Pharma and Logistic Service Providers (LSP)
Synergies and opportunities

GDP, NEW EUROPEAN DIRECTIVES

DB Schenker Healthcare
Conference Europe
April 17 - 18th 2012

J. BERLO
Opportunities for Synergies

Leader in Pharma
GMP

Leader in LSP
GDP

Ensure Product Quality → PATIENT
Content of this Presentation

1. Guideline GDP – Regulatory aspects
   - 92/25/EEC
   - 94/C 63/03
   - 2001/83 – Art. 84
   - Commission Guidelines on Good Distribution Practice of Medicinal Products for Human Use

   - Reason for change
   - Review of the text

3. Practical implementation of GDP Directive
   - Example Belgian Authorities
   - MHRA Example

Article 1 – 2. Purpose of this Directive

- wholesale distribution of medicinal products shall mean all activities consisting of procuring, holding, supplying or exporting medicinal products, apart from supplying medicinal products to the public; such activities are carried out with manufacturers or their depositaries, importers, other wholesale distributors or with pharmacists and persons authorized or entitled to supply medicinal products to the public in the Member State concerned.

Article 3
1. Member States shall take all appropriate measures to ensure that the wholesale distribution of medicinal products is subject to the possession of an authorization to engage in activity as a wholesaler in medicinal products
Guidelines on Good Distribution Practice of Medicinal Products for Human Use (94/C 63/03)

- These guidelines have been prepared in accordance with Article 10 of Council Directive 92/25/EEC
- They do not cover commercial aspects
- Describe the principles of GDP
  + Personnel
  + Documentation (Procedures – Records)
  + Premises and equipment (Receipt – Storage)
  + Deliveries to customers
  + Returns (Returns of non-defective medicinal products
    – Emergency plan and recalls – Conterfeit medicinal products)
  + Self inspections
European legislation


Legislation regulates the Licensing and Manufacture of and Wholesale dealing in Medicinal Products within the European Community


This Directive lays down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use whose manufacture requires an authorisation.

Title I Definitions
Title II Scope
   For placing on the market medicinal products
Title III Placing on the market
   ➢ Marketing authorization (How to obtain an MA – Procedures – Content of dossier)
   ➢ Art. 49 Definition of Qualified Person
   ➢ Labelling – packaging
   ➢ Wholesale distribution (How to obtain the distribution authorisation)
   ➢ ......
Definitions


**Proprietary medicinal product:**
Any ready-prepared medicinal product placed on the market under a special name and in a special pack.

**Medicinal product:**
Any substance or combination of substances presented for treating or preventing disease in human beings.

Any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings is likewise considered a medicinal product.
Steps of the development of a new medicinal product to MA

New compound

Pharmaceutical development

Preclinical studies

- Screening
- Toxicological studies
- Mutagenic
- Carcinogenic
- .......

Synthesis of the active substance

Galenic development (tablets, sirups,..)

Stability studies

Development of the manufacturing process + his validation + storage and distribution conditions

Clinical studies: Phase I --> Phase IV

GMP + GDP

GCP

Registration Dossier

Submission to Regulatory Authorities (EMA)

