TRASTUZUMAB IN THE TREATMENT OF HER2-POSITIVE EARLY AND LOCALLY ADVANCED BREAST CANCER: THE FIRST HTA REPORT OF INEAS-TUNISIA

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OBJECTIVES

The Tunisian National Authority for Assessment and Accreditation (INEAS) has published in 2018 its first HTA report, aimed at informing the national payer on the effectiveness, risks, cost-effectiveness and price-fairness of trastuzumab. This treatment is the first agent to target HER2 positive breast cancer. Since it has obtained its marketing authorization in 2008 in early and locally advanced HER2 positive breast cancer, it has been at the top of pharmaceutical spending of the payer.

METHODS

Evidence on added benefit of trastuzumab were extracted from high quality systematic reviews and recent clinical practice guidelines following the assessment of their quality. The current ex-factory price of trastuzumab in Tunisia was compared to many other countries. A survey was carried out among INAHTA member agencies to collect information on prices, reimbursement status and management modalities in different health systems. In the absence of a submission from the company, cost-effectiveness of trastuzumab was estimated from a ministry of health and a national payer perspective, based on a literature search of cost-effectiveness studies in LMIC. The adaptation of a cost-effectiveness model developed by Pichon et al[(1)] was conducted, followed by a sensitivity analysis to test the robustness of results. Acceptability curves schematizing different scenarios and cost-effectiveness price was estimated by considering an efficiency threshold of 3 GDPPC/QALY.

RESULTS

Trastuzumab significantly improves DFS (HR 0,6, CI 95% [0,50 to 0,71] p<0,00001) and OS (HR 0,66, CI 95% [0,57 to 0,77] p<0,00001), however it increases the risk of congestive heart failure (RR 5,11 ; CI 90 % [3,00 to 8,72] p<0,00001) and reduces the left ventricular ejection fraction (RR 1,83 ; CI 90 % [1,36 to 2,47] p=0,0008)[(2)] (Figure 1).

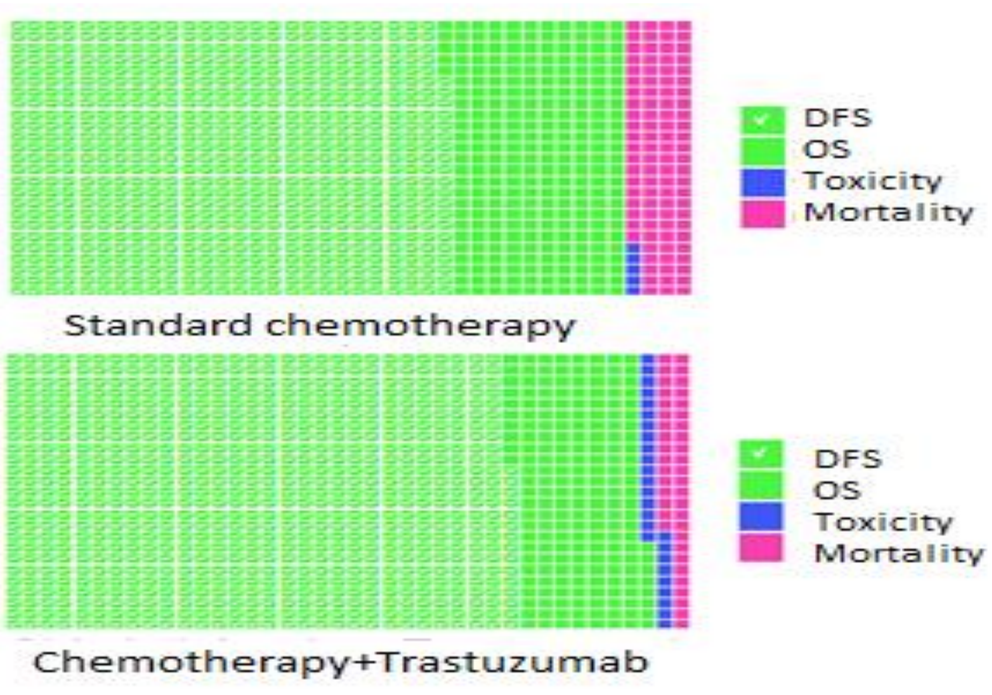

Figure 1. Trastuzumab benefice risk balance

Despite the discounts obtained over time, the 2018 ex-factory price of trastuzumab in Tunisia remains higher than many other countries with much higher GDPPC (Figure 2).

