

Prescription, offer and access to medications for erectile dysfunction: a paradox in public health?

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Abstract *This is an opinion-based article that aims to reflect on the antagonism established between the National Policy of Integral Attention to Men's Health (PNAISH) with specific focus on ED (Erectile Dysfunction), directed to access to medication. It is well-known that PNAISH presents objectives that go beyond sexual and reproductive health, especially, even after 13 years of its publication, since there was no incorporation of medications to treat ED within the SUS. This article was developed based on the scenario observed in the daily care of patients who undergo treatment in the Men's Health Outpatient Service of a High-Complexity Hospital. According to this perspective, it is important to emphasize, that the prescription of medications within the SUS should faithfully follow the Rename; as recommended by Decree 7,508, observing the Resolution SS-83 of 2015, in the state of São Paulo. This establishes that the cost of dispensing medications not included in the SUS pharmaceutical assistance protocols, through judicialization, prescribed by a physician in the state health network, may be funded by the institution to which this physician is affiliated.*

Key words *Erectile Dysfunction, Drug Prescriptions, Men's Health, Health Policy*

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The National Policy for Comprehensive Men's Health Care (PNAISH), established by Ordinance No. 1,944, completed 13 years in 2022¹. Its recognition that male health problems constitute true public health problems is notable. Thus it proposes improvements that make it possible to increase life expectancy, and its general purpose is to reduce morbidity and mortality rates from preventable and avoidable causes among this population. Among its specific objectives, there are references directly related to Erectile Dysfunction (ED), which is considered the most prevalent among sexual dysfunctions. The policy proposes to guarantee lines of care, from the perspective of comprehensiveness, such as stimulate and carry out actions and qualify personnel for attention to male sexual dysfunctions and guarantee access to specialized secondary and tertiary care services for cases identified as deserving of this care¹.

Among the challenges observed in the literature related to PNAISH are: making the male population seek health services, mainly Primary Care. It is considered as a gateway or through the Family Health Strategy (ESF) and not through secondary care, as evidenced by the PNAISH itself. Considering another perspective; would these services be prepared? Is this adequate to serve the male population with a generalist approach to health and ED issues? Would there be diagnostic resources available in Primary Care and referral services to meet demand? Is information about triggering factors and therapeutic resources reaching men?^{2?}

Erectile dysfunction (ED), defined as a man's inability to achieve and maintain a penile erection sufficient to allow satisfactory sexual intercourse³ already had its first records described in the Heber Papyrus around 1600 BC. in ancient Egypt⁴.

Data from the WHO prove that sexual health is the factor that most interferes with the quality of life of the male population⁵. Despite not being lethal, it should be mentioned that erectile dysfunction (ED) may indicate the existence of underlying diseases, be associated with previous cardiovascular diseases, diabetes and depression in different age groups⁶.

It is estimated that 50% of men over 40 years of age present this dysfunction, reaching 90% by the age of 70 (the elderly). The incidence could reach 322 million cases in 2025^{7,8}. According to data from the 2010 IBGE Census, Brazil had 93,406,990 men and 97,348,809 women; this population will live an average of 73.48 years

(69.73 for men and 77.32 for women). Thus, ED will be one of the relevant health problems in a significant portion of the population over 40 years of age².

The causes of ED can be classified as psychological, organic or even a combination of both⁹. The most common psychogenic causes include performance anxiety, psychiatric disorders (anxiety and depression), and relationship conflict. Among the organic factors, there are vascular, endocrine and neurological causes, those related to drugs and urological interventions⁹.

Currently, there are several drugs available on the market for the treatment of ED, such as phosphodiesterase type 5 (iPDE5) inhibitors: sildenafil, tadalafil and vardenafil. The first line of treatment for ED of hormonal origin is testosterone cypionate, nandrolone decanoate, testosterone undecanoate, testosterone undecylate. As a second line, there is the synthetic analogue equivalent to prostaglandin E1 (PGE1) or alprostadil; drug approved for intracavernous treatment and, for third line: the malleable penile prosthesis already offered by the SUS. It is noteworthy that the penile prosthesis is classified as an input and not as a medicine^{10,11}. These therapeutic options are considered effective, safe, cost-effective, based on scientific evidence, with approval from the National Health Surveillance Agency, (ANVISA), European Medicines Agency (EMA) and Food and Drug Administration (FDA).

However, so far, no medications indicated for ED have been incorporated/offered in accordance with the National List of Essential Medicines (RENAME) of the Ministry of Health, which guides the lists of states and municipalities¹². A paradox that is established in line with public policies established for the male population as recommended by PNAISH in relation to access to essential medicines within the scope of the Unified Health System (SUS).

It is clearly observed that PNAISH is committed to demonstrating clarity and integration with other Health Policies in a transversal way. However, this integration does not occur. This can be seen when observing the outline of the National Medicines Policy (PNM)¹³, which advocates access to essential medicines within the scope of the SUS, guaranteeing pharmaceutical assistance and, above all, promoting rational use.

Rational use of medicines is understood when there is an appropriate prescription, timely availability and also affordable prices. It must be dispensed under appropriate conditions, consumed in doses and for the indicated period of

time and at defined intervals, and also the indication of effective, safe and quality medicines¹⁴.

