

NEWS from Nomeco HealthCare Logistics

THEME: Repackaging

There are many reasons, planned or acute, for having to repack medicine. Let Nomeco assist you.

APRIL 2007



Our Concept is Simple and Effective

Henrik Kaastrup, Director Sales & Marketing

Successful (re)packaging of pharmaceuticals is a matter of efficient logistics, professional QA/QC standards, clear responsibilities for processes and goods and of course competitive pricing. For the last six months we have been focusing on extracting the obvious synergies between Nomeco's knowledge on logistics and our subsidiary Unikem's well known competencies on GMP compliant packaging and repackaging.

Now we are through practicing and adjusting our services and this newsletter marks the launch of our new (re)packaging concept customised to meet the needs and demands of the pharmaceutical industry.

The concept is simple and effective - Nomeco takes full responsibility for the goods from the central warehouse stock (prewholesale) through the (re)packaging operation at Unikem and back to the

stock in Nomeco, ready for sales. Our Key Account Manager for (re)packaging secures a single-point of contact and ensures that terms and contracts are developed to match your company's individual needs.

Our (re)packaging concept encompasses nearly all types of secondary packaging of pharmaceuticals, trial medication and medical devices etc. We are able to perform packaging and repackaging at a pace that can match 'stock out' situations resulting from the 14 days 'Takt' windows or at a more steady pace for the plans made 'well in advance' of market delivery.

So, if you face a (re)packaging challenge and if you prefer not to spend your resources on shipping, product insurance and coordination, we offer an 'all in one' package worth exploring.

Nomeco SupplierDivision becomes Nomeco HealthCare Logistics

Nomeco's SupplierDivision is being renamed. From now on, the division will be named 'Nomeco Health-Care Logistics'.

"Our customers are pharmaceutical companies in Denmark, the Nordic countries and Europe, and in this respect 'SupplierDivision' is neither adequate nor informative. HealthCare Logistics is more accurate in describing what the core competences of our division is - effective logistics customised to the healthcare industry. The new name illustrates the direction of our services, and it hopefully provides better meaning for our customers," explains Jørgen Kelkjær, Director Nomeco HealthCare Logistics.

Simultaneously, we have made a few changes to the organisational setup. The sales, administration and specialist functions are separated, similar to the setup found in the pharmaceutical industry. The goal is to make the organisation more transparent and customer-oriented. The new organisational diagram is available on our new website www.nomeco.dk. More information on Nomeco HealthCare Logistics will follow within a few weeks.

Editorial	2
Repackaging in a Jiffy	4
3 Cases About Repackaging	8
It's a Necessity to be elaborate	12
Hospitals Need Barcodes	16



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Repackaging in a Jiffy

There are several reasons, whether planned or acute, for having to repack medicine.

For instance, the necessity for having to change the packaging size and therefore the product number, new demands from the Danish Medicines Agency regarding the package insert or the need for having to adapt a medicinal product to the Danish market. These are just a few reasons why repackaging may become essential for pharmaceutical companies.

This task is handled by Nomeco in a quick and professional manner. All it takes is a phone call to Key Account Manager Mai Loan Le, in order to get the ball rolling. Nomeco collaborates with Unikem, who are specialists in packing and repackaging at GMP level, in order to fulfil the assignment.

Planned or Acute

CEO Morten Just Blangsted explains how Unikem solves the repackaging assignments, where the product is packed or repacked on a regular basis, as well as acute and urgent assignments.

“On all the assignments we produce a packing instruction, which we thereafter follow on every occasion. The urgent repackaging assignments often arise in connection with the alteration of charges, where the producer may have a hard time living up to delivery commitments and therefore be unable to stay within the rate. For instance, one may run out of packages with 28 pieces. In this case the solution may be to divide larger packages or to gather smaller packages. There may also be an acute need to add a Danish packing insert and a Danish label on a foreign package- or a foreign label on a Danish package. All this can be done swiftly, if the need arises,” states Morten Just Blangsted.

Close Collaboration

Unikem is an integrated part of Nomeco’s logistics chain. “We perceive ourselves as one company and as a customer you will not have to function as a coordinator between the two. We handle all of the

continues ...



