Accelerating Therapeutic Innovation: Early Results from France's Accès Direct Scheme

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Monguillon A., Chavade D., de Sauvebeuf C., Biodimed Conseils, Paris, Ile de France, France

Context & Objectives

- "Accès Direct" experimental scheme implemented in May 2023 for 2 years under the 2022 French Social Security Financing Act, aims to accelerate access to innovative therapies. It enables full reimbursement of innovative medicines at a freely set price for one year, immediately after a favorable opinion from the French National Authority for Health (HAS), without price negotiation conclusion with the *Comité Économique des Produits de Santé* (CEPS). Pricing agreements must follow within one year.
- Eligibility Criteria for Direct Access : European marketing authorization + Transparency Committee (TC) approval (SMR: major or important and ASMR I to IV) + no early access + no existing reimbursement status.
- This study evaluates early outcomes in terms of time to market and pricing.

Method

- Timeframe: from 1st May 2023 to 31st October 2025
- Medicines included in the scheme were identified from the French Official Journal (JO) and cross-referenced with HAS data (evaluation dates and ratings). Access timelines and pricing were analyzed.
- Comparators were those defined by HAS.

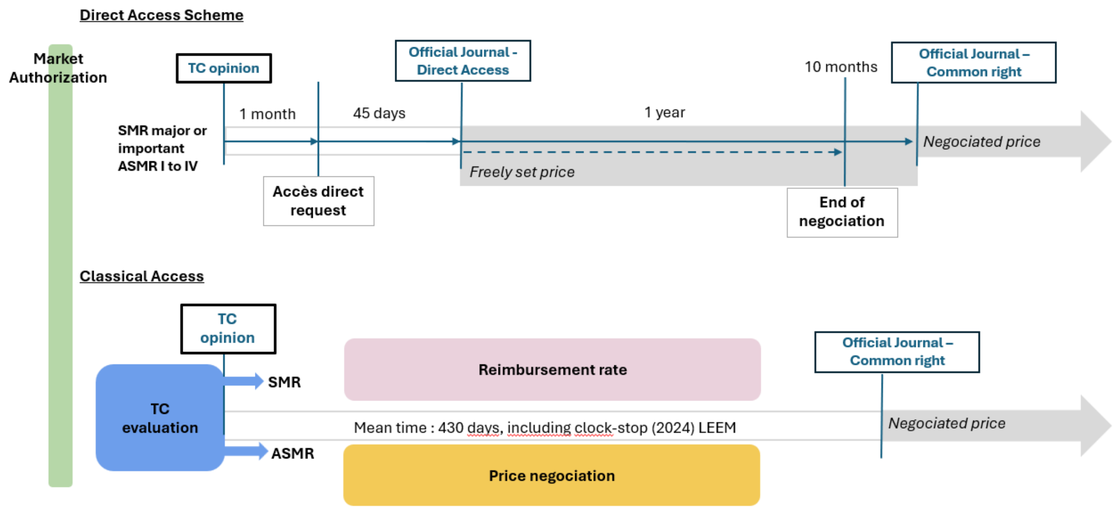

Figure 1. Market Access in France: Standard Process and Direct Access Highlight

Results

- A total of 6 medicines entered the scheme : delgocitinib, danicopan, recombinant adjuvanted herpes zoster vaccine, ruxolitinib, etranacogene dezaparvovec and nemolizumab. Target populations ranged from 270 patients to over 16 million of patients. Therapeutic areas included dermatology, rare diseases, infectious diseases, and gene therapy. Two products had orphan drug designation; one was classified as an advanced therapy medicinal product (ATMP).
- Four products exited the scheme with a median reimbursement time of 191 days (range: 179–310). One was withdrawn after 310 days, likely due to failed pricing negotiations. At the time of analysis, two medicines remained within the program (<179 days).
- Price analyses showed coherent or higher costs (listed price): €163.24 for herpes zoster vaccine, €750.00 for 100g of ruxolitinib cream and €4131.00 for danicopan (vs. €90.00 and no HAS-identified comparators and around 3105.77€ for pegcetacoplan).

Table 1. Identified TC opinion for medicines who entered into the AD scheme

DCI	Indication	Early Access	TC opinion date	SMR	ASMR	Target population	Price – if available	Direct Access start*	Direct Access stop**	Direct Access Duration (day)
nemolizumab	Prurigo nodularis	-	25/06/2025	Important	III	13k patients	-	18/08/2025	-	-
delgocitinib	Atopic Dermatitis	-	26/03/2025	Important	IV	100k to 170k patients	-	21/05/2025	-	-
danicopan	Paroxysmal Nocturnal Hemoglobinuria	R	09/10/2024	Important	III	~ 270 patients	4 131,00€ / month	31/01/2025	24/07/2025	174
recombinant adjuvanted herpes zoster vaccine	Shingles Immunization	-	27/03/2024	Important	III	16 Mio patients	163,24€ / dose	21/05/2024	10/12/2024	203
ruxolitinib	Vitiligo	-	18/10/2023	Important	IV	70k to 108k patients	750,00€ / 100g	26/01/2024	23/07/2024	179
etranacogene dezaparvovec	Gene Therapy Hemophilia B	R	30/08/2023	Important	IV	Max 300 patients	-	12/12/2023	17/10/2024 MAH-Initiated Exit	310

