REIMBURSEMENT AND PRICING TIMES FOR DRUGS DEPENDING ON THE EARLY ACCESS STATUS IN FRANCE (WITH OR WITHOUT AN ATU)

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INTRODUCTION

In France, the Temporary Authorisation for Use (ATU) (early access process) allows patients to be treated by drugs that may not have received a marketing authorisation. These ATUs are provided in the occurrence of unmet medical needs for serious or orphan diseases in the absence of alternative treatments. During this specific early access program, some data may be recorded in order to reinforce the evaluation conducted by the HAS and may impact the P&R delay.

OBJECTIVES

The aim of this research was to compare the mean time spent during the P&R process in France, including the HAS evaluation by the Transparency Committee (TC) and the price negotiation, between medicines that have and that haven't benefited from an ATU.

METHODS

All the TC opinions concerning a first reimbursement inscription published between January 2016 and April 2019 including a delay between the MA and TC opinion of less than 2 years were analysed. Simplified procedures and new applications following a previous withdrawal of application or a previous negative opinion were excluded.

RESULTS

In the selected time period, 180 TC opinions met the inclusion criteria. The time between the MA and the TC opinion was collected for 177 medicines (tisagenlecleucel, midostaurine and atezolizumab had 2 opinions on 2 indications realized at 2 distinct dates), 67 of which had an ATU and 110 did not.

Assessment period for reimbursement

The average time between the MA and TC opinion following the MA was **216 days for medicines with an ATU versus 295 days for those without an ATU** (Figure 2). In general, the evaluation of drugs with an ATU is quicker than for those without an ATU for any ASMR level. Drugs with ATUs and considered as innovative (ASMR II & III) seem to be evaluated faster but the sample size is too small to draw definitive conclusions (Figure 1). On the contrary, the delay increases when the product does not receive an ATU and is judged as unqualified for reimbursement (negative opinion) by the TC. Moreover, in a subgroup analysis specifically focused on orphan drugs, the assessment is shortened by 91 days when an ATU is delivered (Table 1).

Pricing negotiation time period

Regarding the time of TC opinion until price publication, 70 medicines were collected, 25 with an ATU and 45 without an ATU. The average time spent for the pricing negotiation and publication was 344 days for medicines with an ATU versus **234 days for those without an ATU** (Figure 2). In the case of orphan drugs, the price negotiation is much longer (+66 days) when an ATU is delivered (Table 1).

Global delay for P&R

The global average time spent in the P&R processes was **528 days for medicines with an ATU versus 494 days for those without an ATU** (Figure 2). The P&R delay for orphan drugs is not impacted by the presence of an ATU. On the contrary, it is lengthened when compared to the delay observed for non orphan drugs (around 200 days) (Table 1).