CEO Morten Just Blangsted, Unikem, and Key Account Manager Mai Loan Lee, Nomeco HealthCare logistics, work in close collaboration when solving repackaging assignments. Nomeco has a §39-license for distribution, and complies to GDP standards, while Unikem has a §39-license for pharmaceutical production and complies to GMP standards. This makes the two a perfect match, who operate by the watchword: 'Do, what you do best!'

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We are inspected by the Danish Medicines Agency on a regular basis, and moreover attend 20 to 30 customer audits a year, all of which help to ensure a high quality standard.

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steps, from arranging the assignment with Unikem, to securing the correct documentation and ensuring that the products will be transported back and forth, etc” promises Mai Loan Le, who is Nomeco’s Key Account Manager in this area.

“However, it is not the case that, as a customer, you have no contact with Unikem, who carries out the assignment. Unikem will contact the customer directly in order to ensure that all the details are correct, for instance; where the label is placed on the package or how the LOT number should be printed. All this is written in the packing instruction, the document which accompanies the product.”

Once the packing instruction is signed it functions as valid batch documentation. It is also this

document, which is used to release the product thereafter. This is an important step in the process, since the Danish Medicines Agency requires both a packing instruction and batch documentation.

The Best Quality

Unikem possesses a § 39-license, which permits them to handle open units. “We have just over 60 employees. Four of them are pharmacists, which first and foremost ensure double-checking and quality control. We are inspected by the Danish Medicines Agency on a regular basis, and moreover attend 20 to 30 customer audits a year, all of which help to ensure a high quality standard,” reports CEO Morten Just Blangsted.

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Facts

Unikem can handle registered pharmaceuticals, including refrigerated products; as well as narcotics, trial medication and branded goods. A repackaging assignment often includes the following:

- Altering the package size
- Labelling
- Replacing packing inserts
- Adding batch numbers or expiration dates to labels
- Printing directly on packages or cartons



Facts

Nomeco HealthCare Logistics designs and plans the assignment along with the customer. The details regarding the repackaging are agreed upon with Unikem, whom also supply the physical surroundings. Once the repackaging is complete a Control Pharmacist will check to see, that what the customer has ordered in the packing instruction, is also completed and documented. Thereafter, most customers will request a reference sample, prior to the product is released for sale.

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Cases

About Repackaging



Case 1



Statens Serum Institut sent their large volume products to Unikem for packaging, and they were very satisfied with the collaboration.

'Statens Serum Institut' is a Regular Customer

The Danish 'Statens Serum Institut' has for a number of years utilised Unikem in order to pack their vaccines. The institute, themselves, remains in charge of checking and labelling the bottle caps, which thereafter are sent to Unikem along with the other bare materials, which the bottles are to be packed into. Unikem ensures that the vaccines are packed and that the labels are printed with variable data such as batch numbers and expiration dates.

"It is in particular the large volume products, which we send to Unikem for packaging. We regularly send products back and forth three times a week, which amounts to 100-150,000 capped vials on average. The larger assignments involve more than 70,000 packages, while the smaller assignments involve as few as 5,000 packages; this is an exception and not a rule. Thus the assignments vary greatly," explains M.Sci.Pharm. Mette Munch Hansen, who is the superior at the Danish Statens Serum Institut's packing facility.

The department includes about 25 employees and handles a number of packing assignments on their own. However, they do not have the resources for the larger packing assignments; which they sometimes come across.

"It is critical for us to be able to trust the supplier when we outsource large assignments, further we demand that all packing and repackaging follows GMP criteria. To date we have had very few complaints and no withdrawals, including the products packed at Unikem," pinpoints Mette Munch Hansen.

She is extremely satisfied with the collaboration and praises Unikem for continuously developing and remaining open to new suggestions, which may improve the process. "They are very willing to communicate and therefore the packing process is continuously being developed. Unikem fulfils all of our expectations. This is also the conclusion we reached at our recent audit."

Urgent Assignments Dealt with on Record Time

When Bayer needed to re-label 21 pallets of infusion bags from Belgian to Danish, it needed to be done quickly. The Danish hospitals had almost run out of Ciproxin Infusion, therefore it was important to get the necessary supplies into the country as quickly as possible.

“However, our production site in Leverkusen was having trouble with production; therefore we were offered Belgian packages instead. In the mean time, the Danish Medicines Agency required the packages be repacked in order to enter the country. And since the product in question was an antibiotic, it was a matter of life and death, with the shelves in the hospitals almost empty,” explains controller Erling Nørgaard from the Pharma division at Bayer Healthcare.

