



Vancouver November 1, 2022

Jean-Pierre Chanoine, MDPHD
Secretary General
Global Pediatric Endocrinology and Diabetes
Vancouver

To: Expert Committee on the Selection and Use of Essential Medicines
Children's Essential Medicines List
World Health Organization
Geneva

To Whom It May Concern,

Re: Inclusion of somatropin in neonates, infants and young children with hypoglycemia secondary to growth hormone deficiency

Global Pediatric Endocrinology and Diabetes (GPED) is a non-profit organization and a Canadian charity established in 2010. GPED aims at improving the care of children presented with endocrine disorders or with diabetes living in low and middle-income countries (LMICs) through public advocacy, training and education of local health professionals, clinical collaborations and development of translational clinical research.

I am writing this letter as Secretary General of GPED. The Executive Committee of GPED has reviewed the submission and fully supports it. In agreement with this submission, GPED feels that the role of hGH in the prevention and management of hypoglycemia in neonates, infants and young children with GH deficiency is well demonstrated. As such, hGH does prevent severe morbidity (irreversible neurological damage caused by hypoglycemia). Of note, hGH is necessary to prevent hypoglycemia in this situation. Treatment of hypoglycemia secondary to hGH deficiency is not successfully achieved by other means, such as a dietary approach.

GPED suggests that the Expert Committee consider adding this key essential medicine for neonates, infants and young children. In the experience of the Executive Committee members, children older than 2 years with GH deficiency are very rarely prone to hypoglycemia caused by the lack of GH.

Sincerely,

Jean-Pierre Chanoine, MD
Secretary General, Global Pediatric Endocrinology and Diabetes

Address GPED: Suite #334, 3381 Cambie Street, Vancouver BC V5Z 4R3, Canada
Phone: 1-604-8752345, ext 5120
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Wellington, October 14, 2022

Esko Wiltshire, MB ChB MD DipObst DipPaed FRACP
Chair, International Consortium of Pediatric Endocrinology & Diabetes Societies (ICPE)
Professor in Paediatrics and Child Health
University of Otago Wellington and Te Whatu Ora, Capital and Coast Health
New Zealand

To: Expert Committee on the Selection and Use of Essential Medicines
Children's Essential Medicines List
World Health Organization
Geneva

To Whom It May Concern,

Re: Addition of growth hormone to the WHO EMLc

I am writing this letter of support as Chair of the International Consortium of Pediatric Endocrinology & Diabetes Societies (ICPE).

This consortium was founded in September 2015 with the goal of increasing collaborations at all levels between Pediatric Endocrinologists across the five continents. It regroups all major regional Pediatric Endocrine Societies, as well as the International Society for Pediatric and Adolescent Diabetes (ISPAD) and Global Pediatric Endocrinology and Diabetes (GPED): the Arab Society for Paediatric Endocrinology and Diabetes (ASPED); the Asian-Pacific Pediatric Endocrine Society (APPES); the African Society for Paediatric and Adolescent Endocrinology (ASPAE); the Chinese Society for Pediatric Endocrinology and Metabolism (CSPEM); the European Society for Paediatric Endocrinology (ESPE); the Indian Society for Pediatric and Adolescent Endocrinology (ISPAE); the Japanese Society of Pediatric Endocrinology (JSPE); the Pediatric Endocrine Society (PES), the Latin American Society for Pediatric Endocrinology (SLEP) and the Russian Paediatric Endocrinology Group.

ICPE, through their regional societies, represents more than 5,000 pediatric endocrinologists across the 5 continents.

The present submission for inclusion of human growth hormone (hGH) into the WHO EMLc focuses on the neonate and the young child. Although GH deficiency results in short stature during childhood, adolescence and adulthood, a more important consequence of GH deficiency is severe hypoglycemia during the neonatal period, up to the age 6 years. The management of hypoglycemia in these patients requires treatment with hGH in order to prevent the long term, irreversible effects of untreated hypoglycemia on psychomotor development.



This submission was discussed during the ICPE meeting of that took place on April 7, 2022 and ICPE representatives of all regional societies of Pediatric Endocrinology unanimously recommended that hGH deficiency be included in the EMLc. In addition, hGH treatment requires specialized diagnostic and monitoring facilities as well as medical care by a pediatric endocrinologist or, if not available, by a pediatrician knowledgeable in pediatric endocrine diseases (complementary list).

