From: **Rivera, Victor M** <vrivera@bcm.edu>
Date: jue., 24 de ene. de 2019 a la(s) 12:48
Subject: EML
To: eml@who.int <eml@who.int>
Cc: fg (frgiron@gmail.com) <frgiron@gmail.com>, Fernando Hamuy (victhamu@highway.com.py) <victhamu@highway.com.py>

TO THE ATTENTION OF Mr. PER BANEKE, CEO, MSIF.

Dear Mr. Baneke:

Just became aware of the proposal of the MSIF to the WHO regarding the Essential Medications List for MS. I suppose the idea is to provide WHO with a list of the most desirable medications for MS in case that only a few (the only ones) could be selected, which theoretically are efficacious in all types of MS and phenotype changes.

While your diverse panels of experts and evidence resources did a remarkable job putting information and analyzing data, I am disappointed by the fact the conglomerate discarded interferons from the list of essential medications. According to the document the rationale for removal from the preferred list was adverse effects (flu-like syndrome) and the requirement of periodic liver functions tests. The real life utilization argues the flu-like syndrome is totally predictable, manageable prophylactically and of temporary duration in the immense majority of cases. The arguments used for this decision did not consider the problem faced by national health licensing offices in many countries of the world, unable to make appropriate assessments of complex medications, most of these countries also having limited or low economic resources to cover for MS medications. The excellent Atlas the MSIF assisted to create addresses this situation very clearly.

Interferons have been internationally available since the early 1990s. In some low-income countries are the only DMT available (i.e. Cuba, El Salvador, etc.). Most countries in Latin America never approved or had Glatiramer Acetate (even in the generic form) available in their institutional or public market formularies. It comes to mind the legal efforts of the MS Guatemalan Association (ASOGEM) not to allow their Social Security system replace subcutaneous brand interferon 1-a (Rebif@) for a generic formulation, in view of the absence of clinical studies demonstrating efficacy and safety. The FDA and EMA have not provided guidelines for biosimilar interferons approval.

I am certain your group would understand this different position, opinion and concern.
I am copying Prof. Fernando Hamuy Diaz de Bedoya, President of LACTRIMS, and Freddy Giron, VP of ASOGEM.

Sincerely yours.

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