He therefore immediately contacted Unikem, whom Bayer previously used for repackaging. And

then the pace took off. The products arrived on Tuesday and on Thursday afternoon the first 8 pallets were ready for delivery. The remaining were ready on the Friday.

This was a larger assignment with more than 1200 cartons, each of which contained 12 infusion bags. The outer carton was equipped with Danish product numbers as well as Danish marketing numbers. Moreover, each individual flexibag was fitted with a label, so everything had to be opened and taken out.

“We were extremely impressed by how fast Unikem was able to handle such a large assignment, on such short notice. The service was carried out quickly in an emergency situation, where it was a question of life or death. So at Bayer we are very impressed,” concludes Erling Nørgaard.



Case 2



Bayer used Unikem to re-label 21 pallets of Ciproxin Infusion. It was a question of life or death, as the Danish hospitals had almost run out of the life-saving antibiotic. It took less than two days for Unikem to deliver the first 8 pallets.

Handling a Variety of Repackaging Assignments

In the summer of 2006, Janssen Cilag elected Unikem to solve their repackaging assignments. “Previously we have been able to carry out repackaging by ourselves, this was when our warehouse was right next door and we were thus able to keep track of the process. However this is no longer the case, therefore we have chosen to cooperate with Nomeco on repackaging assignments,” explains Logistic Manager Malou Lyngsie from Janssen Cilag.

Having reduced the amount of work pressure on the company, this is a decision she has not yet regretted. “We have a variety of repackaging assignments to be completed, therefore the workload and frequency is constantly fluctuating,” remarks Malou Lyngsie.

Typically the assignments involve inserting a Danish packing insert into the carton. This sort

of assignment usually arises on an ad hoc basis. However, Janssen Cilag also has regular repackaging assignments where for instance, a drug needs to be repacked from a 7 piece pack to a 1 piece pack; as an extra service. In addition, acute assignments may also arise on occasion.

“We are pleased with Unikem, and the quality they supply. If there is the smallest doubt regarding any details on the packing instruction, they are excellent in getting in touch with us immediately.”



Case 3



Janssen Cilag cooperate with Nomeco on a variety of repackaging assignments. Typically the assignment is to remove a foreign packing insert from the carton and replace it with a Danish packing insert.

It's a Necessity to be Elaborate

Preliminary control, process control and double-checking. Unikem has built in a number of internal control processes in order to guarantee zero mistakes. The processes may appear elaborate and complicated, however they are a necessity.

“They might appear elaborate, however they are a necessity. The customer needs to feel completely reassured in our capability to handle the assignment and not to accept mistakes. We have just about reached our set target with help from systematic process control.” This is the conclusion reached by Production Planner Mads Strandløv Nørgaard, who is primarily in charge of repackaging at Unikem.

Unikem specialises in repacking pharmaceuticals, moreover with large capacity are able to divert a large number of resources to urgent assignments. “The type and amount of workload each assignment requires is variable. This month we are replacing 26,000 packing inserts. Furthermore, it is variable how emergent the assignments are. Some assignments need to be completed from one day to the next, while others can wait a few weeks.”

Specialists will solve the Problem

All repackaging is carried out manually, while assignments such as attaching labels on small capped vials or cartons of small tubes are carried out by half automatic machines. Mads Strandløv Nørgaard points out that the benefit of using manual labour is that they easily can assign extra staff to the assignment. “A machine is unable to work any faster than it's capacity, therefore in most cases we cannot rely on machines for this type of work. It is often the case that the batch sizes are relatively small, therefore we are often better off solving the assignments manually, since many of the routines only can be solved by manpower.” The operators who work with repackaging on a regular basis are specialists in this area. “We may have to use temps if we are particularly busy, however they are not allowed to carry out essential assignments. For



Production Planner Mads Strandløv Nørgaard, Unikem, is in charge of the packing and repacking assignments. Here he is entering one of the special rooms only used for packing and repackaging.

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instance, they may open packages which require a new packing insert, however they may not check and secure the package again,” he says.

Repackaging in a Controlled Environment

Products that need to be packed or repacked are received from Nomeco or directly from the producer. Here they are checked by the operations assistant and thereafter a quality control assistant, also known as an acceptance check. Hereafter the pharmaceuticals are placed at the control gate, where they are transported from wooden to plastic pallets.

