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 minoxidil (topical formulation), the scientific conclusions are as follows:

In view of available data on hypertrichosis in children following inadvertent topical exposure to minoxidil from spontaneous reports including in some cases a close temporal relationship, a positive de-challenge, the PRAC considers a causal relationship between the use of minoxidil (topical formulation) and hypertrichosis in infants following inadvertent topical exposure is at least a reasonable possibility. The PRAC concluded that the product information of products containing minoxidil (topical formulation) should be amended accordingly.

In view of available data on the accidental ingestion of topical minoxidil the PRAC considers that the outer and immediate packaging of products containing minoxidil (topical formulation) should be amended accordingly.

Having reviewed the PRAC recommendation, the CMDh agrees with the PRAC overall conclusions and grounds for recommendation.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for minoxidil (topical formulation) the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing minoxidil (topical formulation) is unchanged subject to the proposed changes to the product information.
The CMDh recommends that the terms of the marketing authorisation(s) should be varied.

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 added as follows:
Hypertrichosis in children following inadvertent topical exposure to minoxidil:
Cases of hypertrichosis have been reported in infants following skin contact with minoxidil application sites of patients (caregivers) using topical minoxidil. Hypertrichosis was reversible, within months, when infants were no longer exposed to minoxidil. Contact between children and minoxidil application sites should therefore be avoided.

Package Leaflet

Section 2
Cases of excessive hair growth on the body of infants have been reported following skin contact with minoxidil application sites of patients (caregivers) using topical minoxidil. Hair growth returned to normal within months when infants were no longer exposed to minoxidil. Care should be taken to ensure that children do not come into contact with areas of your body where you have applied minoxidil topically.
Consult a doctor if you notice excessive hair growth on the body of your child during the period you are using topical minoxidil products.
PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

Section 5. METHOD AND ROUTE(S) OF ADMINISTRATION

The following warning should be added (place and lay-out to be agreed upon with the national competent authorities):

Do not ingest.

Annex III
Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	June 2024 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	11 August 2024
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	10 October 2024