

Annex I

**Scientific conclusions and grounds for the variation to the terms of the Marketing
Authorisation(s)**

Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for mesterolone, the scientific conclusions are as follows:

In view of available data on the serious health risks associated with mesterolone abuse as an image- and performance enhancer substance from the literature and spontaneous reports, and in view that such practice is still remarkable, especially in combination with other anabolic androgenic substances (AAS), the Lead Member State considers that warnings in the product information of mesterolone should be strengthened to raise awareness of serious health risks and discourage such a behaviour. The Lead Member State concluded that the product information of products containing mesterolone should be amended accordingly.

The CMDh agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the Marketing Authorisation(s)

On the basis of the scientific conclusions for mesterolone the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing mesterolone is unchanged subject to the proposed changes to the product information.

The CMDh reaches the position that the marketing authorisation(s) of products in the scope of this single PSUR assessment should be varied. To the extent that additional medicinal products containing mesterolone are currently authorised in the EU or are subject to future authorisation procedures in the EU, the CMDh recommends that the concerned Member States and applicant/marketing authorisation holders take due consideration of this CMDh position.

Annex II

Amendments to the product information of the nationally authorised medicinal product(s)

Amendments to be included in the relevant sections of the Product Information (new text **underlined and in bold**, deleted text ~~strike through~~)

Summary of Product Characteristics

- Section 4.4

A warning should be amended as follows:

Drug abuse and dependence:

~~Androgens are not suitable for enhancing muscular development in healthy individuals or for increasing physical ability.~~ **Mesterolone has been subject to abuse, typically in combination with other anabolic androgenic steroids. The abuse of mesterolone and other anabolic androgenic steroids carries serious health risks (e.g., cardiovascular events with fatal outcome in some cases, hepatic and/or psychiatric events, and dependence) and is to be discouraged.**

Package Leaflet

- Section 2: Warnings and precautions

Drug abuse and dependence:

Always take <invented name> exactly as your doctor or pharmacist has told you.

You should not use <invented name>~~Proviron is not suitable for body-building, increasing muscles in healthy men or for increasing other physical ability~~ **alone or with other anabolic androgenic steroids because it carries serious health risks, such as problems to your heart and blood vessels (that can lead to death), liver and/or mental health, or you may become dependent on these drugs.**

Annex III

Timetable for the implementation of this position

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Adoption of CMDh position:	October 2022 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	28 November 2022
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	26 January 2023