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Health Technology Assessment in Portugal: health policies, methodologies and emerging challenges

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Abstract

Portugal is a European country with a high Human Development Index (HDI) and extensive health system coverage. In line with the recommendations of the World Health Organization, Portugal regulates drug prices to ensure better access with financial sustainability. To this aim, health technology assessment is recognized as an essential tool for making informed financing decisions. In consonance with the challenges faced by other countries in this domain in the last few years, the methodologies and criteria used in the evaluation of different health technologies have been put to the test. This article presents an overview of the Portuguese health system and the technology assessment system regarding the latest main implemented policies also on the price regulation system, including the most recent challenges faced in this field.

Keywords: health technology assessment; pharmacoeconomics; drug costs; costs and cost analysis; decision making; Portugal

Avaliação de Tecnologias de Saúde em Portugal: políticas de saúde, metodologias e desafios emergentes

Resumo

Portugal é um país europeu com elevado Índice de Desenvolvimento Humano (IDH) e um sistema de saúde com extensa cobertura. Alinhado com as recomendações da Organização Mundial da Saúde, Portugal pratica regulação de preços de medicamentos para garantir maior acesso mantendo a sustentabilidade financeira. Nesse ínterim, a avaliação de tecnologias em saúde é reconhecida como ferramenta fundamental para a tomada de decisão informada de financiamento. Em consonância com os desafios enfrentados por outros países nessa área nos últimos anos, as metodologias e critérios utilizados na avaliação de diferentes tecnologias de saúde tem sido colocados à prova. Esse artigo apresenta uma visão geral do sistema de saúde e do sistema de avaliação de tecnologias em Portugal quanto às políticas mais recentes adotadas também em regulação de preços, incluindo os mais recentes desafios que esta área tem confrontado.

Palavras-chaves: avaliação de tecnologias de saúde; farmacoeconomia; custos de medicamentos; custos e análise de custo; tomada de decisão; Portugal

Portugal and its health system

Portugal is a country with a Human Development Index (HDI) considered very high by the United Nations (UN). The country has 92,200 km² of total area and 10.3 million inhabitants, which results in a population density of 111.7 individuals per km²[1–3]. With an HDI of 0.864, Portugal occupies the 38th position in the ranking of 189 countries, considerably above the mean of neighboring nations from Europe and Central Asia (0.791), in addition to a GINI index of 32.8 in 2019[4–6]. The birth rate is 1.4 births per woman, stable at this level since 2010 and with infant mortality in persistent decline, from 15 deaths/1,000 in 1990 to 7 deaths/1,000 in 2000 and, currently, only 3 deaths/1,000 live births[4].

As a percentage of the *per capita* and Internal Gross Product (IGP), the health expenses are lower than the European Union (EU) mean. In 2019, Portugal spent the equivalent of USD 4,017.36 PPP *per capita* on health, one-third less than the other EU countries. Health expenses represented 9.5% of Portugal's GDP, also below the EU mean: 9.9%[7,8].

Following the same trend as in most EU countries, medicine shortage is an increasing problem in Portugal. Between 2017 and 2019, reports of shortages increased by more than 100% — especially regarding medicines for the nervous and cardiovascular systems[7].

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Health systems can be classified into three main models: the national health system (*Beveridge* model), social insurance (*Bismarck* model), and private insurance[9]. The *Beveridge* model established in Portugal is based on the right to health regardless of employment, funded by taxes collected from the taxpayers' income and supported by the public system[10].

The Portuguese health system combines public and private funding in three coexistent systems. The National Health Service [*Serviço Nacional de Saúde* (SNS)] (1) is mainly funded by general taxation, in addition to own revenue collection of institutions under the jurisdiction of the Ministry of Health, and for-profit and not-for-profit private and social entities[10–12]. The Health Subsystems (*sub-regimes*) (2) are mainly funded by contributions from employers and employees. Private health insurance (3) is voluntary (SVS)[11,12]. According to the latest report by the Organization for Economic Cooperation and Development (OECD), nearly 25% of the Portuguese population is covered by a health subsystem or SVS regime. Although the SNS is universal, income can be associated with better access to health. In 2019, 3.5% of the people in the income lowest quintile reported having unmet medical needs due to cost, distance or waiting times, when compared to only 0.2% in the income highest quintile[7].

