MARCH 2009

NEWS from

Nomeco HealthCare Logistics

eLMK will handle **70,000** samples this year!

Nomeco is Fighting
Counterfeit Medicines

7TM Pharma
Conducting Clinical Trials

Danish Hospitals
go Robotic Dose Dispensing

Nomeco HealthCare Logistics

WELCOME TO 2009: THE YEAR OF EVALUATION!

By Henrik Kaastrup, Director

Normally, I don't use these lines for commenting on general industry issues. However, during the past few months the Danish distribution model for pharmaceuticals has been subject to some debate – primarily around discounts and overall service level of distribution to private pharmacies. Currently many things point in the direction that 2009 will be remembered as the year where most of the logistical and financial elements defining the Danish distribution model were carefully evaluated and some were redesigned and modernised.

Nomeco always focuses on improving logistics and a lot can and should be done to trim the flow of pharmaceuticals. In this issue of our newsletter you can read about one of Nomeco's latest optimization initiatives – the TMS – for optimizing transportation. However, you also find an article focusing on counterfeiting and how Nomeco's purchasing policy and goods receipt procedures are examples of why the supply chain for pharmaceuticals shouldn't be compared to the one for normal consumer goods, and that the hunt for increased efficiency should never become more important than quality.

Finally, we are pleased to bring you an interesting article about the first dose dispensing robot in operation in a Danish hospital and a customer case on packaging of trial medication for 7TM Pharma.

I hope you'll find our newsletter worth spending the time reading.

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ROBOTS at Hospitals

The first dose dispensing robot for hospital use in Denmark is located at Århus University Hospital, Skejby and it looks like a success. It will result in increased demands and requests to the pharmaceutical industry when robots will dispense medicines in the future.

By Mai Loan Le

The right medicines for the right patient at the right time. This is the main purpose of the dose dispensing robot located at Århus University Hospital, Skejby which is currently supplying the Infectious Diseases ward with dose packed medicines. The medicines are delivered to the patient in a unit dose bag attached to the patented flexible ring with a tag showing patient data, dose and administration time. In the patient room the nurse checks the 2D bar code with a PDA to make sure that there is a match between the patient's bar code bracelet and medicines.

Reducing the risk of medication errors

"At the moment this is the only dose dispensing robot at a Danish hospital and the experiences are so far very positive. The ward, which has been supplied with dose packed and dispensed medicines for more than a year, has concluded in a midway evaluation that it is unimaginable to return to the old manual system. I also expect to find that the medication error rate has declined to a minimum – mainly because the medicine dispensing and the electronic patient record now go hand in hand," says Head of Department, M.Sci.Pharm. Trine Persson. She leads the Skejby Department of the Region Hospital Pharmacy in Århus and she is responsible for the trial with the dose dispensing robot – a solution she is convinced is here to stay.

"First of all unit-packed medicine dispensing provides higher patient safety, secondly there is an optimization in resources for the nurses who save handling time when they no longer dispense

Foto: Martin Busborg

HEAD OF DEPARTMENT, M.SCI.PHARM. TRINE PERSSON is responsible for the dose packaging of medicines at Skejby Hospital. She describes the experiences with the dose dispensing robot as being positive and is quite certain that the use of dose dispensing robots in time will expand to other hospitals. It will place great demands on the pharmaceutical industry to get the products suitable for dose packaging and dispensing - this could become a parameter in annual tender rounds.

