



**Whitepaper**

# HOW TO AVOID PRODUCT RECALLS TRIGGERED BY DELIVERING MEDICINE

QUICK SELF ASSESSMENT TO VERIFY WHETHER  
YOUR DISTRIBUTION SYSTEM IS STILL COMPLIANT

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# How to avoid Product Recalls triggered by Delivering Medicine

Quick self assessment to verify whether your distribution system is still compliant.

Delivering medicines to customers requires special attention in order to avoid falling foul of compliance.

Medicines must only be sent to those allowed to receive them. Therefore delivery processes should be controlled by the SAP system. The purpose of this paper is to remind established pharmaceutical personnel and those new to the industry of their responsibilities and to introduce the basic legislative requirements. We also highlight the necessity of system testing and configuration.

We are all aware that the pharmaceutical industry's manufacturing and research processes are carefully regulated. But perhaps we are less aware that there are also strict regulations regarding the delivery of the end-product.

In any industry a good distribution system should have the following basic aims:

- The customer will receive notification of despatch;
- The customer will be able to track the order;
- The customer will receive the goods in time, in full, in tact and without defects;
- The customer will receive the correct invoice with prices and terms of payment as agreed.

However, the pharmaceutical industry has further regulatory obligations. The consequences of failing in any of these can result in not just a product recall but also the possibility of regulatory investigations, fines and even the loss of the relevant licenses. An example that must be avoided at all cost will be delivering medicines to an unlicensed wholesaler

The guidelines for 'Good Distribution Practice' (GDP) cover such aspects as the receipt and storage of products, the physical delivery to customers and how to handle customer returns and recalls.

You must be licensed to manufacture, distribute, receive and/or sell medicines. A company must follow these GDP guidelines to retain its license. Such licenses are country specific. In Britain the government body responsible for licensing is the 'Medicines and Healthcare Products Regulatory Agency' (MHRA).

The GDP guidelines clearly state that medicines can only be sold to those authorised to receive and resell them. These authorised recipients are further sub-divided into those classified as wholesalers and those who are Authorised Persons.

Wholesalers require a specific license to receive and sell medicines.

Authorised Persons are qualified by nature of their profession and therefore do not need a specific license. For example, pharmacists are Authorised Persons.

It's worth noting that the UK regulations do allow delivery of medicines to unauthorised persons in some exceptional cases. For example in Britain it is permissible to deliver to supermarket distribution centres as long as the site falls under the control of the retailer's superintendent pharmacist. Remember, such cases are the exception and not the norm.

Medicines themselves receive different licenses or categories. These affect who may receive and sell them. These licenses vary from country to country but in Britain the 1968 Medicines Act categorises them as:

- General Sales List [**GSL**]
- Pharmacy [**P**]
- Prescription Only Medicine [**POM**]

Prescription Only Medicines can only be supplied to an end-user after consultation with a healthcare professional.

Pharmacy medicines require the supervision of a pharmacist at the point of sale. This in order to verify a medical condition or avoid potential complications when the product might have side effects when used with other medications.

General Sales List medicines are more widely available and do not need the supervision of a health care professional in order to be sold. However, quite often there will be restrictions on the product such as the number of tablets sold in a pack or the medicine's strength.

These classifications depend on the safety of the product in general usage. Sometimes medicines may be reclassified

having been tried in the market over a period of years from 'POM' to 'P' and sometimes even to 'GSL'. (The cold sore treatment Aciclovir cream is just such an example of this).

There are two types of wholesalers' licenses available in Britain:

- Wholesale Dealer License **[WDL]**:  
With this license you are allowed to receive and resell General Sales List medicines only;
- Full Wholesaler Dealers license **[WL]**:  
You need this license when you want to trade all types of medicine.

The Pharmaceutical Industry is heavily dependent on computer systems in its production processes. The industry has introduced guidelines known as the 'Good Automated Manufacturing Practice' (GAMP) to ensure that computerised systems are implemented which are 'fit for purpose', i.e. regulatory compliant.

Today the demands of the customer, the volumes being shipped and the complexities of delivery require similar computer automated systems to control the supply and distribution chain. Just as systems in production need to be regulated, systems in distribution also need to be regulated. To this end the industry follows distribution guidelines known as 'Good Distribution Practice' (GDP).

Naturally, computerised systems should be absolutely 'bullet proof'. In particular those computer systems used to control distribution by large multi-national companies operating in the pharmaceutical sector. The used hardware and software must ensure that the company supplies the medicine to the licensed customer and that all relevant legislation has been correctly followed.