The SNS was founded in 1979 based on the principle of universal coverage and care equality. However, in 1989, through a revision of the Constitution, the universality principle of the health services was changed to ''biased free'', although nearly 60% of the population is exempted from paying[10,12]. The SNS suffered several reforms throughout time[11,12], Recently, the tax system has become regressive, with strong dependence on indirect taxes. Two-thirds of the expenditure is paid with public funding; however, the share of one-third in direct payments has already shown a burden in family budgets. Application of fees for consultations, emergency services, home visits and complementary diagnostic and therapeutic means is observed[10].

Portugal has different authorities in charge of the health system. The Ministry of Health (MoH) [*Ministério da Saúde* (MS)] is responsible for regulating, planning, and managing the SNS. The MoH formulates and monitors health policies, in addition to coordinating activities of other governmental bodies. The National Authority for Medicines and Health Products, I.P. (Infarmed) is a governmental agency subordinate to the MoH. It performs the evaluation, regulation, and monitoring of human drug markets (subjected to obtaining marketing authorization) and medical devices (subjected to obtaining registration)[11]. However, the Directorate-General for Economic Activities (DGAE) was responsible, until July 2012, for the definition of drug ceiling prices, a competence transferred to Infarmed[11,13].

Incorporation of medicines into the national market

For a medicine to enter the Portuguese market, it is necessary that the interested company requests a Marketing Authorization (MA) [*Autorização de Introdução no Mercado* (AIM)] to Infarmed. The protocol submitted by the company must contain a favorable risk-benefit balance and prove quality, safety, and efficacy duly substantiated by pharmaceutical data and clinical and non-clinical studies[14,15].

After approval, the work done by Infarmed continues in post-market monitoring and pharmacovigilance, with the objective of ensuring the safe use of the medicine during its effective commercialization. To this end, MA holders submit Periodic Safety Reports [*Relatórios Periódicos de Segurança* (RPS)] to Infarmed, which in turn reviews the data on medicines used by the population. The MA renewal process is subjected to an overall review of all the RPS submitted by the MA holder[14,15].

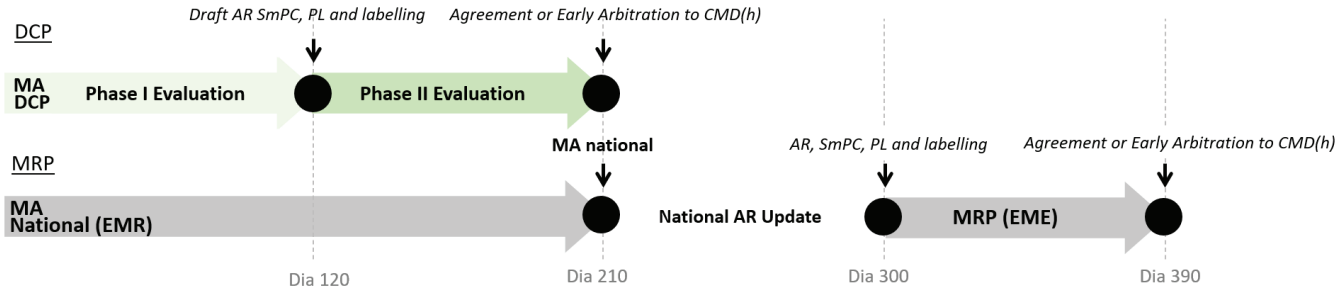
As alternatives to approval and maintenance of registration at the national level, there is centralized approval of the medicine in the EU, by mutual recognition or decentralized. In such cases, the Member States shall agree on the elements necessary for the approval to market the medicinal product in the block (see Figure 1)[15,16].

Accessible information on medicines is on the electronic platform (*Infomed*), managed by Infarmed[17]. The database contains information of interest to health professionals and the general population, a summary of the product characteristics [*Resumo das Características do Medicamento* (RCM)], package insert, additional risk minimization measures, and also the public evaluation report for the MA granting or an evaluation report for public financing purposes [*Relatório da Avaliação para efeitos de Financiamento Público* (RAFP)], when applicable[17].