continues ▸▸

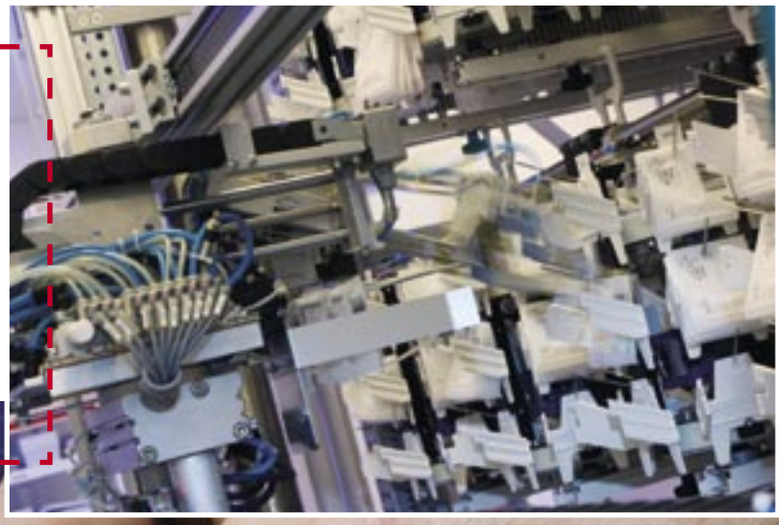
and pack the medicines themselves. Furthermore, we can track the product batches from package to patient and minimize waste when a patient is discharged unexpectedly from the hospital or the treatment is discontinued - we automatically return the bags to the robot and the medications can be restocked."

Ready to 'go live'

The dose dispensing robot in Skejby has been run as a pilot project since 2006. In the first year the robot dispensed and packed the non-patient-specific standard kits for example pain treatments. Since the robot was connected with the electronic patient records on October 1, 2007 it has also managed the patient-specific medicines for the 30 beds in the Infectious Diseases ward. At the moment the trial is being evaluated and the Hospital Management will then make a decision on how to implement the solution of dose dispensed medicines to all 450 beds in Skejby Hospital.

According to Trine Persson, some of the challenges are getting the staff used to the new routines and working procedures as well as learning and handling the new technology. The capacity of the dose dispensing robot will not be a challenge. The equipment is build to handle the 1200-1300 different pharmaceuticals used in the entire hospital and the dose dispensing robot is in principle capable of running 24 hours per day. The robot primarily doses and packs solid dosage forms as tablets and suppositories but also ampoules and syringes can be packed.

The dose dispensing robots have a total capacity of 52,800 pre-packed unit dose bags placed on a 'spear' inside the 2 robot storerooms. An "arm" picks the necessary bags and fastens them in a ring, when it packs to a specific patient. Skejby has selected an Italian robot of the brand Swisslog and a similar one has recently been installed at a major hospital in Oslo.



