

Flow



No. 3 - October 2011

Check out the
Cool News

REPACKING:
Quickly back
on the market

EU:

Draft for new
GDP-Guidelines

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Column 2

Repacking in Nomeco – qualified, fast and simple 3

Cool news:

- More goods to be kept in cold storage 4
- A cool new solution 4
- Nomeco can sample refrigerated products 6
- Refrigerated products to Iceland wear 'a thermo coat' 6
- Suppliers: Enthusiasm for OnSite Stock 7

GDP version 2.0 8

Update:

- Mark the day: Nomecodagen 2012 10
- New loading dock 10
- 100 Nomeco employees competed in the DHL race 10
- Nomeco helps fighting breast cancer 11
- Unit for Legal Affairs 11
- PharmaGolf 12



A BUSY AUTUMN AGENDA

→ By Henrik Kastrup, Director Nomeco HealthCare Logistics



At this point of the year most of the pharma industry is busy focusing on executing the remaining plans for 2011. And, if not already started, the planning and budgeting for 2012 will soon begin to occupy most agendas.

At Nomeco we close the business year 2011 at the end of January 2012, but before we get there a very busy and highly interesting autumn awaits us. At the top of the agenda

is, of course, the result of the election in Denmark which will set the direction for the healthcare agenda looking forward – not least for the political conclusion that will follow when the current analysis of the pharmacy monopoly is completed in April next year. The new government has added the pharmacy sector to the government platform and emphasized that core healthcare services and elements such as availability and professional advice are important factors in a modernisation of the pharmacy sector. It seems that it is no longer just a question of generating more competition in order to create lower prices.

The analysis of a possible liberalisation of private pharmacies continues and is being conducted by a group of people mainly appointed by the Ministry of Health and the Danish Medicines Agency. At this point, it seems as if the group has chosen to work independently and somewhat behind closed doors. Nevertheless, together with several other organisations and interest groups, Nomeco was given the chance to give input to the working group at a meeting at the Ministry of Health.

And to put it bluntly: At Nomeco we find the potential liberalisation of the private pharmacies to be a simple but almost religious question of whether medicines should be part of the healthcare system along with doctors and nurses, or part of the retail sector. At Nomeco we strongly prefer to keep medicines within the secure and regulated fences of the healthcare system. That is simply because we find medicines to be too critical to be commoditized. However, this does not mean that we find the current system perfect. Not at all. And we welcome initiatives to modernise the way things are done today. But, we simply find the downside and potential risk of tearing down the current system too great, just to shorten the queues.

Speculations and debate around the topic of a potential liberalisation will, of course, continue through the autumn and winter and into the spring and summer next year. Currently, the odds at Nomeco point in the direction that we will not see a liberalisation for many years - and we cross our fingers that it is not pure wishful thinking.

Well, while we await the outcome of the analysis there are many other things on the agenda, which potentially could also cause great impact on our industry. Take, for example, the newly issued EU draft for the updated GDP Guidelines. Here the industry might also face a big challenge throughout the entire supply chain. The details of the draft are covered later in this issue of FLOW – which I really hope you will enjoy reading ...

Repacking in Nomeco - qualified, fast and simple

Nomeco now offers repacking and since products are often in stock in the warehouse, valuable time is saved.



← In connection with the facilities for the handling of clinical trials (CTSM) Nomeco has established a special room for repacking. It is also ideal for repacking of commercial medicines, and it is located next to the Central Warehouse which makes the transport easy and saves time.

To an increasing degree, the medicines market in Denmark is characterised by tough competition on the availability of products. Authorities and customers have a low tolerance for failure to supply. In situations where, for one reason or another, the packaging suddenly has to be changed it can consequently be crucial that this is done fast and efficiently without compromising quality.

Nomeco is now, to a higher degree than earlier, able to help in precisely these situations.

In connection with the establishment of a unit for the handling of trial medicines, Nomeco obtained its own GMP packing facility four years ago and expanded the §39 permit also to include secondary packing of clinical trial medicines and marketed medicinal products.

Increased capacity

Initially, focus was strictly on packing and labelling of trial medicines – processes that require the highest level of quality and meticulousness. The frameworks were thus laid for an efficient high-quality packing facility. Gradually as the department grew and knowledge of its existence was spread to our customers, the demand for assistance in packaging of commercial medicines grew.

“Nomeco has increased capacity so we can take on tasks of repacking commercial medicines. We have the expertise, experience, facilities and permits in place so

we can just as well let all of this benefit our customers,” explains Vibeke Halskov who is Director of Quality.

