

OPHACO

OFFICE DES PHARMACIES COOPÉRATIVES DE BELGIQUE
VERENIGING DER COÖPERATIEVE APOTHEKEN VAN BELGIE

GS1 Healthcare Day

*"Improving patient safety & care with the GS1 standards"
18/10/2010 – Neder-over-Heembeek*

***"Tracking, Tracing and authentication:
Patient Safety through the supply chain of
Medicines and Healthcare Products".***

*Marc-Henry Cornély
Secretary-General of OPHACO*

Counterfeit medicines

Parallel trading

Intra-Community trade

Distance selling

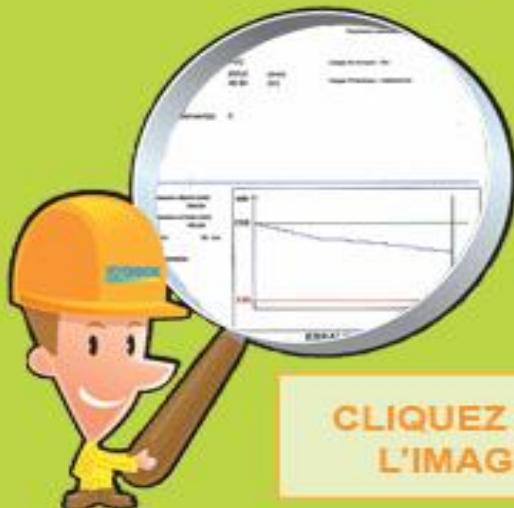
Quotas

Counterfeit-proofing

Counterfeit detection device

Counterfeit detection



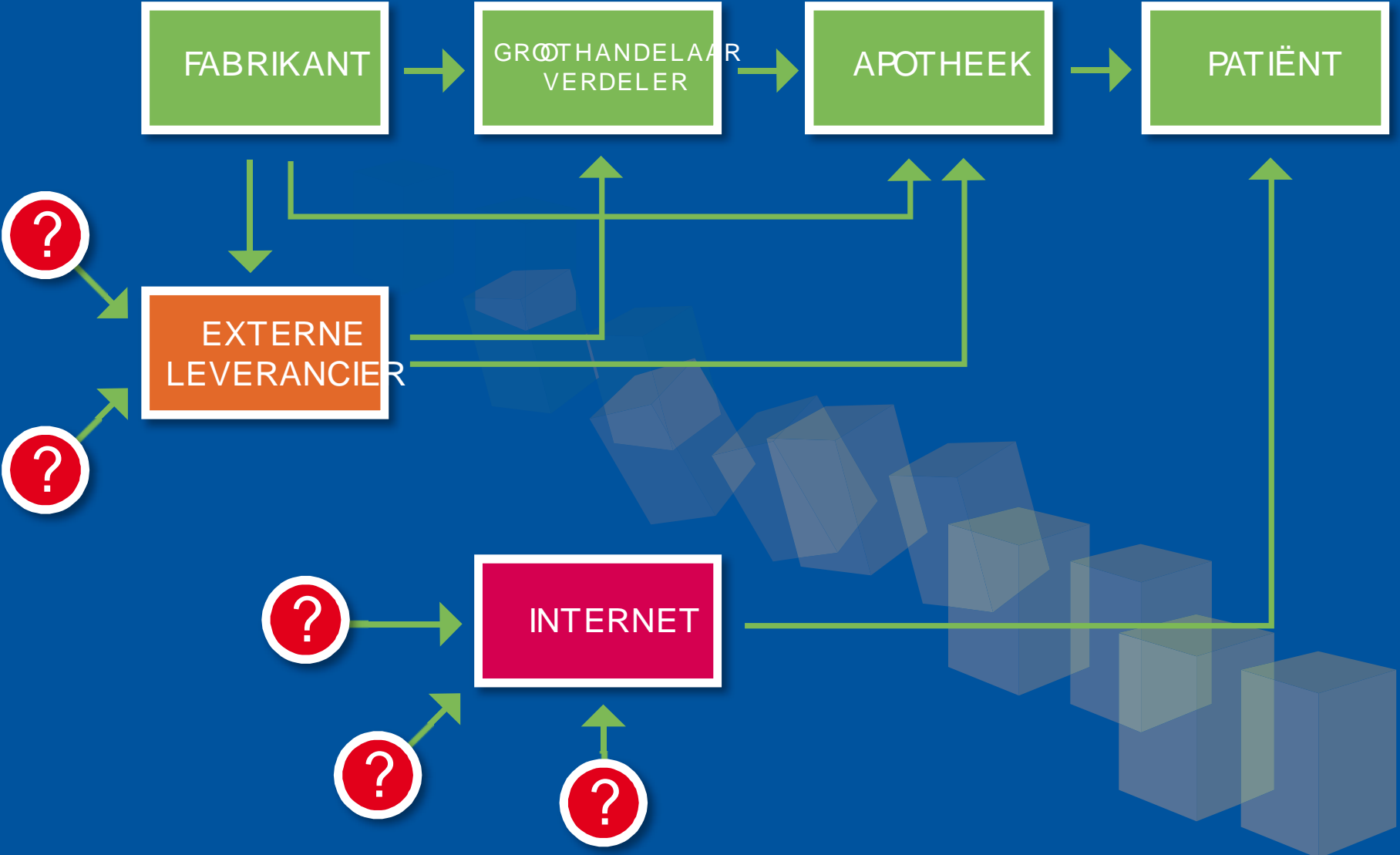


**CLIQUEZ SUR
L'IMAGE!**



**Un devis gratuit?
Une question technique?**

SUPPLY CHAIN



Protecting patients from counterfeit drugs is necessary and desirable in terms of patient **safety** and from an overall Public Health point of view.

Safety is achieved by implementing the Principles of and Guidelines on Good Practices , a.o. Good Distribution Practice (GDP)
Good Pharmacy Practice (GPP)

SUMMARY

- 1 Supporting regulation: The authenticity of medicines
- 2 The integrity of medicinal products and secure services
- 3 Perspectives

DIRECTIVE 2001/83/EC OF THE EP AND
THE COUNCIL OF 6 NOVEMBER 2001 ON
**THE COMMUNITY CODE RELATING TO
MEDICINAL PRODUCTS FOR HUMAN USE**

TITLE VII

WHOLESALE DISTRIBUTION OF
MEDICINAL PRODUCTS

Articles 76 to 85

The Medicines Act of 25 March 1964