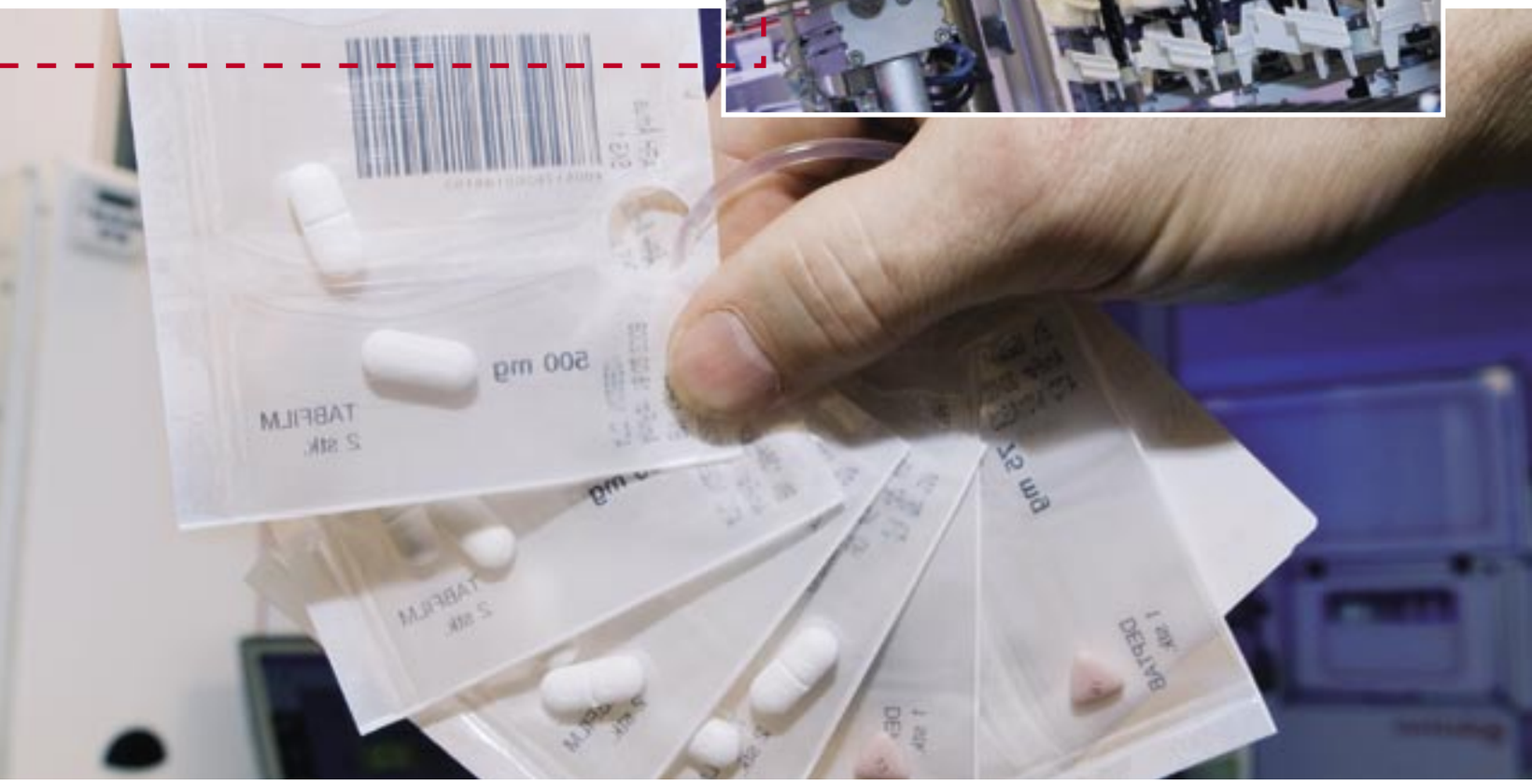
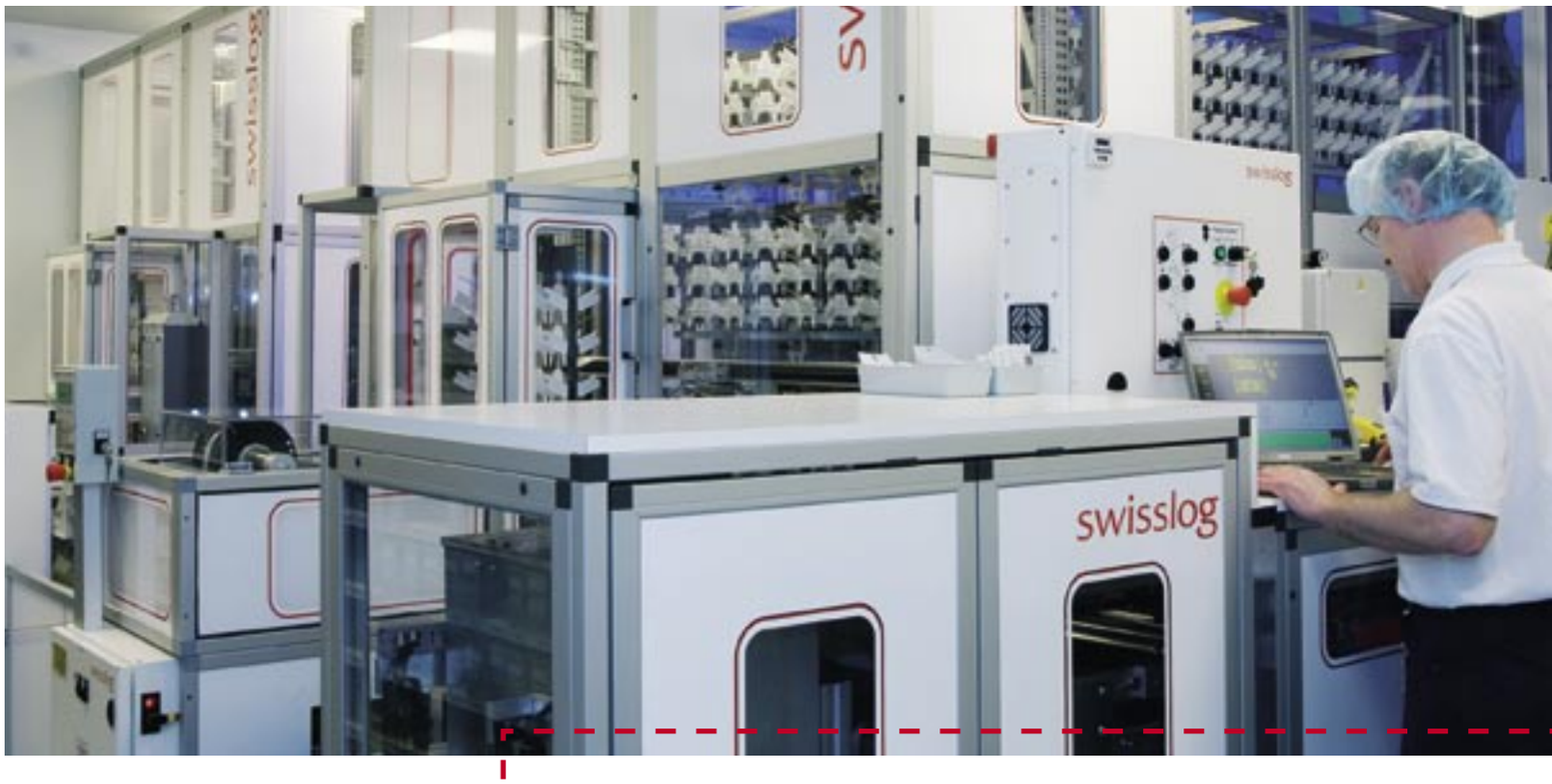