This is because wood is not allowed in the room where repackaging takes place, since it is a ‘controlled environment’ where the particle level needs to be kept under a certain level. Moreover, everyone entering this area needs to pass through an air lock

where they are to put on a working coat, special footwear and a hairnet.

Unikem has several rooms in which repackaging may take place. Only two products are allowed to be repacked per room and this is only if they cannot be confused with one another. Furthermore, a screen must be set up in order to keep the two repackaging tasks separate.

Keeping a Log Book

A kept log book documents all the activities which are carried out in the two repackaging rooms. Here it is clearly documented which products are repackaged and when. Moreover, batch numbers and operators are noted down with care, and someone signs in order to confirm ‘lineclearance’. This means that the room has been cleared for materials from the last assignment, before a new may start.

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Once the operations assistant is finished, Unikem’s four pharmacists will conduct a final inspection and approve the repackaging assignment.

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All the activities in the packing room are clearly documented; once the product is removed from the control gate an operator will carry out a preliminary control, while someone else will check and sign for that this has taken place, and that the room is ready for action. Hereafter the repackaging assignment may start.

Double-checking the Packing Flow

Packing assignments are always double checked, which means that several people are always involved in solving an assignment. If a packing insert needs to be replaced, one operator will open the box and remove the old packing insert, while another operator will replace the new packing insert. Additionally, a third person will check to see that the assignment has been completed and in turn close the boxes again.

“The same principle accounts for the larger assignments with several functions; one thing is done at a time and then the assignment is passed on to a colleague. This allows employees to check each others work,” explains Mads Strandløv Nørgaard. Further, every half an hour the operators carry out a process control of their work. This entails documenting that a few packages are picked up and checked.

Double-checking Numbers

Checking that the operator knows exactly how many packing inserts are received and how many are replaced are all part of the daily routine. It is important that the numbers match up and that no packing inserts are leftover once the assignment

is complete. As an extra precaution the operator will count the old packing inserts before they are destroyed, or whatever the customer wishes done with them.

“A lot is done to make sure the counting is accurate. If a packing insert is leftover once the assignment is complete – then we will start over,” informs Mads Strandløv Nørgaard. He adds that this is rarely the case.

“All this is noted in the packing instruction, which is prepared for each repackaging assignment. The packing instruction is filled in throughout the process and is later utilised as batch documentation for the given assignment. Here the assignment is defined accurately and the form is approved by the customer before we start the assignment.”

The Customer Approves and Releases

Once the assignment is solved the product is quarantined until it is approved. “When the repackaging is complete, the production assistant completes the process with a final check; here the products are checked and the batch journal is reviewed from A to Z. Once the production assistant is finished, Unikem’s four pharmacists will conduct a final inspection and approve the repackaging assignment. Hereafter sample references along with a copy of the batch documentation will be sent to the customer, who thereafter will release the products. Once documentation of this release is received, the product can be sent to Nomeco or the customer,” concludes Mads Strandløv Nørgaard.

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Everyone entering the area used for packing and repackaging needs to pass through an air lock where they have to put on a working coat, special footwear and a hairnet.



Facts

UNIKEM

Unikem A/S is a pharmaceutical company who specialises in delivering analysed pharmaceutical raw materials to private pharmacies, hospital pharmacies, as well as to the pharmaceutical industry. Moreover, Unikem produces drugs and chemical kits as contract work- for instance, mixing and tapping liquid products and suppositories. In addition, they carry out a number of production assignments such as the repackaging of pharmaceuticals.

Unikem A/S is a 100% owned subsidiary by Nomeco A/S and is situated at Halmtorvet in Copenhagen.

Hospitals Need Barcodes

Today hospitals request that all medicine be marked with barcodes. This is essential in order to ensure patient safety and a necessity for the hospitals to be able to check and control the dosing of medicine. However, it is far from all medicines that live up to this requirement. Often medicines only have barcodes on the secondary packaging material and not on the primary packaging material, while others fail to have a barcode at all. This is a problem since the outer packaging is often discarded, resulting in the loss of the barcode.

Pharmaceutical companies, who wishes to help the hospitals by improving patient safety, will need to ensure readable barcodes on the primary packaging material. If you need assistance in producing additional labels with barcodes, feel free to contact Nomeco's Key Account Manager on Repackaging.

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