In 2021, total pharmaceutical expenditure in terms of retail prices (PVP), in the outpatient market with cost sharing corresponded to $3.9 billion (PPP). Generics represented 48.8% of the units consumed, which shows a high penetration level of these products[8,18].

Infarmed aims to improve its current good governance practices and is aligned with the Resolution adopted by the European Union Member States at the 72nd Assembly of the World Health Organization (WHO). Regarding the pillar of the Resolution that aims *at improving transparency of the market for medicines, vaccines, and other health products*, Infarmed has published the monitoring reports of the outpatient and inpatient sectors[14,18], as well as the drug prices for consultation by the general population on its website[17–19].

Figure 1. Simplified representation of the European medicines evaluation system.



CMD(h): Coordination Group For Mutual Recognition And Decentralised Procedures- Human; EME: Involved Member State; EMR: Reference Member State; PL: Package Leaflet; MA: Marketing authorization; DPC: Decentralized Procedure; MRP: Mutual Recognition Procedure; AR: Assessment Report; SmPC: Summary of Product Characteristics of the Drug.

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Price Regulation System

The drug pricing policy in Portugal has evolved since its initial milestone to provide citizens with greater and better access to medicines without compromising the sustainability of the SNS. It is thus expected to obtain gains in health and maximize the citizens' quality of life. The first official milestone that governs the regulation of drug ceiling prices dates from 1988, when Ordinance No. 548 of August 13th, 1988, was published[20], which established that the definition of maximum prices for the commercialization of non-generic medicines in the Portuguese market should include the external price referencing mechanism[20].

Ordinance No. 29 of January 13th, 1990 was a fundamental milestone in making the price regime more consistent with the objectives of stability and transparency[21]. It included necessary adjustments such as the definition of criteria used for the pricing of medicines[20,21]. The publication complied with Directive No. 89/105/EEC of December 21st, 1988, to confer more transparency to the measures adopted by the Member States in the pricing of pharmaceutical products for human use and their inclusion in health insurance systems, incorporating to the national legislation the procedures already adopted in the European region[22]. Ordinance No. 29/1990 thus constituted a pillar in the pricing policy in Portugal. The regulating framework was in force until the publication of Decree-Law No. 65 of 2007, which consecrated a new pricing methodology[22,23].

In general, the pricing system is subdivided into two large groups with different pricing criteria: "non-generic medicines" and "generic medicines". In addition to that, over-the-counter medicines without State participation are not subjected to price regulation[24,25].

As mentioned, Portugal adopts the external price referencing (ERP) mechanism for the pricing of non-generic medicines, and the list of countries is updated annually[26]. For 2022, the reference countries are Spain, France, Italy, and Slovenia[27]. For generic medicines, the maximum price is defined based on the non-generic reference medicine (PVP), applying a minimum discount that has evolved from 20% to 50% (current)[28,29].

Generic medicines may be placed on the market only after the expiry of the patent protection and market protection periods of the respective reference medicinal products. Consequently, it is considered that generic medicinal products should be priced below those of the originators for the following reasons:

- The originator must have already been reimbursed for the investment in Research and Development (R&D);
- Generic medicines do not require expensive clinical trials for their development, as they can cite the clinical trials corresponding to the reference ones[30].

Thus, the advancement concerning penetration of generic medicines in the market generates savings for the patient and for the SNS, which, with free financial resources, manages to advance in universal health coverage without compromising the financial sustainability of the system. The current pricing policy in Portugal is shown in Figure 2.

