppliers, hospital pharmacies and Amgros are part of a supply chain, as shown in the figure below:

SUPPLY CHAIN



Amgros uses electronic communication to exchange orders, invoices, and other information. All orders for

pharmaceuticals from the hospital pharmacies are sent electronically via Amgros to the suppliers. Order confirmations and invoices go from the suppliers via Amgros to the hospital pharmacies. The physical delivery is made place directly from the supplier or the wholesaler / distributor to the hospital pharmacies. See also section 27 "National reception control / Import controls" about the national receipt / import control requirements for delivery to the hospital pharmacies.

In agreement with the authorities, the hospital pharmacies and Amgros established a safety stock in 2020 in connection with the start of the Covid-19 pandemic. The hospital pharmacies and Amgros have chosen to continue to maintain a strategic stock primarily of critical pharmaceuticals to ensure supply to the hospitals in connection with supply failures. Pharmaceuticals that are stored in the strategic warehouse will usually be sold to the hospital pharmacies as soon as possible to ensure a continuous replacement of the stock. Amgros is responsible for the regularly purchasing of pharmaceuticals for the warehouse.

3. Supply chain contact persons

Contact details for all Amgros' employees can be found on our website Amgros.dk via this link: [Kontakt - Amgros](#).

In the event of a change in specific jobs at suppliers where the employee has contact with Amgros, we would appreciate to receive the name and contact information of the future employee(s).

For persons involved in tenders, information should be sent to udbud@amgros.dk.

For people who deal with specific deliveries to hospital pharmacies, you can write to kundeservice@amgros.dk. If it concerns deliveries to Amgros' warehouse, purchasing department can be informed at indkob@amgros.dk.

4. Wholesaler/distributor

It is important that Amgros is informed about the wholesaler / distributor that is used, if any.

Amgros sends a form to all new suppliers to ensure that the hospital pharmacies and Amgros have the necessary information to be able to purchase the pharmaceuticals.

If a supplier changes wholesaler(s)/distributor(s) during the agreement period, or if other changes of importance to the trading relationship occur, the supplier must inform Amgros of this as soon as possible by sending information to: kundeservice@amgros.dk. When Amgros receives this message in good time, we can together ensure that there will be no significant disruptions to the supply to the hospital pharmacies.

5. Definitions

In Amgros' daily work, the "Definitions for back orders" specified in Appendix 1 are used. These are primarily important for back orders.

6. Updating the guide

This guide is updated when Amgros becomes aware of either new topics that should be described or sections that should be updated. Change log is inserted as Appendix 3.

The most recent version of this guide can be found on Amgros' Supplier and Tendering Portal).

7. Scope of guide

The guide applies to all contract goods that are delivered to the hospital pharmacies through Amgros I/S.

8. Purchase orders

Purchase orders from hospital pharmacies

A maximum delivery time of 3 full weekdays has been agreed in the framework agreement. The day for Amgros' dispatch of an order is considered to be day 0. The pharmaceuticals must be received at the hospital pharmacy 3rd weekday thereafter. By "weekdays" is meant Mondays to Fridays except for Danish holidays, Constitution Day, Christmas Eve, and New Year's Eve.

Many suppliers and wholesalers usually have daily deliveries to the hospital pharmacies, so that orders received before 12.00 will be delivered next weekday.

The individual hospital pharmacy issues orders to Amgros on an ongoing basis. Amgros then submits orders to the supplier on an ongoing basis. Ordering is by electronic order or email.

The supplier or wholesaler/distributor immediately confirms the order, if possible, electronically. The orders are confirmed by informing Amgros about item, quantity and expected delivery time. Amgros, on this basis, confirms the orders to the hospital pharmacy.

When the goods are shipped, the supplier or distributor must, if possible, inform Amgros that delivery has taken place through the submission of an electronic shipping advice.

If a hospital pharmacy wants to cancel/change an order, the hospital pharmacy will contact the supplier directly by telephone or email. Immediately thereafter, an update will be made in Amgros' ordering system.

If an urgent need arises for a product, the hospital pharmacy can place an urgent phone order with the supplier or wholesaler/distributor. The product must then be delivered with the next delivery to the hospital pharmacy.

Purchase orders from Amgros to replenish strategic stock

Amgros continuously orders goods for the hospital pharmacies and Amgros' strategic stock.

The orders placed for strategic stock usually include a number of item numbers, which are to be stocked in a larger quantity of each item number than would normally be ordered from a hospital pharmacy.

