Guideline for
Inspections by the Medicines Control Agency

MCA-GL-201, Version 1.0, 13 December 2017
FORWARD

The Medicines Control Agency (MCA) established by an Act of Parliament and assented to on 24th December 2014 is mandated to regulate the manufacture, import, wholesale, storage, distribution and supply of medicines and related products, and to ensure that all medicines and related products sold and used in the country conform to the required standards of quality, safety and efficacy throughout the product lifecycle in The Gambia.

In pursuance of the Medicines and Related Products Act 2014, Part VIII, MISCELLANEOUS, Section 64 Guidelines herein quoted “the Agency may publish guidelines in connection with matters provided for under this Act for the purpose of giving guidance”, the MCA deems it very essential to develop written Guidelines and Standard Operating Procedures (SOPs) to guide the implementation of the various regulatory functions of MCA in ensuring the safety, efficacy and quality of medicines and related products available to the population.
ACKNOWLEDGEMENTS

The Medicines Control Agency (MCA) wishes to thank the Ministry of Health and Social Welfare, members of the MCA Board and the various institutions for their support. Special thanks is extended to the Global Fund through Action Aid International The Gambia (AAITG) for their financial support in the development of the Quality Assurance Policy and Plan, some regulatory guidelines and SOPs for use by MCA and its stakeholders.

Special thanks is extended to the Technical Working Group and staff of the Medicines Control Agency for their commitment and technical input in the development of this guideline.

Gratitude is extended to key stakeholders including the Directorate of National Pharmaceutical Services, Pharmacy Council, Medical and Dental Association, Pharmaceutical Society of The Gambia, Nurses and Midwives Council, Regional Health Directorates, National Aids and TB Control Programs, National Public Health Laboratory Services and Gambia Standards Bureau for their valuable contributions and participation in the validation of the Quality Assurance Plan, which will ensure that all medicines and related products are of the required quality for their intended use.
**TABLE OF CONTENTS**

1. Abbreviations and Acronyms ............................................................................. 5
2. Introduction ......................................................................................................... 5
   2.1 Purpose and Scope ......................................................................................... 5
   2.2 Main objectives of medicine inspection ......................................................... 6
3. Inspectors ............................................................................................................ 6
   3.1 Inspector qualification .................................................................................... 6
   3.2 Attributes of an inspector ............................................................................. 6
   3.3 Organizational aspects .................................................................................. 7
   3.4 Do’s & Don’ts for Inspectors during inspection ............................................. 7
   3.5 Independence .................................................................................................. 7
   3.6 Reference/information sources ..................................................................... 8
4. Types of Inspections .......................................................................................... 8
   4.1 Comprehensive/Routine Inspection ................................................................. 8
   4.2 Concise Inspection ........................................................................................ 8
   4.3 Follow-Up Inspection (reassessment or re-inspection) .................................... 9
   4.4 Special Inspection .......................................................................................... 9
   4.5 Investigative Inspection ................................................................................ 9
5. Establishments to be inspected .......................................................................... 9
   5.1 Areas to be inspected .................................................................................... 9
   5.2 Processes to be inspected ............................................................................ 10
   5.3 Importer ......................................................................................................... 10
   5.4 Retail and hospital pharmacy ....................................................................... 10
   5.5 Clinics, nursing and maternity homes .......................................................... 11
   5.6 Unauthorized markets .................................................................................. 11
6. Inspection Process .............................................................................................. 11
   6.1 During an inspection ...................................................................................... 11
   6.2 Grading of inspection findings ..................................................................... 11
   6.3 After the inspection ...................................................................................... 12
7. Preparation at the establishment for inspections .............................................. 12
8. Final Provisions .................................................................................................. 13
9. References .......................................................................................................... 13
10. Document History ............................................................................................. 13
11. Definitions of Terms ......................................................................................... 13
1 ABBREVIATIONS AND ACRONYMS

COA Certificate of Analysis (Batch Certificate)
GCP Good Clinical Practice
GDP Good Distribution Practice
GMP Good Manufacturing Practice
GPP Good Pharmacy Practice
GSP Good Storage Practice
MCA Medicines Control Agency
NGO Non-Governmental Organisation
POE Port of entry
SOP Standard Operating Procedure

2 INTRODUCTION

Medicines and related products are decisive tools of any health-care delivery system. Consequently, one objective of the national medicines policy is assurance of the quality, safety and efficacy of the products circulating on the Gambia market. An essential part of any medicines and related products control system is the provision of an inspection body with the responsibility and authority to inspect some or all of the activities involved in research, product development, manufacture, import, control, distribution, and supply of medicines and related products. Qualified and experienced inspectors constitute an indispensable component of the inspection system.