The advancement of generics penetration is in line with the implementation of the 2030 Agenda, of which Portugal is a signatory country, notably in the target described in item 3.8 of the Sustainable Development Goals (SDGs), which aims to *"achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to*

Figure 2. Price regulation in Portugal

Medicines covered by the regulation

- Prescription Drugs
- Non-Prescription Drugs with co-participation
- Non-generic
- Generic

Maximim Price Regime

PVP Composition (Retail Price) - Outpatient Clinic Market

- Sale Price to lhe wholesaler (PVA)
- Pharmacy Margin
- Distributor Margin
- Marketing rate (0.04%)
- VAT(6%)

PVH Composition (Sales Price to the Hospital) - SNS Hospital Market

- Distributor Sales Price (PVA)
- Marketing rate (0.04%)
- VAT(6%)

Rules and criteria for fixing/defining PM

Non-generics

- Externai reference price (ES, FR, IT, EV), currently in force. Annually defined
- Maximum marketing margins: 6 tiers (per PVA intervals)
- lt also covers biological and biosimilars
- Outpatient Clinic: Average prices for reference countries
- Hospital: Minimum prices of reference countries

Generics

- Mercado ambulatorial: Redução de 50% /25% do preço do medicamento referência
- Mercado hospitalar: Redução de 30% do preço do medicamento referência

Price changes

Reductions

- Reparis from manufacturers. May occur monthly
- Annual Price Review - Externai price benchmarking once a year. Until 2013, it on ly covered the drugs of the outpatient market, from 2015 it started to also cover medicines used in lhe hospital market.

Increases

- Exceptional Price Reviews
- Notified Price Scheme (increase once a year)

Marketing

Outpatient Clinic Market

- Medicines can enter lhe market without funding assessment. ln this case, the cost fully borne by lhe patient. For this reason, lhe medicine can be set prior to lhe financing assessment.

Hospital Market

- Medicines with MA or indication extension after January 2007 cannot be marketed without funding assessment. For this reason, lhe medicine price is only defined in lhe context of lhe funding assessment itself.

ES: Spain; FR: France; EV: Slovenia; MA: marketing authorization; IT: Italy; PM: maximum prices; PVA: Ex-factory price; PVH Maximum hospital acquisition price; PVP: retail price; SNS: National Health Service; VAT: value added tax.

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safe, effective, quality and affordable essential medicines and vaccines for all". Another mechanism aimed at optimizing the use of available resources to improve universal coverage is to apply a Health Technology Assessment (HTA)[31].

Health Technology Assessment

HTA precedes and supports informed decision-making referring to the use and funding of health technologies in the SNS. Essentially, the method is based on comparative efficacy and safety criteria in relation to the already existing technologies in order to optimize the use of the available resources[32].

HTAs have been applied since 1991 for the medicines of the outpatient market and since 2007 for the in-hospital environment. They precede and ground drug funding decision-making[28]. It was in 1998 that the first methodological guidelines for the evaluation of medicines economic studies emerged[33].

In 2015, the HTA was updated with the creation of the National Health Technology Assessment System [*Sistema Nacional de Avaliação de Tecnologias de Saúde* (SiNATS)], governed by Decree-Law No. 97/2015 and entrusting its management to Infarmed[28].

The main objectives of SiNATS are as follows: to maximize health gains and quality of life of the citizens; to ensure the sustainability of the SNS and efficient use of public health resources; to monitor the use and effectiveness of the technologies; to reduce waste and inefficiencies, and to promote and reward the development of relevant innovation; as well as to promote equitable access to health technologies[32].

After the creation of SiNATS, the evaluation for the purposes of public funding of health technologies other than medicines, such as medical devices (MDs), was initiated. Monitoring of the health technologies after the funding decision (*ex-post* assessment) was reinforced in this system[32].

Overall, the public funding process in Portugal can be divided into the following phases: submission of the request, pharmacotherapeutic evaluation, pharmacoeconomic evaluation, negotiation, and decision-making (Figure 3). After MA granting or obtaining a new therapeutic indication in a previously granted MA (in the case of medicinal products) or after European certification (in the case of MDs), health technologies may be subjected to the evaluation procedure for the purpose of public funding, upon application by the company responsible for placing the medicinal product on the market or its representative[32].

Figure 3. The financing process in Portugal.

Legend: CD: Board of Directors of INFARMED, I.P., responsible for approving the draft decision for financing purposes; DATS: Health Technology Evaluation Directorate, responsible for managing the entire financing process; technical participation in pharmacotherapeutic and pharmacoeconomic evaluation, preparation of the decision project; CATS: Health Technology Assessment Commission, delivers opinions and recommendations on health technologies; MoH: Ministry of Health, responsible for the financing decision, and may be subdelegated.

