Acceptance Code: HTA8

> Gasol M ¹, Head of the Rational Use of Medicine Department

- > Fontanet M¹, Secretary of the Decision-making Commission
- > Guarga L ¹, Consultant of Pharmaceutical Provision Department
- > de Maria A², Vice-president, Patient Engagement
- > Castillo C², Vice-president, Global Market Access
- Ramírez-Peinado S², Senior Consultant, Global Market Access
 Aguado M², Associate Consultant, Global Market Access
- > Porro A², Associate Consultant, Patient Engagement

¹Catalan Health Service, Barcelona, Spain; ²Alira Health, Barcelona, Spain

 ~ 6

> A literature review conducted in 2021, showed that patient involvement in health technology assessments (HTAs) is becoming increasingly relevant across Europe. The study found that the Catalan Health Service (CatSalut), a regional healthcare institution of Spain, was one of the few European bodies in which patients have voting rights. However, published data on this subject is limited. Thus, this study aims to describe patient involvement in medicine appraisal and decision-making in Catalonia.



METHODOLOGY

A secondary literature research was carried out focused on medicine appraisal and decision-making model in Catalonia. Additionally, multiple interviews with Catalan evaluators to collect further information were conducted.

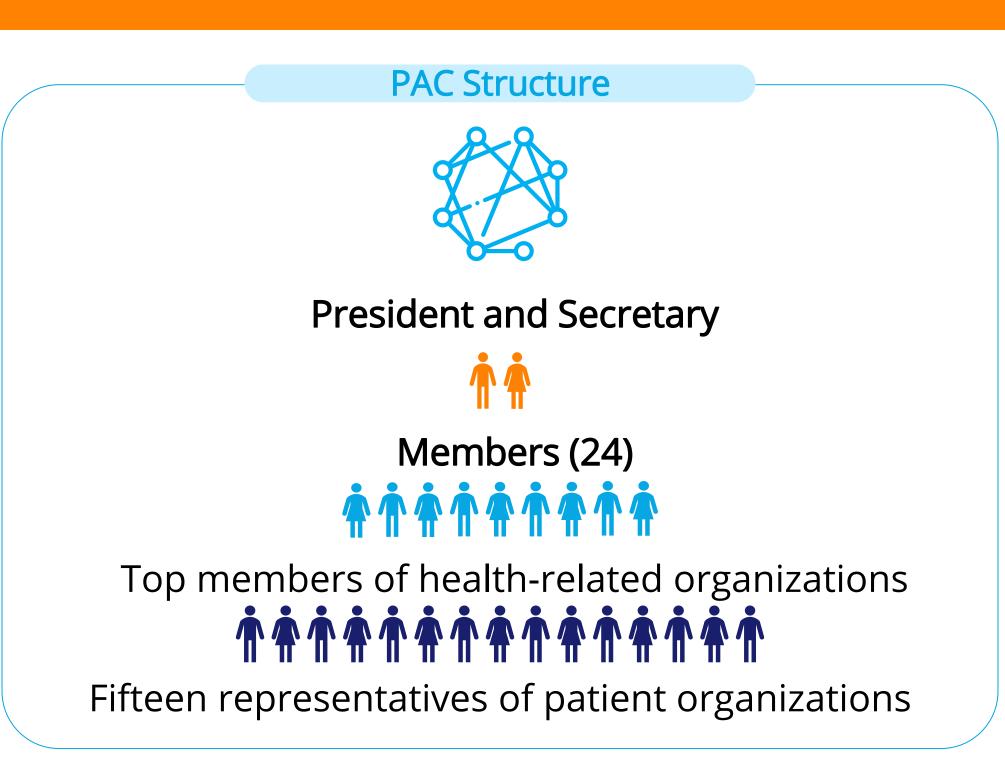


RESULTS

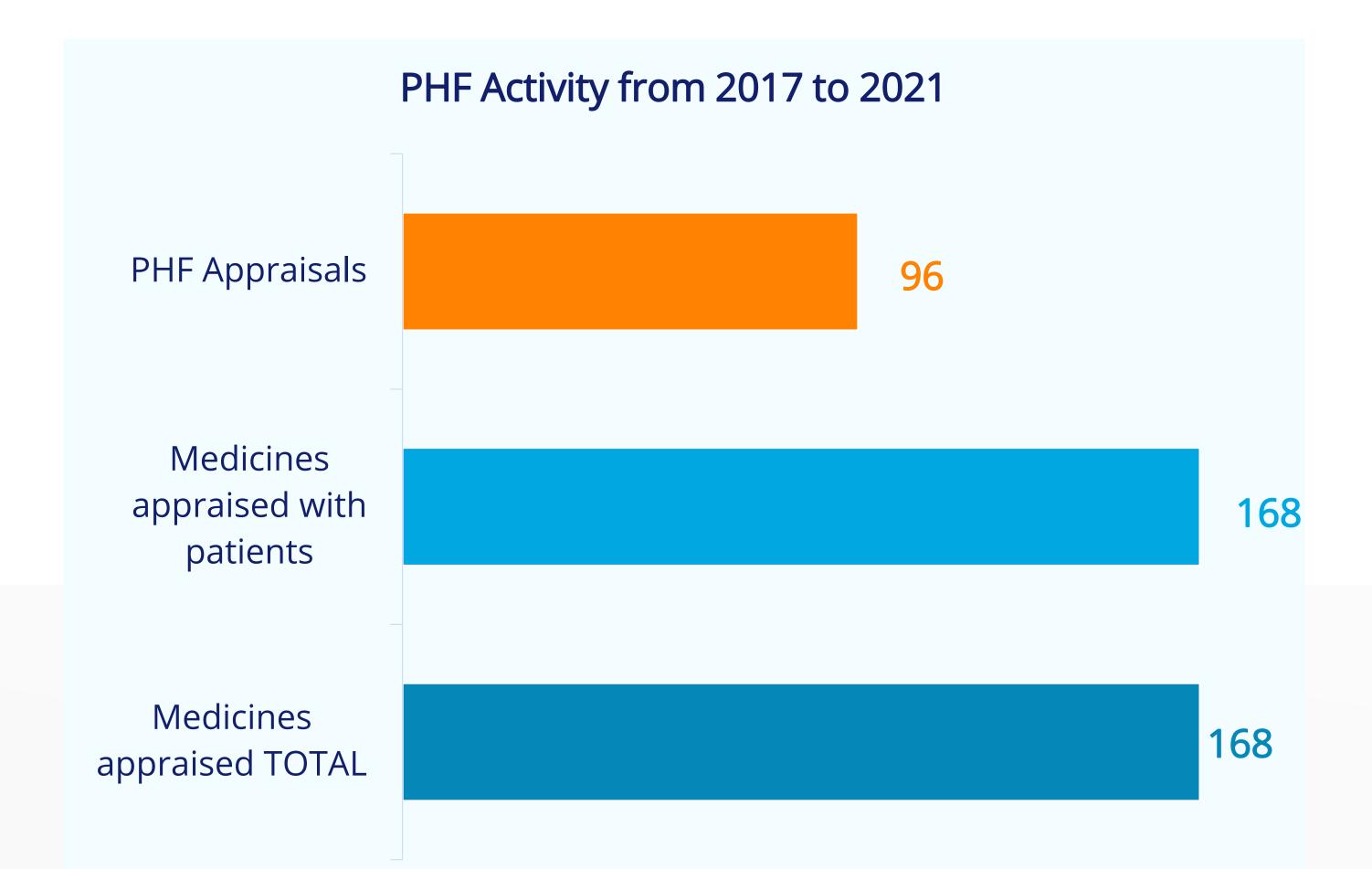
- > CatSalut runs a specific program for medicine appraisal and decision-making. *Programa d'Harmonització Farmacoterapèutica* (PHF), aimed to prioritize innovative medicines according to their added value and considering the needs and budgeting priorities. The PHF follows the process presented in the figure below.
 - 1.Treatment selection and prioritization.
 - 2. Process preparation. Literature research, notification to the marketing authorization holder, etc.
 - **3. Technical reports.** Definition of the therapeutic positioning and recommendations for use based on the assessment of the relative efficacy/effectiveness, safety, and economic aspects.

Stoppage. Waiting for price and reimbursement decision by the Spanish Ministry of Health.

- **4. Decision-making using an adapted reflective MCDA.** Final proposal regarding criteria for use, clinical variables, and access conditions for medicines.
- **5. Communication** to professionals, monitoring their implementation and evaluation of health and economic outcomes.