Art. 12bis, § 1 : Production – Import authorization

Art. 12ter : Wholesale distribution authorization – parallel imports – public-service requirements

Par. 12 Principles of and guidelines on good practices.

RD No. 78 of 10 November 1967 concerning the Healthcare Professions

Art 4 (Pharmacists & pharmacies)

§ 2, bis **Responsible dispensing** ... based on the **Good Dispensing Practice principles and guidelines.**

§ 2, ter, par.2 Every pharmacist has the **responsibility** of ensuring that the **Good Dispensing Practice** is adhered to.

par. 4 implementing terms and rules (RD of 21 1 2009)

Wholesalers and Wholesale-Distributors

RD of 14 12 2006 concerning Medicinal Products for Human use (MPHU) and Veterinary Use (MAU) (M.B. [Belgian State Gazette] of 22 12 2006)

Section 1 MPHU - Section 2 MAU - PART VII. — The wholesale distribution of medicinal products - CH. I. — Wholesale distribution authorization

Art. 94 (MPHU), **221** (MAU) resp., imposes the obligation

3) to supply other authorized licensees only;

7) to keep correct **records** for a period of 5 years, either in the form of **purchase-sales** invoices or in the form of computer-based records which shall contain:

- the date; the name of the medicinal product; the quantity received and/or supplied; **the name and the address of the supplier or the recipient**, the batch number (MPHU: by 1 1 2012 at the latest - article 271).