After approval

Marketing Authorisation of the Medicinal Product
<table>
<thead>
<tr>
<th>Organization</th>
<th>Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASEAN</td>
<td>Guideline “Stability Studies of Drug Products”</td>
</tr>
<tr>
<td>WHO</td>
<td>TRS 863, Annex 5: “Guidelines for stability testing of pharmaceutical products containing well established drug substances in conventional dosage forms”</td>
</tr>
<tr>
<td>EMEA</td>
<td>Note for Guidance on Stability Testing of existing active substance and Related Finished products (Draft), February 2002</td>
</tr>
<tr>
<td>Climatic Zone Countries</td>
<td>Calculated</td>
</tr>
<tr>
<td>-------------------------</td>
<td>------------</td>
</tr>
<tr>
<td></td>
<td>Temp. °C</td>
</tr>
<tr>
<td>Climatic Zone I</td>
<td>20</td>
</tr>
<tr>
<td>“Temperate”</td>
<td></td>
</tr>
<tr>
<td>Japan, United Kingdom’ Northern Europe, Canada, Russia, United States</td>
<td></td>
</tr>
<tr>
<td>Climatic Zone II</td>
<td>21.6</td>
</tr>
<tr>
<td>“Mediterranean, Subtropical”</td>
<td></td>
</tr>
<tr>
<td>Japan, United States, Southern Europe</td>
<td></td>
</tr>
<tr>
<td>Climatic Zone III</td>
<td>26.4</td>
</tr>
<tr>
<td>“Hot, dry”</td>
<td></td>
</tr>
<tr>
<td>Iran, Iraq, Sudan</td>
<td></td>
</tr>
<tr>
<td>Climatic Zone IV</td>
<td>26.7</td>
</tr>
<tr>
<td>“Hot, humid”</td>
<td></td>
</tr>
<tr>
<td>Brazil, Ghana, Indonesia, Nicaragua, Philippines</td>
<td></td>
</tr>
</tbody>
</table>
### Table 3: Example of a Generic, Global Protocol

<table>
<thead>
<tr>
<th>Temp./Humidity</th>
<th>Condition</th>
<th>Climatic Zone</th>
<th>Timepoint</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>t=0</td>
</tr>
<tr>
<td>25°C / 60% R.H.</td>
<td>Long-term</td>
<td>I and II</td>
<td>x</td>
</tr>
<tr>
<td>30°C / 65% R.H.</td>
<td>Intermediate</td>
<td>I and II</td>
<td>(x)</td>
</tr>
<tr>
<td></td>
<td>Long-term</td>
<td>III and IV a</td>
<td></td>
</tr>
<tr>
<td>30°C / 75% R.H.</td>
<td>Long-term</td>
<td>IV b</td>
<td>x</td>
</tr>
<tr>
<td>40°C / 75% R.H.</td>
<td>Accelerated</td>
<td>I, II, III and IV</td>
<td>(x)</td>
</tr>
<tr>
<td>50°C</td>
<td>Stress</td>
<td>-</td>
<td>(x)</td>
</tr>
</tbody>
</table>
### Recommended labelling statements for active pharmaceutical ingredients (APIs)

<table>
<thead>
<tr>
<th>Testing condition under which the stability of the API has been demonstrated</th>
<th>Recommended labelling statement$^a$</th>
</tr>
</thead>
</table>
| 25 °C/60% RH (long-term)  
40 °C/75% RH (accelerated) | “Do not store above 25 °C” |
| 25 °C/60% RH (long-term)  
30 °C/65% RH (intermediate, failure of accelerated) | “Do not store above 25 °C”$^b$ |
| 30 °C/65% RH (long-term)  
40 °C/75% RH (accelerated) | “Do not store above 30 °C”$^b$ |
| 30 °C/75% RH (long-term)  
40 °C/75% RH (accelerated) | “Do not store above 30 °C” |
| 5 °C ± 3 °C | “Store in a refrigerator (2 °C to 8 °C)” |
| -20 °C ± 5 °C | “Store in freezer” |

---

*a* During storage, shipment and distribution of the API, the current good trade and distribution practices (GTDP) for pharmaceutical starting materials are to be observed (1). Details on storage and labelling requirements can be found in WHO guide to good storage practices for pharmaceuticals (2).