The recall was hardly noticed

A current case shows the speed of repacking as the products were on the market again within the same week they were recalled. In practice, this means that the products were withdrawn, repacked, QP checked and back on the market in the course of four days.

Vibeke Halskov states that it is a great advantage that Nomeco already has the products in its warehouse. It saves time and it creates a reliable flow when external transport can be avoided.

“Moreover, we can also keep a watchful eye for our Central Warehouse customers that a product being repacked does not back order all of a sudden. This means that we can plan the repacking taking the market’s needs into account. This gives the supplier a guarantee that for a task in progress there is always stock to meet the current demand.”

Checked by QP

Repacking at GMP level provides security of quality and ensures a fully documented

result. As soon as you change a medicine’s sales packaging, GMP must be complied with.

“If you need a GMP packing task performed, the first step is to enquire at Nomeco. After clarification of the type of task and scope, a batch journal is prepared which is approved in Nomeco’s quality department and possibly by the customer’s QA,” Vibeke Halskov explains.

The batch journal documents the execution of the packing task right from the clearing of the packing area before beginning the task and until the checking of the finished task. All persons involved in the task sign the documents.

The batch journal and the finished task is initially checked by a production supervisor in the department and then by Nomeco’s QP.

“The right GMP quality is in place, the speed is high, and we can keep an eye on the market’s needs. In that way we meet the growing need among our customers who ask for fast and efficient repacking in a smaller scale,” Vibeke Halskov concludes. ■ MWH

Cool News

More goods to be kept in cold storage

Nomeco is experiencing a growing demand for cold storage. There is a definite trend, as confirmed by **Henrik Hansen at UCB Nordic A/S.**



More and more vendors want their products kept in cold storage, and Nomeco has experienced a surge in demand since expanding cold storage capacity.

Henrik Hansen, Supply Chain Manager for the biopharmaceutical company UCB Nordic A/S, confirms that the number of medical products kept in cold storage is growing. "The tougher requirements for storing medical products mean that more and more of them pass through active cold chains. This helps ensure that they are kept constantly in cold storage right from production, through distribution and on to the consumer. We simply want the highest quality assurance possible," explains Henrik Hansen.

Although according to him, it is not just the tougher requirements driving the increased demand for cold storage: "Newly-launched medical products have to increasingly be kept in cold storage, because many of them are biological products. I personally believe that we will see even more investment in the development of biological medical products in the future."

The growing number of cold storage products makes even higher demands of each link in the chain. The process is different compared to handling and storing other medical products, as the temperature of cold storage products has to be constantly checked and logged by manufacturers, wholesalers, distributors and pharmacies.

With the new expansion of cold storage capacity and constant improvements in distribution, Nomeco is already well-resourced to meet the challenge of storing a high volume of cold storage products in the future. ■ MSC

A cool new solution

In spring, Nomeco's headquarters in Copenhagen acquired a new cold storage facility with four high-tech automatic inventory retrieval systems. This makes it possible to store many more refrigerated products in much less space meanwhile reducing CO₂ emission.

A drawer rolls out, tilts slightly and reveals its closely packed content of medicines. A red laser light throws its beam on the location of where the product is to be picked. That is the principle of Nomeco's new automatic inventory retrieval systems which are located in the cold storage at HealthCare Logistics' warehouse.

There are, in total, four such high-technology automatic inventory retrieval systems which are used for refrigerated products with low picking volume. They help to increase capacity in the cold storage, which was put into use before the summer holidays. The automatic inventory retrieval systems mean that you can store a great deal more refrigerated products in much less space. At the same time, a new cold storage facility means that more cooling is obtained from the power used. The new systems are approx. 37 percent more effective than the smaller cold storage facilities, which are now out of operation. Additionally, the new

Four high-tech automatic inventory retrieval systems ensure efficiency, quality and environmental savings in Nomeco's new cold storage. The systems have been supplied by the logistics giant, SSI Schäfer (formerly Handler A/S).

The automatic inventory retrieval system finds the correct drawer and with a laser light points out the pharmaceutical that has to be picked.



Warehouse Assistant Diana Berthou Picks products from a drawer which fits her height and ensures the right ergonomic position.

facilities operate on ammonia, which is a natural refrigerant that does not have an adverse impact on the environment.

Pick-to-light

An automatic inventory retrieval system is a complete and automated warehouse in a huge box. It comprises two shelves with drawers, which are positioned on top of each other. A fast elevator operates in between these drawers, which retrieves the correct drawers containing products, as specified on a control panel by Nomeco's warehouse employee. In addition, Nomeco has invested in wireless picking carts, which will make it much easier to pick the products.