Foto: Martin Busborg



The equipment at Århus University Hospital, Skejby consists of two dose dispensing robots placed in a clean area at the pharmacy. The robot is for the moment operated by two technicians and a pharmaconomist – in this picture **JØRGEN HANSEN** is supervising the operation.

”Furthermore we have the advantage over the dose dispensing robots located at the private pharmacies in Denmark - the hospital sector only invites to tenders once or twice a year. This means that we do not need to adjust the robot that often for new pharmaceuticals.”

Robot brings new demands

The dose dispensing robot has also created new demands in relation to medication. ”The eight-week shelf life of the pre-packed medicines is not enough. This is why we applied for, and were granted, a dispensation for a six-month shelf life from the Danish Medicines Agency for most of the orally administered pharmaceuticals,” says Trine Persson.

She would like to have the master data of the pharmaceuticals such as the dimension of the tablets, as well as the possibility of transferring the products’ data either via a 2D bar code or via a RFID tag directly from the package to the box stations from which the dose dispensing robot picks and packs the bags. She would like to discuss this issue with the pharmaceutical industry.

A future parameter

Not all pharmaceuticals are suitable for packaging in the dose dispensing robot. Because of porosity some tablets tend to break up when being sucked up into the suction pipe of the robot, and others cannot be packed in the medicine robot for contamination reasons – for instance handling antibiotics in the robot is linked to a risk of contamination of the subsequent pharmaceuticals.

