



Ministry of Health and Medical Education
Islamic Republic of Iran

14-May-2026

Subject: Notification regarding a public posting on the French Health Authority (ANSM) website with the Jan 2026 Permanent Scientific Committee meeting minutes

Dear Sir/Madam:

The purpose of this communication is to alert you of the France Health Authority (ANSM) publication of the minutes of the January 2026 French Permanent Scientific Committee meeting to discuss notable adverse events regarding different medicines. The public posting regarding pembrolizumab can be found under “Questions diverses.”

The public posting occurred on 14-Apr-2026 on the France ANSM website and can be accessed at the following link: [Event - Standing Scientific Committee on Pharmaco-surveillance and proper use - Signal restricted training - ANSM](#)

Company position:

Based on a comprehensive review, as well as ongoing robust pharmacovigilance activities, the medical concept of myocarditis-myositis-myasthenia gravis overlap syndrome was added to the Warnings and Precautions section of the Company Core Data Sheet (CCDS) for pembrolizumab in October 2025. This label update was communicated globally and there are currently ongoing procedures to update local labels to include myocarditis-myositis-myasthenia gravis overlap syndrome.

The Company closely monitors adverse events associated with pembrolizumab through a robust routine pharmacovigilance program that includes regular ongoing internal signal detection activities. Based on ongoing pharmacovigilance activities, there has been insufficient evidence to support a causal relationship between the topics of keratitis or tuberculosis with pembrolizumab administration. Any new information regarding events of keratitis or tuberculosis with pembrolizumab will be assessed through routine pharmacovigilance activities and communicated as appropriate.

Vasculitis is currently included in pembrolizumab product labeling as an adverse drug reaction (ADR). While the concept of acral vasculitis is not presented as a standalone ADR, the event of vasculitis is well described in the product labeling, as well as dose modifications for immune related adverse events. Ongoing pharmacovigilance has not revealed any new safety concerns beyond what is currently labeled for vasculitis. The Company will continue to monitor vasculitis via routine pharmacovigilance activities, and no further action is required at this time.



Kindly note that the labeling reference market for Keytruda IV for Iran is USA.

Please refer to page 8 in the below English translation of the France ANSM posting.

Best Regards

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