Inspectors serve as the eyes and ears of the control authority and are on the front lines in maintaining the quality of medicines and related products manufactured and/or marketed in any country. In this respect, inspectors have an important role in protecting consumers. Succinctly, the inspector's job is law enforcement. An inspector authorized by the respective authority is empowered by the law, at all reasonable times, to enter any premises that is on the register or any premises in which he/she has reasonable cause to suspect that the law has been or is about to be contravened. The powers of inspectors are stipulated in the Gambia in the Medicines and Related Products Act, 2014, Section 57 and 58 and in the Pharmacy Council Act 2014, Section 37, 38 and 39.

Effective inspection of medicines and related products will ensure the safety of patients through enforcement of medicine laws and regulations governing manufacture, importation, exportation, storage, distributions and use of medicines and related products.

2.1 Purpose and Scope

2.1.1. This guideline focus on good storage practice (GSP) and good distribution practice (GDP) inspections.

2.1.2. It describes the inspectors, types of inspections, what it entails, what needs to be inspected and the preparation of premises in anticipation of inspection.

2.1.3. The guideline does not cover good manufacturing practice (GMP), pharmacovigilance and good clinical practice (GCP) inspections.
2.2 Main objectives of medicine inspection

2.2.1. To ensure that medicines and related products, either locally manufactured or imported, meet the required standards of quality at all stages of the supply chain in order to ensure patient and public health safety.

2.2.2. At the inspection, inspectors examine the systems used to store and distribute medicines and related products.

3 INSPECTORS

3.1 Inspector qualification

Inspectors should normally be pharmacists who have working experience in community and/or hospital pharmacy. Where persons other than pharmacists are employed as inspectors, they should be adequately experienced in medicines or related products control affairs. Inspectors should be suitably trained in inspectorate functions. They may also be part-time inspectors with specialist knowledge as part of inspection teams.

3.2 Attributes of an inspector

An inspector should possess the following attributes:

- Good knowledge of pharmacy, laws and regulations to be enforced.
- Good command of technical terms and excellent communication skills.
- Awareness of the probable methods of using forged or false documents for transactions in medicines preparations and skills in determining the genuineness of documents presented for examination.
- Maturity, honesty and integrity.
- Responsible conduct which commands respect.
- Willingness to accept challenges.
- Ability to organize their own work with minimum supervision.
- Ability to assess facts quickly and take rational and sound decisions without delay.
- Ability to assess character and honesty of persons being interviewed.
- Good public relations image with key personnel/pharmacists in charge of premises while remaining firm, fair and resolute.
- Ability to hold discussion with company management at the completion of inspection.
- Ability to motivate other inspectors.
- Commitment to hard work and long hours.
- Ethical approach to any potential conflict of interest.
- Have good eye sight.
- Always be presentable and have a pleasant character.
- Ability to adopt new work and assignment.
- Be punctual.
3.3 Organizational aspects

All inspectors are to be authorised by the Medicines Control Agency (MCA). The following aspects should be ensured:

- A job description which describes the duties of the inspector.
- Proper reporting procedures; inspectors should report to the Executive Director of MCA.
- Uniformity of approach.
  (a) Regular meetings of inspectors, in which experiences on the job are exchanged, will help promote a uniform approach to inspection as well as enhance the performance of the inspectors.
  (b) Inspectors should work according to a work plan and to standard operating procedures (SOPs)
  (c) Inspection reports should be in four parts:
    (i) date of inspection and general information on the establishment inspected;
    (ii) description of the inspection activities undertaken, including analytical data of sample taken;
    (iii) observations and recommendations;
    (iv) Conclusions.
  (d) Inspectors should submit monthly reports of work to the Executive Director of MCA.