”This is a problem we need to solve. Today, we cut the blister packaging of antibiotics in pieces and pack the single tablet blisters in the medicine bags, which is inconvenient. One solution could be that the manufacturer coats the tablets so that they are not so ‘powdery’. All things considered, I am convinced that ease of handling will be an important parameter in AMGROS I/S’ annual tender rounds.

> ”First of all unit-packed medicine dispensing provides higher patient safety, secondly there is an optimization in resources for the nurses who save handling time when they no longer dispense and pack the medicines themselves.

Once the robots are located at every hospital, we will face a challenge to handle pharmaceuticals that for some reason do not currently fit the robots. It will be interesting to discuss the solution to these problems with the industry,” Trine Persson concludes. ■

The Solution Was Right on Our Own Doorstep

The biotech company 7TM Pharma chose Nomeco as partner in their recent clinical trial. Expect the unexpected and involve your partner at an early stage are their main recommendations when outsourcing packaging and distribution processes for clinical trials.

By Marianne Søndergaard

"Altogether our trial and the preparation phase have been running very smoothly. The technical part of designing and making the patient packs was just perfect. Our process was good, but quite typical for a clinical trial with late stage protocol changes influencing the design of the patient packs and the labelling. It was nice to work with people who knew what it is all about, when you are running a clinical trial. They know that you have to expect the unexpected. Of cause you must try to avoid problems, but at the same time you must keep in mind that issues will always occur."

This conclusion comes from Paul Little, Director of Chemistry, Manufacturing and Controls at 7TM Pharma, after the completion of a clinical trial project at Nomeco. It is a biotech company focusing on discovery and development of new drugs targeting 7TM receptors. 7TM Pharma's primary therapeutic area is metabolic diseases, including obesity and cardiovascular diseases.

Package design facilitated compliance and accountability

The trial was a Phase I/II double-blind, placebo-controlled 28-day study, which enrolled patients with obesity and was performed in the United States. 7TM Pharma chose to let Nomeco design, pack and label the patient packs and arrange the transportation. The active component is a cold storage product and was to be used by the patients at home on a daily basis. This gave specific demands to the process and one of the solutions was designing a special travel kit for the transportation of study medication from the site to the patient's home address.

"The patients were bringing the trial medicines home, and they had to know exactly what to do. So the design of the product pack was important. I think we found a splendid and very detailed design solution in cooperation with Nomeco. It contributed to the high level of compliance to our protocol as well as improving drug accountability and in that way enhanced the quality of our trial," says Paul Little. It is all about making the most out of the investment you bring into your clinical trial.

> "It was nice to work with people who knew what it is all about, when you are running a clinical trial.

Benefits from short distances

He is pleased to have found a partner in the Copenhagen area close to 7TM Pharma's location. According to Paul Little it makes cooperation easier and more efficient when you can arrange meetings on short notice and don't have to spend a lot of time travelling. "As we outsource a lot we are quite used to be looking for partners. We will go all over the world to find the right partner and in this case we were lucky to find the solution right on our own doorstep. But closeness isn't all. It is also extremely important to find the right people with the right competencies and understanding of, what can go wrong in a process like this. And believe me – lot's can go wrong," he underlines.

Early involvement is important

Another important experience from the cooperation between 7TM Pharma and Nomeco is that you have to find your supplier as early in the process as possible. "We were in contact with Nomeco quite a long time before we actually started to work together. It is important to have your partners lined up as early as possible and to have had an introductory meeting before really starting up. When you start early and have an open dialog about the process, it makes it all much more flexible and amenable," Paul Little sums up. ■

Foto: Piet Simonsen

PAUL LITTLE

Director of Chemistry, Manufacturing and Controls at 7TM Pharma, developed in close cooperation with Nomeco a patient pack and a travel kit with a lot of design elements for a clinical trial.

