

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: Application for Inclusion of Calcitriol (1,25-dihydroxy-cholecaliferol) and alfacalcidol ( $1\alpha$ -calcidol) in the WHO Model List of Essential Medicines for adults and for children

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 (ISPAE); the Japanese Society of Pediatric Endocrinology (JSPE); the Pediatric Endocrinology (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.



Vitamin D analogues (calcitriol and 1-alfacalcidol) are used in children for the management of chronic kidney disease as well as for less common conditions such as hypophosphatemic rickets and hypoparathyroidism. They decrease morbidity in chronic kidney disease and hypophosphatemic rickets and are life saving medicines in hypoparathyroidism. They are affordable.

ICPE members fully support the inclusion of these medicines in the EMLc.

Yours Sincerely,

Esko Wiltshire

**ICPE** Chair



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: Application for Inclusion of Calcitriol (1,25-dihydroxy-cholecaliferol) and alfacalcidol (1a-calcidol) in the WHO EML and EMLc

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 calcitriol and 1 alfacalcidol are part of a family of medicines that can be considered as essential for the management of medical conditions associated with resistance to Vit D. Although to our knowledge there are no published cost-effectiveness studies, the cost of these medicines, that significantly decrease morbidity and have been used for many years in high-income countries, is modest and should not an obstacle to their inclusion in the EMLc. Patients in need of calcitriol or 1 alfacalcidol are usually followed by pediatric endocrinologists or by pediatricians in specialized centers, and as such, we suggest that the proposed medicines should be included in the complementary listing of the EMLc.

GPED respectfully suggests that the Expert Committee consider adding this key essential medicine for neonates, infants and young children.

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 Website: www.globalpedendo.org





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

Board 2022

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Helena Teede Australia Dear Colleagues,

I am currently President of the International Society of Endocrinology. The International Society of Endocrinology (ISE) represents the global endocrine community through its members and partners; national and regional organizations of clinicians, researchers, academics, nurses, dietitians and other allied health professionals active in the field of endocrinology. It collaborates with over 50 national and regional societies, comprising more than 23.500 health professionals globally. ISE promotes the dissemination of the latest scientific discoveries and clinical translations of such discoveries through a biennial international congress and other meetings all over the world. The ISE has developed new diverse training and education opportunities for the international community of endocrinologists, including a continuing medical education program which aims to help foster the globalization and inter-regional development of existing national meetings by offering ISE supported Symposia and travel fellowships to national member societies and an online portal – the ISE Global Education Hub that gathers and blends educational content from ISE's own and supported meetings. The portal serves as a year-round virtual community for CME accredited online educational resources in endocrinology.

The ISE has worked from the beginning with an international committee of adult and pediatric endocrinologists, pharmacists, economists and dietitians to perform a comprehensive review of the medicines included in the "Endocrine Disorders" section of the EML and EMLc. This committee was co-chaired by Dr. Mark Molitch, our appointed representative and by Dr Jean-Pierre Chanoine, pediatric endocrinologist.

The present letter aims at supporting the addition of calcitriol (1,25-dihydroxy-cholecaliferol) and alfacalcidol to the WHO Model List of Essential Medicines for adults. Analogues of Vitamin D are used in a variety of diseases of calcium and bone metabolism in adults (as in children, although the type and frequency of the disease differs markedly between the two age groups). Specifically, in adult endocrinology, hypoparathyroidism, whether acquired (post surgery) or of genetic origin requires the use of calcitriol or alfacalcidol. The morbidity and mortality associated with severe hypocalcemia is important. Having access to these two lifesaving medicines also decreases significantly admission of these patients to the emergency room or to the ward. We feel that these medicines are affordable, easy to use (oral) and very effective and should be included in the EML.

The ISE enthusiastically supports the inclusion of calcitriol (1,25-dihydroxy-cholecaliferol) and alfacalcidol to the upcoming WHO Model List of Essential Medicines.

Sincerely,

Margaret Wierman, MD

President

International Society of Endocrinology



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 Kenyha, 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 calcitriol (1,25-dihydroxy-cholecaliferol) and alfacalcidol ( $1\alpha$ -calcidol) for the management of relevant disorders of bone and calcium metabolism, in adults and in children.

The Endocrine Society agrees that these medicines are currently used clinically in many countries and have already proved to be of great benefit to thousands of patients. The Society enthusiastically supports their inclusion in the upcoming WHO Lists of Essential Medicines.

Sincerely,

Ursula Kaiser, MD

Unda Karjen

President

Endocrine Society



12/01/22

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

Dear Committee Members,

I am writing this letter on behalf of members of our Scientific Advisory Board, regarding the application for the inclusion of Phosphorus in the WHO Essential Medicines- children's List (EMLc), for use in hypophosphatemic rickets, submitted by the Global Pediatric Endocrinology and Diabetes society.

We support this effort by the GPED, noting the importance of using both phosphate and alfacalcidol/calcitrol available for effective management of XLH (X-Linked Hypophosphatemia)

Thank you for your consideration.

Sincerely,

Susan Faitos

**Executive Director** 

The XLH Network, Inc.

Susan Faitos