ASMR : Clinical Added-Value (*Amélioration du Service Médical Rendu* (from I to V)) ; MAH : Marketing Authorization Holder; SMR : Clinical Benefit (*Service Médical Rendu*) ; R : Refusal ;
* Start with JO publication / CEESP publication; ** Stop with JO publication
a. AD starts with JO publication ; b. AD stops with price publication in JO, MAH request or withdraws its reimbursement application, refusal of reimbursement

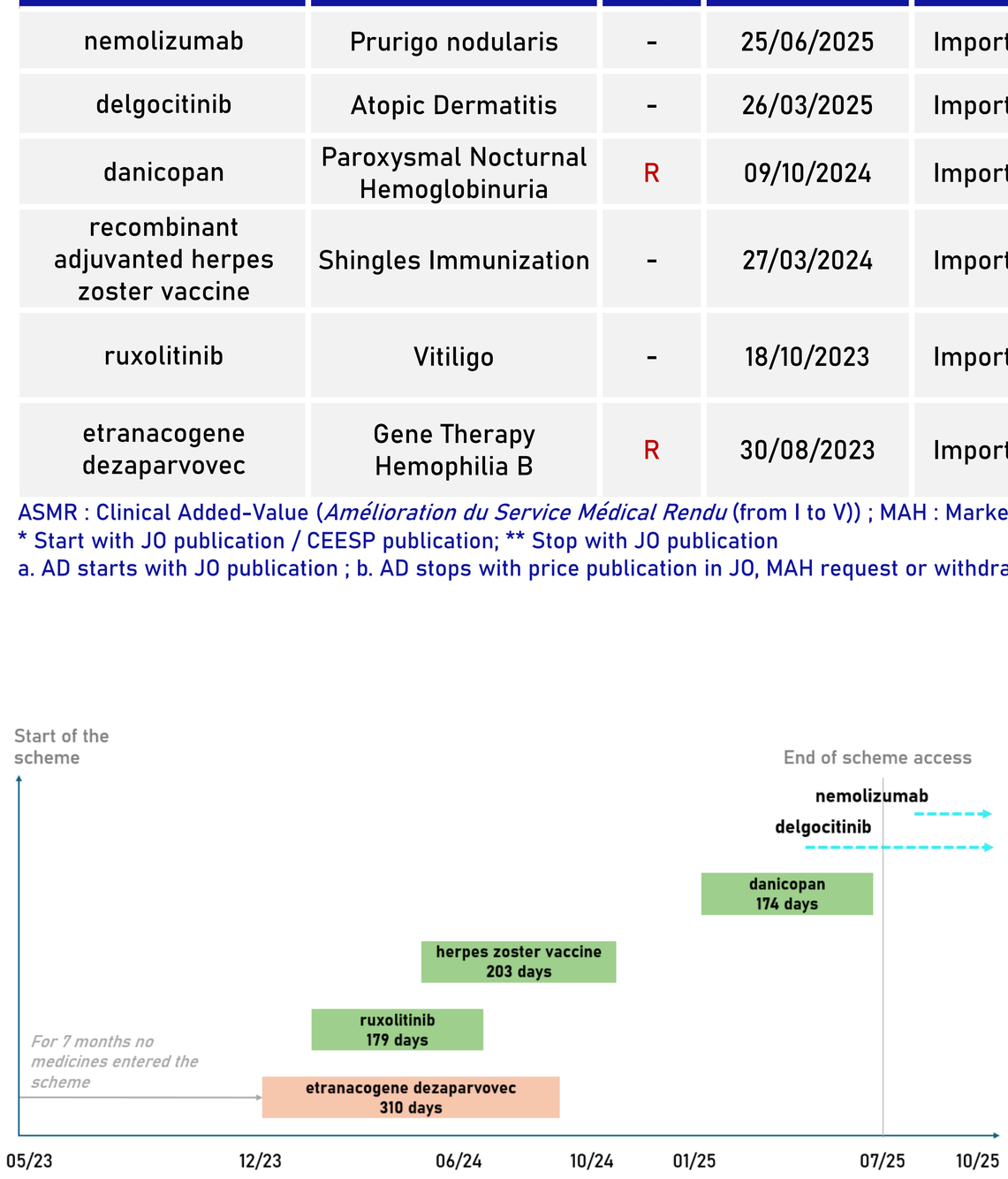

Figure 2. Treatment Timeline of medications in the Direct Access Program

Conclusion

The small number of medicines included and initial rejection of etranacogene dezaparvovec may reflect selection bias favoring suitable candidates.
However, preliminary findings suggest that "Accès Direct" effectively reduces time to reimbursement and improves patient access. While the scheme allows earlier funding, pricing remains similar or higher than comparators. Its role appears strategic in the context of restricted early access and extended negotiation timelines.

Direct access in PLFSS 2026 (*French Social Security Financing Act Draft*)

- Continuation of the "Direct Access" scheme proposed in the PLFSS 2026
  - Expansion to include extension of indication
  - Potential 3-year duration limit for medicines included in the scheme
- Approximatively 20 medicines per year may benefit from the scheme
- Post MA Early Access alignment with the same pricing negotiation timeline, feeding into this scheme
- Removed by the Social Affairs Committee on 31st October. If not reinstated, no changes to early access programs will be included in the 2026 Social Security Financing Act.

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CONSEILS
34 rue Laffitte, 75009 Paris, FRANCE