3.4 Do’s & Don’ts for Inspectors during inspection

- Exercise confidentiality: do not reveal to a third party findings/observations regarding your work.
- Make accurate reports of the facts observed.
- Be courteous and demonstrate poise and competence in your work.
- Refrain from expressing personal views; such remarks or opinions may be interpreted as official.
- Do not lose temper when abused or accused.
- Do not miss a single object, correspondence, record, accounts book, chit, rough book, or other relevant papers, which may prove to be material evidence in establishing conduct, transactions, circumstances and so on of the establishment being inspected.
- Do not fail to mention or record all items seized. Full details and descriptions of the incriminating articles or circumstances for which a charge will be opened (in case of intention to institute legal charges) should be recorded with witnesses present and signatures of responsible persons should be on the seizure document.

3.5 Independence

Inspectors should never depend on the hospitality of the facility to be inspected for example for inspection costs, transport, etc.
3.6 **Reference/information sources**

3.6.1. When inspecting establishments, the inspector will use the appropriate references.

3.6.2. The method of inspection will be laid down in a SOP which also contains the requirements for a specific type of establishment. When sampling is part of the inspection, the SOPs will contain guidance for the inspector.

3.6.3. The reference/information sources to be used by inspectors should include:

- Medicines and Related Product Act, 2014
- Pharmacy Council Act, 2014
- National Medicines Policy, 2007
- Good Storage Practice (GSP)
- Good Distribution Practice (GDP)
- Good Pharmacy Practice (GPP)
- Codes of professional ethics
- Available data on registration/ imports/exports/controlled drugs
- Inspection checklists.

4 **TYPES OF INSPECTIONS**

There are five types of inspections;

- Comprehensive/Routine
- Concise
- Follow-up
- Special
- Investigative

4.1 **Comprehensive/Routine Inspection**

4.1.1. Comprehensive/Routine inspections are generally full inspections of

- all applicable components of applicable regulatory requirements and good practices and licensing of premises; or
- new premise; or
- existing premise for renewal of license to operate; or
- for an establishment that has important changes in its key personnel, equipment or changed to new premises; or
- has not been inspected for a long time; or
- has a history of non-compliance.

4.1.2. The inspection may be announced for a new premise but can be unannounced for established ones.

4.2 **Concise Inspection**

4.2.1. Concise inspections are generally for establishments that have previously been routinely inspected with a view to assessing a limited number of standards of applicable regulatory requirements and good practices
selected as indicators of overall performance and identification of significant changes which has been introduced since last inspection. The outcome of the inspection helps in the proper assessment of the establishment.

4.2.2. These inspections can be announced or unannounced.

4.3 Follow-Up Inspection (reassessment or re-inspection)

4.3.1. A follow-up inspection is normally made to monitor corrective measures that have been undertaken following advice and notice given during a previous inspection.

4.3.2. Where a time limit was given for undertaking corrective measures depending on the deficiencies and work to be undertaken, normally restricted to specific requirements.

4.3.3. The inspection should be unannounced.

4.4 Special Inspection

4.4.1. A special inspection is conducted to assess the performance of
- a new establishment whose scope of operations was previously unknown; or
- complain of product defect; or
- report of adverse drug reactions.

4.4.2. It can also be conducted to gather specific information on a product, group of related products or to investigate specific operations such as reconstitution, packaging or labelling.

4.4.3. It can be done in order to advice medicines importers, wholesalers, retailers, storekeepers and dispensers on regulatory requirements.

4.4.4. The inspection should be unannounced.

4.5 Investigative Inspection

4.5.1. An investigative inspection is conducted to verify complaints received about non-compliance with standards of good and/or professional practice.

4.5.2. The inspection should be unannounced.

5 ESTABLISHMENTS TO BE INSPECTED

Site visits may include any premise or facility or process involved in purchasing, storing, distributing and/or dispensing medicines or related products.

5.1 Areas to be inspected
- Ports of entry (POEs) - Sea, Air and Land
- Wholesalers, warehouses, Central Medical Store, Regional Medical Stores
- Pharmaceutical stores at Hospitals and Health Centres, public and private
- Pharmacies, Drugstore outlets, Private or NGO Clinic Pharmacies
Any other premise that stores, distribute, dispense or sells medicines or related products

5.2 Processes to be inspected
- Stock and stock management
- Temperature and humidity monitoring
- Purchasing and sales functions
- Transportation arrangements
- Staffing and Personnel performance
- License status

5.3 Importer
- All medicines and related products accompanied by import documents such as bill of lading, export authorization, product licence and batch certificate;
- Controlled drugs also accompanied by export authorization certificate or export declaration, whichever is applicable;
- Imported medicines and related products are in original packs, except for medicines and related products imported in bulk for repackaging and/or manufacturing medicine formulations.

