

ANALYSIS OF THE REIMBURSEMENT AND PRICING OF VACCINES IN FRANCE

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CONTEXT

Vaccines are a special type of health products, with an important role to play in public health by preventing diseases through immunization. In France, the Vaccination Technical Commission (CTV) is responsible for drawing up vaccine policy. Then, the clinical benefit of candidate vaccines is evaluated by the Transparency Committee (CT), with impact on the reimbursement decision, and the efficiency is evaluated by the Commission for Economic Evaluation and Public Health (CEESP). In case of reimbursement, the Economic Committee for Health Products (CEPS) will negotiate the price.

OBJECTIVES

The aim of our study was to describe the challenges and opportunities of vaccines market access in France.

METHODS

We conducted a systematic retrospective analysis of vaccines evaluated for reimbursement in France between 01/01/2017 and 03/31/2023.

RESULTS

OVERVIEW OF VACCINES EVALUATIONS BETWEEN 2017 AND 2023

Overall, **25 evaluations about 20 vaccines** were conducted by the HAS for reimbursement in France between **01/01/2017** and **03/31/2023**. These evaluations were conducted by the CT: 15 for a first registration, 6 for an indication’s extension, 4 for a reevaluation of their clinical benefit (SMR) and improvement in clinical benefit (ASMR).

Two vaccines were also evaluated by the CEESP. On 31 March 2023, 16/20 vaccines had a published price in France. The 4 other vaccines had no published price because they were limited to hospital use (in this case there is no negotiation of the price) and one because of long price negotiation with the CEPS – since 12/11/2019.

OUTCOMES OF THE CT AND CEESP ASSESSMENTS

All of the 25 vaccines evaluated by the CT obtained an **important SMR** except one, DENGVAXIA (dengue prevention), which obtained a low SMR because of the low impact it could have on the population. Regarding ASMR, **18/25 (72%)** obtained a level **V** and **2/25 (8%)** a level **I**. Seasonal vaccines (6/20) all obtained an ASMR **V**.

TABLE 1. HAS VACCINES EVALUATIONS FROM 2017 TO 2023

	Total	ASMR I	ASMR II	ASMR III	ASMR IV	ASMR V
Vaccines evaluations	25	2	1	2	2	18
Target populations						
Paediatrics	17	1	1	1	2	12
Adult	18	2	1	2	0	13
Elderly	11	1	1	0	0	9
Seasonal vaccination	10	0	0	0	0	10

Two vaccines were eligible to an evaluation by the CEESP : Efluelda® and Gardasil® 9. Only important reservations were made by the HAS, which focused on : **efficacy data, cost items, transition probabilities and the presentation of the results**.

