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Notice Regarding Limited Distribution Network for Revlimid® (lenalidomide), Pomalyst® (pomalidomide), and Thalomid® (thalidomide)

This notice provides information for 340B covered entities regarding the distribution of Revlimid® (lenalidomide), Pomalyst® (pomalidomide), and Thalomid® (thalidomide) by Celgene Corporation (“Celgene”).

At the direction of the FDA, Celgene has implemented Risk Evaluation and Mitigation Strategies (“REMS”) for Revlimid®, Pomalyst®, and Thalomid®, which are Category X products that can cause severe birth defects and fetal death. The REMS for each of these products mandates that only a trained network of providers subject to contractual agreement with Celgene may dispense the product and, in turn, requires Celgene to engage in rigorous training, certification, auditing and monitoring activities. To satisfy its ongoing REMS obligations in a manner that optimizes both patient safety and access, Celgene has adopted a limited distribution network of specialty pharmacies, hospitals, and clinics that are authorized to purchase and dispense each of these three products.

Celgene’s selection criteria for accepting providers into the limited distribution networks is and has been based on factors unrelated to a pharmacy’s 340B status. Those selection criteria have centered on the dispensing site’s ability to protect patient safety and to serve a broad patient base. 340B covered entities are proportionately represented in the limited distribution networks for all three products.

Celgene has analyzed the scope of the limited distribution networks and has determined that the less than 250 providers in the networks are sufficient to meet patient drug access needs. Allowing more providers to enter the limited distribution networks could unnecessarily weaken the operation and effectiveness of our REMS and could make the certification, training, auditing, and monitoring requirements of the REMS infeasible. Therefore, in 2013 Celgene closed the limited distribution networks to all new entities, 340B or otherwise, and we do not anticipate adding any new entities at this time.

Patients of providers that are not included in the limited distribution networks may access Revlimid®, Pomalyst®, and Thalomid® by purchasing these products from one of the specialty pharmacies within the networks. A listing of these specialty pharmacies is available at <http://www.celgene.com/patients/rem-s-pharmacy-network/>.

Celgene takes seriously both its obligations to protect patient safety and to comply with the 340B statute. We have reviewed the composition and selection criteria for the limited distribution networks with HRSA and are posting this notice at the Agency’s request, in order to ensure that our distribution procedures are transparent to all 340B program stakeholders. If you have any questions regarding the limited distribution networks for Revlimid®, Pomalyst®, and Thalomid® or would like further information on how your patients may access these products, please contact Celgene at REMSnetwork@celgene.com.