Unfortunately, our experience at NO TIE GENERATION CONSULTANCY has shown us that there are many systems in use that do not reach the expected standards. This increases the risks of human error triggering product recalls. This jeopardises the company's ability to comply with relevant legislation. These include a) invoicing errors, b) sending the wrong product or quantity and c) sending goods to unlicensed or wrongly licensed customers. For instance, an order for medicine to be sent to a supermarket with a pharmacy might be shipped to another branch with no pharmacy.

When in need of a product recall due to human error, the person responsible for the data entry that led to the error may well be reprimanded. But this is not a solution. The question that needs to be asked is why the system allowed the error to be made in the first place?

Even though the data entry was incorrect, modern systems should not allow such fundamental data input errors to slip through the net. And most don't when they have been configured correctly.

Therefore, the correct configuration of distribution systems is as important as awareness of the regulations in the first place. Incorrectly configuring a system can lead to compliance issues that may have serious consequences for the production company.

All distribution managers, consultants, and others involved in distribution must regularly ask three basic questions.

Does their system allow:

- Shipping medicine to non-licensed customers?
- Shipping medicine to customers with an expired license?
- Invoicing medicine shipped to a competitor?

If the answer to any of these is 'yes' then the distribution system could be open to data input errors leading to serious compliance issues.

Here's a quick test to self assess the robustness of your distribution system:

Find a sales order for a Pharmacy [P] or Prescription Only Medicine [POM] for which delivery has not been initiated. The order is registered for a customer with a valid Full Wholesale Dealer License [WL] to be delivered at their address.

As stated earlier, those with a WL license are allowed to receive any kind of medicine.

1. Change only the recipient address manually and save the sales order.

A compliant computerised system must block the sales order for further processing, and require an authorised person within the company to validate the manually changed address and release the blocked sales order.

When non-compliance is identified, then implement a blocking mechanism.

When using SAP R/3, it is advised to introduce the user status functionality as it allows the release of the blocked sales order through authorisation management.

2. Change the goods recipient to a location of the customer that has a Wholesale Dealer Licence [WDL].

A compliant computerised system must not allow further processing of the sales order items referring to the Pharmacy [P] or Prescription Only Medicine [POM]. This is because the recipient does not have a Full Wholesale Dealer License [WL] and therefore only allow the receipt of General Sales List [GSL] medicines.

When non-compliance is identified, force that a delivery document cannot be created for the sales order items referring to Pharmacy [P] or Prescription Only Medicine [POM].

When using SAP R/3, it is advised to use SAP Legal Control functionality as it is developed to manage licenses and it can be implemented without the need for custom development.

3. Change the goods recipient into a competitor of the ordering customer before saving the changes in the sales order.

A compliant computerised system must not allow the sales order to be saved. This will be irrespective of whether the changed goods recipient has a valid Full Wholesale Dealer License [WL].

When non-compliance is identified, force an error when saving the sales order.

Similar to point 2, it is advised to implement Legal Control functionality when using SAP R/3.

These tests are of vital importance. It can easily reveal compliance problems and if it does immediate action can be taken. If steps are not taken to revisit the system the production company runs a serious risk of non-compliance with the statutory regulations. The outcome could involve product recalls triggering external audits, fines and the risk of legal action.

When using SAP R/3, it is advised to implement the Legal Control functionality. Also approach consultants who are not complacent regarding compliance to examine and reconfigure the system to assure compliance.

In conclusion: managers new to the pharmaceutical sector, external consultants and those currently engaged in the distribution aspects of the pharmaceutical industry need to be aware of the legal requirements of the country in which they are based and to be absolutely familiar with the responsibilities associated with such regulations. All those working in distribution need to be fully aware of the range of customer licenses and the nature of product licenses and all distribution systems should be capable of over-riding human error and configured to ensure compliance. Systems should be tested to ensure they are 'operator proof' and if not they should be re-configured as a matter of urgency.

For further information on this or any SAP related matter please contact Isard Haasakker at 'NO TIE GENERATION CONSULTANCY' on +44(0)2071006888 or email us at [isard@NoTieGeneration.eu](mailto:isard@NoTieGeneration.eu) .

More information regarding compliance is available in our paper entitled, "COMPLACENT OR COMPLIANT?" - An introduction to compliance and the role of the Qualified Person (QP) for new employees, suppliers and contractors within the Pharmaceutical industry.

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