

Providing tools and references

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We publish a large number of reference documents and tools relating to health products, and make them available to our audiences:

- <u>Good practice references</u> ; manufacturing, pharmacovigilance, distribution, etc.
- <u>Public medicine database</u>
- French Pharmacopoeia
- Registries:
 - <u>Registry of medicines</u>
 - <u>Registry of generic medicines</u>
 - <u>Registry of generic groups of herbal medicines</u>
 - <u>Registry of clinical trials</u>
- List of medicines subject to additional risk reduction measures and associated documents
- List of medicines available over the counter in pharmacies
- List of medicines subject to supply tensions
- List of vaccines subject to supply tensions
- List of medical devices and in vitro diagnostic medical devices subject to supply tensions
- Pharmacy-compounded, hospital, and pharmacy-prepared preparations
- <u>Thesaurus of Medicine Interactions</u>: pharmaco-therapeutic prescription guidance aimed at healthcare professionals
- Tools for the general public and healthcare professionals on the proper use of healthcare products
- + View reference documents

Defining good practices

Inspections apply to all human health products and cosmetic products. To this end, ANSM is involved in drafting texts applicable to operators, particularly good practices defined in decisions made by the Director General.

- <u>Good Laboratory Practice</u> (GLP) provides the framework applied by all trial facilities in countries adhering to the OECD Mutual Acceptance of Data system to ensure the quality and international admissibility of non-clinical safety studies.
- <u>Good Clinical Practice</u> (GCP) provides the framework for clinical trials on medicines.
- <u>Good Manufacturing Practice</u> (GMP) provides the framework to be applied by all manufacturers and importers of medicines, including innovative therapy medicines, and active substances used in their composition, and also by operators marketing proprietary medicines.
- <u>Good Wholesale Distribution Practice (GWDP)</u> of medicines provides the framework to be applied by all wholesalers carrying out logistical operations, but also by medicine operators and brokers.
- <u>Good Pharmacovigilance Practice (GVP)</u> defines the role and obligations of the various parties involved in the
 ANSM Page 1 sur 2 17.09.2025 11:56

pharmacovigilance system: healthcare professionals, regional pharmacovigilance centres, businesses or organisations operating medicines, and also patients and patient associations. It supplements European Good Pharmacovigilance Practices on a national level.

- <u>Good Distribution Practice (GDP)</u> for active substances applies to sites carrying out distribution operations in respect of active substances for human use.
- **<u>Good Preparation Practice</u>** (GPP) applies to preparations prepared in hospital and community pharmacies.
- <u>Good Cell and Tissue Culture Practice</u> provides the frameworks applicable to the extraction, preparation, storage, transport, distribution and sale/transfer of tissues and cells of human origin.
- <u>Good Transfusion Practice</u> applies to all operations in the transfusion chain, from the collection to the delivery of labile blood products, including donation qualification.
- **<u>Good Breast Milk Bank Practice</u>** applies to the manufacture and safeguarding breast milk from breast milk banks.
- Good practice aimed at ensuring biological safety and security applies to Microorganisms and Toxin (MOT) authorisation holders and the directors of the sites concerned.
- In the case of **medical devices and in vitro diagnostic medical devices**, the applicable references are the harmonised European standards ensuring compliance with the essential requirements in respect of safety and health.