*b* “Protect from moisture” should be added as applicable.
<table>
<thead>
<tr>
<th>Testing condition under which the stability of the FPP has been demonstrated</th>
<th>Recommended labelling statement</th>
</tr>
</thead>
</table>
| 25 °C/60% RH (long-term)  
40 °C/75% RH (accelerated) | “Do not store above 25 °C” |
| 25 °C/60% RH (long-term)  
30 °C/65% RH (intermediate, failure of accelerated) | “Do not store above 25 °C” |
| 30 °C/65% RH (long-term)  
40 °C/75% RH (accelerated) | “Do not store above 30 °C” |
| 30 °C/75% RH (long-term)  
40 °C/75% RH (accelerated) | “Do not store above 30 °C” |
| 5 °C ± 3 °C | “Store in a refrigerator (2 °C to 8 °C)” |
| -20 °C ± 5 °C | “Store in freezer” |

* During storage, shipment and distribution of the FPP, the current good distribution practices (GDP) for pharmaceutical products are to be observed (3). Details on storage and labelling requirements can be found in WHO guide to good storage practices for pharmaceuticals (2).

* “Protect from moisture” should be added as applicable.
### Additional labelling statements for use where the result of the stability testing demonstrates limiting factors

<table>
<thead>
<tr>
<th>Limiting factors</th>
<th>Additional labelling statement, where relevant</th>
</tr>
</thead>
<tbody>
<tr>
<td>FPPs that cannot tolerate refrigeration</td>
<td>“Do not refrigerate or freeze”*</td>
</tr>
<tr>
<td>FPPs that cannot tolerate freezing</td>
<td>“Do not freeze”*</td>
</tr>
<tr>
<td>Light-sensitive FPPs</td>
<td>“Protect from light”</td>
</tr>
<tr>
<td>FPPs that cannot tolerate excessive heat, e.g.</td>
<td>“Store and transport not above 30 °C”</td>
</tr>
<tr>
<td>suppositories</td>
<td></td>
</tr>
<tr>
<td>Hygroscopic FPPs</td>
<td>“Store in dry condition”</td>
</tr>
</tbody>
</table>

* Depending on the pharmaceutical form and the properties of the FPP, there may be a risk of deterioration due to physical changes if subjected to low temperatures, e.g. liquids and semi-solids. Low temperatures may also have an effect on the packaging in certain cases. An additional statement may be necessary to take account of this possibility.
World Health Organization

**Good Distribution Practices (GDP) for Pharmaceutical Products**

2005 – Guidelines - Content

- Organization and Management
- Personnel
- Quality Management
- Premises, warehousing and storage (+ Cleanliness- pest control...)
- Vehicles and equipment
- Container and container labelling
- Dispatch
- Transportation and products in transit
- Complaints
- Recalls
- Rejected and returned products
- Self-Inspection
Commission Guidelines on Good Distribution Practice of Medicinal Products for Human Use - 2011 -

• Legal basis for publishing GDP Guidelines:
  Article 84 – Directive 2001/83 EC

• Proposed Guidelines will replace the Guidelines on GDP published in 1994 in the Official Journal of the European Community
Wholesale dealing or distribution

Directive 2001/83/EC

Defines wholesale distribution of medicinal products as:

All activities of
- Procuring
- Holding (such as requested LSP)
- Supplying
- Exporting medicinal products within EC or those countries covered by the EEA, apart from supplying medicinal products to the public
Good Distribution Practice

“Standards of Good Distribution Practices (GDP) are applied to ensure that the high level of product quality achieved by observing Good Manufacturing Practice (GMP) is maintained throughout the distribution network”
Opportunities for Synergies

Leader in Pharma

Leader in LSP

GMP

GCP

GDP

Regulatory Authorities

Ensure Product Quality → PATIENT
Manufacturer of Medicinal Products for Human use
Storage of Finished Pharmaceutical Product after Manufacturing Process

Internal company storage before distribution
  ↓
Wholesaler
  ↓
Pharmacist
  ↓
Patient

Wholesaler Distributor
  ↓
Pharmacist
  ↓
Patient

External storage
  ↓
Logistic Service Provider

External storage
  ↓
Prewholesaling – Warehousing
  ↓
“Holding (only) of the Medicinal Products”
  ↓
(Active substance, Final Product, Licensed or Unlicensed Product)

Subject to Authorisation by National Health Authorities
Commission Guidelines on Good Distribution Practice of Medicinal Products for Human Use - 2011 -

