

## OPINION

Dear Editor,

Upon reading the recently published article entitled “Latin American algorithm for treatment of relapsing-remitting multiple sclerosis using disease-modifying agents”<sup>1</sup>, we wish to clarify several relevant points to the current natalizumab (Tysabri®) label for relapsing-remitting multiple sclerosis registered in Brazil in June 2010<sup>2</sup>.

Specifically, current requirements in Brazil for treatment with natalizumab do not include “[...] continuous monitoring by a certified doctor throughout the period of infusion [...]” and, in addition, there is no requirement “[...] to have immediate access to a cardiac defibrillator during infusion [...]”.

We also wanted to highlight important aspects of risk stratification developed for natalizumab that were not clearly represented

in the article. Biogen Idec facilitated development of an ELISA test (Stratify JCV™) to detect presence of anti-JC virus antibodies in serum, a key risk factor for developing progressive multifocal leukoencephalopathy (PML)<sup>3</sup>. Stratify JCV™ test was made globally available (including Brazil and other Latin American countries) for all natalizumab treated and eligible patients at the end of 2011.

Lastly, we wanted to further clarify (due to two conflicting statements in the article) that currently neither natalizumab<sup>2</sup> nor interferon  $\beta$ -1a (Avonex®)<sup>4</sup> is approved for pediatric use in Brazil or globally.

Thank you in advance for the opportunity to clarify statements recently published in your journal in effort to provide your readership with complete and correct information regarding our products.

Gorana Dasic

## References

1. Finkelsztejn A, Gabbai AA, Fragoso YD, et al. Latin American algorithm for treatment of relapsing-remitting multiple sclerosis using disease-modifying agents. *Arq Neuropsiquiatr* 2012;70:799-806.
2. Tysabri® (natalizumab) - PI approved by Brazilian Regulatory Agency (ANVISA)/ 21 June 2010.
3. Sørensen S, Bertolotto A, Edan G, et al. Risk stratification for progressive multifocal leukoencephalopathy in patients treated with natalizumab. *Mult Scler* 2012;18:143-152.
4. Avonex® (interferon  $\beta$ -1A) - PI approved by Brazilian Regulatory Agency (ANVISA)/27 October 2009.

**Correspondence:** Gorana Dasic; Medical Director of Medical Affairs Department, Biogen Idec; Avenida Dr. Cardoso de Melo 1184 / 17º andar; 04548-004 São Paulo SP - Brasil; E-mail: gorana.dasic@biogenidec.com

**Conflict of interest:** There is no conflict of interest to declare.

Received 29 January 2013; Accepted 05 February 2013.