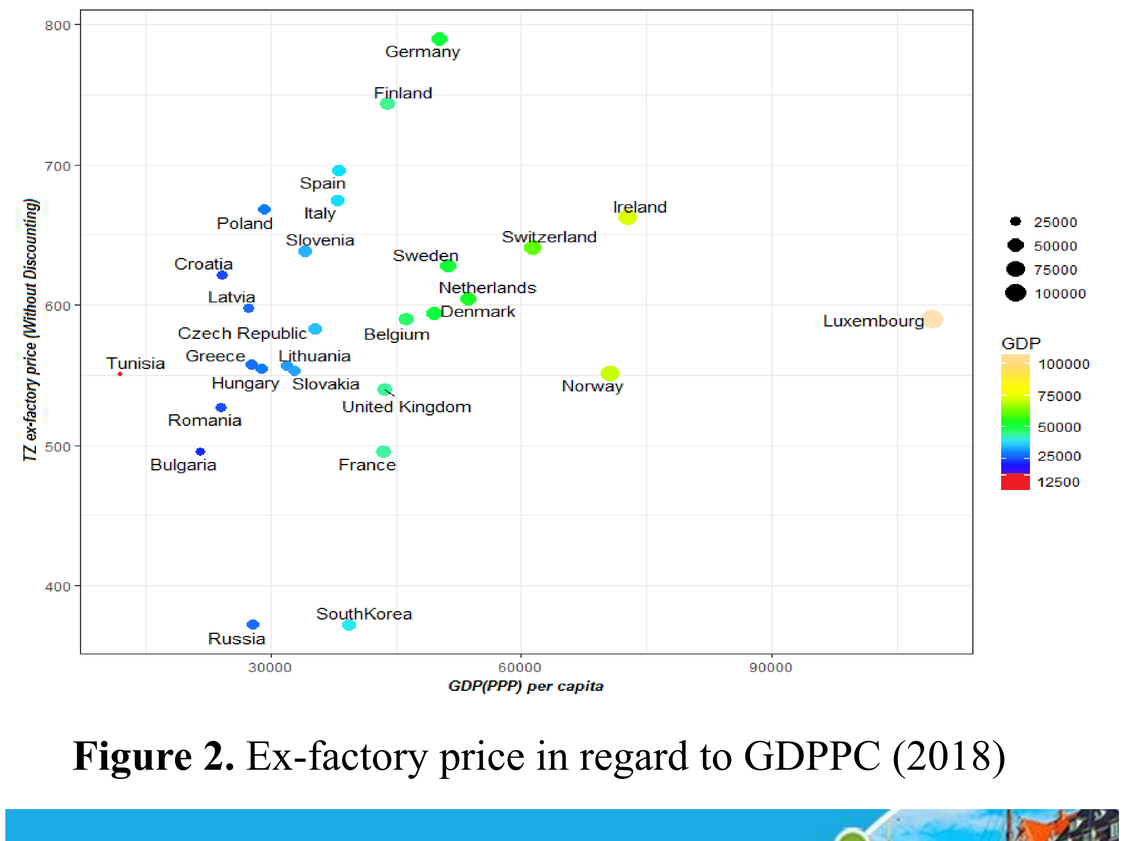

Figure 2. Ex-factory price in regard to GDPPC (2018)

The ICER of trastuzumab was 49 670,67 USD/QALY from the ministry of health's perspective (4,5 times the 3 GDPPC/QALY threshold as suggested by WHO[(3)]), while, it was 6,8 times the threshold from the national payer's perspective. Probabilistic sensitivity analysis showed 0 % probability of being cost-effective at the current acquisition price. A 78% discount is required to reach the cost-effectiveness threshold. These results provided a set of recommendations for the payer and informed the negociation of the biosimilar's price, that just entered in the Tunisian market.

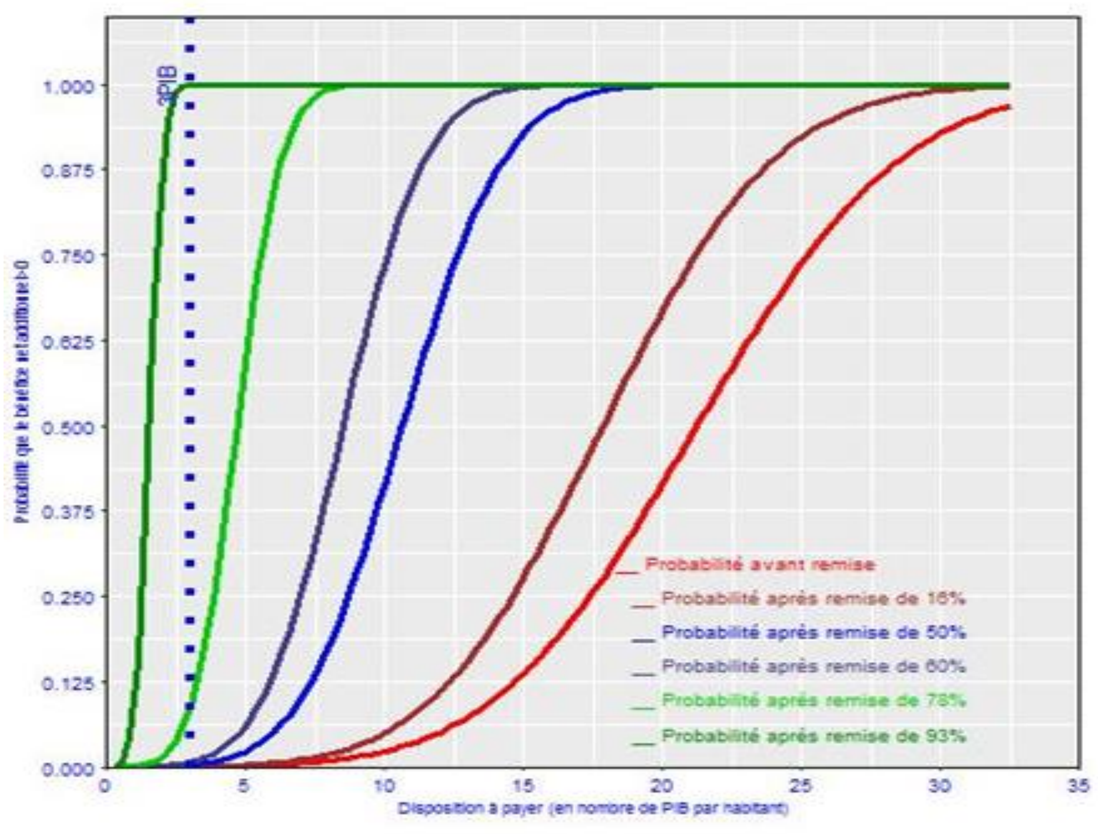

Figure 3. Acceptability curves for the Tunisian context

CONCLUSION

Trastuzumab's added benefit has been demonstrated in high quality studies. Nevertheless, strong evidence-based mechanisms should drive price negotiation and reimbursement decisions. This HTA report clearly illustrated the crucial role of an HTA body in informing prices' negotiation.

REFERENCES

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