- Public consultation → to 31 December 2011

- Reasons for changes:
  - Advancements of practices for an appropriate storage and distribution of medicinal products in the European Union
  - Prevention of the entry into legal supply chain of falsified medicinal products (Directive 2011/62/EU – 8 June 2011)
Contents of new GDP guidelines

- Chap. 1  Quality Management
- Chap. 2  Personnel
- Chap. 3  Premises and equipment
- Chap. 4  Documentation
- Chap. 5  Operations
- Chap. 6  Complaints, returns, suspected falsified medicinal products and medicinal product recalls
- Chap. 7  Contract operations
- Chap. 8  Self-inspections
- Chap. 9  Transportation
- Chap. 10 Specific provisions for brokers
CHAPTER 1  QUALITY MANAGEMENT

• Quality System
• Management of Outsourced Activities
• Management Review and Monitoring
• Quality Risk Management
Quality Management System

A quality management system is the organisational structure, responsibilities, procedures, processes, documentation and resources for implementing quality management.
Quality Management Systems
Cold Chain Distribution or/and normal temperature distribution

The system should ensure that:

- there is a programme of calibration of measuring devices
- storage facilities are monitored, qualified/re-qualified
- transport arrangements are validated and monitored
- there is a comprehensive staff training programme
- there is a periodic review of activities
- there is a process for implementing corrective and preventive actions and assessing their effectiveness
CHAPTER 2  PERSONNEL

• Responsible Person
• Other Personnel
• Training
• Hygiene
Responsible Person (RP)
MHRA – UK
(Medicines and Healthcare products Regulatory Agency)

Regulation 10(1) of the Medicines for Human Use
(Manufacturing, Wholesale dealing and Miscellaneous Amendments)

RP is responsible for safeguarding product users against potential hazards arising from poor distribution practices
Duties of a RP to ensure:
- Provisions of the licence are observed
- Operations do not compromise the quality of medicines
- Adequate quality system is established and maintained
- Oversee audit of the quality system + to carry out independent audits
- Adequate records are maintained
- All personnel are trained
- Full and prompt cooperation with product licence holders in the event of recalls
Responsible Person (RP)
MHRA – UK

To carry out his duties, RP should have:
- Clear reporting line to the license holder (MAH)
- Personal knowledge of the products traded under licence and conditions necessary for their safe storage and distribution
- Access to all areas, sites, stores and records related to the licensable activities
- Regularly review and monitor all such areas
Responsible Person (RP)
MHRA – UK

- There is no statutory requirement for the RP to be a pharmacist. Although this is desirable.

- If RP is not a pharmacist to act as QP (as defined in Directive 2001/83/EC), he should have at least 1 year’s practical experience in following area:
  - Handling
  - Storage
  - Distribution of medicinal products
  - Selling – supplying or procuring medicinal product
Definition of Qualified Person


A qualified person shall be in possession of a diploma, certificate or other evidence of formal qualifications awarded on completion of a university course of study, or a course recognized as equivalent by the Member State concerned, extending over a period of at least four years of theoretical and practical study in one of the following scientific disciplines: pharmacy, medicine, veterinary medicine, chemistry, pharmaceutical chemistry and technology, biology.
Belgium - Qualified Person

Described in article 84 of the Royal Decree dated 14th December 2006.

Chap II. § 2

Only Industrial Pharmacist is agreed as Qualified Person
CHAPTER 3  PREMISES AND EQUIPMENT

• Premises
• Temperatures and Environment Control
• Equipment
• Computerised Systems
• Qualification and Validation
Storage Temperatures

- Products requiring controlled temperature storage should be identified on receipt and stored in accordance with written instructions.
- Temperatures should be monitored and recorded daily. Records should be reviewed regularly.
- Controlled temperature storage areas should be equipped with temperature recorders. Control should be adequate to maintain.
Compliance Issues: Storage

- Temperature monitoring records
- Temperature mapping
- Alarm systems
- Response to out-of-specification (alarm) conditions
- Qualification/re-qualification
- Cleanliness – including Pest Control
- Receipt of cold chain goods (time outside cold store)
Calibration

