JULY 2008

NEWS from

Nomeco HealthCare Logistics

NOWA TRAINING

Make a Note in Your Calendar!

RESTRICTED ACCESS

Only authorised personnel have access to Clinical Trial Supply Management stock, and a log registers who has been in the area, when and why

Nomeco HealthCare Logistics

Our Focus Remains the Same

By Henrik Kaastrup, Director

As many will already know, a well-known face, Jørgen Kelkjær, has left Nomeco to take on new challenges. I would like to wish Jørgen all the best in his new career.

However, although faces are changing, our focus and mission at Nomeco HCL remain the same – offering solutions of strategic importance to the pharma industry and hospital pharmacies.

In this issue of the Nomeco HCL newsletter we focus on solutions which are of critical importance to the "buyer" – no matter if it is a pharma company conducting a clinical trial, or a hospital ordering an unlicensed product for the treatment of a rare disease.

In connection with the previous issue of our newsletter, we carried out a reader survey. All the answers have now been processed, the results have been extracted, and the response has been very positive concerning the perceptions of content, layout, etc. We are especially proud that a very large proportion of the respondents rated the newsletter content as being highly relevant to their job. And, as you can see, the majority of our readers continue to prefer to receive our newsletter in English and on paper.

Finally, I would like to wish all our readers a great summer and a relaxing vacation when the time comes.

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SAFETY

has Top Priority in the Clinical Trial Supply Warehouse

Nomeco now handles supply for over 60 clinical trials. When handling Investigational Medicinal Products (IMP) the focus is firmly on quality and safety.

Safety, control, overview, security, documentability. All these elements are characteristic of Nomeco's Clinical Trial Supply Management (CTSM) setup. The aim is to bring the right experimental medication of documentable quality to the right patient at the right time and under the right conditions.

"We often handle phase III trials as these are usually larger, cover more countries and are more complex. We are the partner that brings IMP safely to trial centres, GPs and hospital departments, who then take care of the immediate contact with patients," says Study Manager, Winnie Søjborg Pedersen.

Now, one year after Nomeco HCL introduced this service, they take care of over 60 clinical trials for a number of different companies. Some trials are national, others are Europe-wide. Soon we will begin providing distribution to research sites in the USA, Russia and South Africa.

"Not only are we present in a number of countries, we are also involved in a wide number of different

Foto: Niels Jensen

WAREHOUSING:

Only 4 people are authorised to access the 1000 metres of fully automatic shelving, and access is controlled by a microchip.

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Foto: Niels Jensen

Study Manager Winnie Søjborg Pedersen points out that she and her colleagues are very careful with the documentation.

types of studies - from trials of cancer and asthma medicine, and treatments for cardiovascular disease and chronic bronchitis to medication for more unusual conditions."

> There is absolutely no room for mistakes when you're handling medicine. One small misunderstanding can endanger the results of an entire clinical trial.

When time is money

In Winnie Søjborg Pedersen's experience, when a clinical trial is given the green light the clock is already ticking. "Time is money, and even small delays to the development of a new medication can have significant financial consequences for the sponsor company. That's why it's important to start clinical trials straight away, and without any delays occurring along the way. We take pride in getting new trials underway quickly – we can often have a trial up and running within only a few weeks."

Speed always plays second fiddle to safety and quality however. And, with the necessary documentation and facilities as well as dedicated personnel at hand, the job of bringing new trials into being in such a short space of time is made much easier.

Double checking across the board

"We are very very careful with our documentation and everything gets checked twice. There is absolutely no room for mistakes when you're handling medicine. One small misunderstanding can endanger the results of an entire clinical trial," underlines Winnie Søjborg Pedersen.

Checking everything twice also ensures that no inappropriate information gets passed on to the trial site or to trial participants. "If it's a blinded trial, some patients receive the actual medicine and others a placebo. As a rule the Investigator site may under no circumstances be informed as to which patients receive the actual medicine. We often receive orders from an international Interactive Voice Response (IVR) system in a blinded and a non-blinded version, and it is crucial that only the blinded documents get sent to the site."

In some trials the new product is tested to see how it performs up against a medicine that has already reached the market – but not necessarily the Danish market. Nomeco are often in a position to arrange for supplies of such medicine, called a comparator, from reputable sources in Europe or the USA, for use in clinical trials (see page 6). In addition, Nomeco can provide packaging, re-packaging or additional labelling in connection with clinical trials.

"When the trial is over, we make sure that all the loose ends are tied up. We often also take care of excess medicine, and ensure that it is destroyed responsibly with the correct documentation," says Winnie Søjborg Pedersen. ■

QUARANTINE:

Upon receipt of a delivery of trial medicine, it is transported directly to the quarantine area. Here, the medicine is checked by two people and a message is sent to the sponsor asking them to authorise the medicine's release. When authorisation has been received, the medicine is transferred to the warehousing area. In the event that medicine requires cold storage, the entire reception process takes place in a 2-8˚C environment.

