Price regulation, the mandatory minimum discount and a maximum government procurement price (PMVG) have led to great savings, helping to increase the access to medicines. They allowed the procurement of more than twice the volume for 2,3 times the number of patients in 2018, compared to the previous year.

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Case study of the judicialisation of eculizumab (Soliris®): challenges in the price regulation and the impact of establishment of the maximum government price in Brazil

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INTRO

- In Brazil, access to health, including the access to medicines is a Constitutional right;
- Due to limited budgets, there is "*judicialisation*" (court cases) to ensure access to medicines in the Unified Health System (SUS);

OBJECTIVES

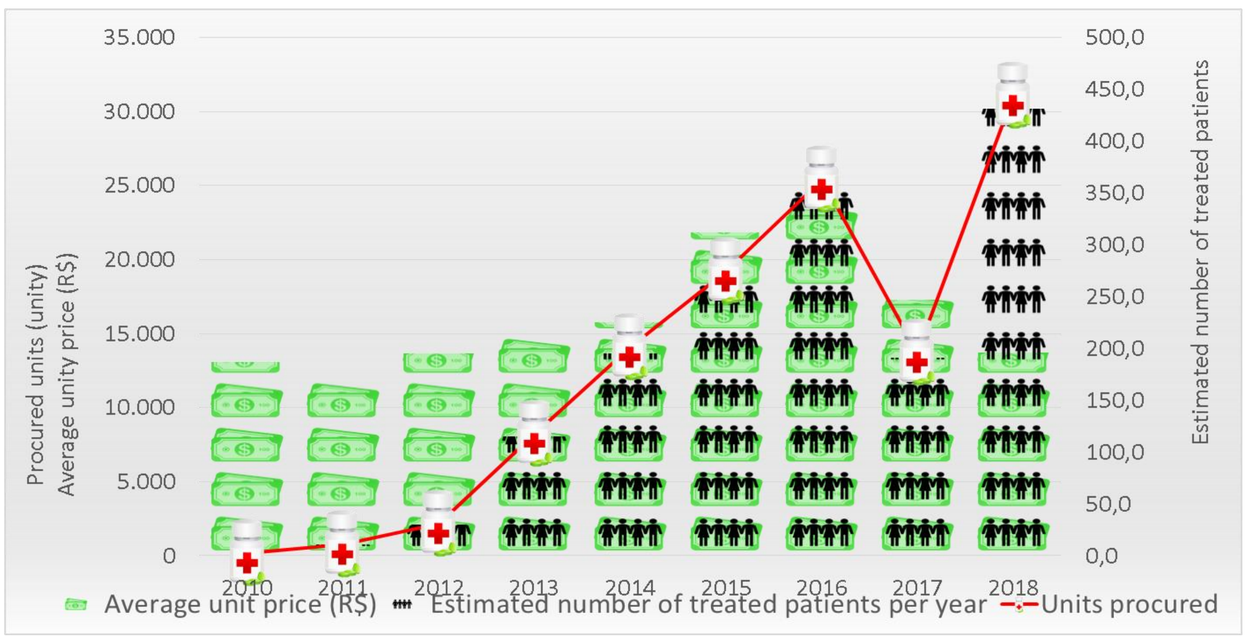
The objective of this study was to describe and review how the economic regulation has contributed to promote access to medicines for very high-priced medicines in Brazil.

METHODS

- Policy analysis combining a descriptive study with data review from the Medicines´ Market Monitoring System (SAMMED) and the national public procurement system (Compras-net) regarding the procurement of eculizumab (Soliris) from 2010 to 2018, reviewing key results.
- Region covered: National study in Brazil (PAHO/WHO region).

RESULTS

- In 2016, eculizumab (Soliris®), for treatment of paroxysmal nocturnal haemoglobinuria (PNH), a rare disease, costed USD 187 million (R$ 620 million) to the SUS (average unit price: USD 8.347,82, R$ 27,614.60), purchased due to court cases, before marketing authorisation and its incorporation to the health system.
- In 2017, when the eculizumab became regulated by CMED, it had a CAP discount of 19,28% and CMED established the PMVG of USD 3.710,00 (R$ 12,274.83).
- Due to this price difference, in 2018, MoH purchased more than twice the volume (31,056 units for 431 patients) compared to 2017 (13,721 units for 190 patients), based on the recommended daily doses for adults in the main indication (figure 1).



* The average procurement price was calculated based on the different procurement processes through each year and number of units and the estimated number of treated patients per year was calculated based on the adults' recommended daily doses for paroxysmal nocturnal haemoglobinuria (PNH)

Figure 1. Number of units, average unit price of eculizumab (Soliris®) procured by the Brazilian Ministry of Health and the estimated number of treated patients from 2010-2018.

CONCLUSIONS AND LESSONS LEARNED

- External Reference Pricing (ERP) is still a very useful tool for pricing. Therefore, price transparency and cooperation with information sharing among countries is important.
- Despite great savings and increased access to medicines, there are still challenges for the health system in providing very high-priced medicines, with few or no external reference prices.
- The legal provision for setting a provisional maximum price and PMVG "ex oficio" with administrative process and penalties for commercialisation before approval can contribute to tackling very high prices.

Price Regulation

- The Law 10.742/2003 sets the basis for medicines prices regulation and established a governance and administrative structure – the Medicines' Market Regulatory Chamber (CMED) with representatives from the Ministry of Health (President), the Presidency´s Office (Casa Civil), the Ministry of Economy and Ministry of Justice and Public Security.
- The Medicines' Market Regulatory Chamber (CMED) regulates medicines' prices (price cap) since 2003, based on Health Technology Assessment, External Reference Pricing (ERP) and Internal Reference Pricing (IRP).
- In 2006, CMED established the Price Acquisition Coefficient (CAP), a mandatory minimum discount with a maximum government procurement price (PMVG) to a positive list of medicines.
- The Resolution CMED no. 2/2018 established that it is an infringement to offer a medicine without an authorised price by CMED and that CMED will provisionally set the maximum price allowed *(ex oficio)*.