9) to abide by the Best Distribution Practice principles and guidelines;

Wholesalers and Wholesale-Distributors

Art. 99 (MPHU), **228** (MAU), resp., lays down the duty to provide the persons authorized to supply or provide the public with medicinal products with information.

The licence holder shall supply all **the relevant information with every delivery** from which the following information can be **derived**:

- date; name and pharmaceutical form, quantity supplied; **names and addresses of the supplier and of the recipient; consignment number ... (in effect for MPHU on 1 1 2012 at the latest); final use-by date (only applicable to MAU)**

Pharmacies

RD of 21 1 2009 (B.S. [Belgian State Gazette] of 30 1 2009) *laying down the instructions for pharmacists*

DOCUMENTATION memory containing dispensing details, prescriptions, purchases.

Art. 34, 36, 37, information register of medical products dispensed on the basis of prescriptions:

- serial number of the prescription (MAU order form);
- dispensing date (MAU delivery);
- name of the prescriber (of the veterinary surgeon prescribing the MAU);
- name of the patient (name of the person in charge of animals for MAU);
- quantity dispensed (or MAU supplied);
- batch number (MPHU on 1 1 2013 at the latest – art. 55).

Art. 40 the pharmacist shall **store** the **DOCUMENTATION (data)** required to **trace** the MPHU and MAU, Medical Devices (MDs) and Active Pharmaceutical Ingredients (APIs) in **electronic** or in **written** format for a period of 5 consecutive years:

- the date of **purchase**;
- the name and the pharmaceutical form (...);
- the quantity acquired;
- the name and the address of the supplier;
- the batch number (applicable once **consignment numbers are processed automatically** and on 1 1 2013 at the latest – art. 55)

RD of 14 12 2006 concerning medicinal products for human use (MPHU) and for Veterinary use (MAU) (M.B. 22 12 2006)

Annexe V: Good wholesale distribution practice principles and guidelines (WHL and WHL-DSTR).

II. Principle

Nothing but the highest quality **throughout the medicine's entire distribution network**

Ensuring that the medicinal products are:

- **distributed** in accordance with prevailing Community legislation;
- that the medicinal products are **delivered to the intended recipient.**

Monitoring system, recall procedure.

IV. Documentation : **AUTHENTICITY**

Orders

5. Solely for licence holders art. 74 and 201 (S, I) , 90 and 217 (WHL) and 100 and 226 (WHL-DSTR) or WHL, WHL-DSTR – S - I granted by another MS (Directive 2001/83, 2001/82, resp.).

Registration: TRACKING and TRACING

7. Allows to **follow all the activities or events** over a period of at least 5 years.

8. **Every purchase and every delivery** (date, particulars, quantities received/supplied, name and address of the supplier/recipient). **Within the framework of transactions between manufacturers and WHL/WHL-DSTR and between WHL and WHL-DSTR, the records should show where the medicinal products originated and to whom they were supplied,** for instance, by featuring the relevant batch numbers, **so that all suppliers and potential recipients can be located.**

VI. Supplies AUTHENTICITY

17. **Only the following persons may be supplied**

WHL, WHL-DSTR, RPh, Vets.

18. **All deliveries must be documented** (date, name and pharmaceutical form, quantities, name and address of the supplier/recipient).

20. Medicinal products must be **transported in such a way: a) that their labels remain intact;**

Counterfeit medicinal products

31. Any counterfeit medicinal products **discovered** ... shall be stored separately. They ... shall **not be supplied**.

The minister or his authorized representative and the WMA shall be notified immediately.

