NEWS from
Nomeco HealthCare Logistics

JULY
2007

Nomeco makes complex "Clinical Trial Supply" easy and offers to distribute your medical samples directly to doctors. Both services are critical to the Pharma industry and our documented solutions secures compliance with all relevant legislation and standards.

Nomeco
HealthCare Logistics

Feel Free to be Inspired

By Jørgen Kelkjær & Henrik Kaastrup

Throughout the past four issues of this newsletter we have focused on specific business areas, such as Nordic central warehouse solutions, general logistics, business intelligence and repackaging. In this issue we have chosen to take a different approach – rather than focusing on a specific theme we would like to address some of the specialised services we offer, targeted at solving complex challenges for the Pharma industry, ranging from handling investigational medication to distribution of medicine samples directly to doctors.

Finally, upon request from several Pharma companies, we also feature an article exploring one of the major trends of the private pharmacies – the implementation of robots.

Although this newsletter was not intended to have a specific theme there seems to be a common reoccurring theme anyhow – since all articles are about solving complex problems and challenges, by developing and employing practical solutions throughout a close partnership.

We hope you will enjoy reading this newsletter and that you will feel inspired to challenge Nomeco HealthCare Logistics, to further strengthen our relationship and the solutions we offer.

We wish you all a warm and relaxing summer …

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CTSM

Clinical Trial Supply Made Easy

Supplying the correct trial medication, in the right way, at the right time, to the right person is a highly complex administrative task, especially since every step has to be documented at GMP-level. Nomeco has developed a solution, which handles the complexity and turns trial supply into a simple task for the Pharma Industry.

Nomeco's unique position in the pharmaceutical supply chain and key competences within healthcare logistics is the foundation for developing a new state of the art service to the Pharmaceutical Industry: Nomeco's Clinical Trial Supply Management (CTSM).

The solution is designed to enable pharmaceutical companies to outsource all or parts of their trial supply operation. Further, pharmaceutical companies can select to utilise Nomeco's GMP, GCP, GDP and GLP compliant production, warehouse, laboratory facilities and staff, in connection with conducting clinical trials.

"We can assist the pharmaceutical companies in all steps of the Clinical Trial Supply process, from packaging over global distribution, to accountability and destruction of excess materials. It is important for us, that Sponsors have full insight and control over the processes performed by Nomeco, but with a minimum effort from their side" informs Marianne Søndergaard, Medical Affairs Manager in Nomeco.

Use Nomeco's standard or a tailor made solution

Nomeco offers a fully functional and "ready-to-use" set of CTSM SOP's and forms, which makes it possible to cut off timeconsuming steps, when initiating the active phase of a study. Depending on volume and complexity a normal clinical packaging task can be completed within 15 workdays. Preparing the distribution phase can usually be done parallel to the packaging process and requires approx. 10 workdays.

"Our solution is flexible and can be customised to meet the specific design of each specific trial and/or Sponsor. Some studies are handled 100% according to the Nomeco Standard Solution, whereas others are 100% tailor fit. However, the most common method is somewhere in between, just as it is for one of the companies who have recently outsourced all of their clinical trial supply management to Nomeco. They wanted their own Regulatory Green Light and Confirmation of Receipt integrated with Nomeco's documented standard workflow for storage and distribution. This was agreed on, by both parties, in the beginning and then described in

Facts: Nomeco Storage Facilities

Nomeco's Warehouse is GDP compliant and approved by the DKMA. Trial medication is kept in a dedicated and isolated area where only authorised personnel have access to the CTSM Stock. Nomeco offers both ambient (15-25 °C), cold (2-8 °C) and frozen (below -18 °C) storage. All storage areas are temperature and humidity monitored.

the study specific "Study Supply Manual", which is prepared for each trial handled by Nomeco," Marianne Søndergaard reports.