5.4 Retail and hospital pharmacy
- Compounding of medicines carried out by or under the supervision of a pharmacist;
- Quality of raw materials used in compounding complies with pharmacopoeial specifications;
- Dispensing of prescription medicines or related products carried out by or under the supervision of a pharmacist;
- Entries of dispensed prescription medicines or related products made in prescription book and for controlled drugs in controlled drugs register;
- Prescriptions for prescription medicines or related products retained on premises for periods required by Pharmacy Council;
- Dispensed medicines or related products labelled appropriately with name of medicines or related products, name of patient, name and address of pharmacy, clinic or hospital, instructions for using the medicines or related products and, where appropriate, warning labels;
- Counselling of patients on use of dispensed medicines or related products;
- Adequacy of containers for dispensed medicines or related products;
- Personnel observe high standard of personal hygiene and wear clean protective clothing;
- Dispensing area clean, adequate and has necessary equipment;
- Walls in dispensing area easily cleaned;
- Quality of extemporaneous preparations;
5.5 Clinics, nursing and maternity homes
- Sources of medicines or related products supplied and administered;
- Records of controlled drugs used, supplied and administered;
- Storage facilities and security for controlled drugs.

5.6 Unauthorized markets
- Investigate sources of medicines or related products in the unauthorized market;
- Seize medicines or related products in the unauthorized market.
- Sample seized medicines or related products for quality assessment;

6 INSPECTION PROCESS

6.1 During an inspection
6.1.1. The inspectors should identify themselves as authorised inspectors.
6.1.2. The inspection team will
   - interview relevant personnel;
   - review documents;
   - conduct site visits.
6.1.3. The inspection team may ask for additional documentation and samples for testing during the inspection. They may also change the focus of the inspection if they suspect serious non-compliance.
6.1.4. If any sample is taken during inspection for further testing, a receipt for the sample should be provided to the person in-charge of the facility.
6.1.5. Upon completion of inspection, the inspector should conduct an exit meeting to provide feedback and to discuss the findings with facility staff. The inspector may agree timelines for corrective actions.

6.2 Grading of inspection findings
Deficiencies found during inspections are graded at 3 levels.

Critical deficiency
A critical finding is any departure from regulatory requirements or good practices that result in a significant risk to patients. This includes an activity which increases the risk of substandard or falsified medicines or related products reaching patients.

Major deficiency
A non-critical deficiency which:
   - has or may produce a product that does not comply with its marketing authorisation;
Guideline for Inspections by the Medicines Control Agency

MCA-GL-201, v1.0, 13 December 2017

- indicates a serious deviation from regulatory requirements or good practices or from the terms of the manufacturer or wholesale license that might result in a risk to patients;
- indicates a failure to carry out satisfactory batch release procedures (GMP);
- a combination of several 'minor' deficiencies which on their own are minor may together represent a major deficiency and should be explained and reported as such

**Minor deficiency**
A deficiency which cannot be classified as either critical or major or there is not enough information to classify it as critical or major but which indicates a departure from applicable regulatory requirements or good practices.

6.3 **After the inspection**

6.3.1. After the inspection exit meeting, the inspectorate will provide a post inspection letter usually within two weeks confirming any deficiencies found.

6.3.2. The inspectorate will expect a written confirmation of the proposed corrective actions and dates for when these actions will be completed.

6.3.3. The inspectorate will review the response and if he or she accepts it, the inspectorate will conduct a follow-up inspection and/or provide a written feedback.

6.3.4. If the compliance to the inspection findings is poor, regulatory actions may be taken.

7 **PREPARATION AT THE ESTABLISHMENT FOR INSPECTIONS**

7.1. There should be a procedure in place for inspections.

7.2. This procedure should include instructions for the staff how to receive the inspectors, which senior staff members should be notified, and what arrangements should be made, such as workspace for the inspectors, ready availability of documents and records, and providing access to sites.