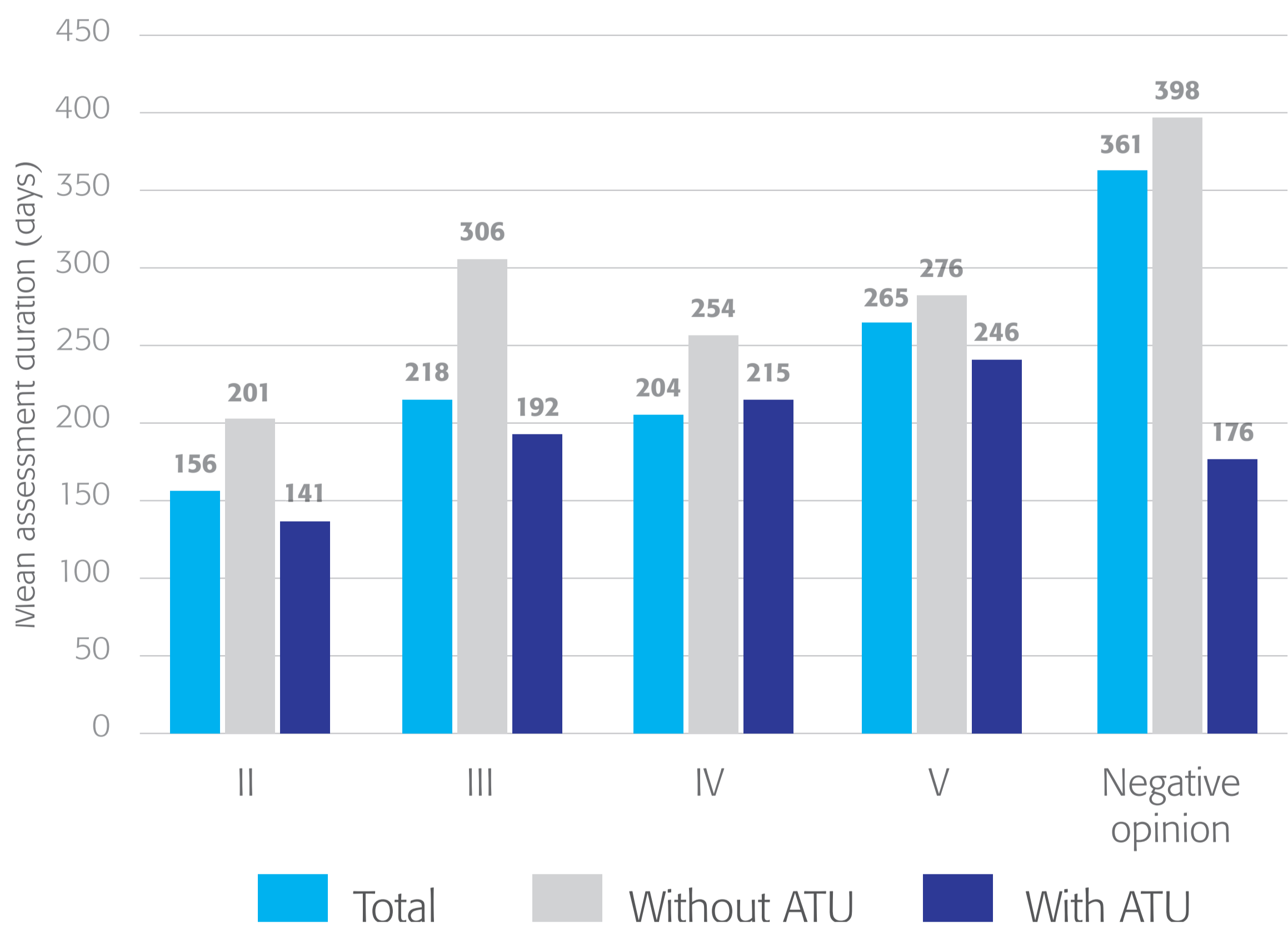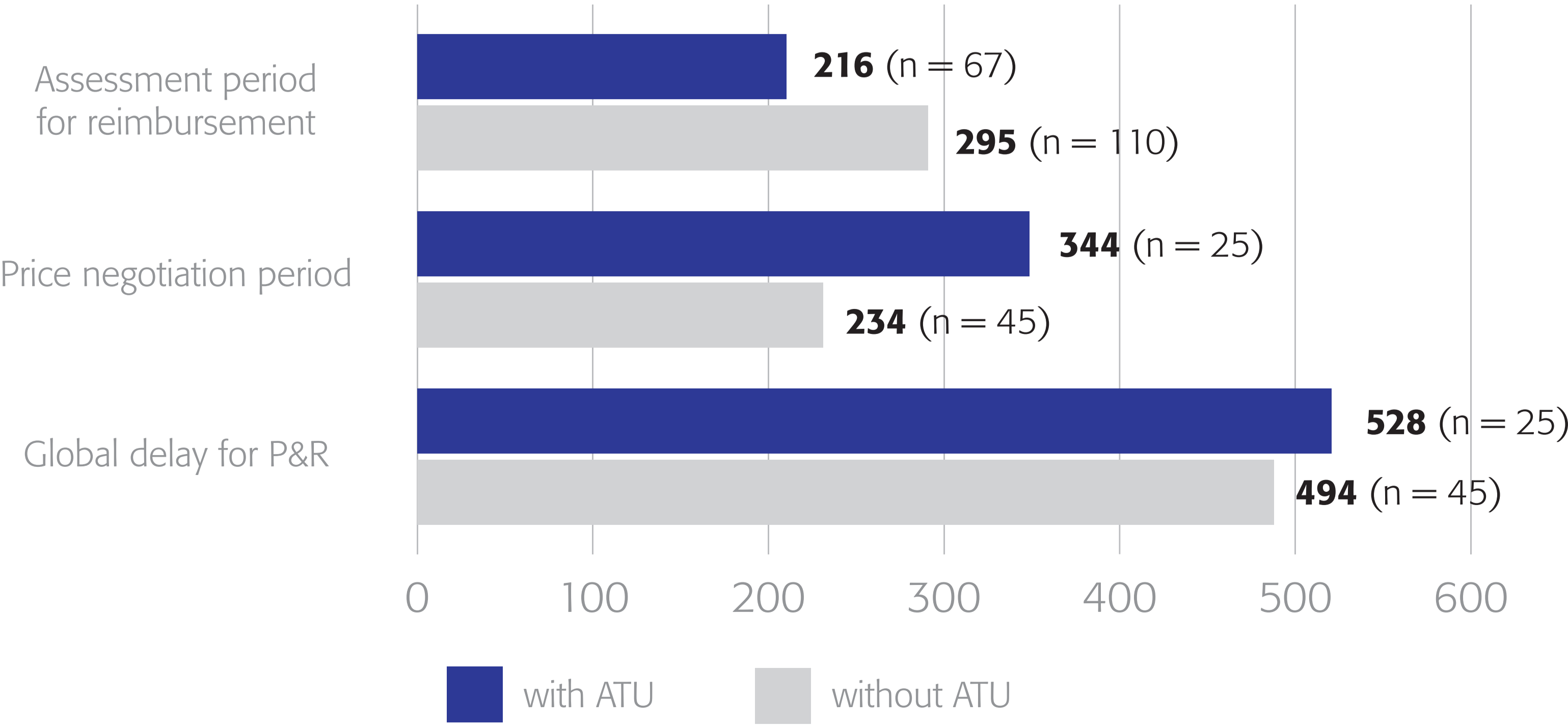Figure 1: Assessment period by ASMR level (days)

Table 1: Subgroup analysis according to the orphan status (days, n products)

ATU	With ATU		Without ATU	
Orphan drug	Yes	No	Yes	No
Assessment period for reimbursement	238 (n=35)	184 (n=32)	329 (n=14)	290 (n=96)
Price negotiation period	455 (n=8)	291 (n=17)	389 (n=6)	210 (n=39)
Global delay for P&R	653	466	659	458

CONCLUSION

Figure 2: Comparison of the mean time spent during P&R processes in France between medicines with or without an early access program named (ATU)

An ATU may accelerate assessment delays (216 versus 295 days). However, the global average time spent in P&R processes is similar with 528 days for medicines with an ATU versus 494 days for those without an ATU. **The time saved during the evaluation is spent during the negotiation time.**

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