Amgros usually sends an order inquiry before the final order. The inquiry includes the goods and quantities that are de-sired to be delivered. If the supplier cannot deliver the full amount of all item numbers, a reduction can be agreed in more detail with Amgros' purchaser. Amgros usually sends the final order electronically.

9. Supplier room on the Supplier and Tendering Portal (Mine firmasider)

Communication with the supplier about agreements and back orders takes place as far as possible via a company-specific supplier room, called "Mine firmasider", which can be accessed via levportal.amgros.dk.

This communication includes documents concerning tenders, among other things, information on ESPD documentation, order award letters, framework agreements, estimates and extensions, as well as previously submitted offers to Amgros.

Here you will also find an overview of back orders and stock for goods in the strategic warehouse, if any as well as statistics for sales of the same to the hospital pharmacies.

The functionality on "Mine firmasider" is continuously expanded based on the needs of suppliers and Amgros. New needs can be sent to: kundeservice@amgros.dk, and these will be assessed in connection with ongoing development.

Functions, documents, and other information on these pages are exclusive to the supplier with which the user is associated and cannot be accessed by other suppliers. Amgros wants to have as up-to-date information as possible regarding any backorders. Therefore, from this page, an email can be sent directly to Amgros' customer service with updated information about current or expected backorders.

On "Mine firmasider", the supplier must also upload current ESPD documentation and section 39 license (company license/GDP).

10. Backorders

Amgros is obliged to ensure adequate supplies of medicines to all patients in public Danish hospitals. Therefore, it is important to have good cooperation and a close dialogue between suppliers and Amgros. Information about backorders, delivery and any suggestions for solutions are sent in writing to Amgros via Amgros' Supplier and Tendering Portal, alternatively, send an email at kundeservice@amgros.dk

If the delivery time of 3 full weekdays cannot be met for an ordered pharmaceutical, the supplier is obliged to **immediately** inform Amgros in writing. The information must contain the reason for the delay, **when** delivery to the hospital pharmacy is expected and number of packages expected to be delivered. The supplier must also notify Amgros in writing when the supplier can foresee that delivery problems may occur for a pharmaceutical. In the case of early information, Amgros will be able to manage backorders, which may subsequently lead to a limited claim for damages against the supplier.

When Amgros has a fair view of an expected backorder situation, Amgros will together with the supplier try to distribute existing stock to the hospital pharmacies as needed. At the same time, Amgros will try to obtain replacement goods from another supplier.

When the supplier informs of a delivery time, the supplier must specify specific dates for when the hospital pharmacies can again expect delivery of the pharmaceutical (cf. appendix 2). Can a supplier only state a period for expected resumption of delivery, Amgros will make use of the definitions of delivery time described in Appendix 2.

In connection with information about goods in stock, information is also requested on the quantity expected to be received. The information is important for Amgros to acquire knowledge of expected future delivery problems for the individual pharmaceutical. If the existing back orders cannot be delivered in full when goods arrive, Amgros will distribute the quantity received to the hospital pharmacies according to their needs.

11. Supplier's own solution of backorders

If the supplier does not expect to be able to deliver goods for an extended period, the supplier is always welcome to make suggestions for replacement goods to Amgros, which can be included in Amgros' consideration of the purchase of compensation. The framework agreement states that for backorders that have been notified by the supplier with a minimum of 6 weeks' notice, the supplier can indicate a proposal for a

solution for replacement purchases. Suggestions for resolving a backorder are sent to Amgros by email at kundeservice@amgros.dk or on Amgros' Supplier and Tendering Portal.

Amgros will then assess whether the solution can be accepted. The supplier must have sent his proposal for the solution to the order back to Amgros no later than 4 weeks before the first day of the backorder period.

For the supplier, an active contribution to solving the backorder situation means that the extra cost for replacement purchases is limited as much as possible. When the order backlog ends and the supplier can again deliver, the supplier must immediately inform Amgros in writing of when the supplier in practice will be able to deliver again. This can be done by email at kundeservice@amgros.dk or on the Supplier and Tendering Portal.

12. Compensation for additional costs and mitigation of damages

If the supplier does not deliver an ordered product with the agreed quality and residual shelf-life within 3 full weekdays, the supplier is considered to be in back order. The backorder period continues until the supplier has goods in stock again (see Appendix 1 - Goods in stock).