- > The PHF comprises two advisory councils, one for hospital outpatient drugs and one for primary care drugs (CAMH and CAMAPCE), and a decision-making commission (CFT-SISCAT). CAMH and CAMAPCE carry out tasks included in the third step and CFT-SISCAT in the fourth, of the process shown previously.
- According to the Instruction 05/2017, each PHF panel include different professional and clinical backgrounds, to provide a holistic and multidisciplinary approach to medicine assessment. In particular, the advisory council's accounts with more clinical experts and the decision-making commission with regional and hospital payers. Each PHF panel accounts with two representatives from different patient associations, appointed by the Patients' Advisory Council (PAC) of Catalonia's Department of Health. PAC is the official body representing patient organizations in Catalonia, composed by 24 members from health-related and patient organizations.



> Patients' representatives are trained on administration procedures to provide their considerations at each medicine appraisal and if necessary, their vote (with the exemption of appraisals concerning their own disease). From 2017 to 2021, PHF conducted 96 appraisals for a total of 168 medicines (more than one treatment can be included in each appraisal). In all the appraisals, patients were involved in the decision-making process.





CONCLUSION

> The Catalan program for medicine appraisal and decision-making has a high level of patient involvement, integrating them during each step to provide a multi-disciplinary medicine assessment.





REFERENCES

- > Reyes-Travé, A., Guarga-Solé, L., Roig-Izquierdo, M. *et al.* Characterization of the Pharmaceutical Risk-Sharing Arrangement Process in Catalonia. *PharmacoEconomics* **39**, 973–982 (2021). Available in the following link
- > Gerència d'Harmonització Farmacoterapèutica Àrea del Medicament, CatSalut, Generalitat de Catalunya Departament de Salut *et al.* Document informatiu Procediment d'avaluació per part del Programa d'harmonització farmacoterapèutica (PHF), 2018. Available on the following <u>link</u>
- CatSalut, Generalitat de Catalunya, *et al.* CatSalut. Instrucció 05/2017 Programa d'harmonització farmacoterapèutica del CatSalut, 2017. Available in the following <u>link</u>
- > Generalitat de Catalunya Consell Consultiu de Pacients, *et al.* Pla Estratègic del Consell Consultiu de Pacietns de Catalunya, 2017. Available in the following <u>link</u>