- Manual and electronic recording devices used in critical areas should be calibrated at least annually against a traceable reference device.
- Records should include pre- and post-calibration readings and details of any adjustments made or corrections to be applied.
- Alarms be checked at least annually for correct functioning.
CHAPTER 4  DOCUMENTATION

• General
  - Procedures
  - Instruction
  - Contracts
  - Records
  - Archiving ($\geq$ 5 years)
  - Availability of the documentation
  - Info on records: Date, name of product,
  ...
CHAPTER 5  OPERATIONS

- Qualification of Suppliers
- Qualification of Customers
- Marketing authorisation
- Receipt of Goods
- Storage
- Segregation of Goods
- Destruction of obsolete Goods
- Picking
- Packing
- Delivery
- Export
CHAPTER 6  COMPLAINTS, RETURNS, SUSPECTED FALSIFIED MEDICINAL PRODUCTS AND MEDICINAL PRODUCT RECALLS

- Complaints
- Returned Medicinal Products
- Suspected falsified Medicinal Products
- Medicinal Product Recalls
CHAPTER 7  CONTRACT OPERATIONS

• Contract Giver
• Contract Acceptor
• Contract
GMP Compliant Technical Agreement

A crucial document for a successful partnership

- References to concerned Pharma Regulation

- Responsibilities of Contract Giver – Contract Acceptor
CHAPTER 8  SELF-INSPECTIONS

• Self-Inspections
CHAPTER 9  TRANSPORTATION

- Transportation
- Containers, packaging and labelling
- Transportation of Products requiring special Conditions
- Temperature Control during Transport
Temperature controlled chain supply
Transportation

- Storage conditions
- Deviation during transportation → Reported
- Adapted vehicles and equipment
- Delivery drivers - trained
- Procedures maintenance vehicles
- Temperature monitoring during transport
- Subcontracting transport

§9.12 Medicinal products held > 24 h on the premises
  → = Acting as a storage site

wholesale distribution authorisation
Containers, packaging and labelling

- Selection of containers and packaging
- Labelling specifications
Transportation of products requiring special conditions

- **Products at risk from freezing:**
  - vaccines, insulin, biotech products, blood products
  - those physically unstable, e.g. some emulsion systems

- **Products at risk from elevated temperatures**
  - those described above, and
  - those chemically unstable at elevated temperatures, e.g. chloramphenicol eye drops
  - some semi-solids, e.g. fatty-based suppositories
Temperature control during transportation

- Validated temperature control system (thermal packaging, temperature controlled containers, refrigerated vehicles)
- Precautions with cool-packs + reuse control
- How to control the seasonal temperature variations
Temperature data logger/ Indicator devices

- **Validated** temperature control system (WHO)
- Compliance with FDA Standard 21 CFR part 11
- ISO 19005-1 Document Management Standardised file format PDF/A for electronic documents for long term archiving
- USB port
- Detailed evaluation of raw date
- Userfriendly – **simply for users devices**
- No wrong manipulation possible
- A simple display and print out that can **immediately** be sent to any destination
Temperature chain monitoring

Just before the transport starts, press **TRANSLIT button** to activate the alarm monitoring.

Press **ARRIVED button** at the end of the transport

*Simply for users*
ADHESIA Rapport Contrôle de températures

Informations supplémentaires

ADHESIA
Aéroport de Gosselies
Rue Antoine de Saint-Exupéry, 8
B-6041 Gosselies
Tel: 01733400
Fax 00000000

Configuration de l’appareil

Type: Libero T11 V1.28
Identification: 20062028
Intervalle / durée: 16 m / 166.7 J
Mode: Continu
Base de temps: 06h 00m
Configuré par: C193, BERLO-POJacques, 11.03.2012 22:17:47