When an employee has to pick an order, this takes place by logging on to the automatic inventory retrieval system via a computer screen. Here, the order to be picked is selected and is then paired with a location on a wireless picking cart.

When the picking commences, a screen displays, the box in the automatic draw from which the product is to be picked. At the same time, the exact box in the automatic inventory retrieval system's drawer is illuminated by a red laser light making it even easier to pick the correct product. Moreover, the location from where

the picking takes place is scanned. A red location light on the picking cart then indicates the position on the cart where the picker has to place the order. This concept is called "pick-to-light" and eases the picking for the individual employee. At the same time, it reduces the number of erroneous picks.

Improved working conditions

In addition to the picking becoming easier for Nomeco's warehouse employees, the working conditions have also improved. The automatic inventory retrieval systems' PLC controlled system also saves information about the individual employee's height. When the employee then logs onto the system, the picking height is adjusted to suit the individual 100 percent. Furthermore, the automatic inventory retrieval system's drawers tilt when the products are picked. In so doing, the picking depth is minimised and the employees avoid having to stretch in order to reach the products in the innermost drawers.

The four automatic inventory retrieval systems thus contribute to tremendous space saving and a significant reduction of CO₂ emission. They also ease the work, reduce the number of erroneous picks and improve the employees' working conditions. ■ MSC

Nomeco can sample refrigerated products

Nomeco HealthCare Logistics can offer samples of refrigerated products on the same terms as standard storage products. With Nomeco HealthCare Logistics' online tool (eLMK) the medicines representative's constant focus is ensured on efficiency, quality

management and compliance with the applicable regulations in connection with sampling to physicians.

Samples of refrigerated products are stored in Nomeco's new cold storage, ensuring the products constantly to be kept within the correct temperature range.

At the same time, Nomeco ensures that the products are always handled pursuant to the strict GDP regulations. Consequently, there is certainty that the quality requirements are complied with when the refrigerated product is delivered to the physician. This means that the physician can safely use the product. ■ **LMC**

Refrigerated products to Iceland wear 'a thermo coat'



How do you keep the goods cool and at the correct temperature when transporting them all the way to Iceland? The solution is very simple. Nomeco has conducted numerous tests which show that the use of so-called thermo covers reduces the temperature fluctuations of the refrigerated products during transport. Thermo covers function in the same way as tea cosies. During transport to Iceland, the thermo covers are placed over the pallets containing refrigerated products and the products are then ready to be freighted by ship to Iceland.

This ensures that the individual products always live up to the quality requirements and is an example on how Nomeco HealthCare Logistics constantly works on optimisation and continual improvements in the distribution of medicines. ■ **LPR**

Suppliers:

Enthusiasm for OnSite Stock

Better supply chain transparency and easier access to new products. These are some of the advantages mentioned by the suppliers when they are introduced to Nomeco's new service, OnSite Stock.

After months of planning the new service, Nomeco OnSite Stock, is a reality. The first refrigerator is now in place in Capital Region Pharmacy, and the first products are stored and ready to be picked. The medicines are owned by the supplier until they are picked from the refrigerator by the pharmacy staff. Nomeco owns the refrigerator and the concept is approved by the Danish Medicines Agency.

The interest in having pharmaceuticals in the refrigerator is very high, according to Key Account Manager Pia Berg:

"Almost all the suppliers I have talked to about OnSite Stock are giving us very positive feedback. They can see many advantages in the "minibar" concept – also advantages we haven't seen ourselves," she says. OnSite Stock has been presented to suppliers of hospital pharmaceutical cold storage products with e.g. short shelf life or

fluctuating usage. It is also relevant for high priced products and in regards to product launches.

Increased supply chain transparency
"One of the advantages mentioned by the industry is that better access to the products allows the treatment to start as soon as the diagnosis is set - also outside normal working hours. Another argument is that it increases supply chain transparency. Since the products are picked directly for use from the stock, the supplier can monitor the sales and the use more directly," says Pia Berg.

"Several suppliers also mention to me, that when launching new products on the market, availability is very important - especially during the first phases of the introduction. That makes Nomeco OnSite Stock ideal for this purpose. Furthermore, it will ensure optimal service related to the newly launched products."