For reasons of the practical handling and organization of the purchases, the backorder period will be considered to have ceased at the earliest on the 2nd weekday after the time when the supplier has convincingly demonstrated to Amgros his ability to deliver and stockpile (see Appendix 1 - Backorder period). During the entire backorder period, Amgros is entitled to make replacement purchases, and the supplier is obliged to cover the additional costs of the replacement purchase during the entire backorder period. The contractual liability applies regardless of whether the purchased pharmaceuticals are used in full during the backorder period.

According to the framework agreement, the hospital pharmacies and Amgros must follow the general rules on duty of mitigation, however, considering the conditions set out in the applicable framework agreement. Amgros' decision on replacement purchase is made considering patient safety and resource issues, which means that continuous changes of items should be avoided as far as possible. The consideration of ensuring a stable supply can also have a significant impact on Amgros' decision to purchase compensation.

13. Replacement purchase

Replacement purchases are managed according to the framework agreement.

If a supplier cannot deliver a pharmaceutical in accordance with a framework agreement, the hospital pharmacy purchase replacement with an equivalent pharmaceutical. The difference between the corresponding pharmaceutical, purchased for replacement, and the contract price must be reimbursed by the supplier.

Settlement for replacement purchases is usually settled once a quarter. In the event of late receipt of information from the hospital pharmacies regarding replacement purchases, Amgros reserves the right to settle additional costs as soon as Amgros is made aware of this or postpone the settlement to the following quarter.

If Amgros has purchased a pharmaceutical for Amgros' stock, this stock must be emptied before the supplier becomes liable for compensation due to back orders.

14. Reimbursement orders

If a supplier cannot deliver a pharmaceutical according to an agreed framework agreement, the hospital pharmacy can purchase this as a reimbursement order. This means that the hospital pharmacy purchases the same pharmaceutical (item number) from a wholesaler for AIP (the pharmacy's purchase price). The difference between AIP and the contract price must be reimbursed by the supplier.

15. Trifle agreements

The hospital pharmacies will not be reimbursed for any additional costs based on back orders for pharmaceuticals purchased on trifle agreements.

16. Packing and shipping

The work in receiving goods at the hospital pharmacies can be simplified and work better if a few simple conditions are followed. The supplier should therefore ensure the following:

- If a product with multiple batch numbers is delivered, these should be clearly separated.
- Pallets are required to be transport-protected with a transparent stretch foil.
- The number of transport units and the goods storage conditions must be stated in the consignment note.

For liquids (e.g., Glucose and NaCl solutions), further:

- The pallet height must not exceed 160 cm.
- A whole and unbroken pallet is preferred.
- Cardboard marks must be visible on the shipping package.
- Mixing of multiple batch numbers should be avoided. If mixing is required, place the largest batch at the bottom of the pallet.

17. Shelf life

The shelf life of pharmaceuticals must not be less than 12 months upon delivery. For some cytostatics, where it appears from the current framework agreement, however, at least 6 months. For pharmaceuticals, where it is stated at the time of ordering that they are to be resold to Greenland, the shelf life upon delivery must not be less than 18 months.

For pharmaceuticals whose shelf life according to the product summary is shorter than 24 months, the actual remaining shelf life upon delivery must be longer than half of the shelf life stated in the product summary for that pharmaceutical. For example, a pharmaceutical which according to the product summary has a shelf life of 18 months must have a shelf life of at least 9 months when delivered to the hospital pharmacy.

If the supplier only has the option to supply pharmaceuticals with a shorter shelf life than stated above, the supplier must inform the hospital pharmacy about this before delivery. In this connection, the hospital pharmacy can refuse to receive the pharmaceutical.

Pharmaceuticals delivered to Amgros' warehouse have the same shelf-life requirements as pharmaceuticals delivered directly to hospital pharmacies.

18. Returns

In general, the hospital pharmacies do not have the right to return purchased pharmaceuticals.

If pharmaceuticals have been delivered with a shelf life shorter than stipulated in the framework agreement, the supplier is always obliged to take back the pharmaceuticals or part of them against reimbursement of purchase price and any additional costs, if the hospitals have not used the pharmaceutical in question before the expiry of the shelf-life period or when the pharmaceuticals can no longer be used in the clinic.

Unless otherwise agreed with the individual supplier, returns can be made using PostNord to the Supplier's address specified on the framework agreement. The hospital pharmacy's responsibility for pharmaceuticals that are returned ends when the drugs are handed over to the carrier.

The supplier must issue a credit note to Amgros no later than 8 days after receipt of the returned pharmaceuticals.

19. Quality complaints

Complaints regarding quality and delivery are settled directly between the hospital pharmacy and the supplier. This includes, for example, complaints regarding shelf life, damaged goods, wrongly delivered goods and the like.