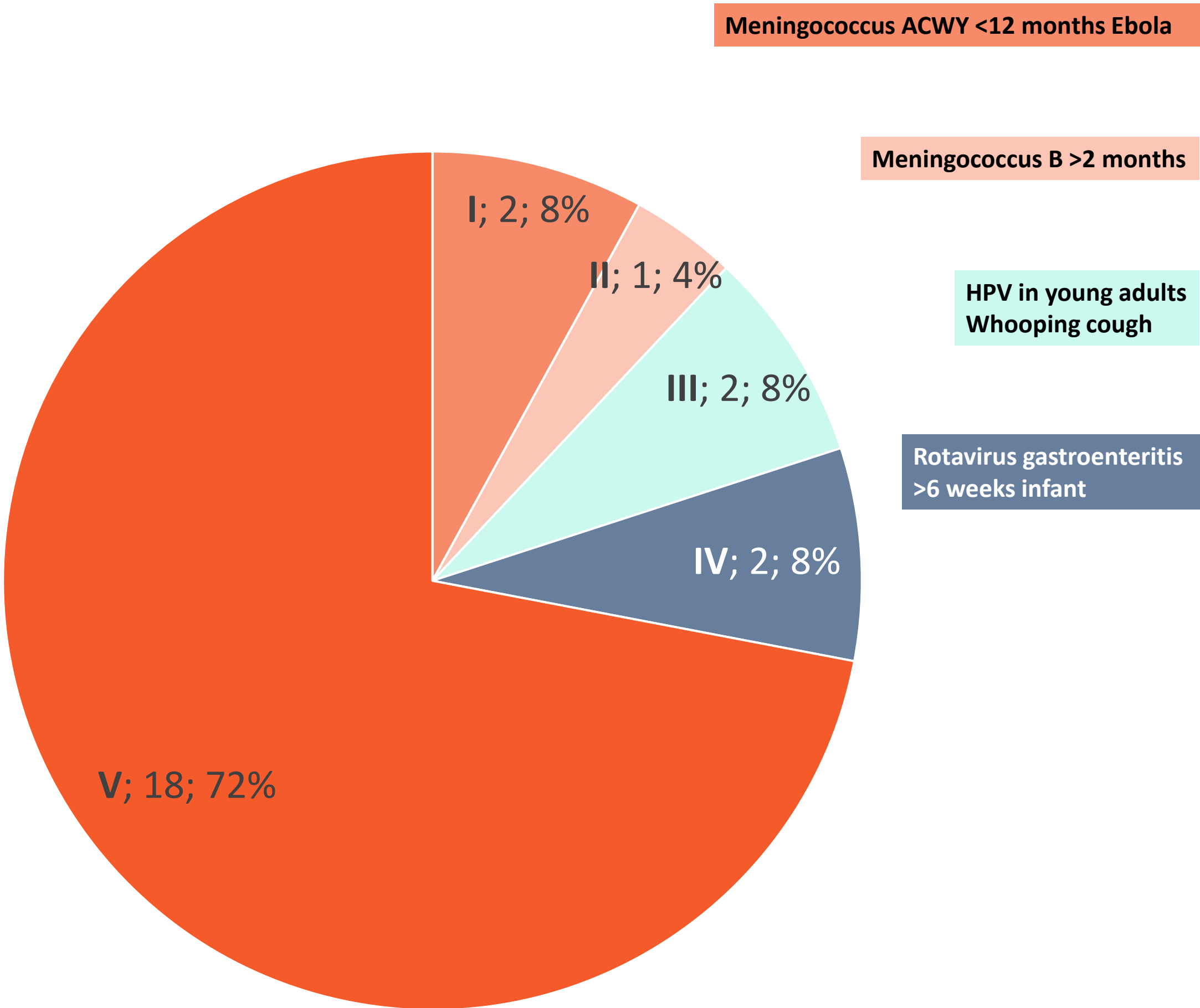


FIGURE 1. Vaccines ASMR (2017-2023)

VACCINES PRICING IN FRANCE

TABLE 2. NON-SEASONAL VACCINES PRICES IN FRANCE VERSUS ASMR OBTAINED

Vaccine	Disease	ASMR	Public Price
NIMENRIX	Méningocoque ACWY	I	35.00 €
BEXSERO	Méningocoque B	II	72.00 €
GARDASIL 9	HPV	III	100.00 €
BOOSTRIX/TETRA	Coqueluche	III	18.04 €
ROTATEQ	Gastro-entérites à RV	IV	44.52 €
ROTARIX	Gastro-entérites à RV	IV	50.00 €
PREVENAR 13	Pneumonie à pneumocoque	V	41.61 €
VAXELIS	DTCP, l'hépatite B	V	29.50 €
PNEUMOVAX	Pneumonie à pneumocoque	V	15.45 €
MENQUADFI	Méningocoque ACWY	V	35.00 €
TRUMENBA	Méningocoque B	V	72.00 €
MENVEO	Acwy	V	33.25 €

The average price of the 4 **seasonal vaccines** was **€11.56**. The average price of the 12 **non seasonal vaccines** was **€45.53**. Considering the number of doses recommended (primary vaccination and booster dose), the average cost of a **complete vaccination schedule** was **€125.91**.

There is **no link between the level of ASMR obtained and the public price** in France for non-seasonal vaccines (Table 2).

The median **time to market for new vaccines in France** was **675 days** (between marketing authorization (MA) and publication of the price in the Official Journal; min-max: 125-5992) including a median **time between MA and publication of CT opinion of 527 days** (min-max: 71-5846) and a median **duration of the price negotiation of 146 days** (min-max: 50-1926). No trend was observed between the level of ASMR and these durations.

CONCLUSION

Vaccines appeared to be consistently reimbursed by obtaining a sufficient SMR. Nevertheless, in most cases, no ASMR was granted. Additionally, achieving an ASMR superior to V did not necessarily result in a better price. Time between marketing authorization and CT opinion publications seemed to be 3 times longer for vaccines (527 days) than for drugs (114 days). This can be partly explained by the additional assessment by the CTV, which only concerns vaccines. This additional time may appear to be an additional challenge for vaccines, particularly when compared with preventive medicines.

COI : Lauriane VILLEMUR, Justine CORTES and Prunelle GAUGY are employees at CEMKA, one of the first French consulting firms in the field of evaluation of products, programs and organizations in Health. The study was not sponsored.