Setting up a clinical trial supply solution begins with an initiation phase, where employees from Nomeco's Medical Affairs department and the Sponsor define how the individual services are conducted, whether new SOP's or forms are needed etc. The terms are documented and approved by both parties.

Global sourcing of trial materials

Nomeco has a highly skilled purchasing department and is very experienced in sourcing products from all over the world.

In connection with CTSM, these skills are used to offer efficient and reliable global sourcing of comparators, add-on medication and other products needed in clinical trials. This could be country specific packages for studies conducted in several countries or a specific Danish product relabelled with multilingual labels.

Since Nomeco is licensed to import/export pharmaceutical products and operates its own

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Cand.pharm, Marianne Søndergaard, Medical Affairs Manager in Nomeco, assists the pharmaceutical companies in all steps of the Clinical Trial Supply process - from packaging over global distribution, to accountability and destruction of excess materials.

Trial Design Phase:

- Sourcing of support medication and comparators
- Sourcing of packaging materials
- Logistics consulting and planning
- Translation (coordination with agency/Sponsor and review).

Trial Supply Packaging Phase:

- Design of patient packs
- Label design and printing
- Bulk handling and storage
- Packaging (active substance, placebo and references)
- Pilot-scale production (i.e. blistering)
- On demand assembly

Trial Supply Logistics Phase:

- Receipt of investigational materials and resupply
- Import control / receipt inspection and customs clearance
- Receipt of shipment requests and service to sites, sponsor or CRO staff
- Storage of bulk, packaging materials and investigational medication
- Pick and pack of shipments
- Global distribution incl. track and trace

Post Logistics Phase:

- Return handling (accountability and storage)
- Destruction
- Chemical quantitative analysis (Ph.Eur)
- Stability testing
- Quantitative weighing
- Final hand over of Study Documentation package incl. forms and SOPs (ICH and Annex 13 compliant)

GMP-production facilities, it is possible to source, purchase, repack/relabel comparators and other products, all in one workflow.

"The main challenge in sourcing comparator drugs from other producers is their request for information about the clinical project before agreeing to supply. Often Nomeco solves these difficulties by sourcing through an international wholesaler network", explains Tina Holstein Hansen, Nomeco's specialist in global pharmaceutical sourcing at Nomeco.

Maintaining the Cold Chain

Nomeco offers all relevant types of shipments. In this regard, there are almost no geographical limitations in regards to destinations. Further, Nomeco can offer shipment of cold storage medication to almost any destination.

The domestic distribution of cold storage products is validated, during distribution from Nomeco to the sites. For export, Nomeco recommends courier transport in validated thermo-boxes or refrigerated vans.

The optimal shipment method (transportation, security, tracking, packaging materials etc.) is normally decided in corporation between Nomeco, the sponsor/CRO and sometimes the receiving sites.

GMP Level Documentation

The right level of documentation is essential when it comes to performing clinical trials. Nomeco's CTSM services comply with relevant GCP, GMP and GDP regulations and standards, and provides full documentation of all parts of the process. The documentation covers i.e. SOP's, Inventory flow, packaging specifications, shipments, deviations etc. All SOP's, instructions and tools are electronically controlled in an internal quality process specification system. Documentation of study specific transactions (i.e. goods receipt and shipments to sites) and staff training are performed manually, allowing the Sponsor to receive the original documentation at the end of each trial as needed for the Trial Master Files.

Nomeco has extensive experience on quality assurance techniques and will monitor and supply the Sponsor with necessary documentation on request i.e. prior to an Audit.

Site Service

Nomeco Site Service includes receiving shipment requests from sites by e-mail or fax, coordinating shipments with the receiving site (i.e. notifying the site by e-mail on dispatch from Nomeco), follow-up on the receipt of shipments and being available for questions by phone or e-mail. The Site Service is also involved in contacting sites to make sure there will be personnel present to receive shipments. It also includes coordinating the pick-up of return medication from the sites.