If it is a pharmaceutical that has been purchased for Amgros' warehouse, Amgros oversees the complaint in relation to the supplier, based on information from the hospital pharmacies.

20. Complaints about price and quantity

If an error is discovered in the quantity delivered in relation to the quantity ordered, the hospital pharmacy or Amgros contact the supplier for correction. Kundeservice@amgros.dk must be c.c. in all emails between the supplier and the hospital pharmacy regarding errors in quantity. If the discussions between the hospital pharmacy and the supplier take place by telephone, the supplier must subsequently inform Amgros of the outcome of the discussions.

If Amgros discovers an incorrect price, Amgros contacts the supplier.

21. Stock size

For the sake of consistency in supply, the supplier must have at least 3 months expected consumption in stock at the start of the purchase period. For the remainder of the purchase period, the supplier must maintain a suitable stock for each pharmaceutical, as appropriate, unless otherwise stated in the framework agreement e.g., that 1/6 of the estimate must be in stock throughout the purchase period. The size of an "appropriate stock" must be assessed based on the stated estimates, the purchases made under the framework agreement and the market development in general, so that the supplier can **always** deliver all received orders within 3 full weekdays.

During the entire purchase period, the supplier must be able to demonstrate on Amgros' request that the requirement for an appropriate stock is met. In addition, Amgros has the right to conduct physical inventory checks with the supplier to verify that the requirements for storage structure and size are met. If the supplier has placed his stock of the drug at the wholesaler (s) / distributor (s), the supplier shall ensure that Amgros has

access to conduct similar physical inventory checks at the wholesaler / distributor. Amgros will announce the time for the physical warehouse check in advance.

22. Estimates

In connection with the award of a framework agreement, Amgros informs about the expected estimate for purchases during the purchase period. If the hospital pharmacies' consumption of a pharmaceutical is changed, the individual supplier can see the latest updated estimate on the Supplier and the Tendering Portal (see also section 9 "Supplier room on the Supplier and the Tendering Portal").

The supplier is asked to check his ability to supply in relation to the estimates and confirm the delivery ability via the Supplier and the Tendering Portal. If delivery problems are expected, Amgros must be informed in good time; preferably via the email function on the tab "Estimator" on the Supplier and Tendering Portal or via email at kundeservice@amgros.dk

Amgros provides daily sales figures to Dansk Lægemiddel Information A/S (Danish Pharmaceutical Information).

23. Information about lead time, batch sizes, security stock, quantity in shipping unit, etc.

On "Mine firmasider" on Amgros' Supplier and Tendering Portal, the individual supplier can provide information on leadtime, to the extent that this information is available, batch size, security stock, quantity in a shipping unit, etc. per pharmaceutical.

If this information is specified for the individual pharmaceutical, the hospital pharmacies and Amgros use it, e.g. in connection with major estimate changes, backorder processing, quantities purchased etc. (see also section 9 "Supplier room on the Supplier and Tendering Portal").

24. Information sharing

To ensure a smooth and easy communication between suppliers, hospital pharmacies and Amgros, Amgros is constantly working on developing Amgros' Supplier and Tendering Portal and a separate portal for the hospital pharmacies. Amgros continuously informs the hospital pharmacies about e.g. the back-order situation via this portal for the hospital pharmacies.

If you as a supplier have ideas for improvements to Amgros' Supplier and Tendering Portal, we would like to hear about it. Proposals can be sent to kundeservice@amgros.dk

25. ESPD and ESPD-documentation

As part of the tender process, Amgros requires that all suppliers submit an ESPD (European Single Procurement Document). In Amgros' pharmaceutical tenders, the ESPD is used as a self-declaration from each supplier. Amgros uses electronic submission of ESPD in connection with the tenderer submitting his offer.

The self-declaration serves as preliminary proof that the tenderer is not covered by a number of grounds for exclusion mentioned in the Public Procurement Act. Amgros may only award a contract to tenderers who can

document that the information about the reasons for exclusion that they have submitted in the ESPD is correct. Detailed information on the ESPD and the ESPD documentation can be found in Appendix B to the general tender conditions "Guide to the Common European Procurement Document (ESPD) and Documentation for Exclusion Grounds", which is part of the tender material.

In connection with the war in Ukraine, the EU has drawn up a regulation requiring all bidders to submit a Declaration regarding Regulation (EU) No. 833/2014. Completing and signing this is a prerequisite for a supplier to be awarded an agreement. Similar to the ESPD, the declaration is submitted electronically, in connection with the tenderer submitting an offer.

