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health professional, of the dispensation information and of the authorised medicinal product (on different levels).

3. These guidelines are applicable to authorised medicinal products. Out of scope are extemporaneous / magistral pharmaceutical preparations. These guidelines do not cover medical devices, non-pharmaceuticals and shall not apply to medicinal products subject to special medical prescription provided for in Article 71(2) of Directive 2001/83/EC.

4. These guidelines could serve as a guiding principle for the development and implementation of national systems for ePrescription and eDispensation.

5. The use of electronic prescriptions and dispensations in the cross-border context provides support to patients exercising their right of free movement. It also allows for the portability of data, which is one of the rights embedded in several legislative acts, such as GDPR.

Article 2: Definitions

For the purpose of these guidelines, the definitions of Directive 2014/24/EU, of the eHealth Network General Guidelines and the following definitions shall apply:

Term	Definition
Prescription	means a prescription for a medicinal product issued by a member of a regulated health profession within the meaning of Article 3 (1) (a) of Directive 2005/36/EC, who is legally entitled to do so in the Member State in which the prescription is issued, as defined by Article 3 (k) of Directive 2011/24/EU[2].
ePrescription	means a medicinal prescription issued and transmitted electronically, as defined in point 3 (f) of Commission Recommendation on cross-border interoperability of electronic health records[3].
Medicinal product	means 1. any substance or combination of substances presented as having properties for treating or preventing disease in human beings or 2. any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a

	medical diagnosis, as defined by Article 1 (2) of Directive 2001/83/EC[4].
eDispensation	is defined as the act of electronically retrieving a prescription and reporting on giving out the medicine to the patient as indicated in the corresponding ePrescription[5].
Authorised medicinal product	is a medicinal product for which a marketing authorisation has been issued by the competent authorities of Member States in accordance with Directive [2001/83/EC] or an authorisation has been granted in accordance with Regulation (EC) No 726/2004, read in conjunction with Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and Regulation (EC) No 1394/2007, as defined in Article 6 (1) of Directive 2001/83/EC.
Generic prescription	means the prescription of medication by a health professional using the generic name of a substance. This allows the dispensing pharmacist to choose between generic equivalent products of different brands.
Substitution	means the replacement of a prescribed (branded) product by another product with equivalent qualitative and quantitative composition, pharmaceutical form and route of administration. Substitution can be either "generic substitution" entitling the pharmacist to choose between products with the same active substance(s) or "therapeutic substitution" entitling the pharmacist to replace the prescribed branded or generic product by a product containing a chemically different substance within the same therapeutic group. Generic substitution applies to local substitution or reimbursement rules and may be limited to a given set of substances or connected with rules considering galenic particularities (f. ex. modified release formulations).
Unit of presentation	is a qualitative term describing the discrete countable entity in which a pharmaceutical product or manufactured item is presented, in cases where strength or quantity is expressed referring to one instance of this countable entity (Source: EDQM Standard Terms).
Route of administration	means the path by which the pharmaceutical product is taken into or makes contact with the body (Source: EDQM Standard Terms)