Conditions d’alarme

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<thead>
<tr>
<th>Limites</th>
<th>Temps total</th>
<th>Statut</th>
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<tbody>
<tr>
<td>Limite supérieure: 25,0 °C</td>
<td>Temps au-dessus limite: 30 s</td>
<td>ALARME</td>
</tr>
<tr>
<td>Limite inférieure: 15,0 °C</td>
<td>Temps sous limite: 0 s</td>
<td>OK</td>
</tr>
<tr>
<td>Temps de retard: 0 s</td>
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Résultats de l’enregistrement

<table>
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<tr>
<th>Paramètre</th>
<th>Valeur</th>
<th>Date/Heure</th>
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<tr>
<td>Température maximum:</td>
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</tr>
<tr>
<td>Température minimum:</td>
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<tr>
<td>MKT</td>
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Rapport d'évaluation créé par Libero, le PDF Logger®
CHAPTER 10  SPECIFIC PROVISIONS FOR BROKERS

- Quality Management System
- Personnel
- Documentation
What Happens When Things Go Wrong?

- Risk to patients
- Expensive recalls
- Loss of confidence in the company
- Regulatory action
  - suspension of manufacturing/distribution authorisation
  - compulsory variation of authorisation
  - revocation of authorisation
  - sanctions against the QP (Qualified Person) or RP (Responsible Person)
What Distributors Should Have In Place

• A comprehensive quality system
• A process for continual quality improvement
• A cold chain distribution strategy
• An ambient and cold chain distribution strategy
• A risk assessment programme
The Ultimate Objective

Organisations involved in the distribution of medicines should adopt a culture that focuses on:

- protecting the patient
- ensuring the quality of the products handled
- satisfying customer requirements
Bij toepassing van de artikels 12bis en 12ter van de wet van 25 maart 1964 op de geneesmiddelen.

De firma: SCHENKER NV
Ondernemingsnummer: 0406 316 776
Maatschappelijke zetel: Noorderlaan 147 - 2030 ANTWERPEN
Administratieve zetel: Noorderlaan 147 - 2030 ANTWERPEN
Plaats van de verrichtingen: Brucargo - Building 755 - 1931 ZAVENTEM
Vertegenwoordigd door: Dhr. Ulrich Pütz, bestuurder
Dhr. Harald Moser, bestuurder

Wordt vergunning verleend om:
* voor het houden van:
  de geneesmiddelen aangegeven op bijlage HG (1 blad bevattend)

Op elke bijlage is aangegeven waar de bovenvermelde verrichtingen geschieden. Bij elke wijziging van de benaming, plaatsen of andere inlichtingen die op deze vergunning (met inbegrip van de bijlagen) voorkomen, moet de vergunning noodzakelijk vernieuwd worden.

VOOR DE MINISTER VAN VOLKSGEZONDHEID,
DE ADMINISTRATIEU GENERAL.

[Signature]
HET HOUDEN VAN DE VOLGENDE GENEESMIDDELEN

Wordt de vergunning verleend voor het houden van geneesmiddelen in opdracht van derden en dit voor geneesmiddelen voor diergeneeskundig gebruik die dienen bewaard te worden bij kamertemperatuur of bij 2-8°.

Deze vergunning kent aan de houder ervan niet het recht toe een activiteit van handel in het groot of van distributie in het groot uit te oefenen.

Plaats van de verrichtingen:
Brucargo – Building 755 – 1931 ZAVENTEM
Wholesale Dealer’s Licence
How to obtain a licence - UK

Applicant

Submitting Application form

Inspection of the site(s)

If complying with:
- Directive 2001/83/EC
- Directive 94/C63/03. Guidelines on GDP of medicinal products for human use
- Rules and Guidance for Pharmaceutical Manufacturers and Distributors

Wholesale Dealer’s licence

MHRA – Guidance Note N°6
Notes for applicants and holders of a wholesale dealer’s licence
content

• Wholesale dealing or distribution
• Persons requiring a wholesale dealer’s licence
• How to obtain a licence
• Wholesale dealer’s obligations
• Responsible Person
• Inspection
• Counterfact and diverted medicines
• Powers to vary, suspend or revoke wholesale dealer’s licence
• Fees
• Glossary of legislation
Wholesale dealer's licences application forms

This page contains all the forms for wholesale dealer's licence applications, including change of ownership and variations. It covers licences for products for human use and veterinary use.