FACTS ABOUT

7TM PHARMA

7TM Pharma was founded in 2000 as a spinout from the University of Copenhagen by internationally recognized pioneers in 7TM receptor research. 7TM Pharma is a biotech company focusing on discovery and development of new drugs targeting 7TM receptors and the primary therapeutic area is metabolic diseases. 7TM Pharma has a pipeline of discovery and development programs based on in-house research and development. Investors include Index Ventures, Novo A/S, Alta Partners, LD Pensions, Johnson & Johnson. The biotech company is based in Denmark and is running clinical trials in several countries all over the world.

PHARMACEUTICAL COUNTERFEITING

In pharmaceuticals, the margin between bad quality and counterfeiting is blurred - and poor quality may be regarded as inadvertent or intentional counterfeiting.

By Henriette Vindmar

Until now, counterfeiting has not been registered in the authorized pharmaceutical supply chains in Denmark. This may be due to the fact that, when comparing Denmark to the global market, countries like the UK, Germany, France and of course the US are much more lucrative due to their sizes and international languages. As such, Denmark is far more complex because of its language barrier and in general Denmark has a very high level of inspection and security.

Inadvertent counterfeiting, where the effect of a drug fails because of use of a poor or counterfeit active ingredient, is impossible to stop if the product is sent to the market via the

HENRIETTE VINDMAR, Quality Director at Nomeco, is responsible for Nomeco's defence against counterfeiting.

normal trusted channels. Only GMP compliance throughout the production including API (Active Pharmaceutical Ingredient) and packaging process, in combination with an effective callback alert-system can stop such products reaching the pharmacies' shelves. Intentional counterfeiting, where the hunt for fast profit drives unscrupulous criminals to try to channel inactive or harmful drugs into the trusted channels, is possible to prevent and here Nomeco feels a great responsibility to play an active role. The risk of intentional counterfeiting appears high whenever there is a heavy demand for a specific drug or if the drug is marketable, carrying easy money.

For all pharmaceutical companies it is important to focus on all processes in the supply chain - from the suppliers of raw materials to the manufacturers, the wholesalers and to the carriers. Obviously, the more steps in the supply chain, the more vigilance are needed. Therefore, increasing the security partnerships in the supply chain should not only rely on trust but also on a critical evaluation, and auditing should be standard between the parties.

> We collaborate with the pharmaceutical companies through authorised channels, and we believe that the different steps in the supply chain are secure and comply with the ministerial orders according to The Danish Medicines Agency.

Sourcing of medicines is part of Nomeco's core business. However, the vast majority of the products sold from Nomeco to the pharmacies and hospitals are sourced directly from the original manufacturer or an authorised domestic importer. The number of products which are purchased by Nomeco abroad from other wholesalers or international brokers is limited to unlicensed medicines. And even in this area we only buy from well-known manufacturers or trusted wholesalers within the EU, United States and Switzerland.

Nomeco believes that supply chain security starts at the source. The manufacturer is responsible for the product and the observance of GMP.

Nomeco's main line of defence against counterfeiting is our goods receipt and import inspection procedures. With a copy of the manufacturer's company approval from the local authorities, Nomeco receives the goods and carries out the agreed inspection procedure. Nomeco is authorised to approve every batch for which the correspondence described has been recognised, and the qualified staff are trained in receiving goods and are aware of the challenges they might face. In the event that the correspondence described cannot be stated or if the control report lacks information, Nomeco quarantines the batch in question. Each step will be followed by the processes to secure that the manufacturer and Nomeco act according to the applicable law.

> Only GMP compliance throughout the production and packaging process, in combination with an effective callback alert-system can stop such products reaching the pharmacies' shelves.

Nomeco continues to focus on safety against counterfeiting within its distribution of pharmaceuticals. Nomeco collaborates with the pharmaceutical companies through authorised channels, and believes that the different steps in the supply chain are secure and comply with the ministerial orders according to the Danish Medicines Agency. ■

Update

Transport Management System TMS

Nomeco has, over the past few years, experienced an increase in the amount of its consignments, for both domestic and export orders. As a result a new system - "Transport Management System" - has been launched. TMS is an optimization of our existing shipping system.

