

We are pleased to announce that the ANSM (French National Agency for the Safety of Medicines and Health Products), the Club Inter Pharmaceutique and GS1 France have formalised the framework to guarantee the continuation of the current codification system of medicinal products in France, for a transition period of three years, renewable once.

The identification of medicinal products is essential to ensure the health and safety of patients in France and is a key EU requirement (i.e. Delegated Regulation (EU) 2016/161 of the Commission of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council). The codification in France is now framed by a Decree, an Order and a tripartite Agreement, aiming at ensuring the continuity of the supply chain, traceability and reimbursement of medicines in France and securing the supply of medicines in France to patients.

The <u>decree</u> and the <u>order</u> of the French Ministry of Health (MoH) dated of 30 December 2021 and related to the allocation and technical specifications of the codification of medicines (i.e. Article R. 5121-4 of the Public Health Code) bring the CIP and UCD (see below details) codes in the French legislation. **Article 1** states that the codes used to identify medicines authorised on the French market are:

- The national number identifying each presentation called " code identifiant de présentation " (CIP code)
- And, where applicable, the number identifying the common dispensing unit, called the "code identifiant l'unité commune de dispensation " (UCD code).

These are the current 13-character codes, with the first 4 digits being the prefix 3400. This code, when preceded by a "0", complies with ISO/IEC 15459-3 2014 and ISO/IEC 15459-4 2014, and therefore with the GS1 standards.

The tripartite agreement specifies the implementation details of the above mentioned legislation, and in accordance with the GS1 standards, illustrated below:





Pictures for illustration only



In parallel, the French MoH has set up a Steering Committee in June 2021, bringing together the stakeholders involved in codification of medicinal products in order to:

- identify public and private needs in terms of medicines codification in France in relation to existing solutions;
- analyse the codification solutions adopted by different EU countries;
- conduct interviews with public and private actors impacted by the codification of medicines as well as with experts in this area;
- and define the permanent solution to be implemented in the next 3 to 6 years.

In conclusion, this transitional framework will enable the preparation of the future and the proposal, by mid-2022, of a permanent solution for the codification of medicinal products in France. One of the solutions will consist in dissociating the logistical identification of the medicine from its market authorisation number and its reimbursement code, with the objective of harmonising the harmonising the French codification system with EU codification systems.

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