Good Pharmacy Practice

F 4 PROVISIONING – RECEIPT - STORAGE

PRINCIPLE

The quality of the products received and the storage conditions allow pharmacists to **guarantee the quality of the medicinal products they dispense.**

GENERAL RULES

Pharmacists:

- **Select suppliers who abide by the good manufacturing and wholesale distribution practice for medicinal products.**
- **Comply with and check the storage conditions.**
- **Take the necessary steps not to hold products that can only be sold in a designated quarantine area.**

Summary of the WHL+ WHL-DSTR + RPh supporting regulation

Approval

Person in charge - qualified

Good practice, **mutual recognition** of the operators

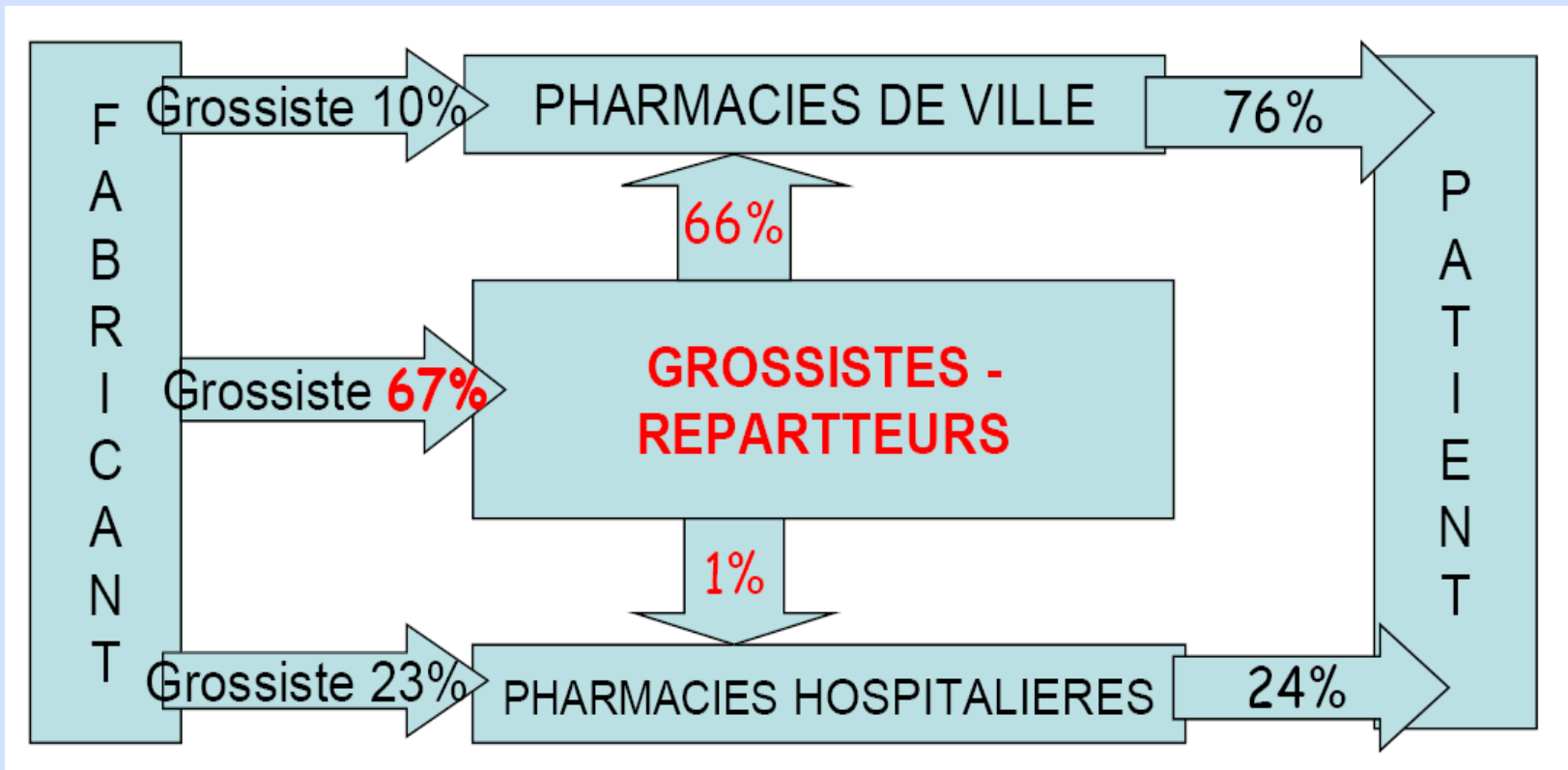
Information and traceability

Wholesalers, wholesale–distributors and pharmacists shall implement **tracking and tracing** as far as the product's final destination.