26. § 39 in the Medicines Act (company authorisation)

Amgros is § 39 approved by the Danish Medicines Agency for the wholesale of medicines within the EU / EEA. In order to ensure compliance with the GDP rules, it is a requirement that Amgros receives, no later than at the start of the purchase period, the individual supplier's § 39 license (company authorisation).

The § 39 authorisation/company authorisation must be uploaded via Amgros' Supplier and Tendering Portal/ "Mine firmasider"/"Mine dokumenter". Subsequently, updated versions of the individual supplier's § 39 authorization must be uploaded via the Supplier and Tendering Portal at each version update.

For foreign suppliers, Amgros must receive a corresponding authorization issued by a competent authority at the latest at the start of the procurement period.

The latest updated company authorization for Amgros can be found on the Supplier and Tendering Portal/"Udbud og Bagateløb"/"Vigtige informationer".

27. National reception control / import controls

Pursuant to the framework agreement entered into, the supplier must ensure that all pharmaceuticals delivered to the hospital pharmacies and the strategic warehouse are subject to national receipt/import control prior to delivery in accordance with applicable Danish legislation.

This means that the hospital pharmacy must only accept deliveries where receipt control has been completed. If the supplier does not want to conduct this himself in Denmark, this service can be conducted by the wholesalers or by some Danish companies that specialize in this.

It is the supplier's responsibility that national receipt/import control has taken place before the item is delivered to the hospital pharmacy or the strategic warehouse. If a receipt check has not been conducted on goods delivered, the supplier will be charged a fine per not receipt-controlled batch number in accordance with the framework agreement.

28. Amgros' own warehouse

In connection with the Covid pandemic, the hospital pharmacies and Amgros established a national safety stock at Nomeco. This warehouse is maintained, now as a strategic warehouse.

Amgros' two warehouses appear in Amgros' §39 authorisation, where both JetPak in Kolding and Nomeco in Køge are included as contract takers.

The hospital pharmacies and Amgros decide on stocking of pharmaceuticals based on:

- An assessment that it is considered necessary to ensure a stable supply of medicines to the Danish hospital pharmacies.
- That availability of stock is critical for patient care.
- Requirements from the authorities to maintain a safety stock.
- That there are other business benefits that exceed the costs of operating the warehouse.
- Agreement to purchase a minimum quantity of a pharmaceutical within a given period.

29. Transfer of framework agreement

The supplier cannot transfer his rights and obligations to third parties without Amgros' written consent.

The process of transferring framework agreements is available on Amgros' Supplier and Tendering Portal under "Hjælp og Support"/"Vejledning".

30. New item, other item in framework agreement or change of item number

The process for including a novel item or other item in a framework agreement is available on Amgros' Supplier and Tendering Portal under "Hjælp og Support"/"Vejledning".

Amgros must be informed in good time about the item number change on a contract item e.g., when packaging material is updated. Inform by email to kundeservice@amgros.dk.

Amgros must approve the change before it can be implemented.

31. Barcodes

The hospital pharmacies and Amgros continuously develop the use of bar codes.

Current requirements for barcodes for the individual product types, desired types of barcodes and placement of these on the pharmaceuticals and packaging are shown in Appendix 2 to the framework agreement.

The supplier must enter and maintain information about the barcodes used on the primary package on Amgros' Supplier and Tendering Portal.

In order to follow up on whether barcodes are registered correctly, Amgros has established a monthly follow-up that barcodes have been entered on the Supplier and Tendering Portal. If a supplier fails to enter the agreed barcodes on this, the supplier will receive a monthly "reminder email" to update these. If there are problems entering the barcodes on the Supplier and Tendering Portal, the tender department can be contacted at udbud@amgros.dk, who can be of assistance if in connection with bar code questions.

32. Serialization

The hospital pharmacies and Amgros are subject to the rules for serialization according to the "Directive on falsified medicinal products".

33. The Danish Medicines Council's treatment guidelines

Amgros' purchases of pharmaceuticals, which are covered by the Danish Medicines Council's treatment guidelines, are often characterized by great uncertainty at the start of the purchasing period. This is because the historical consumption of a pharmaceutical is often not a fair indication of the consumption that will be after a treatment guide/medicine recommendation has been drawn up. There will often be major changes in the consumption pattern of pharmaceuticals that have the indication that is dealt with in the guidance. Suppliers who wish to bid for tenders that are covered by one or more treatment guidelines should therefore be aware of the additional uncertainties that exist for these tenders.

