Reviewer No. 2  checklist for application of:
HYDROCORTISONE and FLUDROCORTISONE tablets (inclusion)

In the WHO Essential Medicines List for Children

(1) Have all important studies that you are aware of been included?
   Yes ☒       No ☐

(2) Is there adequate evidence of efficacy for the proposed use?
   Yes ☒       No ☐

(3) Is there evidence of efficacy in diverse settings and/or populations?
   Yes ☒       No ☐

(4) Are there adverse effects of concern?
   Yes ☐       No ☒

(5) Are there special requirements or training needed for safe/effective use?
   Yes ☒       No ☐

   Diagnosis, initial management and ongoing review require specialist knowledge.

(6) Is this product needed to meet the majority health needs of the population?
   Yes ☒       No ☐

(7) Is the proposed dosage form registered by a stringent regulatory authority?
   Yes ☒       No ☐

(8) What action do you propose for the Committee to take?

Include hydrocortisone 4 or 5 and 10 or 20 mg scored tablets and fludrocortisone 100 microgram scored tablets in section 18.1 Adrenal hormones and synthetic substitutes
for the management of congenital adrenal hyperplasia.
Additional comment, if any.

It is important to specify scored tablets to allow dosage adjustment.

Fludrocortisone tablets may be dispersed in water and this may be preferable to extemporaneous oral liquid products because of concern over bioavailability.

Hydrocortisone suspension (commercial or extemporaneous product) may be available. There are concerns over bioequivalence with tablets. Not all strengths of tablets will be available in all countries. 10 mg scored tablets may be a reasonable compromise if only one strength can be made available. Corlan® pellets (hydrocortisone 2.5 mg) have also been used.