Pharmacotherapeutic Evaluation

For the pharmacotherapeutic evaluation, evidence-based medicine methodology is used and, therefore, the interventions benefit in terms of probability is evaluated: the benefit is demonstrated when the intervention increases the probability of a given beneficial outcome or reduces the probability of a non-beneficial outcome[34].

Comparative and randomized clinical trials are considered the most suitable method to estimate measures of the treatment's relative effects. They should be integrated into a systematic review and synthesized through a meta-analysis, either conventional or network. Sensitivity analyses are necessary to identify the uncertainties present in the evidence submitted[34].

It will only be possible to use non-randomized evidence with due justification and in specific situations, such as rare or ultra-rare diseases. It is the responsibility of the creator of the health technology (or its legal representative) to submit the application for a funding evaluation, including all relevant evidence about the technology[34].

The pharmacotherapeutic evaluation is initiated with a definition of the research questions; in other words, by defining PICO. PICO is an acronym that summarizes the criterion matrix which supports the evaluation for public funding purposes: P – Population; I – Intervention; C – Comparator(s); and O – Outcome(s).[34]. More detailed information on the elaboration of PICO in the Portuguese context can be found in the supplementary material.

According to the current legislation, funding of medicines is cumulatively conditioned to the technical-scientific demonstration of therapeutic innovation or its therapeutic equivalence for the therapeutic indications requested, as well as to demonstration of its economic advantage. For other health technologies, in the case of public health reasons or proven economic advantages, the Portuguese State can participate in the acquisition of MDs for the SNS beneficiaries through co-participation mechanisms[32].

The evaluation process compares the treatment effect of the health technology under evaluation with the treatment effect of the comparators identified in the set of therapeutic efficacy and safety measures that were defined in the PICO matrix. For each comparison, the effect of the treatment on the outcome measures is evaluated using the measures selected in the evaluation matrix. For each one, it is then possible to determine whether the effect of the treatment with the drug under evaluation is superior or not in relation to each comparator. The overall treatment relative effect is assessed by estimating the relative effect of the treatment observed on the outcome measure to which greater importance was attributed and whose outcome is more reliable. A possible result of the evaluation described above are the scenarios shown in Figure 4[34].

Figure 4. Conclusions of the pharmacotherapeutic evaluation in the evaluation for financing purposes.

Avaliação Farmacoterapêutica		
Inferiority or non demonstration of "comparability" or superiority the overall treatment effect shows that the treatment under evaluation is not superior to the comparator and the drug 's benefit has not been demonstrate	**"Comparability"** the overall treatment effect shows that the treatment under evaluation is not superior to the comparator, but there is a beneficial effect of the drug	**Added therapeutic value** the overal I effect of treatment shows that the treatment under evaluation is superior to the comparator

Based on the GRADE methodology, the magnitude of the additional therapeutic value is also classified considering the estimate of the overall effect of the treatment and its confidence interval in one of the following ways: major, moderate, minor, and non-quantifiable. Regarding the analysis of the evidence quality, the assessment conclusions are expressed in line with the level of certainty of the results[34]:

- "proof" (high certainty of results when the evidence quality is high);
- "indication" (moderate certainty of results when the evidence quality is moderate);
- "suggestion" (low certainty of results when the evidence quality is low), or;
- none of the above when there is no data available or when the evidence quality is very low.

Pharmacoeconomic Evaluation

For the purpose of demonstrating economic benefit, if the medicine proves to be equivalent to others already funded, a cost minimization analysis or a price comparative analysis should be performed. The economic advantage is achieved by: (1) Price reduction in relation to the alternative, in the case of a new pharmaceutical form, new dosage or packaging size significantly different from already funded medicines with the same qualitative composition; or (2) Price reduction of at least 10% in relation to the non-generic alternative, in the case of a new medicine with a qualitative composition identical to that of other already marketed and funded drugs, in the same pharmaceutical form and dosage, and with the packaging of a similar size[32].

If the medicine demonstrates an additional therapeutic advantage (ATV) over the alternatives selected as comparators, an economic evaluation study should be submitted by the AM holder to quantify the expected health gains of the new technology against the additional costs that it may entail for the SNS[36].

