# RIO DE JANEIRO DECLARATION

**Position of Medical Societies on Compounded Hormone Implants**

The undersigned medical and scientific organizations, legitimate representatives of the specialties involved in hormone therapy, gathered on the occasion of the 20th World Congress on Menopause, express their deep concern regarding the use of compounded hormone implants in Brazil, particularly in women during the menopausal transition and after menopause.

Menopausal hormone therapy, when appropriately indicated, is a legitimate and effective treatment supported by robust scientific evidence. When its indications and contraindications are respected, this therapy improves women's health and quality of life. This conclusion, however, cannot automatically be extended to compounded subcutaneous hormone implant formulations, whether used alone or in unstudied combinations, without an adequate assessment of efficacy and safety.

Compounded implants containing testosterone, gestrinone, estradiol, and/or other substances have been offered for menopausal symptoms, sexual dysfunction, weight loss, muscle gain, vitality, physical performance, and anti-aging purposes. For these uses, there are no high-quality clinical trials supporting the claimed benefits or safety data supporting their use.

These products are not equivalent to registered medicines and have not undergone the full range of studies required to demonstrate batch-to-batch consistency, stability, sterility, purity, bioavailability, the rate and duration of hormone release, the relationship between the implanted dose and the dose actually absorbed, or long-term safety. The term "bioidentical," used as part of a marketing strategy, does not guarantee efficacy, pharmaceutical quality, or a lower risk profile.

The implant route adds a further significant clinical challenge: after insertion, hormone exposure may persist for months. In the event of irregular or supraphysiological concentrations or adverse events, the dose cannot be promptly reduced and administration cannot be readily discontinued, as it can with other formulations. Removal may be difficult or incomplete, particularly with bioabsorbable pellets.

In postmenopausal women, fundamental questions remain unanswered regarding endometrial and breast safety, cardiovascular risk, thromboembolism, stroke, lipid metabolism, liver health, cancer, and safety following repeated exposure. Caring for patients experiencing adverse effects from hormone misuse, particularly involving compounded implants, has become a daily occurrence in medical practice.

There is also concern about the emergence of a commercial ecosystem in which the use of these implants shifts away from individual clinical need toward the expansion of a large economic chain. The practices of a limited number of compounding establishments depart from the legitimate, individualized nature of pharmacy compounding and take on the characteristics of large-scale industrial activity: mass production, maintenance of inventories, commercial standardization of protocols, recruitment and training of prescribers, and direct or indirect promotion to the public through social media.

Legitimate pharmacy compounding is intended to meet a specific individual need that cannot be addressed by an available medicine. It must not be used to create commercial product lines, induce demand, maintain inventories, promote short training courses on prescribing, implantation, and monetization, or advertise to the public. Such practices are incompatible with the purpose of compounding and, in the case of advertising compounded hormone implants and recommending them for aesthetic or performance-enhancing purposes, are expressly prohibited.

Testosterone has only one indication in women supported by international consensus: hypoactive sexual desire disorder in carefully assessed postmenopausal women, using doses that maintain concentrations within the physiological female range. Implants, injections, and preparations that produce supraphysiological levels are not recommended. There is no scientific evidence supporting its use to promote weight loss, muscle gain, cognitive improvement, increased energy, cardiovascular prevention, or longevity.

Gestrinone is a synthetic steroid with no scientifically established indication for menopausal therapy, hormone replacement, metabolic improvement, or anti-aging purposes. Its adverse effects include acne, hirsutism, alopecia, voice changes, clitoromegaly, and metabolic alterations, some of which may be persistent.

Other pharmaceutical products delivered through implants, such as metformin, oxytocin, tadalafil, oxandrolone, and/or NAD, have no ethical or scientific basis whatsoever for such use.

The exceptional regulatory framework applicable to compounding must not serve as an entry route for hormone products used on a large scale without the clinical development and regulatory review required for registered medicines. Individualized prescribing does not mean experimentation without evidence or safeguards.

In light of this situation, the signatory societies call upon the Brazilian Health Regulatory Agency (ANVISA), with the participation of the Ministry of Health; the Federal and Regional Councils of Medicine and Pharmacy; the Public Prosecutor's Office; the Public Defender's Offices; consumer protection agencies; and the Legislative Branch, to adopt the necessary measures to prohibit the compounding, stockpiling, commercialization, distribution, advertising, and use of compounded hormone implants in Brazil.

They also call for stronger oversight, pharmacovigilance, mandatory reporting of adverse events, and accountability throughout the commercial chains that promote hormone products beyond the purposes and limits established by health regulations.

This Declaration does not oppose hormone therapy. Registered, studied, adjustable, and monitorable formulations are available and can be administered orally, transdermally, vaginally, or through other approved routes. These formulations can safely address indications for hormone therapy both in menopausal care and in other settings, including endometriosis and other disorders. The objective is to ensure that every patient safely receives the appropriate treatment, at the lowest effective dose, through the appropriate route, with the possibility of monitoring and discontinuation when necessary.

Personalized medicine begins with the uniqueness of each patient, but it must remain within the boundaries of science, ethics, and public health protection.

Rio de Janeiro, October 2026.

**Proposed signatory organizations**

**Websites of the signatory entities:**

**https://www.endocrino.org.br/**
**https://www.febrasgo.org.br/**
**https://www.imsociety.org/**
**https://diabetes.org.br/**
**https://abemss.org/**
**https://abeso.org.br/**
**https://portaldaurologia.org.br/**
**https://sbmastologia.com.br/**
**https://sbrh.org.br/**
**https://www.portal.cardiol.br/**
**https://sbhepatologia.org.br/**
**https://sobrac.org.br/**
**https://sbendometriose.com.br/**
**https://cmba.org.br/**
**https://sbpt.org.br/portal/quem-somos-sbpt/**
**https://amb.org.br/**
**https://www.aapec.org/**
**https://abran.org.br/**
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