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Brazil Prepares To Clear Backlog Of 25 Switch Applications

by Tom Gallen

Brazil's drug regulator Anvisa is seeking comments on its backlog of 25 Rx-to-OTC switch applications as it looks to make more prescription products available OTC.

Brazil's national drug regulator Anvisa has revealed it has a significant backlog of switch applications relating to 25 different active ingredients.

The agency has a total of 45 applications from sponsors covering the 25 ingredients. The oldest applications were made in November 2016 with the most recent submitted in August 2019.

As the table below shows, a wide selection of categories are covered by the applications from erectile dysfunction (yohimbine hydrochloride) to seasonal allergic rhinitis (fluticasone propionate). Blockbuster prescription drugs such as Nexium are included on the switch list, as well as submissions for herbal treatments and vitamins and minerals.

Recognizing the need to clear the logjam and make progress with the applications, Anvisa is inviting interested parties to submit their opinions on the submissions.

The agency wants “medical associations, patients and the general public” to offer their opinion through an [online consultation](#) on the advantages and disadvantages of reclassifying one or more of the prescription drugs on the switch list as OTC.

Respondents are also requested to submit any relevant evidence in support of their opinion.

According to legislation governing prescription reclassifications – Resolução da Diretoria Colegiada (RDC) 98/2016 – drugs available OTC must:

- Be indicated for the treatment of non-serious diseases

- Have a low potential for toxicity and interactions with other drugs, as well a history of safe use
- Have a short duration of use
- Be easy to handle by the patient, caregiver or upon the advice of the pharmacist
- Present a low risk to the patient
- Not have the potential to generate chemical or psychic dependence

Anvisa's list of received switch applications on which the agency is yet to make a decision:

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