Marianne Søndergaard quotes: "Any site involved will benefit from our Site Service setup in regard to availability and our proactive problem solving capability. By keeping in mind this is an area of "clockwork precision," we never loose sight of our goal, which is making everything work smoothly and providing satisfied customers".

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CTSM

Effortless Administration and Satisfied Sales Reps

Satisfied sales reps, lighter administration, economised use of internal resources and correctly distributed samples – are benefits Boehringer Ingelheim have taken advantage of, since deciding to outsource the handling of samples to Nomeco.

It was the increasing dissatisfaction from Boehringer Ingelheim's approx. 30 sales reps, which encouraged the company to look around for a better way to handle their pharmaceutical samples. The distribution of samples to doctors and special doctors had been heading downhill for a while. The sales management at Boehringer Ingelheim was annoyed with this development, being aware of the marketing value samples offer.

"The sales representatives were generally dissatisfied with a number of points regarding the way we handled the distribution of our samples. Each sales rep had to have a local supply of samples stored. For security reasons they could not be left in their car, which meant they had to empty it each evening. Moreover, a number of storing precautions had to be carefully followed, for instance preventing children and pets from getting a hold of the medicine. Additionally, the sales representatives had to keep monthly accounts of the samples. These are assignments, which the sales representatives found unproductive and time consuming. They are more interested in contacting the doctors and handing-out samples, than with the follow-up administration," informs Kim Hannibal, Sales Manager.

Chose eLMK Direct

Something had to be done, therefore at the turn of the year the company started using eLMK Direct. Practically, this means that the sales rep does not bring the samples along when visiting the doctor, but agrees with the doctor which samples he will receive. Thereafter a requisition form is filled out and sent to Nomeco. Nomeco enters the data into the system, simultaneously checking to see if the doctor has received the sample previously in the current calendar year. Once the requisition form has been approved in eLMK, the samples are picked and along with the product resume, are sent directly to the doctor. The samples distributed, are transferred via a file from eLMK Direct to Boehringer Ingelheim's Customer Relationship Management-system (CRM-system).

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Facts: eLMK

Via a web-based solution the sales rep can, independent of time and place, order pharmaceutical samples. Thereafter, the company will approve the order, if the optional clearance flow is activated. Next, Nomeco will print the requisition forms, pick the samples and apply a label reading "Free sample – not for sale". The samples and requisition forms are either sent directly to the sales rep, or alternatively to the closest Nomeco branch, where the sample are picked-up by the rep. The sales rep will bring along the requisition form and sample when visiting the doctor. This way she/he can hand out a sample upon request. Subsequently, the sales rep will enter the hand-out of the sample into the eLMK system.

eLMK also features a auto-order-loop. In this case each sales rep is initiated with a certain stock of samples and based on the sales rep's registrations and the predetermined delivery frequency, Nomeco will ensure an automatic supply of samples and requisition forms.

At Boehringer Ingelheim it is no longer a requirement for the sales rep to keep their own local supply of samples. The result is an empty trunk in the car and being free from having to handle multiple boxes. This is one of the reasons why Pharmaceutical Sales Rep Arlette Scheuer and Sales Manager Kim Hannibal are both satisfied with eLMK.

Facts: eLMK Direct

In the newest version of eLMK the sales rep will not bring along samples when visiting the doctor, but instead a dummy product and a requisition form. During the visit, the doctor and sales rep, will agree upon which samples the doctor shall receive. The sales rep then sends the signed requisitions to Nomeco, who will check if a similar sample has been requested before. If not, Nomeco will send the required samples to the doctor via post. Finally, Nomeco will file all the signed requisition forms and post a copy of the form to the company for future reference.

Further, in connection to the eLMK Direct solution Nomeco offers to send SPC's or other printed materials along with the medical samples.