Pia Berg concludes that it has been very interesting to present the Onsite Stock concept to the industry and that it has been well received. She invites suppliers to contact her if they are interested in having their pharmaceuticals in stock and placed closer to the patient. ■ **MWH**

For more information about OnSite Stock, contact Key Account Manager Pia Berg:

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About OnSite Stock



- Products are placed under consignment in the refrigerator placed at the hospital pharmacy (the Supplier owns the product until it is picked from the refrigerator)
- The sale is registered as soon as the product is picked from the refrigerator – 'the minibar' concept
- Replenishment is performed by Nomeco
- Ensuring quality procedures and storage is the responsibility of Nomeco
- Nomeco insures the products in Nomeco OnSite Stock

Read more on www.nomeco.dk.



GDP

version 2.0

The draft for the new GDP-Guideline is an enormous expansion of the rules, and some of the suggested elements have reached a point where the potential benefit is rather academic – not least, in a local Danish context.

→ By Henrik Kastrup, Director Nomeco HealthCare Logistics and Vibeke Halskov, Director of Quality, Nomeco

In August the EU Commission sent out a draft for commenting on the coming updated GDP-Guidelines for Products for Human use. In the introduction, the Commission states that the reason for updating the GDP Guidelines is that the current guidelines are no longer adequate. This is due to the general development in logistics since 1994, when the current guidelines were published. Furthermore, the Commission wants to merge several relevant amendments into one Guideline including the recent Directive relating to the prevention of the entry of falsified medicines into the legal supply chain.

Interest groups in all EU member states are asked to comment on the draft GDP Guidelines before December 31, 2011. The

deadline for putting the guidelines into practice is six months after publication.

Nomeco has also been asked to comment on the draft guidelines, not directly but via our parent company, Phoenix, who is represented at EU level by the umbrella organisation for pharmaceutical full-line wholesalers, GIRP.

28 pages of additional guidelines

At Nomeco we fully agree that guidelines dating back more than fifteen years need to be updated. And in general we welcome all initiatives that improve quality and security of medicines for the benefit of the patients. But, the draft GDP Guidelines adds an additional 28 pages of “do’s and don’ts” to the existing four pages of well-tested

guidelines. And from our point of view, some of these 28 pages are out of scope compared to the cost and effort necessary if they are to be implemented.

So, at Nomeco we tend to agree with Per Helboe, the former head of approval of pharmaceuticals at the DKMA who, in the June issue of “Pharma”, was quoted in regard to the ever increasing quality demands: “In principle, the many guidelines are a good thing, but now I think we have reached a stage where you have to ask where to go. Requirements are constantly being added to and corners are found that are not covered by a guideline. But how much benefit do these new guidelines really entail? How much is ‘nice to have’, and how much is a ‘must have’? When you look at the list

of deficiencies in the documentation that an applicant for approval of a new drug will receive, I will venture the claim, that there is a whole raft of questions concerning both quality, safety and efficacy that are neither beneficial to patients nor others.”

Is the guideline expansion too much?

Although Per Helboe is referring to the increasing demands within GCP and GMP it seems that the “guideline expansion” has also hit the GDP area. Most guidelines, including much of the draft GDP-Guidelines are, of course, highly relevant. However, we are tempted to raise the question of whether some elements of the draft GDP Guidelines have reached a point where the potential benefit is rather academic and the risk of non-compliance is virtually zero – not least, in a local Danish context.

Let’s take a few examples: In Denmark any pharmacy or hospital can be reached by the

wholesalers within maximum three hours drive and in emergency situations we often use taxis to supply rush orders. In these cases it seems a bit out of scope to demand controlled ambient transportation.

Another example could be the suggested widespread demand for utilising Responsible Persons or QP’s, i.e. in handling returned goods. If this really comes into force the cost and time required will result in severe bottle-necks and delays in the product flow - not to mention the increase in handling costs which, one way or the other, will have to be covered by the pharma industry. Therefore, in our opinion this must be the responsibility of the MA holder.

We also see a challenge in implementing the suggested extra control of the documentation in order to prevent counterfeit products, because how can we control the actual validity of the documents?

Time and pragmatism, please

At Nomeco we look forward to the upcoming improved GDP Guidelines, which do contain a lot of relevant improvements and directions. Nevertheless, when it comes to implementing the new guidelines we hope for patience and pragmatism by the authorities. Some of the improvements will require massive changes in procedures and heavy investments in new technology and systems.

