02/02/2022 - Communication on the issue of coding - Club Inter-Pharmaceutique

Medicinal product coding is a very important issue, because it is an intrinsic part of medicinal product safety.

The coding system used must address three central needs:

- Regulatory: to identify those medicinal products with market authorization, and those listed in publicly accessible databases (especially the ANSM database), and to ensure pharmacovigilance oversight of medicinal products contained in medico-economic databases and also those used in retrospective and prospective observational studies
- Logistics: to identify medicinal products at every link in the community pharmacy and hospital pharmacy supply chain, as well as in contract bids, orders and invoices, and to enable traceability
- Reimbursement: to identify reimbursable medicinal products in the information systems of reimbursement process stakeholders, and primarily the *Assurance Maladie* French Health Insurance Fund.

For many years, presentations of medicinal products have been identified by the Presentation Identifier Code **(CIP** code**), which meets all three needs in full**.

Similarly, the needs of healthcare facilities are met by the **Common Dispensing Unit** code **(UCD code)** assigned at the request of the pharmaceutical company concerned.

The regulatory framework for medicinal product coding in France has recently been clarified, and the codes used formalized in two legal texts published in the OJ (Official Journal) on December 31, 2021:

A ***Decree*** (2021-1931) that:

- Requires every medicinal product authorized for marketing and use in France to have a national identification number. Where applicable, Common Dispensing Units are also numbered, thereby including the CIP and UCD codes in the French Public Health Code
- Mandates the ANSM to allocate these numbers, or optionally to delegate this responsibility to a third party
- Requires that the specification for this numbering system is set out in a subsequent ministerial order

A ***Ministerial Order*** that sets the process for specifying this number for CIP and UCD codes **for a period of six years**.

These specifications make no change to the CIP and UCD code characteristics that have been in place and used for many years.

- **There is therefore no change in the coding of authorized medicinal products in France.**

This regulatory framework is accompanied by a tripartite agreement entered into in early January 2022 between the ANSM, the CIP and GS 1 clarifying the roles of each party.

In parallel, **the French Ministry of Health began work a few months ago to set out** (over the next three to six years) **the future coding system** for medicinal products authorized for marketing and use in France.

In this context:

- A Steering Committee whose members represent all stakeholders involved in the coding process has been set up under the aegis of the DGS (French Health Directorate)
- The Steering Committee analyzes the coding solutions adopted by other European countries
- The Steering Committee conducts interviews with public and private stakeholders involved in the coding of medicinal products, and experts in the field

The goal of the committee is to bring forward recommendations for the future of medicinal product coding in France by the end of the first half of 2022, together with a timetable for implementation. This timetable will depend on the system recommended, and more specifically on the nature and extent of any recommended changes to, and/or developments of, the current coding arrangements.

https://solidarites-sante.gouv.fr/soins-et-maladies/medicaments/article/la-codification-des-medicaments

https://ansm.sante.fr/actualites/codification-des-medicaments-a-usage-humain-lansm-et-le-club-interpharmaceutique-acteurs-de-la-delivrance-des-codes-cip-et-ucd