TRANSPORT:

The CTSM warehouse features a transport area, allowing shipments of trial medication to be prepared for dispatch in-house which ensures that the entire dispatch process only involves specially trained personnel.

PACKING:

The CTSM warehouse also features a certified environment for the packing of secondary medicine, meaning that medicine ca be repackaged, shelf life extended additional labelling may be applied or a new product information leaflet may be replaced.

Nomeco Specialises in Unlicensed Medicines

A full-time specialist, an extensive stock of unlicensed medicines, excellent international contacts and 70% share of the wholesaler market. That's what makes Nomeco an excellent partner – both for companies that transport unlicensed medicines to their own storage facilities, and for companies who outsource these services.

The market for licensed medicine in Denmark is relatively small; there are only slightly in excess of 6.700 licensed medicines on the market. By comparison, there are 50-60.000 licensed medicines in Germany where the market is large enough for it to be worth the manufacturer's while to bring even a niche product into the market.

Christine Tilsted Villesen (Msc Pharm) is Nomeco's unlicensed medicines expert, and the only person in Denmark who works full-time giving advice about and securing supplies of unlicensed medicine.

"Some of our unlicensed medicines are stored here in Nomeco's own facility. We have about 825 unlicensed medicines in our books. Of these, we distribute about 270 products from our HCL warehouse, as some suppliers acquire and store unlicensed medicines themselves," says Christine Tilsted Villesen.

You don't need to hold stock yourself

Many companies have decided not to maintain the range of their unlicensed medicines in Denmark. Sometimes it's the organisation's international arm who have made a strategic decision not to maintain a storage facility for unlicensed medicines. Stock control can be difficult, especially if sales are low. That's why Nomeco import large numbers of unlicensed medicines, a number of which are kept on stock – either because they sell well or because demand for them can rise acutely.

"Pharmacies can order our wholesale unlicensed medicine online and have it delivered straight away, that's a significant advantage for all parties. We are an excellent partner for manufacturers, who can leave the job of sourcing unlicensed medicines up to us. I can source a product within a couple of

continues ▸▸▸

Foto: Niels Jensen

FREE DETECTIVE WORK

CHRISTINE TILSTED VILLESEN (Msc pharm) is Nomeco's unlicensed medicine expert. As the only full-time adviser of unlicensed medicines she often uses detective methods to find the products around the world - if it is not found in Nomeco's warehouse.

Foto: Niels Jensen

CHRISTINE TILSTED VILLESEN
(Msc pharm)

is Nomeco's unlicensed medicine expert, and she receives approximately 30 sourcing requests per month for unlicensed medications – typically from hospitals, pharmacies and specialists – and approximately one third of these result in an order.

"Finding the correct product can be a lengthy and difficult process. I begin by checking whether Nomeco already stock the product or a generic equivalent. If we have never previously investigated the products availability I'll check a number of pharmaceutical databases to see whether the product is licensed on the international market. My top priority is sourcing an E.U. licensed medicine, and one that is as cheap as possible. If this is not possible, I try to find generic products or medicine that is licensed in the United States.

In some instances a different formulation of the drug exists - in which case I'll ask the pharmacy whether it's acceptable for the doctor who ordered it."

Christine Tilsted Villesen normally gets her medicine, or at least an equivalent product. But sometimes she does have to admit defeat; if, for example, a medicine is undergoing clinical trials a supplier may not wish to release it.

weeks or even quicker where necessary, and I don't have to order a whole shipment. I can order one package for an individual patient where necessary."

Extensive network in Europe and America

Christine Tilsted Villesen steps in when pharmacists and doctors are looking for a new product, especially if they need information concerning product availability regulatory issues or need specific information about the product.

"We often source unlicensed medicines from Germany, England, Scandinavia, France, Spain, Italy, America and Canada - all countries where Nomeco have excellent and stable contacts. We only deal with suppliers we trust and with whom we are in regular contact. We don't normally deal with companies in China or India or other places outside the EU or USA unless we are 100% certain that medicine has been manufactured according to GMP. We are also very vigilant in ensuring that no counterfeit products get through," says Christine Tilsted Villesen.

"We maintain import controls, and can thereby ensure that the medicine we supply to pharmacies is as it should be. When we import medicine from countries outside the EU there's more documentation involved and that means it may take longer importing the medicine." ■

IRS

(Ikke Registrerede Specialiteter)

What are Unlicensed Medicines (Abbreviated as IRS at Nomeco)?

