



**World Health  
Organization**

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ENGLISH ONLY**

**EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION  
Geneva, 20 – 24 April 2026**

**Proposals for discontinuation of WHO reference material projects  
for biologicals**

**NOTE:**

This document has been prepared for the purpose of inviting comments and suggestions on the proposal(s) contained therein. Written comments on the proposal(s) **MUST** be received in English by **23 March 2026** and should be addressed to:

Product Standards, Specifications and Nomenclature  
Department of Medicines and Health Products Policies and Standards  
World Health Organization  
1211 Geneva 27  
Switzerland

Comments may also be submitted electronically to **Dr Ivana Knezevic** at email: [knezevici@who.int](mailto:knezevici@who.int).

The distribution of this document is intended to provide information to a broad audience of potential stakeholders and to improve the transparency of the consultation process. Following consideration of all comments received, the proposal(s) will then be considered by the WHO Expert Committee on Biological Standardization (ECBS) prior to a final decision being made and published in the WHO Technical Report Series.

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### **Proposals for discontinuation**

1. Discontinuation of the First WHO International Reference Panel for HBsAg, genotype A
2. Discontinuation of the First WHO International Standard for human Growth Hormone (pituitary)

**HBsAg, genotype A**

<b>Proposal (title)</b>	Discontinuation of the First WHO International Reference Panel for HBsAg, genotype A, 03/262		
<b>Proposer (name of Institution)</b>	MHRA	<b>Principal contact</b>	Ben Cowper
<b>Rationale</b>	<p>This product was prepared around the same time as the 2<sup>nd</sup> WHO IS for HBsAg, 00/588. It is a 4-point dilution series of 00/588 intended for assay sensitivity assessment and thus avoids the need for end users to prepare their own dilution series. 00/588 was replaced by 12/226, which contains a different HBsAg subtype (B), which is itself in the process of being replaced.</p> <p>03/262 is distributed at a relatively low rate (approximately ~60 ampoules per year) and stocks are expected to be depleted within 3 years. Although it contains a different subtype to the WHO IS, HBsAg assays are not genotype-specific, and thus 12/226 (and its eventual replacement) is a suitable alternative for HBsAg assay sensitivity assessment where 03/262 has been used previously (although dilution will need to be performed by the end user). In addition, a WHO HBsAg genotype panel is available from Paul-Ehrlich Institut (PEI), for characterisation of assay specificity.</p> <p>Considering all of the above, MHRA does not intend to replace 03/262, and proposes that this standard is formally discontinued on exhaustion.</p>		
<b>Anticipated uses and users</b>	N/A		
<b>Source/type of materials</b>	N/A		
<b>Outline of proposed collaborative study</b>	N/A		
<b>Issues raised by the proposal</b>	None – alternative WHO standards are available. Previous customers have been notified and are supportive of the proposal.		
<b>Action required</b>	ECBS to endorse proposal.		
<b>Proposer's project reference</b>		<b>Date proposed:</b>	1 February 2026
<b>CONSIDERATIONS FOR ASSIGNMENT OF PRIORITIES (TRS932)</b>			

<b>Approval status of medicine or in vitro diagnostic method</b>	N/A
<b>Number of products or methods</b>	N/A
<b>Public health importance</b>	N/A
<b>Global importance</b>	N/A
<b>Global need from regulatory &amp; scientific considerations</b>	N/A
<b>ECBS outcome</b>	[BLANK]

**Human Growth Hormone, Pituitary**

<b>Proposal (title)</b>	Discontinuation of the First WHO IS for human Growth Hormone, Pituitary (80/505)		
<b>Proposer (name of Institution)</b>	MHRA	<b>Principal contact</b>	Ben Cowper
<b>Rationale</b>	<p>This product was prepared in the early 1980s for calibration of hGH bioassays, and in the late 1980s its use was expanded to immunoassay calibration as well. It was later superseded, for bioassay and immunoassay, by the 2<sup>nd</sup> WHO IS for somatropin (98/574), but has since continued to be distributed at a very low rate (10-20 ampoules sold per year), primarily for doping control purposes.</p> <p>Stocks are expected to be exhausted in the next 4-5 years. Considering the limited use of the product, MHRA will not replace 80/505 when stocks are exhausted, and proposes that the product is therefore discontinued.</p> <p>In recognition of the importance of doping control activities for which 80/505 still finds use, an alternative product, 80/521, will be made available as a NIBSC standard for this purpose.</p>		
<b>Anticipated uses and users</b>	N/A		
<b>Source/type of materials</b>	N/A		
<b>Outline of proposed collaborative study</b>	N/A		
<b>Issues raised by the proposal</b>	None – alternative WHO standards are available. Previous customers have been notified of intentions for several years now and have not raised objections.		
<b>Action required</b>	ECBS to endorse proposal.		
<b>Proposer's project reference</b>		<b>Date proposed:</b>	1 February 2026
<b>CONSIDERATIONS FOR ASSIGNMENT OF PRIORITIES (TRS932)</b>			
<b>Approval status of medicine or in vitro diagnostic method</b>	N/A		

<b>Number of products or methods</b>	N/A
<b>Public health importance</b>	N/A
<b>Global importance</b>	N/A
<b>Global need from regulatory &amp; scientific considerations</b>	N/A
<b>ECBS outcome</b>	[BLANK]