

BACKGROUND

- 3D printing makes it possible to tailor the dose, the release profile and the dosage form to each patient.
- Its roll-out in hospitals is held back by the absence of a dedicated regulatory framework.
- In France, neither the printed medicine nor the pharmaceutical ink has a defined status.

OBJECTIVE

Compare the regulatory frameworks of five countries and draw practical lessons for French hospital pharmacy.

MATERIALS & METHODS

Review of the regulatory texts and of the scientific literature of five countries: United States, United Kingdom, Spain, Belgium and the Netherlands. Sources: laws, implementing texts, agency guidance and scientific publications.

Analysis structured around nine criteria

- Legal classification
- Legal basis
- Authorisation
- Responsibilities
- Traceability
- Validation
- Batch release
- Pharmacovigilance
- Grey areas

CONCLUSION - DISCUSSION

- The 2023 good preparation practices give France a solid basis to integrate 3D printing without any new text.
- Printers and inks should be treated as critical items: qualification, controls suited to very small batches and clear contracts with suppliers.
- The EMA classifies pharmaceutical inks as intermediate preparations, and further work is needed to establish a framework for their characterization.

RESULTS

0 / 5

countries created a legal status of their own

5 / 5

place printed medicines in an existing preparation regime

1 / 5

created a framework dedicated to production close to the patient

2 / 5

ran a clinical trial with printed tablets

The regime chosen in each country

 United States	Pharmacy compounding is under two distinct regimes 503A and 503B	One printed medicine approved since 2015. Draft guidance citing 3D printing in January 2025.
 United Kingdom	Medicine prepared for a patient without a marketing authorization – “specials” program	Since July 2025, a framework dedicated to patient-side production, managed by a central site and decentralized production sites
 Spain	Magistral or official preparation	HIDROGUM21: European pediatric clinical trial of printed hydrocortisone tablets in doses ranging from 1 to 6 mg
 Belgium	Magistral or hospital preparation	A 2020 article citing 3D printing as an innovation that warrants special attention
 Netherlands	GMP-Z: Adaptation of Good Manufacturing Practices (GMP) for the Hospital Pharmacy Setting	Printer certified at Leiden University Medical Center; equivalence of the printed sildenafil formulations demonstrated compared to the reference tablet.

Expected in all 5 countries

 Qualification of the printers

 Digital file in the batch record

 **Open questions**

 Status of the pharmaceutical ink undefined

 Liability for the digital file unassigned