Some of the suggested changes can, of course, be implemented right away. Others will however take years to fully implement and some need to be “down-sized” to a reasonable and practical level. And, looking at the overall quality level throughout the pharmaceutical supply chain in Denmark, there should be no acute need to rush the implementation of the new Guidelines. ■

Key elements of the new draft GDP

Responsible person:

- Must be appointed at each single site
- Must be involved in all handling of returned goods

Returned goods:

- Increased demands for handling of returned goods in general

Quality Management:

- Change Control Management must be implemented
- Quality Risk Management is included in several parts of the guideline

Facilities:

- Increased demands on mapping of premises

Product complaints:

- DKMA must be informed about product complaints

Counterfeit products:

- Increased focus on counterfeit medicines
- Falsified documentation

Transport:

- Increased focus on transport related activities
- Documented temperature during transport, both cold chain and ambient products

Batch control:

- This is necessary towards the Pharmacies to fulfill the demands of this draft guideline



Nomecodagen January 26, 2012

Shop or healthcare center? What kind of pharmacy do we wish to have in the future? And what kind of pharmacy do we believe is in store for us? That is the question the pharmaceutical sector has been discussing for many years – and it will be the topic of Nomeco's conference January 26 next year. The conference is currently on the drawing board and editor of Dagens Medicin, Kristian Lund, has agreed to be the moderator throughout the day. He will lead the discussion and has already now promised to make sure that there will be time enough for mingling.

An invitation for the conference will be sent out during autumn.

CONFERENCE

← Kristian Lund from Dagens Medicin has agreed to be the moderator throughout the day.



New loading platform



The covering of the loading platform in Nomeco's Copenhagen warehouse is almost finished now. The building project has taken place during the summer and has periodically created problems for the chauffeurs who load and unload goods.

"We apologise for all the inconvenience as the goods receipt often had to be carried out on a minimum of space. All gates are now established, and the loading now takes place in a hermetically sealed environment," Operation Manager Peter Kastberg tells. He is in charge of the central warehouse run by Nomeco HealthCare Logistics.

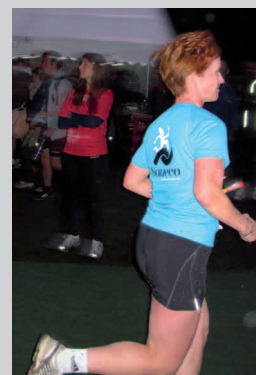
When the truck approaches the gate, the chauffeur gets help from

the barriers entire height which grip the tires of the truck. This helps directing the vehicle as the parking has to be very precise. The gate is closed as the truck parks and it does not open until an air cushion is inflated and forms a sealed border around the gate.

"In that way we can be sure that no rain or cold air enter while loading or unloading the truck. This is essential due to the GDP environment at the warehouse – where the temperature is monitored and kept stable all year round."

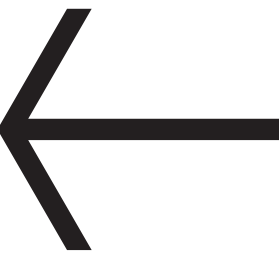
The rebuilding is not yet finished behind the gates, but it will be finished by the end of the year. At that time the covering of the loading platform has added 700 m² to the warehouse.

More than 100 Nomeco employees competed in the DHL race



This year, more than 100 employees from Nomeco tied the laces on their running shoes and participated in the DHL race. The race took place in Copenhagen, Odense and Aalborg since Nomeco has branches all over the country. "We run for health" was printed on Nomeco's new blue running shirts. This is a slight re-write of Nomeco's slogan: "We work for health".

Update



Nomeco helps fighting breast cancer

True to tradition, Nomeco is supporting the Danish Cancer Society's campaign "Støt Brysterne" in September and October. Nomeco contributes with free distribution of support bracelets to the country's pharmacies which are then sold for DKK 25 each.

Unit for Legal Affairs

Nomeco is adjusting the organisation on a number of areas to match the goals and volume of work. This also applies to Nomeco HealthCare Logistics where a number of changes are taking place. Since the volume of contracts as well as their complexity are on the increase, a Legal Affairs unit has been established with **Søren Vesti Esbensen** in charge. The division will comprise a Contract Team as well as B2B Sales. Furthermore, Nomeco HealthCare Logistics has formed an independent development unit to strengthen the development work focusing on the pharma industry.

See the new organisation at www.nomeco.dk.



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PharmaGOLF

In June, this years PharmaGOLF tournament took place at Simons Golf Club in Kvistgård. See the complete results and photos from the tournament at www.pharmagolf.dk.

Next years PharmaGOLF will also take place at **Simons Golf Club, Friday June 15 2012.**

The event will be sponsored by:



The team competition was won by:



The winners of the individual groups were:

Group A



Group B