Pharmaceutical Sales Rep Arlette Scheuer:

"It is 100 times easier with the new system. Not only am I free from having to drive around with the samples in my car, but I no longer have to deal with all the administration. I have no interest in it – the exciting part of being a sales rep for a pharmaceutical company, is the opportunity to work with the doctors and this is what I would like to be able to focus on. I have the opportunity to do so now, since I no longer have to keep accounts of the samples," says sales rep Arlette Scheuer.

She describes eLMK Direct as a good safety system, since she no longer has to be concerned with whether she is distributing too many samples. "It is easy to check the system to see, which samples are sent to which doctors and when. It is also an advantage that the doctor receives a reminder twice. When I visit the doctor to discuss the sample, I carry an empty package in my bag. The doctor is reminded once again, when the sample arrives after a fortnight.

Today the system works effectively and our sales reps are extremely satisfied. It is no longer necessary for them to keep an individual store of medicines in various packages and strengths. Furthermore, they no longer have to consider the particular storage conditions or keep account of their distributions. Through our CRM-system our sales reps can see who has received what and when," Kim Hannibal explains.

He stresses four areas which are important in regards to the sales force: focusing on sales, professional value for the doctors and maintaining a strong relationship with the target group. Further, it is important that the sales reps are pleased and satisfied with their jobs. The Sales Manager emphasises, that eLMK Direct is a perfect fit.

The company distributes between 12-15,000 packages of human medicine each year. Approximately 3000 postages, with 3-4 packages in each, are sent out per year.

Steering clear of destruction

Since Nomeco has acquired the responsibility for the requisition forms, the administration has become lighter. The warehouse personnel are satisfied with no longer having to spend time posting samples and handling those returned.

Kim Hannibal emphasises how, this way, their company steers clear of having to destroy massive amounts of pharmaceuticals. "This is an advantage we can feel directly in our pockets. Previously, we destroyed large amounts of pharmaceutical samples, for instance if a sales rep quit their job and their samples were returned to us. I estimate that we save approximately 25,000 kr on account of this."

Living up to the rules

"Finally, our internal registrations have become optimal. Our sales reps were not very good at reporting back on accounts and requisition forms, thus giving us trouble. However, today we live up to the rules 100 %, regarding distribution and handling of samples. Therefore we have nothing to fear if the authorities come for a visit."

The rules state that only one sample, of the smallest package, per drug, may be distributed to each doctor once a year. If these rules are not maintained, the company may risk having to pay a fine.
Despite never having received a fine, Kim Hannibal remembers a summer where "our Sales Director spent the first week of his vacation, getting on top of the company's accounts of sampling, and distributions thereof," he explains convincingly.

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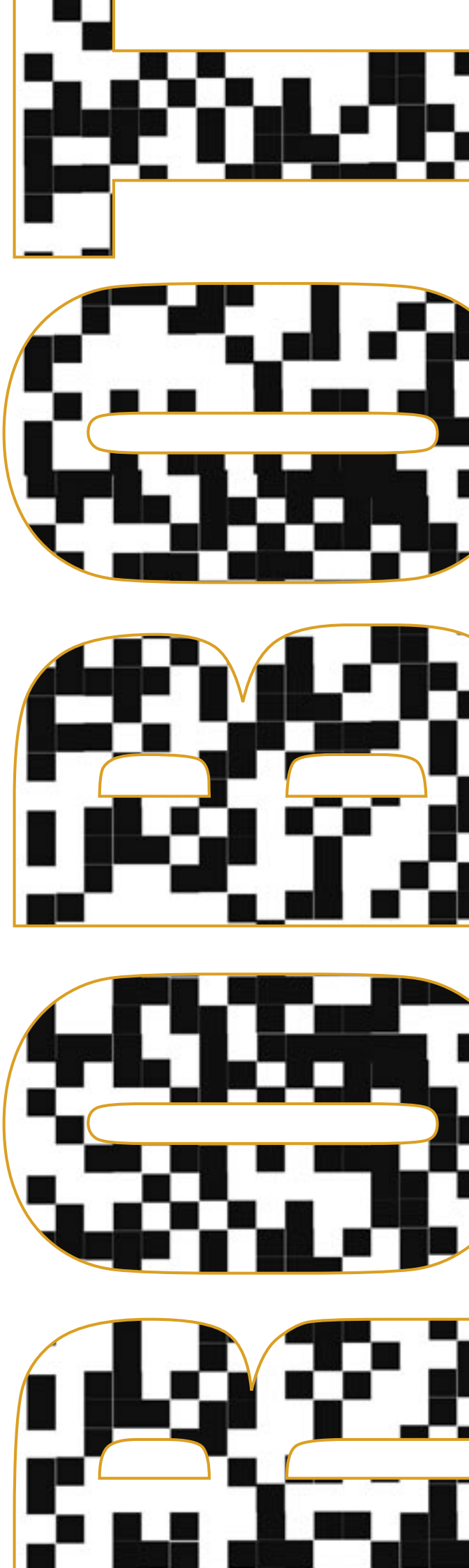
The Shape of Packages Challenge the Robots

