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Oregon Prescription Drug Affordability Board (PDAB)
350 Winter Street NE
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Re: Concerns with Selection of KEYTRUDA® (pembrolizumab) for Affordability Review

Members of the Oregon Prescription Drug Affordability Board,

Merck appreciates the opportunity to submit the following comments in response to the Board's decision to select KEYTRUDA for an affordability review. Merck is committed to supporting policies that reduce or eliminate barriers to patient affordability and submits the following comments to ensure the process utilized by the Board to assess affordability is robust, accurate, and consistent with its statutory obligations.

Merck remains strongly opposed to the selection of KEYTRUDA for an affordability review. The Board's decision raises two fundamental defects that go to the legality and integrity of the review itself.

1. The Board's current approach violates the relevant statute and is inconsistent with the purpose of the orphan-drug exclusion, which exists to protect patients with rare diseases and limited treatment options. By excluding those patients from the dataset and then proceeding to evaluate the same drug based only on the remaining population, the Board risks rendering a meaningful group of protected Oregon patients effectively invisible.
2. Oregon's affordability-review framework requires consideration of criteria that are inherently confidential, yet the Board has already acknowledged that its current process cannot reliably accommodate confidential information that manufacturers may voluntarily provide to help inform the affordability review.

For these reasons, Merck urges the Board to reconsider the selection of KEYTRUDA and withdraw it from the list of products selected for affordability review.

Statutory Purpose and Patient Protections Reflected in the Orphan-Drug Exclusion

Any selection of a drug with an orphan designation, even if the drug is also approved for non-orphan indications, violates the PDAB's statute, which expressly exempts orphan-designated drugs from affordability review.[1] The statute states that "[a] drug that is designated by the Secretary of the United States Food and Drug Administration, under 21 U.S.C. 360bb, as a drug for a rare disease or condition is not subject to review" under the PDAB process.

[1] Or. Rev. Stat. § 646A.694(2)

The exemption for orphan-designated drugs is a provision to protect patients, not merely a technical exception. We believe the Legislature created the PDAB with guardrails designed to protect patients with orphan conditions whose access and treatment circumstances warrant special care. Section 646A.694 of the Oregon Revised States directs the Board to protect patients in several ways, including the prohibition on the use of quality-adjusted life-year methodologies that take into account a patient's age or severity of illness or disability.[2] Most importantly here, ORS 646A.694(2) provides that a drug designated under 21 U.S.C. § 360bb as a drug for a rare disease or condition is not subject to review.[3] Read together, those provisions reflect a series of legislative choices to protect medically vulnerable patient populations.

That carve-out makes sense considering the federal orphan-drug framework. FDA explains that a rare disease is one affecting fewer than 200,000 people in the United States, that many rare diseases are life-threatening, and that most do not have approved treatments. FDA further explains that orphan-drug incentives exist because some rare-disease therapies historically were "orphaned" or discontinued for lack of sufficient financial incentive and because the small size of rare-disease populations makes drug development especially difficult. Against that backdrop, Oregon's decision to place orphan-designated products outside the affordability-review process is best understood as a deliberate recognition that patients with rare diseases often face limited therapeutic options and heightened access vulnerabilities.

Nevertheless, the Board now proposes to review products with orphan designations but exclude consideration of patients with orphan-designated conditions. In so doing, the PDAB is effectively making protected patients invisible in the affordability review but ultimately subjecting them to the outcome of the review.

The PDAB Lacks a Workable Process to Accept and Evaluate Voluntarily Submitted Confidential Information

Oregon's affordability-review rule requires the PDAB, to the extent practicable, consider rebates, discounts, other price concessions, estimated net price, the net economics of therapeutic alternatives, and any information a manufacturer chooses to provide. But the PDAB has already recognized that its current process cannot reliably accommodate review of confidential information: its own policy states that, because of the public nature of Board activities and the presence of media in executive sessions under ORS 192.660, the Board will not accept, review, or retain information claimed to be trade secret, confidential, or proprietary.

Because the PDAB does not have a mechanism to protect voluntarily submitted confidential information, it cannot evaluate information such as confidential discounts, rebates, and related contracting terms that a manufacturer may choose to submit. As a result, the Board may be unable to meaningfully assess several of the pricing factors Oregon law tells it to consider, including net price and concession-based comparisons among therapeutic alternatives.

Additionally, if stakeholders are unable to voluntarily provide information beyond what is in the public domain, this will limit their ability to provide additional context or correct data inaccuracies. And as a result, it will hamper the Board's ability to accurately assess affordability and identify potential contributing factors.

[2] Or. Rev. Stat. § 646A.694

[3] Or. Rev. Stat. § 646A.694(2)

Just as importantly, a process that excludes voluntarily submitted confidential information leaves the record artificially incomplete. For these reasons, Merck respectfully urges the Board to reconsider and withdraw the selection of KEYTRUDA for affordability review.

The Board's current approach violates the statute, does not faithfully implement the patient-protection purpose of the orphan-drug exclusion, and does not provide a workable means to evaluate confidential information voluntarily submitted. Proceeding under these circumstances would not produce a fair, reliable, or legally sound review.

Additionally, we are in the process of reviewing the meeting materials posted on April 7th and will be following up with additional comments on the processes and methodologies outlined in those materials.

We thank the Board for the opportunity to provide written comments and look forward to engaging in the future.

Sincerely,

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