In December 2019, the New Methodological Guidelines for economic evaluation studies of health technologies were published, which updated the Methodological Guidelines for Economic Evaluation Studies (1999). The update incorporates improvements in the area, such as new techniques to address uncertainty, model long-term effects, synthesize evidence, and more accurately measure the therapeutic effects[37].

The New Methodological Guidelines, which should guide preparation and evaluation of the economic studies submitted for funding purposes, currently favor the use of cost-effectiveness and cost-utility studies, complemented with budget impact analyses, these being important tools to support decision-making[37].

In addition to that, the price proposed cannot be higher than the one resulting from external price referencing and may also undergo some reduction as a result of its comparative analysis with the alternatives identified[32].

The negotiation phase is initiated once the pharmacotherapeutic and pharmacoeconomic evaluations are finished. Thus, the magnitude of the ATV and the degree of certainty of the results, as well as the incremental cost-effectiveness results and the budgetary impact, are important elements to be considered. In addition, the existence of therapeutic alternatives on the market, including generic or biosimilar ones, as well as the use of *Horizon Scanning* tools on new medicines that will soon be introduced to the market, are also of particular relevance in the negotiation of the new technologies. After the agreement between the MA holder and Infarmed, a provision is made for the possibility of formalizing a contract between the parties, which defines the funding conditions, including the therapeutic indications for which the medicinal product may be used, the maximum purchase price and the amount of the charges to be funded by the State[32].

Generally, funding is based on financial agreements, which can be covered by contracts with a discount on the price of the packaging; contracts that set the maximum amount of charges for the SNS; and price-volume contracts, in which the price is reduced according to the increase in packaging units sold (Figure 5)[32].

In case of uncertainty associated with the decision linked to the scarcity of robust evidence up to the initial evaluation date, the SNS may include risk-sharing clauses in the contracts with the company that markets the medicine. Agreements of this nature associate payment with the results of using the medicine after it has been effectively used in the population. The provision of additional evidence is fundamental for those. Alternatively, the SNS can propose contracts which, in addition to financial conditions, are based on effectiveness results, in which the SNS bears the negotiated cost associated with the medicine if the results obtained in the real context are equal to or higher than those of the clinical trials[32].

Implementing such type of contract requires greater investment by the State in means of sharing information with the hospitals in order to monitor their application. Formalization of a funding contract is compulsory for medicinal products for hospital use and optional for medicinal products for outpatient use[32].

After the funding decision, which is the responsibility of the member of the Government responsible for the health area, it is duly communicated to the stakeholders and published in Infomed, through a Public Funding Assessment Report [*Relatório de Avaliação de Financiamento Público* (RAPF)] that summarizes the main conclusions of the evaluation[17,32].

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Figure 5. The drug financing system in Portugal.

Drug Financing System

Criteria	Medicines Lists	Co-Participation Fees	Co-Participation Fees
Value-based pricing • Therapeutic value (additional) - relative efficacy and safety • Cost-effectiveness/ Cost-utility/ costminimization • Budget impact	**Positive list in force** https://extranet.infarmed.pt/INFOMED-fo/	**Outpatient** • Differentiated %. Different types of medications, according to the pharmacotherapeutic classification; • General scheme: 100%, 90%, 69%, 37%, 15% • Special regime••: 100%, 95%, 74%, 42%, 20%	**Hospital** 100%(no co-payments)

Policy measures for new medicines

Horizon Scanning	Economic Evaluation	Financing Contracts	Reference Price System
Based on the information provided by the pharmaceutical industry on a platform developed by Infarmed, and in addition to the publicly available information on the new technology, the alternatives that will enter the market in the future are identified and analyzed.	**Avaliação de estudos de custoefetividade/utilidade** Para novas DCI e novas indicações terapêuticas com valor terapêutico adicional.	• Main contract type is based on financial agreements. • At the same time, conditions based on results can be defined	• GH level ATC-5 • Reference price based on lhe average of the 5 lowest GH prices. If this value is higher than the price of the most expensive generic, then the reference price will be the later