7.3. This allows the inspection to commence promptly and in an orderly fashion.

7.4. **Self-inspection**

7.4.1. The quality system at the establishment should include self-inspections. These should be conducted to monitor implementation and compliance with the applicable regulatory requirements and good practices and, if necessary, to trigger corrective and preventive measures.

7.4.2. Self-inspections should be conducted in a detailed way by a designated, competent person.

7.4.3. The results of all self-inspections should be recorded. Reports should contain all observations made during the inspection and, where
applicable, proposals for corrective measures. There should be an effective follow-up programme. Management should evaluate the inspection report and the records of any corrective actions taken.

8 FINAL PROVISIONS

8.1. This guideline is the first version published by the MCA.
8.2. This guideline will become effective on 01 January 2018.
8.3. The guideline will be reviewed within 2 years of becoming effective.

9 REFERENCES

- Medicines and Related Products Act, 2014
- Pharmacy Council Act, 2014
- MCA Guideline for Storage and Distribution of Medicines and Related Products, 2017
- MCA Guideline for Dispensing of Medicines, 2017
- MCA Guideline for Repackaging and Labelling of Medicines, 2017
- MCA Guideline for National Pharmacovigilance System, 2017
- MCA Guidelines for Registration of Medicines in The Gambia, 2017
- MCA Guidelines for Import, 2017
- MCA Guideline for Recall of Medicines and Related Products, 2017
- MCA Guideline for Safe Disposal of Medicines and Related Products, 2017

10 DOCUMENT HISTORY

<table>
<thead>
<tr>
<th>Version No:</th>
<th>Issue Date:</th>
<th>Reasons for Change:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0</td>
<td>13 Dec 17</td>
<td>New document</td>
</tr>
</tbody>
</table>

11 DEFINITIONS OF TERMS

The definitions provided below apply to the words and phrases used in the MCA guidelines. Although an effort has been made to use standard definitions as far as possible, minor alterations have been made in some cases.

**Adverse drug reaction:**
A noxious and unintended response to a medicine

**Batch (or Lot):**
A defined quantity of products processed in a one process or series of processes so that it is expected to be homogeneous.
Batch number (or Lot number):
A distinctive combination of numbers and/or letters which specifically identifies a batch

Bulk product:
Any product which has completed all processing stages up to, but not including, final packaging

Clean area:
An area with defined environmental control of particulate and microbial contamination, constructed and used in such a way as to reduce the introduction, generation and retention of contaminants within the area

Compounding:
A practice in which a registered Pharmacist or Pharmacy Support Personnel combines, mixes, or alters ingredients of a medicine to create a medicine tailored to the needs of an individual patient

Container
The material employed in the packaging of a medicine; containers include primary, secondary and transportation containers

Contamination:
The undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or onto a medicine or related product during handling, sampling, packaging or repackaging, storage or transportation

Dispensing:
Refers to the process of preparing and giving a medicine to a named person or animal on the basis of a prescription

Distribution
The holding, storing, selling, supplying, importing, exporting, or movement of medicines or related products, with the exception of the dispensing or providing medicines directly to a patient or his/her caregiver

Efficacy:
The measurement of a medicine's desired effect under ideal conditions, such as in a clinical trial

Extemporaneous preparation:
A pharmaceutical preparation individually prepared for a specific patient or patient group, supplied after preparation

Falsified medicine:
This is a fake medicine that passes itself off as real, authorised medicine

Good Distribution Practice (GDP):
A code of standard practices ensuring that the quality of a medicine or related product is maintained throughout the distribution network so that authorised
medicines or related products are distributed to retail pharmacies and others selling medicines to the general public without any alteration of their properties

**Good Manufacturing Practice (GMP):**
A code of standard practices concerning the production, processing, packing, release and holding of a medicine which ensure that medicines are consistently produced and controlled according to quality standards appropriate to their intended use and as required by marketing authorisation

**Good Pharmacy Practice (GPP):**
A code of standard practices of pharmacy that responds to the needs of the people who use the pharmacists’ services to provide optimal, evidence-based care; it requires that the welfare of the patient is the pharmacist’s prime concern at all times

**Good Storage Practice (GSP):**
A code of standard practices that ensures that the quality of medicines and related products is maintained by means of adequate control throughout the storage thereof

**Guideline:**
A document providing guidance on the scientific or regulatory aspects of medicines; MCA expects that justification is provided for any deviations and is approved by MCA