It is important to highlight that the prescription of medication within the SUS scope must be in accordance with RENAME, with the PCDT of the Ministry of Health (MS), or with the State List of Essential Medicines (RESME), district and municipal medicines list - Municipal List of Essential Medicines (REMUME)¹⁴, including in a rational way.

With the unavailability of these medications in the SUS, even when prescribed meeting the criteria, users can go to court to request the medication. When granted by the judiciary, a lawsuit is generated against the state or municipality, which does not characterize the best path to promoting rational access, considering the sustainability of the health system. The ineffectiveness of access to medicines in the programs responsible for supplying medicines can often be related to the presentation of prescriptions for medicines not available in the SUS and, as a consequence, there is an increase in the number of legal actions¹⁵.

In the state of São Paulo, Resolution SS-83 of 2015 was published, establishing that the cost of dispensing non-standardized medicines or medicines not included in the SUS pharmaceutical assistance protocols, prescribed by a doctor from the state health network, may be covered by the institution to which the doctor is linked¹⁶. It should be noted that the discount will occur through the transfer of financial resources destined to state health institutions, immediately after the medication delivered to the user at the respective health establishment has been discharged.

Given this scenario, it becomes unfeasible and antagonistic for doctors working in the SUS, especially in establishments under state management, to prescribe medications for the treatment of ED in line with the guidelines established by the SUS and what PNAISH recommends. Given this exposure, it is observed that users are often prevented from receiving the indicated and most appropriate therapy, deviating from the basic principles of the SUS, in particular, equity. It is important to emphasize that there are no records of submission of these technologies to the National Commission for the Incorporation of Technologies in the SUS (CONITEC)¹⁷, nor a justification for this. It is believed that the failure to incorporate these technologies into pharmaceutical assistance programs may have occurred due to negligence, including by the pharmaceu-

tical industry, which currently occupies the first place as a claimant in CONITEC¹⁸.

It is observed that the Generic Medicines Policy¹⁹, from this perspective, may have favored user access, mainly by presenting in its list the majority of medicines indicated for ED, as can be seen on the ANVISA website²⁰ and, above all, by offering them at more affordable prices²¹. On the other hand, no specific medications were observed for the treatment of ED in the *Farmácia Popular do Brasil* Program²².

It is important to highlight that the drug sildenafil from the class of Phosphodiesterase inhibitors type 5 iPDE-5 is already supplied by SUS, incorporated by CONITEC, according to RENAME version 2022, currently available within the scope of the Specialized Component of Pharmaceutical Assistance (Ceaf), for Arterial Hypertension pulmonary disease (PAH), and for Systemic Sclerosis (SSc)^{11,12}.

An inconsistency is observed when consulting the medication sildenafil citrate in the MED-SUS application (app), available on the website (gov.br), considered an important tool to support health professionals in preparing medical prescriptions/prescriptions within the SUS. However, sildenafil citrate in 50mg and 100mg presentations, even though it is described in the app, is not offered in the SUS for ED, what characterizes a paradoxical orientation¹².

Currently, aiming for the sustainability of the system, decisions about which treatments should be made available in the SUS need to be based on health needs²³. In this scenario, the importance of Health Technology Assessment (HTA) is evident with the aim of providing information for decision-making for managers in all spheres²⁴.

In Brazil, it is noteworthy that the assessment for the incorporation, alteration or exclusion of technologies is carried out by CONITEC²⁵. In this scenario, the importance of Health Technology Assessment Centers (NATS)²⁶ is observed, considering that most of them are linked to large hospitals. These institutions are mostly considered references for the male population, including for the treatment of ED.

It is worth noting that there are other ways of offering medicines not guided by RENAME even if they are not incorporated by CONITEC. The medicine can be provided at the state level, through State Technical Standards. They are established by the State Health Departments or by municipalities in accordance with REMUME. Both situations can occur through the Therapeutic Pharmacy Commission – CFT, according to

the mapping of the epidemiological profile of its coverage^{27,28}.

It is important to highlight that when one intends to request expanded access to an already incorporated technology, such as sildenafil citrate, either through the preparation of Scientific Technical Opinions (PTC) or the preparation of a Dossier; it becomes feasible, since there are available data considered essential for carrying out HTA for decision-making, such as safety, effectiveness and, above all, the analysis of the budgetary impact²⁹.

There is another important therapeutic option, the drug tadalafil 5 mg, currently prescribed both to improve sexual performance in patients with ED, and for the treatment of some cases of

Benign Prostatic Hyperplasia (BPH) or for both cases, an optimized dose. Studies with a high level of scientific evidence, graded by GRADE (Grading of Recommendations Assessment, Development and Evaluation)³⁰ prove the effect of PDE5 inhibitors (iPDE-5) in the treatment of BPH. Currently, tadalafil 5 mg (once a day) is approved in Brazil for the treatment of urinary symptoms associated with BPH³¹.

This set of actions can provide a sustainable health system in line with established public policies, access to medicines in a rational way, prescription of treatment based on scientific evidence, and safe and effective assistance for the user, therefore enabling the achievement of satisfactory outcomes.

Collaborations

AL Godoi and FN Facio Junior contributed equally to the conception, preparation of the manuscript, critical review and approval of the final version.

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