### Wholesale dealer's licence application forms - Products for human use - New applications

- **Pending changes to obligations for Wholesale Dealer's licences** (37Kb)
- **The application process** (352Kb)
- **Guidance: How to apply for a wholesale dealers licence** (329Kb)
- **Wholesale dealer's licence (WL) application form** (1199Kb)
- **Guidance Note 6: Notes for applicants and holders of a wholesale dealer's licence** (279Kb)

### Wholesale Dealer's licence application forms - Products for human use - Change of Ownership

- **Change of ownership WL and WDL** (192Kb)

### Wholesale Dealer's licence application forms - Products for human use - Variations to existing licences

- **Fee calculation** (57Kb)
- **Forms to be used** (51Kb)
- **Where to send your variations** (146Kb)

[http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Informationforlicenceapplicants/Licenceapplicationforms/Wholesaledealerslicencesapplicationforms/index.htm](http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Informationforlicenceapplicants/Licenceapplicationforms/Wholesaledealerslicencesapplicationforms/index.htm)
<table>
<thead>
<tr>
<th><strong>Person completing the application form</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title</strong></td>
</tr>
<tr>
<td><strong>First Name(s)</strong></td>
</tr>
<tr>
<td><strong>Surname</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Contact Details</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Telephone</strong></td>
</tr>
<tr>
<td><strong>Mobile</strong></td>
</tr>
<tr>
<td><strong>E-mail</strong></td>
</tr>
</tbody>
</table>

Are you a consultant/representative applying on behalf of the proposed Licence Holder?  

Yes [ ] No [ ]

<table>
<thead>
<tr>
<th><strong>Application Date</strong></th>
<th><strong>Purchase Order Number</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Type of Application**
COUNTERFEIT DRUGS KILL!

IMPACT
International Medical Products Anti-Counterfeiting Taskforce
IMPACT working groups

- Communications
- Legislative and Regulatory Infrastructure
- Regulatory Implementation
- Enforcement
- Technology

Each Working Group will develop proposed work plans, report and submit proposals to the General Meeting through the Planning Group.
Participants of the General Meeting: WHO Member States, international organizations, enforcement agencies, national drug regulatory authorities, customs and police organizations, non-governmental organizations, associations representing pharmaceutical manufacturers and wholesalers, health professionals and patients’ groups.
Development of the EDQM anti-counterfeiting service

Strasbourg, 01.02.2012 – The Council of Europe and its European Directorate for the Quality of Medicines & HealthCare (EDQM) have launched “eTACT”, an IT-based traceability service which will allow patients to check the authenticity of their medicines using smartphones or the internet.
The aim of eTACT is to ensure the traceability of individual packs of medicines using **mass serialisation**.

It is based on the principle of generating a **Unique Medicine Identifier (UMI)** at the manufacturing stage.

This UMI can be traced and verified by the different stakeholders in the legal supply chain. Verification must be performed at the dispensing stage. Patients are also allowed to verify the authenticity of their medication.
Proposed EDQM Traceability Service

Manufacture
- Distribution
- Pharmacies
- Internet/mail-order pharmacies

Patients

Governance: EDQM as an intergovernmental organization guaranteeing sustainable confidentiality of data
EDQM ANTI-COUNTERFEITING TRACEABILITY SERVICE FOR MEDICINES

1. MANUFACTURERS
2. DISTRIBUTORS
3. RE-PACKAGERS
4. INTERNET PHARMACIES
5. HOSPITAL PHARMACIES
6. RETAIL PHARMACIES
7. PATIENTS
8. AUTHORITIES
Opportunities for Synergies

Ensure Product Quality

PATIENT