When the tendering process has been completed, the Danish Medicines Council can draw up a recommendation list and the final estimated consumption can be determined. At the tender, the tendered quantity will be the historical consumption and will only be a preliminary indication of the quantity that is expected to be consumed. When the recommendation is made public by the Danish Medicines Council, the estimates in Appendix 1 will be updated. It is important to note that there can be large deviations in the estimates, which can go "both ways" for the pharmaceuticals covered by the treatment guidelines.

34. Registration of pharmaceuticals in Medicinpriser.dk

The pharmaceuticals must be included in www.medicinpriser.dk during the entire purchase period.

In the framework agreement, a date is set for when the pharmaceutical must be registered at www.medicinpriser.dk at the latest. It is usually two tariff periods before the start of the purchase period. The Danish Medicines Agency must receive the information from the supplier no later than 14 days before the price period for which the pharmaceutical is to be included in www.medicinpriser.dk. See also: <http://laegemiddelstyrelsen.dk/da/tilskud/priser/anmeldelse-af-priser-og-sortiment/tidsfrister>

Example: At the start of the purchasing period on April 1, 2024, pharmaceuticals must be registered at www.medicin-priser.dk no later than February 5, 2024.

If an item number is to be deleted from Medicinpriser.dk during the purchase period, Customer Service must be informed at: Kundeservice@amgros.dk with information about when the item number will be deleted and when it is expected to be recorded in Medicinpriser.dk again.

If an item number has been temporarily removed from Medicinpriser.dk, e.g., due to delivery failure, Amgros can reopen the item number for the hospital pharmacies and in its own systems, so that the hospital pharmacies can purchase the item, for example, from a strategic warehouse, if such is available.

If an item number is permanently discontinued or deleted by Medicinpriser, e.g., due to a change of item number, the item may no longer be sold. In this situation, the pharmaceuticals will be returned to the supplier from the hospital pharmacies and strategic warehouse for the purpose of crediting the supplier.

35. Closing days

If the supplier is closed in connection with public holidays or during a holiday period, it is a major help if the supplier informs Amgros of any closing days. The information Amgros requests can be entered in the form found in appendix 2, which can be emailed to kundeservice@amgros.dk in good time.

Please note that:

- Regardless of whether the supplier has informed Amgros of a closing day or closing period, the supplier is still obliged to deliver all orders within 3 working days, even if the closing period may extend over more than 3 full working days. In other words, the supplier must ensure that there is a contingency in place to manage any orders that may be sent to the supplier during the closing period. If the supplier is unable to deliver an ordered item within the 3 working days, the hospital pharmacy is entitled to make a replacement purchase, for which the supplier is liable to compensate.
- All public holidays mentioned in this description are based on Danish holidays. If the supplier uses foreign ware-houses or offices that are closed for periods, this is considered to be closing days.

36. Recalls

Recalls must follow the supply chain.

If a supplier wishes to recall a medicinal product or specific batch numbers thereof, this must be done to the customers to whom they have sold the medicinal product. This means that pharmaceuticals that have only been delivered to Amgros' warehouse must be recalled through Amgros. If the pharmaceutical is delivered directly to the hospital pharmacies, the recall must be made to them.

The recalls received from suppliers must contain specific instructions about where the medicinal product is being re-called, e.g. clinic or pharmacy, as well as the recipient and delivery address for the recalled pharmaceutical.

Contact information for hospital pharmacies and Amgros can be found in the section "Emergency numbers/emergency contacts for hospital pharmacies".

37. Emergency numbers/emergency contacts for hospital pharmacies

On Amgros' Supplier and Tendering Portal as well as on Amgros' website, there is a list of email addresses and telephone numbers that can be used in the event of an urgent need to contact a hospital pharmacy or Amgros, for example in connection with a recall.

The list can be found on Amgros.dk under the item "[Urgent contact - recalls](#)" ([Akutkontakter](#)) at the bottom of the front page. On the page you get to, "[Emergency contacts for hospital pharmacies](#)" ([Akutkontakter til sygehusapoteker](#)) is used.

38. Regular contact with the hospital pharmacies (non-acute)

On Amgros' website there is a list of email addresses that can be used in the event of a general need to contact a hospital pharmacy or Amgros. The list is available on Amgros.dk by using the "Emergency contacts" button at the bottom of the front page.