They shall guarantee the **authenticity** by supplying approved premises and authorized persons only.

Watertight?

What do you think?



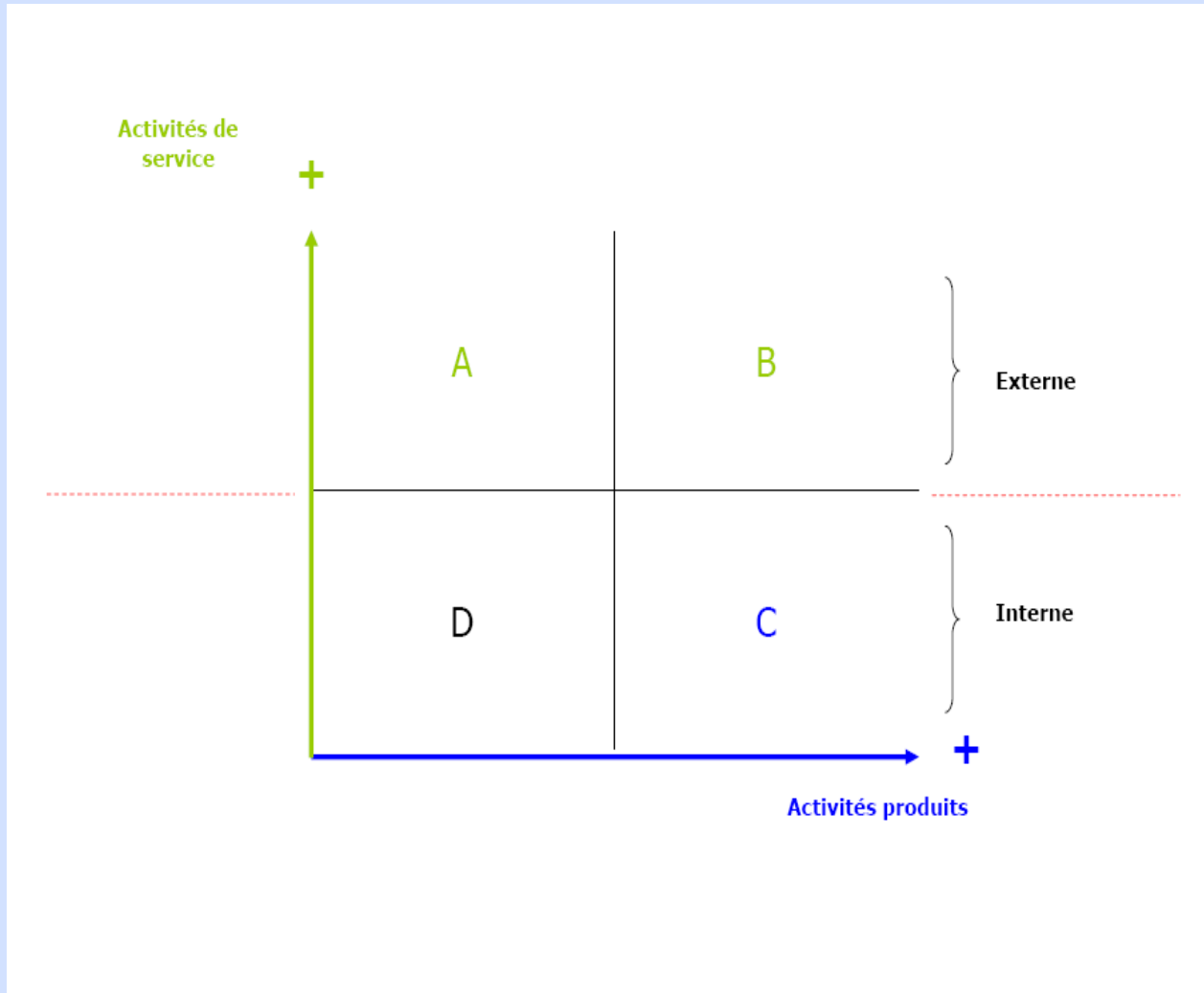
SUMMARY

1 Supporting regulations: Authenticity of medicinal products

2 Integrity of the medicinal products and secure services

3 Perspectives

Two axes and Four areas for safety



Quality, effectiveness, safety

Safety

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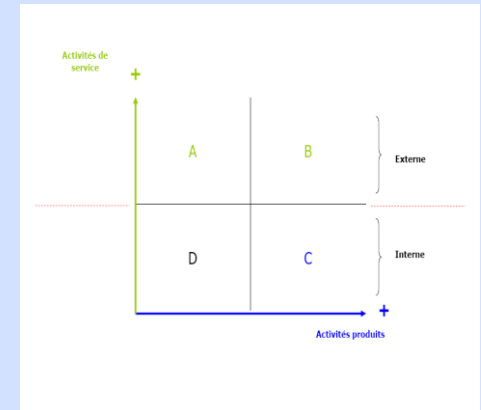
Integrity

+

Authenticity

A: Service Activities

A2 Historical overview of the supply flows

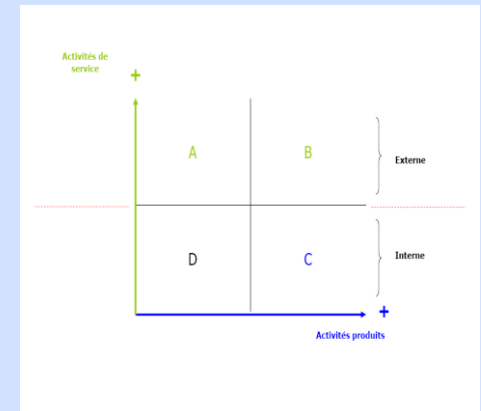


A5 Safety: information

C: Medicinal-product activities

