MEDIA STATEMENT

SAHPRA clarifies the benefits and risks of medroxyprogesterone acetate

Embargo: Immediate release

Pretoria, 17 January 2025 – The South African Health Products Regulatory Authority (SAHPRA) has recommended that the product information of medroxyprogesterone acetate (MPA)-containing products be amended by updating the safety warnings to include the potential risk of meningioma.

MPA is a synthetic oral and injectable form of the hormone progesterone and is used for contraception and the management of endometriosis-associated pain. It is also indicated in the palliative treatment of recurrent and/or metastatic endometrial cancer, renal cancer and breast cancer in postmenopausal women.

The MPA-containing products registered in South Africa are Depo-Provera®, Provera®, Petogen®, Medroxyprogesterone Mylan®, Sayana®, Omrastoz®, Trivina® and Triclogyn®.

Background

SAHPRA has been informed by a Holder of a Certificate of Registration (HCR) of regulatory action taken in Europe in respect of products containing MPA, noting the potential risk of meningioma. The regulatory action, which entailed updating product labelling, was based on the results of two epidemiological studies conducted in France[1] and the United States[2] which observed an increased risk of cerebral meningioma with prolonged use of MPA.

Increased risk of meningioma was also detected with prolonged use of other progesterones (medrogestone and promegestone). ***No medicines containing these substances are marketed in South Africa at present.***

Risk of adverse drug reactions associated with MPA

A meningioma is a tumour, usually non-cancerous (benign), that arises from the membranes surrounding the brain and spinal cord. Signs and symptoms of meningiomas vary depending on the tumour's location. Meningiomas are the only brain tumour more common among women than men. Meningiomas tend to occur in middle-aged and older adults.

The available evidence suggests that an increased risk of meningioma in people taking MPA is possible, but the development of meningioma is likely a very rare event. Globally, 32 cases have been reported in 20 years, between 2004 and 2024, which suggests that the absolute risk of developing meningioma is small, given the widespread usage of MPA-containing products. **Currently, no cases have been reported in South Africa.**

SAHPRA wishes to assure the public that the benefit-risk profile of registered MPA-containing medicines remains favourable. MPA is safe to use for its approved indications.

Advice for healthcare professionals

Healthcare professionals are encouraged to provide counselling to patients about the side effects of MPA detailed in the product information (https://pi-pil-repository.sahpra.org.za/). SAHPRA recommends that patients treated with MPA should be monitored for signs and symptoms of meningioma in accordance with clinical practice. If a meningioma is diagnosed in any patient treated with MPA for a non-oncological indication, the use of MPA must be stopped, as a precautionary measure. If a meningioma is diagnosed in any patient treated with MPA for an oncological indication, the need for further use of MPA should be carefully considered on a case-by-case basis, considering individual benefits and risks.

Advice for patients

Understanding the potential side effects of any medicine is important for making informed choices about contraception and the management of endometriosis-associated pain. Patients should talk to a healthcare professional before taking or continuing MPA. It is important to

use MPA for its approved indications and to follow the directions for use provided by healthcare professionals.

Report any suspected adverse drug reactions

Healthcare professionals and members of the public are urged to report any suspected adverse drug reactions (ADRs) related to the use of MPA and other health products to SAHPRA via the eReporting link available on the SAHPRA website (https://www.sahpra.org.za/e-services/) or complete an ADR reporting form accessible via the SAHPRA website and email it to adr@sahpa.org.za. Alternatively, reporting can be done via the Med Safety App, downloadable through Google Play or the Apple App Store.

References

1. Roland N, Neumann A, Hoisnard L, Duranteau L, Froelich S, Zureik M, Weill A. Use of progestogens and the risk of intracranial meningioma: national case-control study. BMJ. 2024 Mar 27;384:e078078. doi: 10.1136/bmj-2023-078078.

2. Griffin RL. The association between medroxyprogesterone acetate exposure and meningioma. Cancers (Basel). 2024 Sep 30;16(19):3362. doi: 10.3390/cancers16193362. PMID: 39409982; PMCID: PMC11482550.

Ends

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Notes to Editors:

SAHPRA will post this media release on its website. Navigate to the News section on the website.

Should you wish to request an interview, please send your request to media@sahpra.org.za and Madimetja.Mashishi@sahpra.org.za

Updates on vaccine registration can be accessed here:

Vaccines - News and updates (sahpra.org.za) - https://www.sahpra.org.za/news-and-updates/vaccines-news-and-updates/

About SAHPRA:

SAHPRA is tasked with regulating (monitoring, evaluating, investigating, inspecting and registering) all health products. This includes clinical trials, complementary medicines, medical devices and in-vitro diagnostics (IVDs). Furthermore, SAHPRA has the added responsibility of overseeing radiation control in South Africa. SAHPRA's mandate is outlined in the Medicines and Related Substances Act, 101 of 1965, as amended, as well as the Hazardous Substances Act, 15 of 1973.

SAHPRA has three pillars to ensure that medicines, medical devices and IVDs meet the requisite standards to protect the health and well-being of all who reside in South Africa:

- Safety
- Efficacy
- Quality

It is these three pillars that define the ethos of SAHPRA.