Generic Prescrription/Replecement		Exchage for Biossimilars	Generic Co-participation	Biosimilar Co-participation
Prescription by INN Mandatory for INN with generics	**Generics Substitution** Allowed (mandatory), With some exceptions defined in legislation ¥	Allowed (for some active substances) and the prescriber must present the proposal to patients, duly informed about conditions and safety. This change should involve all clinically stable patients being treated with a certain brand for at least 6 months.	**Outpatient** • From the 51h MG the PVP is less 5% of the PVP of the previous GM, with valid request, with a limit of 20% of the PVP of the RM • Additional generics included in HG: PVP < in 5% of the LOWER-PRICED GM PVP, with at least 5% of GM QM in HG **Hospital** • 30% lower than lhe RM price	• 20% lower lhan the price of lhe reference biological medicine OU • 30% lower lhan PVH of the reference biological medicinal product if biosimilar medicinal products of the sarne INN already exist wilh at least 5% markel share

**Pensioners with low incomes, as provided for in Article 19 of Decree-Law No. 48-A/2010 of 05/13/2021 (amended by Article 6 of Decree-Law No. 106-A/2010, of 10/01/2010); ¥ As defined in Law No. 11/2012 of March 8; ATC. Chemical Therapeutic Anatomical Classification; GM. Generic Medicine; GH. Homogeneous Group; INN. International Nonproprietary Name; PVH: Maximum hospital acquisition price; PVP: retail price; QM. Market share; RM. Reference Medicine.

Monitoring

For the purposes of monitoring and reviewing the contracts, Infarmed has developed electronic registries that allow for the evaluation in the real use context of the health technologies, in addition to partnership agreements with public entities or medical societies. The information system in the real context allows monitoring effectiveness of these technologies, contributing to the review and monitoring of contracts based on results[32].

Since 2015, prescription and dispensing of medicines and health products has been done almost exclusively through the Electronic Medical Prescription (EMP) program[38,39]. Dematerialization of physical prescriptions aims at a lower number of unnecessarily issued prescriptions, greater security in authentication, ease in issuing prescriptions, autonomy, mobility and convenience for the patient, and greater rigor in the fight against fraud. EMP reduced 80% of the frauds already in the second year of its implementation, currently reaching a 99% reduction and traceability reference in Europe. In 2018, the program encouraged the expansion of the health digital transformation in Portugal and initiated the internationalization process in other European countries[38].

Final considerations

The HTA process aims to identify the evidence about the health effects and expected costs for the SNS, associated with the adoption of the new technology in view of the relevant alternatives, as well as to describe uncertainty and identify its sources. The economic evaluation should therefore be in line with the results of the pharmacotherapeutic evaluation. It is important that the methodologies used for this evaluation remain up-to-date and in line with the developments recorded in the area, not leaving aside European challenges in this area, particularly with the adoption of Regulation (EU) 2021/2282 of the European

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Parliament and the Council of 15 December 2021 on the evaluation of health technologies.[40] Hence, we highlight the importance of synergies arising from European collaboration in matters related to HTA, especially the European network for Health Technology Assessment (EUnetHTA) and the group created by the Declaration of La Valletta, in which Portugal participates.

In the current financing system, generally, the revision of financing conditions two years after the start of the contract gives greater dynamism and contributes to the improvement of the efficiency of the system as a whole. Additionally, the Annual Price Review (RAP) is a measure of expense control, providing price reduction with consequent savings for users and the SNS. In the search for all these activities, it is essential to capture and invest in qualified resources to ensure that the best results are obtained, thus strengthening the entire evaluation, financing and monitoring system, and contributing to the improvement of access to health and sustainability technologies of the SNS.

Collaborators

SC: conceptualization, writing of the original draft, writing- review and editing; DPK: conceptualization, writing of the original draft, writing- review and editing; CF: conceptualization, writing of the original draft, writing- review and editing; FF: conceptualization, writing of the original draft, writing - review and editing. JAO: conceptualization, writing of the original draft, writing - review and editing. SAC: conceptualization, writing of the original draft, writing- review and editing. All authors reviewed and approved the final version of the paper and agreed to be responsible for all aspects of the work.

Conflict of interest statement

The authors have no conflicts of interest to declare in relation to this article.

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