

Monday, December 5, 2022

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

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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 ketoconazole to the WHO Model List of Essential Medicines for adults. In particular, ketoconazole, which has been used for many years, is very affordable and has an acceptable risk benefit profile. It definitely has its place in the overall approach of Cushing syndrome management and ISE enthusiastically supports its inclusion to the upcoming WHO Model List of Essential Medicines.

Sincerely,



Margaret Wierman, MD
President
International Society of Endocrinology

Wellington, December 7, 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 ketoconazole in the WHO Model List of Essential Medicines for adults

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 (CSPERM); 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.

Ketoconazole is a medicine that is used by pediatric endocrinologists for the management of Cushing in children and adolescents. This is rarely seen under the age of 12 years. As such, we do not feel that ketoconazole should be included in the EMLc. However, we fully support the inclusion of ketoconazole in the adult EML. Specifically, we support the concept that in settings where neurosurgery is not easily available, ketoconazole may represent the first line therapy.

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

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 oral ketoconazole tablets for the management of patients with Cushing syndrome.**

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.

Sincerely,

Ursula Kaiser, MD
President
Endocrine Society



**THE
PITUITARY
SOCIETY**

President:

KALMON POST, MD
Mt. Sinai Medical Center
New York, New York

Secretary-Treasurer:

SHLOMO MELMED, MB, CHB
Cedars-Sinai Medical Center
Los Angeles, California

November 17, 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 Pituitary Society. The Pituitary Society is an international organization of endocrinologists, neurosurgeons and others interested in pituitary disease and includes clinicians and basic scientists. The Society is dedicated to furthering the understanding of diseases of the pituitary gland. The Society sponsors educational conferences highlighting new advances in research and clinical care of pituitary diseases, provides information to the public about pituitary diseases, publishes a peer-reviewed journal that focuses on pituitary disease, and publishes clinical Guidelines for clinical care, including ones on the management of patients with prolactinomas, with acromegaly and with Cushing's disease.

The Pituitary 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 Pituitary 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, Donahue, 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.

These new medications (see list attached) 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 this list should be part of the core list of recommended medications for the upcoming revision.

The Pituitary Society has reviewed this list and agrees that these medications are currently used clinically in many countries and have already proved to be of great benefit to thousands of patients. The Pituitary Society supports the inclusion of these medications in the upcoming core list of recommended medications.

Sincerely,

A handwritten signature in blue ink, appearing to read 'K. Post', is displayed on a light gray rectangular background.

Kalmon Post, MD
President
The Pituitary Society