Soon every tenth Danish pharmacy has a robot; handling their warehouse, and locating and fetching their products. This sets requirements for the product's packaging and barcoding.

The Danish pharmacies are increasingly serviced by pharmacy robots. A number of robots are available on the market, each with slightly different purposes. However, the tendency leans towards pharmacies opting for fully-automatic robots. These are able to shelve products inside the robot and simultaneously 'pick' the products upon request.

In other words, one puts the pharmaceuticals on a conveyor belt at one end of the system and they are retrieved at the pharmacy's counter once the receipt is handled.

"By the end of the year approx. 10 % of all pharmacies will have purchased a robot – a number which is likely to increase over the years to come. There are a number of benefits with using the robots. For instance, they may relieve the pressure on logistics and rectify for the shortage of staff, which also the pharmacy sector is likely to be burdened by in the future," predicts Claus Faurschou Larsen. He is Nomeco's adviser for pharmacies concerned with the robot issue.



Every fourth package is round

Further, he receives an increasing number of requests from pharmaceutical companies, wanting to know how they best can adapt their products to fit the robots.

This is with good reason, since the robots find round packages challenging. Therefore, it is unfortunate that 25 % of all administered pharmaceuticals on the Danish market are round. This is an extremely high percentage, in comparison to Germany, where only 5 % of the packages are round.

”The robots cannot immediately handle the round packages. This means that the robot must either be fed manually with the round packages or they are put in a box. And when approximately every fourth package needs to be handled manually, this may lead to high expenses. Therefore, many pharmacies choose to abandon the robot solution for the high frequency, round packages, and place them on shelves in the shop area,” informs Claus Faurschou Larsen.

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Claus Faurschou Larsen is a Market Developer and Nomeco’s expert when it comes to pharmacy robots. He has also started counselling the pharmaceutical industry, on adapting their products to the new technology.

Round shaped packages can cause

PROBLEMS

Coloured barcodes on packages can cause

PROBLEMS

He encourages the industry to take note of the situation and take it into account when designing or re-designing new packaging.

Remember the barcode has to be black

Also barcodes are of increasing importance to the pharmacies. Partly because the robots utilise the barcodes to identify the medicine and partly because the barcodes are used as the primary method for checking the product in connection with distribution. This means, that there is rarely the need for human double-checking.

"Today the barcode on the receipt and the one on the pharmaceutical are scanned and checked to see if they match. Thereafter the label with the patient's name, dosing and instruction is printed and applied to the package before the medicine is handed out. As a result, to ensure quality and safety, all outer packaging needs to be fitted with a barcode, this should be printed in black. It is likely, that the robot may have trouble scanning barcodes in other colours," explains Claus Faurschou Larsen.