On the page you come to, "[Emergency contacts for hospital pharmacies](#)" is used, where the [non-emergency contact list](#) can be seen at the bottom. The list is also available on Amgros' Supplier and Tendering Portal under the item "Levering/Tilbagekaldelser".

39. Social responsibility

The supplier must carry out his obligations considering the environment and climate and assume social responsibility by following national laws and agreements, as well as respecting international guidelines, conventions and agreements on human rights, labour rights, the environment and anti-corruption, etc. as described in the OECD's (2011) guidelines for multinational companies with any later changes and updates and the UN guidelines for human rights and business (2011).

To ensure compliance with the above, the Supplier must have a due diligence process for the supply chain. This means that the Supplier must identify, prevent, limit and remedy current and possible negative impacts on human rights, the environment and anti-corruption in connection with its own activities and group-affiliated companies.

In relation to own sub-suppliers, including group-affiliated companies' own sub-suppliers, the supplier must seek to prevent or remedy such impacts and take the necessary measures to stop or prevent the impact.

Amgros can at any time request the supplier for documentation for this due diligence process.

40. Questions and comments

If this guide on the cooperation with the hospital pharmacies and Amgros gives rise to questions or comments, please contact kundeservice@amgros.dk.

Appendix

Appendix 1. Definitions

Used in communication between hospital pharmacies, suppliers, wholesalers / distributors and Amgros.

Purpose

Amgros has prepared the following definitions, which are used in connection with back orders, etc. The purpose of the definitions is to create a common language and a mutual understanding when hospital pharmacies, suppliers, wholesalers / distributors and Amgros communicate about back orders.

Basis of definitions

The definitions have been prepared based on Amgros' handling of backorders, with a focus on when the hospital pharmacies get their goods delivered. Suppliers who work in other and more links in the supply chain may perceive the situation differently from Amgros, based on their location in the supply chain as well as their stock, order, and delivery situation.

Where "RA" is used below, it refers to Amgros' standard framework agreement, which is based on the preparation of framework agreements with the individual supplier. An example of a standard framework agreement is available on Amgros' Supplier and Tendering Portal ("Udbud og Bagatelkøb"/"Vigtige informationer").

Definitions

Agreement period

The agreement period covers from the time a framework agreement is signed until pharmaceuticals are no longer purchased based on this. That is, after the purchase period has ended.

Purchase period

The purchase period is the period during which hospital pharmacies purchase a pharmaceutical based on a signed framework agreement plus any extension.

Normal delivery period = timely delivery (RA clause 15.1)

For timely delivery, delivery must take place no later than 3 full working days after the supplier's receipt of the order. "Workdays" means Mondays to Fridays, except for Danish public holidays, Constitution Day, Christmas Eve, and New Year's Eve.

For pharmaceuticals to be delivered to Amgros' own warehouse, delivery must take place no later than 10 working days after the supplier's receipt of an order, unless otherwise agreed in writing in connection with the specific order.

Backorder = non-timely delivery (RA clause 18.1)

- The supplier is considered to be on backorder in the following cases if:
- An ordered product is not delivered on time in the ordered quantity.
- The supplier announces in advance that the ordered quantity of the product cannot be delivered on time.
- The goods are not recorded in Medicinpriser.dk at the time specified in RA section 2.3.
- The goods are not in Medicinpriser.dk on the RA point. 2.3 stated time, Amgros is entitled to assume that the supplier will be backordered for 3 months, and to make replacement purchases accordingly.

In the event of a back order, the supplier is obliged to reimburse any additional costs for the hospital pharmacies and Amgros.

If a supplier cannot deliver pharmaceuticals with a shelf life in accordance with the agreement entered into, it is perceived as a back order if the hospital pharmacy cannot use a shorter shelf life for the pharmaceutical.

If a pharmaceutical is stored in Amgros' warehouse, back orders only appear when this stock is sold out or can no longer be used, e.g., due to a short shelf life.

Termination of back order (RA clause 18.3)

Unless Amgros and the supplier expressly agree otherwise in writing, the supplier is considered to be on backorder until the Supplier can again meet the orders in full and has built up a suitable warehouse, as described in RA section 13. The backorder period is considered to have ended 2 business days after that time at the earliest, where the supplier has convincingly proved its ability to deliver and build up stock to Amgros.

Backorder period (RA clause 18.2)

The Supplier is obliged to immediately give Amgros written notice via the menu item "My company pages" (Mine firmasider) on Amgros' Supplier and Tendering Portal as soon as the Supplier should anticipate that delivery problems and thus a backorder situation may arise.