**Importation:**
The act of bringing or causing any goods to be brought into a customs territory (national territory, excluding any free zone)

**Inspection:**
The act of looking closely at something to ensure that it meets certain prescribed or known standards and specifications

**Labelling:**
Information on the primary or secondary packaging of a medicine

**Manufacture:**
Includes the operations involved in the production, preparation, processing, refining, transformation, packaging, repackaging and labelling of medicines or related products

**Manufacturer:**
A company or entity that carries out operations such as production, packaging, repackaging, labelling and relabelling of medicines or related products

**Marketing authorisation (or Registration):**
A legal document issued by the MCA for the purpose of marketing or free distribution of a product in The Gambia after evaluation for safety, efficacy and quality.
It must set out, inter alia, the name of the product, the pharmaceutical dosage form, the quantitative formula (including excipients) per unit dose (using INNs
or national generic names where they exist), the shelf-life and storage conditions, and packaging characteristics. It specifies the information on which authorization is based (e.g. “The product(s) must conform to all the details provided in your application and as modified in subsequent correspondence”). It also contains the product information approved for health professionals and the public, the sales category, the name and address of the holder of the authorization, and the period of validity of the authorization. Once a product has been given marketing authorization, it is included on a list of authorized products — the register — and is often said to be “registered” or to “have registration”. Market authorization may occasionally also be referred to as a “licence” or “product licence”.

**Medicine:**
A substance or mixture of substances prepared, sold or represented for use in the diagnosis, treatment, mitigation or prevention of disease, disorder of abnormal physical state or the symptoms of it, in man or animal, restoring, correcting or modifying organic functions in man or animal, including nutritional supplements or herbal medicines

**Medicine inspection:**
The act of examining or looking closely at all the attributes and conditions of medicines and related products and all the facilities that manufacture, import, store, distribute or dispense or use medicines or related products

**Packaging (or Packing):**
All operations, including filling and labelling, which a bulk product has to undergo in order to become a finished product

**Pharmacist:**
A pharmacist registered under the Pharmacy Council Act 2014, holding a current certificate of registration

**Pharmacovigilance (PV):**
The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine related problem (WHO).

**Prescription (Rx):**
Any written instruction in the prescribed form by an authorised prescriber to dispense or supply any medicine or related product for the purpose of the medical or dental treatment of any person or animal

**Primary container/packaging (or Immediate packaging):**
Container that is in direct contact with the product

**Product:**
Refers to a medicine and/or a related product

**Product information:**
Documents providing officially approved information for healthcare professionals and patients on a medicine; the product information includes the summary of product characteristics, package leaflet and labelling
Professional:
The person responsible for supervising the dispensing, preparation, sale or supply of medicines and related products in approved pharmacy premises

Quality system:
An appropriate infrastructure, encompassing the organisational structure, procedures, processes and resources, and systematic actions necessary to ensure adequate confidence that a product (or services) will satisfy given requirements for quality

Recall:
The removal of specific batch/batches of a medicine or related product from the market for reasons relating to deficiencies in the quality, safety or efficacy

Related product:
An article other than medicine which includes cosmetics, homeopathic medicines, medical device, instrument or apparatus including, components, parts and accessories of it, manufactured, sold or represented for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or the symptom of it in man or animal

Repackaging:
The act of taking a medicine from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the medicine

Sampling:
Operations designed to obtain a representative portion of a medicine or related product, based on an appropriate statistical procedure, for a defined purpose, e.g. quality testing, acceptance of consignments or batch release

Secondary container/packaging (or Outer packaging):
Container that is not in direct contact with the medicine

Shelf-life:
The period of time during which a medicine or related product, if stored correctly, is expected to comply with the specifications as determined by stability studies on a number of batches of the product; the shelf-life is used to establish the expiry date of each batch

Standard operating procedure (SOP):
An authorized, written procedure giving instructions for performing operations not necessarily specific to a given product but of a more general nature (e.g. equipment operation, maintenance and cleaning, validation, cleaning of premises and environmental control, sampling and inspection)

Storage:
The storing of medicines and related products from manufacturing up to their point of use
Summary of product characteristics (SmPC): A document describing the properties and the officially approved conditions of use of a medicine; summaries of product characteristics form the basis of information for healthcare professionals on how to use the medicine safely and effectively ensure the safety of patients.