



Translation of the Movianto publication issued in Chemische Rundschau No5, 5/2008

Distribution of Narcotics

Dealing securely with sensitive goods

The storage and delivery of controlled drugs is complex. Manufacturers of pharmaceuticals are therefore contracting these highly sensitive operations out to specialised logistics partners with increasing frequency.

In order to store and transport narcotics correctly, numerous precautions have to be taken: service-providers need a permit from the Federal Opium Agency and must provide evidence of trained personnel including a person responsible for controlled drugs; in addition there are all the statutory duties in terms of documentation and reporting to the Federal Institute for Drugs and Medical Devices plus building requirements and security measures under the terms of the Betäubungsmittelgesetz (BtMG) (Narcotics Act), including securing storage rooms by burglar alarms which operate on the principle of structure-borne noise detection. This short list alone reflects the fact that expenditure greatly exceeds what is necessary for the storage and transport of normal medicines.

High security section under the microscope

The term "controlled drugs" includes substances which are classified either as narcotic or psychotropic substances, i.e. which stimulate or subdue consciousness and have a certain addictive potential. To prevent misuse of these substances, they and their preparations must be securely stored. Anyone participating in "trading controlled drugs" therefore needs a permission (under the terms of § 3 BtMG) from the Federal Opium Agency at the Federal Institute for Drugs and Medical Devices. Codeine or Fentanyl, for instance are classified as narcotics which may be circulated and prescribed - i.e. are legal.

To satisfy the security regulations, narcotics are not only stored separately: the premises must also be secured against access by unauthorised persons and illegal removal of the medicines – both mechanically and electronically. The structural measures therefore have to be agreed at the design stage for the building with the Federal Opium Agency. These depend on the type, scope and degree of hazard of the narcotics stored.

The mechanical security of the premises starts with a certified door to a safe-deposit room with a defined level of strength, and continues through regulations on the method of construction and thickness of walls, ceilings and floors, to the arrangement of windows. The Federal Opium Agency distinguishes here between existing rooms and those to be newly built. If it is a new building, windowless rooms are mandatory, with ventilation via steel pipes. This represents a further challenge, as the temperature range for storing drugs at room temperature has to be kept between 15°C and 25°C.

Electronic security for the rooms is established on the basis of the structure-borne noise principle. When the system is switched on, the corresponding detectors trigger an alarm as soon as someone is in the room. The alarm itself goes off either through a permanent connection to the police or via the police emergency number. For example: if the person responsible for the dangerous drugs or one of his colleagues wishes to enter the room, he needs a transponder key and also a numerical code for identification before he/she can do so.

For most products, the formalities involved in crossing borders within the EU have been abolished – but not for narcotics. It is still necessary to register the import of these with the relevant authorities within the country. An import licence has to be applied for, and the import procedure followed. To import narcotics from a third country (i.e. non-EU country such as Switzerland or the USA), an import licence is required in advance. The full import procedure for each import includes an import licence application, the granting of the licence and, finally, the import notification – i.e. administrative tasks which a logistics partner can perform.

Import and export: the burden of formalities

The import application is sent to the Federal Opium Agency. The Agency checks whether the logistics company has fulfilled all the preliminary conditions and that the corresponding licence for participating in the circulation of controlled drugs has been obtained, and issues an import licence. →



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As soon as the supplier has been informed that the licence has been granted by being sent a copy, he despatches the goods and the narcotics set off on their journey. For example: on receipt of the goods in the dangerous drugs warehouse, Movianto carries out a detailed check on, amongst other things, the version of the instructions for use, the collapsible box and the quality and quantity of the supply. For dangerous drugs, goods inwards inspection is carried out on the exact number of items, i.e. original boxes are opened and checked to ensure that there is the correct quantity of individual packages. As "double-entry stock-taking" is mandatory for dangerous drugs, it is not sufficient to count the number of collapsible boxes – stocks have to be broken down into the smallest unit. This means that, depending on the form in which the drug is administered, each individual tablet or each individual plaster must be recorded in parallel to the packaging. If everything is correct, the import notification is sent to the Federal Opium Agency. These regulations apply equally to exports. Double-entry stock-taking is also necessary because there is a half-yearly duty to provide information to the Federal Opium Agency on all "movements of controlled drugs". These reports contain detailed information on the import, export, acquisition, handover and destruction of the narcotics. To be able to supply this complete data, the company requires documentation on the number of items for each individual movement of stock.