The notification must contain the reason for the backorder and its expected duration. If the notice does not contain information about the expected duration of the backorder, and such information is not sent to Amgros no later than 5 business days after the backorder occurred, Amgros will assume that the Supplier is in backorder for 3 months, and the Supplier will be liable for compensation for the replacement purchases made in this connection.

During the backorder period, specific orders can be delivered on an ongoing basis if the supplier is given the opportunity to deliver part of the backorder quantity.

Goods in stock

An item is considered to be in stock at the supplier when it is physically in the supplier's distribution warehouse and in terms of quality has the status of released, so that it can be immediately dispatched to a hospital pharmacy after receiving the order.

Notification of delivery time

In the event of a back order, the supplier must notify Amgros of the time when the supplier or its wholesaler(s)/distributor(s) will in practice be able to resume normal delivery. That is, the time when the supplier is able to deliver a released pharmaceutical from stock at the usual distributor to a hospital pharmacy.

If the supplier uses various wholesalers/distributors, Amgros must be informed of which distributor(s) a delivery time applies to.

Delivery day/delivery date

Amgros must be informed of the exact date when an item on back order is expected to be in stock and available for delivery to the hospital pharmacies. If the supplier cannot initially provide an exact date, the delivery week or delivery month will be provided.

Delivery week

If a supplier provides a week number for when an item is expected to be in stock, Amgros assumes that the item will be in stock at the usual distributor of the supplier's pharmaceuticals on Monday morning of the following week.

Delivery month

If a supplier provides a month for when a product is expected to be in stock, Amgros assumes that the product will be in stock at the usual distributor of the supplier's products on the first working day of the following month. If the beginning, middle or end of the month is specified, the information is interpreted in the following way:

Provided by the Supplier	Expected to be received and released during the period	Released goods are expected to be delivered from stock at the usual distributor
Early	From the 1st to the 10th of the month	The 11th of the month
Medio	From the 11th to the 20th of the month	The 21st of the month
End	From the 21st to the last day of the month	The 1st of the following month

If one of the stated dates falls on a weekend / on a public holiday, the goods are expected to be in stock the next day thereafter.

Quantity

If the supplier does not inform Amgros of the quantity expected to be received in stock, Amgros expects the entire backorder quantity to be covered by the next delivery.

Note: The backorder period only ends when the supplier can once again deliver released goods from stock upon receipt of orders from the hospital pharmacies.

Appendix 2: Template for notification of closing days

It is a major help that the supplier informs Amgros about any closing days in connection with public holidays.

The information Amgros requests can be entered in the form below, which is emailed to kundeservice@amgros.dk well in advance of the closing days/closing period.

Please note that regardless of whether the supplier has informed Amgros of a closing period, the supplier is still obliged to deliver all orders within 3 working days, even if the closing period may extend over more than 3 full working days. In other words, the supplier must ensure that there is a contingency in place to manage any orders that may come to the supplier during the closing period.

Supplier/product	Last order time	Supplied	Later orders will be delivered	Comments
Supplier X	12.05.20XX at 12:00 p.m.	13.05.20XX	18.05.20XX	Possible emergency order via telephone: XX XX XX XX
Supplier X, product A and B	12.05.20XX at 1:00 p.m.	13.05.20XX	19.05.20XX	

Appendix 3: Change log

Version	Changes to previous version
<i>Version No. 1</i>	New document
<i>Version No. 2</i>	Clarification of text regarding replacement purchases and replacement products in the sections "Backorders" and "Compensation of additional costs and mitigation of damages".
<i>Version No. 3</i>	Addition of the sections "Leverandørrum på Leverandør- og Udbudsportalen (Supplier room on the Supplier and Tendering Portal)" and "Imports and receipt control". New Appendix 3: Template for notification of closing days. Annex 4: Change log:
<i>Version No. 4</i>	Addition of the section "ESPD and ESPD documentation"
<i>Version No. 5</i>	Addition of the section "Packing and shipping"
<i>Version No. 5.1</i>	A) Change in "Leverandørrum på portalportalen (Supplier room on the Supplier and Tendering Portal) (Mine firmasider) ((My company pages)): ESPD has been deleted B) Change in the section "ESPD and ESPD documentation": Appendix number changed to Appendix 1.
<i>Version No. 6</i>	The entire document has been updated with conditions that appear from the framework agreements that start on 1 April 2019. In addition, some new sections have been inserted and the language has been clarified.
<i>Version No. 7</i>	Update with strategic stock as well as changed framework agreement conditions in addition to textual updates.