Yours Sincerely,

Esko Wiltshire
ICPE Chair

December 16, 2022

24th Meeting of the Expert Committee on the Selection and Use of Essential Medicines
World Health Organization
Geneva, Switzerland

Dear Colleagues,

I am currently President of the **Endocrine Society**. The **Endocrine Society** is an international organization of over 18,000 endocrinologists that includes clinicians and basic scientists. It promotes breakthroughs in scientific discovery and medical care through publishing in its peer-reviewed journals, hosting an annual scientific meeting, creating resources and educational materials to help clinicians and investigators accelerate the pace of scientific discovery and translation of the latest science into clinical care, advocating for appropriate support and policies that benefit healthcare providers and patients, and educating the public about hormones and the roles that endocrine scientists and clinicians play in achieving optimal public health. The Endocrine Society publishes Clinical Guidelines for clinical care and these Guidelines discuss many of the medications being submitted now for inclusion in the recommended medicines for WHO.

The Endocrine Society has worked from the beginning with the current committee in bringing to the WHO this new list of medications that are felt to benefit patients with endocrine diseases world-wide. Dr. Molitch, a member of the Endocrine Society, is Co-Chair of this committee. It is important for the WHO to understand that this committee truly has world-wide representation, including Drs. Chanoine, the Chair, and Dr. von Oettingen from Canada, Dr. Molitch, from the USA, Dr. Villarroel from Bolivia, Drs. Ewen and Beran from Switzerland, Drs. Kalra and Paulose from India, Dr. Abodo from the Ivory Coast, Dr. Karekezi from Kenya, Dr. Ramala from Tanzania, Dr. Donahue from Australia, Dr. Junfen Fu from China, Dr. Besancon from Mali, Dr. de Beaufort from Luxembourg, and Dr. Gary from the UK. In addition, the committee included not only endocrinologists (Drs. Chanoine, Molitch, Villarroel, von Oettingen, Kalra, Abodo, de Beaufort, Donaghue, Paulose, Ramalya, and Fu) but also economists (Drs. Ewen and Beran), pharmacists (Drs. Gray and Karekezi), and a dietitian (Dr. Besancon). The endocrinologists were equally divided into pediatric and adult endocrinology.

The applications for these new medications were discussed in depth by this committee to determine both their health benefits, potential adverse effects, and costs. The committee was well aware of cost and logistical limitations of some of the medications in various countries but felt that these medications should be part of the core or complementary lists for adults or children of recommended medications for the upcoming revision.



The Endocrine Society hereby supports the **Application for inclusion of somatropin (recombinant human Growth Hormone) in neonates, infants and young children with hypoglycemia secondary to growth hormone deficiency.**

The Endocrine Society agrees that this medication is currently used clinically in many countries and have already proved to be of great benefit to thousands of patients. The Society enthusiastically supports the inclusion of this medication in the upcoming WHO List of Essential Medicines for children.

Sincerely,

A handwritten signature in black ink that reads "Ursula Kaiser".

Ursula Kaiser, MD
President
Endocrine Society



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Letter of Support for the Selection and Use of Essential Medicines List
Regarding: Inclusion of somatropin in neonates, infants and young children with hypoglycemia
secondary to growth hormone deficiency.

31 October 2022
Attention: Executive Committee
World Health Organization
Geneva, Switzerland

Dear Honorable WHO Official,

This letter is submitted in support of the petition by Jean-Pierre Chanoine, MD and the Global Pediatric Endocrinology and Diabetes organization, requesting the WHO approval and inclusion of the vital treatment of growth hormone therapy to hypoglycemic neonates, infants and young children in the EMLc. MAGIC Foundation is the global leader in endocrine health, advocacy, education, and support (www.magicfoundation.org)

In respect of your time, I shall not repeat the medical details of this critically necessary care for these children as you already have thorough documentation. However, as the global authority in advice to medical professionals around the world, your approval and inclusion of this medical treatment for impacted children has the potential to significantly decrease morbidity and to be life saving for thousands of children worldwide.

Your consideration of inclusion of adding this medical authorization in the EMLc is complicated and yet so simple. Therefore, on behalf of thousands of affected children, The MAGIC Foundation families, and international division (representing endocrine societies and patient organizations around the world), thank you for your serious consideration.

Respectfully,

Jamie Harvey, CEO of ICOSEP
The MAGIC Foundation, Co-founder