Unlicensed medicines are pharmaceuticals that are not authorized or marketed in Denmark, but which are authorized or under clinical investigation in another country; they include:

- **Products that are not authorized or temporarily not marketed in Denmark.**
- **Newly developed pharmaceuticals, not yet licensed for the Danish market.**
- **Pharmaceuticals which have never entered the Danish market.**
- **Pharmaceuticals, which are under clinical investigation and are not yet authorized.**

According to the Danish Medicines Act. No. 1180 of 12 December 2005, doctors, veterinarians, and dentists can apply to the Danish Medicines Agency for dispensation (compassionate use permission) when they require a medicinal product which is not authorized or marketed in Denmark. They can apply to use the medicine in a hospital (general application) or for use with a named patient (single application). Doctors have to justify treating the patient with a product that has not been authorized or marketed in Denmark to receive authorization.

If authorization is granted, the applicant must provide a copy of the authorization and the prescription when contacting a pharmacist.

The Danish Medicines Act. No. 1180 of 12 December 2005

§29. (1) In special circumstances, following application, the Danish Medicines Agency may authorise the sale or dispensing in limited amounts of medicinal products which are not covered by a marketing authorization or not marketed in Denmark (compassionate-use permit).

Note A compassionate-use permit for experimental treatment with non-marketed medicinal products may be issued if all other options of documented treatment or treatment offered as part of registered trials have been attempted, and if it is possible (in the sense that "if there is a certain degree of probability") that the treatment suggested could cure the disease or prolong the patient's life, cf. the memorandum of 22 May 2003 issued by the Danish Ministry of the Interior and Health (reference file no. 2003-12103-46).

Update

New Nomeco HCL Director

As of the 1st of May 2008, **HENRIK KAASTRUP** has been appointed Director of Nomeco HealthCare Logistics. He thereby takes over the leadership of Nomeco's industrial and hospital activities; a position previously held by Jørgen Kelkjær, who has chosen to seek new challenges.

Henrik is 42 years old. He secured the titles Msc. Pharm in 1994 and CBA in 2004. He joined Nomeco six years ago after working as a Director for Sundhed.dk, with NetDoktor and Nycomed. He was originally appointed as a consultant covering the hospital sector, which at that time was part of the pharmacy division. More recently, Henrik has been responsible for sales, marketing and business development in Nomeco HealthCare Logistics.

NOWA TRAINING

Make a Note in Your Calendar!

As a NOWA user you are invited to participate in the NOWA Training sessions. This autumn's NOWA Training will take place on the following dates:

Thursday 11 September 2008 at 9.00 a.m. - 2.00 p.m.
Tuesday 16 September 2008 at 9.00 a.m. - 2.00 p.m.

An invitation will be sent to you!

About the

READER SURVEY

90% of those questioned remember having received the most recent edition of the newsletter, and only 3% of those are not interested in reading it.

8 out of 10 find that the magazine has improved their knowledge of the industry, and more than 9 out of 10 say that it has improved their knowledge of HCL's services.

85% of the respondents normally read the newsletter when they receive it and find the subject matter relevant. Of these 92% report that all or some of the articles are relevant to their work, and 45% of the respondents discuss articles with their colleagues.

42% prefer to receive the magazine in English, and 42% have no preference - so we will continue to publish it in English.

7 out of 10 respondents say that the magazine provides them with input for their business.

2 out of every 3 readers have management responsibility. Every fourth reader who participated in the survey has more than 10 employees.

Thank you for your participation in the reader survey. The winner of the iPod is Marianne Ekström, Novo Nordisk, Sweden.

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You can order extra copies by sending an e-mail to sas@nomeco.dk.

BUSINESS INTELLIGENCE

- Do you get the right business data when you need it?

Web Reports mean easy reporting and business data when you need it!

Nomeco HCL is proud to announce the launch of Web Reports – a new reporting tool for those who need more than just PDF reports, but don't require a NOWA solution.

Via the Internet you can access the reports by logging in to Web Reports. With a few logical clicks you have access to sales and logistics figures for the period you are interested in.

Unlike NOWA or PDF reports, Web Reports can combine, e.g. sales and stock figures, so that you can access all the data you need in just one combined report. Reports are predefined by Nomeco, and can be accessed via the Internet for the period you are interested in at any time.

Web Reports is an add-on service to your central warehouse solution. For further information, please contact **June Kragelund (juk@nomeco.dk) or Lars Pretsch (lpr@nomeco.dk).**

Web Reports' technical specifications:

- Access via the Internet
- Built in Cognos 8
- Data updated daily before 7 AM

Web Reports' information provision e.g.:

- Sales & stock reports (data for YTD + 2 years)
- Stock movement (data for YTD + 2 years)
- Stock reports with batch (data for YTD + 2 years)
- Back orders (current back orders)

HOW WEB REPORTS WORKS