

# ACMD

## Advisory Council on the Misuse of Drugs

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Rt Hon Dame Diana Johnson DBE MP  
Minister for Policing and Crime Prevention  
2 Marsham Street  
London  
SW1P 4DF

13th August 2025

Dear Minister

**RE: ACMD advice on the classification and scheduling of somapacitan, lonapegsomatropin, and somatrogen**

The Advisory Council on the Misuse of Drugs (ACMD) is grateful to the Medicines and Healthcare products Regulatory Agency (MHRA) for providing a written submission and oral presentation on three growth hormone agonists, somapacitan (Sogroya<sup>®</sup>), lonapegsomatropin (Skytrofa<sup>®</sup>), and somatrogen (Ngenla<sup>®</sup>). All three are designated as orphan medicinal products and have been granted a marketing authorisation in the UK. Further to these representations, the ACMD is able to provide advice regarding the appropriate classification and schedule for these three medicines under the Misuse of Drugs Act 1971 and Misuse of Drugs Regulations 2001, respectively.

- Somapacitan (Sogroya<sup>®</sup>) is for use in the replacement of endogenous growth hormone (GH) in children aged 3 years and above, adolescents with growth failure due to growth hormone deficiency (paediatric GHD), and adults with growth hormone deficiency (adult GHD).
- Lonapegsomatropin (Skytrofa<sup>®</sup>) is for use in the replacement of endogenous GH in children and adolescents aged from 3 years up to 18 years with growth hormone deficiency (GHD).
- Somatrogen (Ngenla<sup>®</sup>) is for use in children and adolescents from 3 years of age with GHD.

The MHRA reported that there have been no post marketing reports of misuse of somapacitan and lonapegsomatropin. Post marketing surveillance has identified a very small number of cases of reported misuse with somatrogen, however these

were related to non-compliance with the treatment regimen, for example, due to refusal of the injection and administering a dose lower than prescribed.

## **Classification**

It is likely that the potential harms of somapacitan, lonapegsomatropin, and somatrogon would be commensurate to the three growth hormone medicines already controlled under Class C: somatotropin, somatropin, and somatrem.

### **Recommendation 1**

The ACMD recommends that somapacitan, lonapegsomatropin, and somatrogon should be controlled as Class C drugs under the Misuse of Drugs Act 1971.

### **Lead Department**

The Home Office.

### **Measure of implementation**

Legislative changes to the Misuse of Drugs Act 1971.

## **Scheduling**

The three growth hormone medicines already listed in the Misuse of Drugs Regulations 2001, somatotropin, somatropin, and somatrem, are currently scheduled under Schedule 4 (Part 2) of the Misuse of Drugs Regulations 2001.

### **Recommendation 2**

The ACMD recommends that somapacitan, lonapegsomatropin, and somatrogon should each be scheduled under Schedule 4 (Part 2) of the Misuse of Drugs Regulations 2001.

### **Lead Department**

The Home Office.

### **Measure of impact**

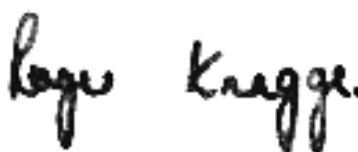
Legislative changes to the Misuse of Drugs Regulations 2001 (as amended).

Yours sincerely,



**Professor Owen Bowden-Jones**

Chair of the ACMD



**Professor Roger Knaggs**

Chair of the ACMD Technical Committee