Material product-
management activities

Procurement,
Storage
Supply

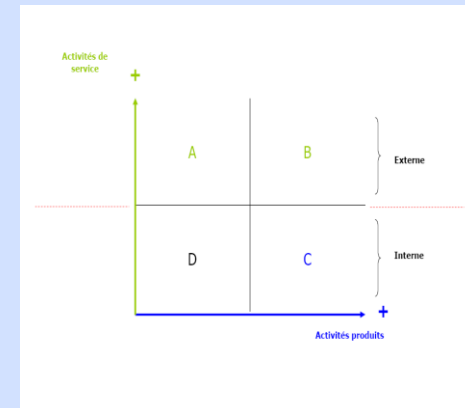


B: Combined Service + Product Activities

Activities to combine the service provider – product distributor dimensions

Central activities' process:

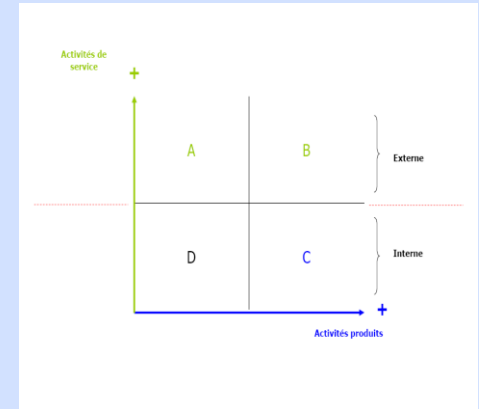
Delivering an authentic product to the correct recipient, at the right time



D: Resources

Activities which are not directly linked to the product or the service, but which are necessary to properly succeed in three other areas:

- **Staff**
- **The fitting out of the premises**
- **Information system**
- **Transport**



D4 Documentation system, traceability of the activities.

