

# Assessment of impact of level of ASMR on the drug's price and its negotiation time with the health authorities in treatments that benefited from the French early access program

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## Objective

Assessment of the correlation between the added medical value (ASMR) level attributed by the Haute Autorité de Santé (HAS - French Health Technical Assessment authority) and the price and the length of the pricing negotiations for drugs having entered the French Early Access Program (ATUc)

## Context

- ATUc (Autorisation Temporaire d'Utilisation de cohorte) is a specific French early access drug program. The inclusion of a drug in this program is requested and evaluated by the French Regulatory agency (Agence Nationale de Sécurité des Médicament – ANSM) on the basis of the preliminary results before a Market Authorization (MA) is granted. The ANSM validates a protocol specifying the conditions of prescription and the target population who will benefit from the drug.
- Drugs included in the ATUc program may be distributed free of charge or the firm could ask for a compensation fee. If the drugs are priced, the cost is covered by the French National Social Security until their MA is granted.
- The "post-ATU" process allows drugs that were in the ATUc program and have obtained their MA, to continue to be covered until their official reimbursement and price are obtained.
- The post-ATU process was set up in France on January 1<sup>st</sup> 2014 following its application decree.
- The price and time to market for a new drug are two major parameters for the pharmaceutical industries in France to plan the launch and anticipate the revenue of a drug. They largely depend on:
  - the ASMR, a criterion assessed and rated from I to V by the HAS and used as the main determinant of the price
  - the length of the pricing negotiations

## Method

The study period begins on January 1<sup>st</sup>, 2014 until June 1<sup>st</sup>, 2019. On this period, we found usable data for 26 drugs:

- ❖ We had the publication dates of ASMR's granting and market price, for the 26 drugs and we could calculate the average length for each group of ASMR
- ❖ We found the compensation fee for only 15 drugs so the average price cut per group of ASRM was calculated on less data than the average length

The price cut reflects comparison between the compensation fee in the ATUc/post ATUc program and the official price obtained and the length represents time between the granting of the ASMR and the publication of the price

We have sorted the data by ASMR level and for each of them (ASMR III, IV and V) we have calculated the average price reductions and length of negotiations to determine if the level of ASMR has an impact on these parameters.

• Sources:

- ❖ We found the ATUc compensation fee in the table "Montant de l'indemnité maximale réclamée aux établissements de santé pour les médicaments bénéficiant d'une autorisation temporaire d'utilisation (ATU) ou étant en post-ATU" on the Ministry of Health website<sup>a</sup>
- ❖ We found the official price/date of publication in the French "journal officiel"<sup>b</sup>
- ❖ The levels and dates of ASMR were found in the transparency committee appraisals of each drugs on the HAS website<sup>c</sup>

## Results

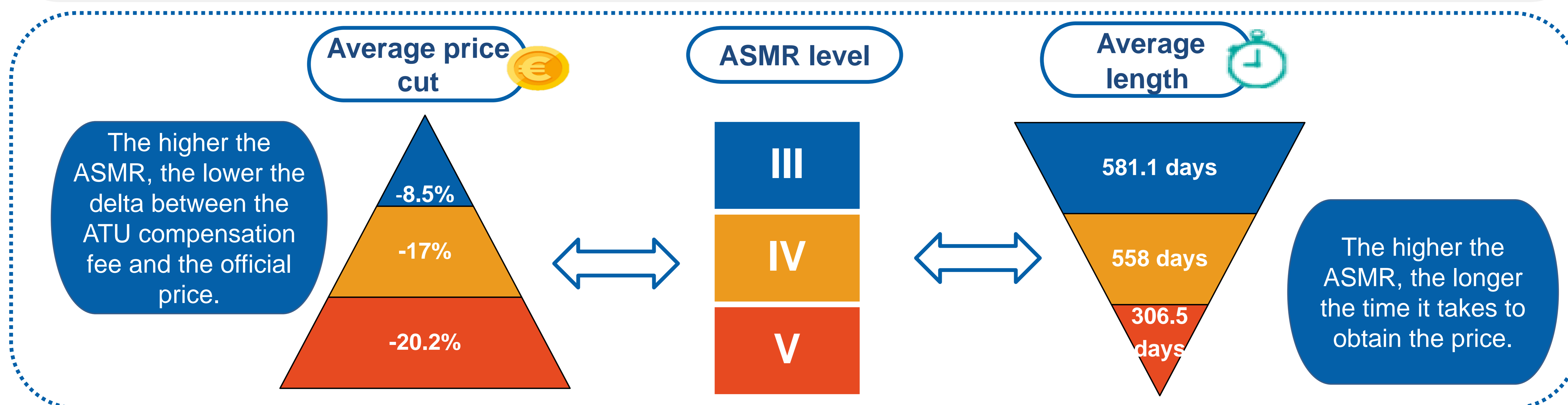
In each group of ASMR (III, IV and V), we obtained the average price cut by calculating the means of the price differences between the compensation fee in the ATUc/post ATUc program and the official price for 4, 6 and 5 drugs granted with ASRM III, IV and V respectively. And for the average length, we also calculated the means of time to obtain the price for 7, 13 and 6 drugs granted with ASRM III, IV and V respectively.

Table of range of data analyzed:

	price cut range (%)	length of the pricing negotiation range (day)
ASMR III	7 - 33	240 - 1379
ASMR IV	0.16 - 16	149 - 1121
ASMR V	13 - 36	9 - 442

After the analyze of these two parameters for each group of ASMR level, we found a correlation between the ASRM level, the price and the length of the pricing negotiations: the higher the ASMR is, the lower the price cut is and the longer the time is to obtain the price.

The price cut is almost 2.4 times higher in the ASMR V group than in the ASMR III group (20.2% vs 8.5%) and exactly twice higher in the ASMR IV group than in the ASMR III group (17% vs 8.5%). Furthermore, it takes almost twice the time to obtain the official price for the ASMR III group compared to ASMR V group (581.1 days vs 306.5 days).



## Conclusion

The correlation between the price and the level of ASMR is explained in particular for ASMR III, since according to the "accord cadre"<sup>d</sup> (framework agreements between the Ministry of Health and pharmaceutical companies), this level of ASMR allows the firm to claim a price based on the European corridor, higher than the comparators already available in the French market price.

Furthermore, firms expectations in terms of price/volume agreement are higher for a level of ASMR III than a level V, this lead to longer negotiations to reach a consensus.

Thus, this study allows us to anticipate the average time required to negotiate prices with the authorities and the price decrease to be expected compared to the compensation fee set in the ATUc/post ATUc for drugs included in this early access program.

<sup>a</sup> <https://solidarites-sante.gouv.fr/ministere/acteurs/instances-rattachees/article/atu-autorisations-temporaires-d-utilisation>

<sup>b</sup> <https://www.legifrance.gouv.fr/initRechExpTexteJorf.do>

<sup>c</sup> <https://www.has-sante.fr/jcms/>

<sup>d</sup> [https://solidarites-sante.gouv.fr/IMG/pdf/accord\\_cadre\\_version\\_definitive\\_20151231.pdf](https://solidarites-sante.gouv.fr/IMG/pdf/accord_cadre_version_definitive_20151231.pdf)