Two-dimensional barcodes on their way

He predicts a development within barcode technology; they have become two-dimensional and therefore can contain a lot more information. There is a need for this in the pharmaceutical area:

"From the 1st of April 2007, the wholesaler and the pharmacy, are required to register the batch-number on all there veterinarian medicine. Several manufacturers of veterinarian medicine have already started applying two-dimensional barcodes on their products. This two-dimensional barcode allows the registering to be done electronically, ensuring a safer and more effective handling than the one completed manually today," reports Claus Faurschou Larsen.

He foresees that in time the authorities will require that all human medicine is batch-number registered. "Therefore, we can expect that the demand for two-dimensional barcoding to spread. It is necessary that the industry starts preparing for this," advises Claus Faurschou Larsen.

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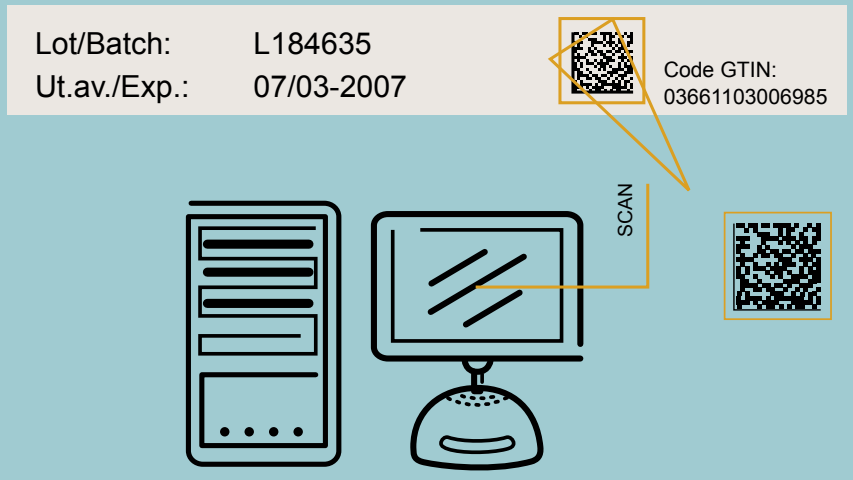
Two-dimensional barcodes

The two-dimensional barcode, where datamatrix is the international standard, can hold more information than the present one. This means that the barcode is able to hold information regarding the product's identity, expiry date and batch-number. Several manufacturers of veterinarian medicines have started to make use of the two-dimensional barcodes. The 1st of April it became a requirement in Denmark, that all veterinarian medicine should be registered by batch-numbers. Both the wholesaler and the pharmacy, now have to register who has received what batch-number. This is a link in the chain in implementing EU's programme 'From earth to table' ('Fra jord til bord'). The veterinarian pharmaceutical industry in Europe has agreed to apply this barcode on their products, before the end of the year. It is predicted, that the requirement for batch-number control will be increased to cover human medicine as well.



Morten Just Blangsted
Site Director
Nomeco Site Halmtorvet

UNIKEM

Unikem Merges with Nomeco

Nomeco and Unikem are already well established outsourcing partners for the Pharma industry and Hospitals. On the 1st of June, the two companies merged and Unikem became an integrated part of Nomeco HealthCare Logistics.

”Our customer base is the same irregardless of our services and therefore it makes sense to manage our customers professionally as a whole. This way we can obtain a central position in the market,” explains Site Director Morten Just Blangsted, previous Director of Unikem.

With a significant expertise in GMP-level packaging, sales of raw materials and laboratory analyses, Unikem is the preferred partner for a number of industrial and public sector customers, within the food and healthcare sectors. With their 65 employees, Unikem prevails over a number of laboratories, as well as storage and packing facilities at Halmtorvet in Copenhagen.

The services offered by Unikem today will continue to be readily available via Nomeco HealthCare Logistics. The future name is ’Nomeco Site Halmtorvet’, while ‘Unikem’ will remain a brand on certain products and services.

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