D7 Monitoring third-party service provisions

Summary WHLR, WHLR-DSTR, RPh Quality, Effectiveness, Safety

**Medicinal products:
Assurance in terms of quality,
integrity, **authenticity****

**Supply of services:
Managing **safety information:**
**traceability, identification,
authenticity****

SUMMARY

- 1 Supporting regulations: Authenticity of medicinal products
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3 Perspectives

Currently

Non-uniform codifications!

Increased focus on safety aspects (batch codes, production/expiry dates).

The distribution chain is only as strong as its weakest link

Legal vagueness about what system governs products that are not destined for the market;

ACTION: implementing identification / authentication standards for medicinal products so that they can be traced from the manufacturer all the way to the patient.

TO DO

- Affixing specific **security features** (e.g., identification code, non-removable seals) on the packaging of medicinal products
- Completing existing good practices
- Standardizing the process to **authenticate medicinal products throughout all the transaction stages starting at the manufacturers'**

Technology can help us make essential progress in terms of traceability, identification codes and the authentication process.

It will allow us to check every transaction on the basis of the manufacturers' authentic reference codes directly, without having to resort to intermediaries.

Moving towards Data Matrix registration which would allow us to intensify tracing and authentication, as is currently required

ACTION: setting up an “identification codes” task force.

1. IDENTIFICATION (Tracking)

Batch code

Registration serial code

2. TRACABILITY (Tracing)

Establishing where a medicinal product originated and following its path from the manufacturer's all the way to the patient.

MEANS

<p>1. CNC or EAN 128 bar codes</p> <ul style="list-style-type: none">• Product particulars (reference file) CBU = CNC + individual serial number, batch number, expiry date• Reading/box	<p>2. Data Matrix (CB2D) MPHU</p> <ul style="list-style-type: none">• Product particulars• Individual registration• Batch number• Expiry• Reading/packaging or homogenous packaging groups	<p>3. RFID costly</p> <ul style="list-style-type: none">• Product particulars• Individual serial number• Batch number• Expiry date, other information• Hertz reading
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DATA MATRIX APPLICABILITY

1. PHARMACIES: Individual readout with a special reading device >> the ideal.
2. WHL and WHL-DSTR: readout by homogenous groups
3. SWEDISH example:
Consignments of boxes and batches are identified **as soon as they are received or consigned** (Data matrix packing list). Storage in a designated area, only activated when the oldest batch is exhausted.

Proposal for a DIRECTIVE OF THE EP AND OF THE COUNCIL amending Directive 2001/83/EC OF 6 NOVEMBER 2001 ON THE COMMUNITY CODE RELATING TO MEDICINAL PRODUCTS FOR HUMAN USE as regards the **prevention of the entry into the legal supply chain of medicinal products which are falsified in relation to their identity, history or source.**

TITLE VII WHOLESALE DISTRIBUTION OF MEDICINAL PRODUCTS, *Articles 76 to 85*

Reducing the risk of non-authentic presentations of medicines entering the legal supply chain :

Obligations for **other players** than wholesale distributors, active in the distribution chain and involved in the transactions without actually handling the products (auctioneers or brokers).

Obligatory audits of supplying wholesale distributors of medicines in order to **ensure reliability of business partners.**

Obligatory specific **safety-features** (such as a serialisation number, seal)

Spread the responsibility across *all* actors, the pharmaceutical industry, wholesalers, API suppliers and importers

Extend the Community database of GMP-compliant companies to **GDP-compliant wholesale distributors.**

Obligation for all traders (brokers, wholesale distributor, parallel traders) to ensure that the **marketing authorisation holder is informed about suspected cases** in order to allow the withdrawal of other products that could be concerned to the same incident.

The responsibilities of the wholesale distributors are clarified.

**I thank you for your attention.
Any questions?**