As for all other finished drugs, a reserve sample has to be taken from every batch which will be available if there is an investigation. In principle, at least one sample must be kept for each packaging procedure – and held for at least one year after the expiry date. The specialist logistics partner can take over storage of this reserve sample. Otherwise the reserve sample would have to be imported on request via a separate import procedure, which would not be feasible in a short time when required.

Reserve sample under control

All stock movements of the narcotics have to be documented individually and in detail via the "handover receipt procedure." This contains the following details: date, narcotic number and address of the person handing over, narcotic number and address of the acquirer, central pharmaceutical number and product description, precise weight of the controlled drug received or handed over, or, for divided preparations, the number and new stock level calculated subsequently. Even before receipt or handover, the logistics company checks directly when the order is received and whether the customer has the necessary licence. The actual handover receipt procedure then starts with commissioning: the delivery note, confirmation of receipt and stamped addressed return envelope are enclosed with the goods. The order only leaves the secure controlled drug area, however, when the person responsible for narcotics hands the commissioned goods over to the driver responsible. This procedure is also documented by signature: on handover, the recipient signs the handover receipt and sends it back to the place from which the delivery originated in the stamped addressed envelope enclosed. Apparently minor details in the service, for example the stamped addressed envelope enclosed, save costs and make it easier for the recipient to return the handover receipt quickly.

Disposal direct "into the fire"

If controlled drugs have to be destroyed or disposed of, there are also procedures to be followed, particularly to prevent re-use of the substances. Narcotics which can no longer be put into circulation, for example batches past their expiry dates and reserve samples whose reserve periods have expired, are destroyed. These preparations are stored with "blocked" status until the person responsible for dangerous drugs, together with two witnesses, has agreed a destruction date at the power station (approximately twice a year). In fact, a precise date is agreed for when the dangerous drugs will be destroyed "directly in the fire" – this means that re-use of the drugs is completely excluded. The person in charge of dangerous drugs and his/her witnesses confirm this in writing. →



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One major prerequisite for a functioning collaboration is a reliable IT connection between the provider of logistics services and the client. It goes without saying that this provides consistent, transparent, validated processes, from acceptance of the order through to invoicing, which allow the manufacturers to have an up-to-the-minute view of what is happening.

The continuous data transfer to a central IT platform makes it possible for all information to be called up in real time – this is particularly important for sensitive goods such as dangerous drugs in transit. The tasks and processes outsourced can be constantly monitored by the client, which reinforces trust in the collaboration.

Orders received by Movianto clients are entered in the company's IT system and transmitted via an interface; directly after processing, an acknowledgement is sent back, so that the sales figures for the goods despatched are quickly available and invoices can be sent, even when the volumes are large. If, for example, orders are received simultaneously from several wholesalers, everything passes off smoothly and flexibly. In comparison to other sectors, pharmaceutical manufacturers tend to be hesitant in outsourcing tasks to logistics partners. This may have to do with the fact that drugs are sensitive goods to transport, particularly when they are prescription-only drugs – and this applies to an even greater extent where controlled drugs are concerned. Pharmaceutical manufacturers have recognised that concentrating on core competencies brings benefits, not only under pressure to reduce costs.

Requirements placed on logistics partners can be clearly described: the highest priority generally is keeping their own involvement with distribution small, without compromising on high quality standards in storage and transport. All logistics services should also improve customer service, increase their own flexibility and be all under one roof as far as possible to guarantee transparency and – not least – reduce costs. Because of the special logistical requirements for dangerous drugs, it is best to rely on specialist partners – in every respect.

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