Keywords like efficiency, automation, coordination and work simplification were communicated to the project group. The aims were to unite the many different systems into one and simplify the heavy manual work processes, with the result of gaining an improved overview of the transport process.

With TMS, Nomeco implements EDI and consolidates the consignments in order to optimize the daily workflow for transport.

The project has been broad-based with several people involved in building and adjusting the system, as well as testing the final set-up.

With its "Transport Management System", Nomeco HealthCare Logistics feels well equipped for the future. "With this resource we will be able to measure the quality and safety of our transport suppliers and make certain that future systems can be implemented easily," says Ronni Legaard, Transport Manager at Nomeco.

PharmaGOLF 2009

Friday September 4

Venue: Skovbo Golfklub, Dalbyvej 50, 4140 Borup

For further information and registration:
www.pharmagolf.dk
www.skovbogolfklub.dk

elmk®
POWERED BY NOMECO

The Danish Medicines Agency audited Nomeco's eLMK solution in December 2008. Following the inspection eLMK is now officially approved.

In general the Danish Medicines Agency believes that from a quality perspective sampling directly to doctors is a better way to sample compared to solutions where samples are stored in the car boots and handed out by the medical representatives.

Thumbs up for eLMK

By Lars Pretsch

Nomeco's sample distribution service, eLMK, has now been on the market for 2½ years. The sample service was introduced at the right time and hit a dry spot in the market. Many pharmaceutical companies want to hand out samples but prefer to outsource the heavy administration and accounting of samples, further they want to increase the quality level of the sampling process. eLMK combines these wishes. From being a service handled only by a few employees, eLMK has grown bigger and is today the responsibility of a team of 5 specialists. The eLMK specialists are expected to handle approximately 70,000 samples in 2009.

FACTS:

New eLMK handling procedures in Nomeco

In January 2009, a new setup for handling eLMK orders was implemented internally at Nomeco named eLMK II. It optimises the order process. With eLMK II, Nomeco can now scan sample requisitions and transfer them electronically to the computer of the eLMK specialist who enters the orders into the Nomeco ERP system. The system provides all the necessary information on screen. The new setup is also able to recognise products and doctor selection, making the order process even more simple and secure.

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You can also find an electronic version on www.nomeco.dk.

Foto: Piet Simonsen

MAI LOAN LE

New Business Unit Director of Hospitals

As of the beginning of 2009, Mai Loan Le was constituted Business Unit Director of Hospitals at Nomeco HealthCare Logistics. Mai Loan Le's educational background is pharmacist. Mai started her career in Nomeco in March 2007 as Key Account Manager and most recently as Production Manager at Nomeco's former production unit Site Halmtorvet. Previously, Mai Loan Le worked for Pfizer, which provided her with knowledge of the pharmaceutical industry.

"I look forward to continue developing our services towards hospital pharmacies and in close cooperation with the pharmaceutical industry," says Mai Loan Le.

Hospitals is a business unit focusing on product-neutral supplies to hospital pharmacies. Nomeco delivers pharmaceuticals and non-pharmaceuticals via multi channel distribution – either via a Nomeco wholesaler or directly from the pharmaceutical companies' central warehouse in Nomeco HealthCare Logistics.

Furthermore, the hospital pharmacies can benefit from the knowledge of the specialist in unlicensed medicines - Nina Grøntved, whose educational background also is as a pharmacist. Nina sources unlicensed medicines from preferred partners worldwide. Nina Grøntved will be of assistance to the hospital pharmacies regarding questions in the pharmacological and regulatory fields within unlicensed medicines.

"Our goal is to secure and optimize the availability of pharmaceuticals and we are therefore committed to being a proactive link between hospitals and the pharmaceutical industry," states Mai Loan Le.