

Corporate Integrity Agreement ^[1]

On September 30, 2010, Novartis Pharmaceuticals Corporation (NPC) reached a global resolution with the US Attorney's Office for the Eastern District of Pennsylvania regarding the previously disclosed investigation into civil and criminal allegations of the off-label promotion of Trileptal® as well as civil allegations relating to five other medicines: Diovan®, Exforge®, Sandostatin®, Tekturna® and Zelnorm®. Under the agreement, the company will pay a total of USD 422.5 million in criminal and civil claims.

As part of the settlement, the Company entered into a Corporate Integrity Agreement (CIA) with the Office of the Inspector General of the US Department of Health and Human Services. Under the terms of this agreement, NPC was required to implement additional compliance-related measures, which include additional monitoring, auditing, training, education, reporting and disclosures for a period of five years. The Company met these obligations although a more recent settlement with the government resulted in an adjustment to the terms.

On November 20, 2015, Novartis Pharmaceuticals Corporation (NPC) reached a resolution with U.S. Attorney's Office for the Southern District of New York related to NPC's interactions with specialty pharmacies for the drugs Exjade® and Myfortic®. As part of the settlement, we have agreed to pay \$390 million to the federal government and state Medicaid programs. NPC has also agreed to new Corporate Integrity Agreement (CIA) obligations relating to the company's interactions with specialty pharmacies in an Addendum to the existing CIA the company entered into in September 2010, which will be extended for five years.

Under the terms of this new Addendum, NPC will implement the agreed upon controls to ensure appropriate support for patients, and compliance with all Federal Healthcare program requirements related to specialty pharmacies. These controls include enhancing policies and procedures at NPC for specialty pharmacy service arrangements and contracts, training for NPC associates, as well as strengthened monitoring and tracking processes to ensure that services are provided in a compliant manner. NPC will provide its contracted specialty pharmacies with a clear understanding of the Novartis Code of Conduct and training on the policies that guide our activities. The Company will also provide a comprehensive annual report to the government on our continued compliance with these and other CIA obligations.

Our extended CIA obligations and additional protocols related to specialty pharmacies are consistent with our sustained focus on ethics and compliance policies throughout our operations and steps we have already taken in this important area.

NPC is committed to high standards of ethical business conduct and has a comprehensive compliance program in place to help ensure we consistently act in a responsible manner.

[View the full Corporate Integrity Agreement](#) ^[2]

[View the Corporate Integrity Agreement Addendum](#) [3]

[View the NPC Code of Conduct](#) [4]

[View the NPC Code of Conduct US Supplement](#) [5]

[View the NPC Compliance Navigator Anti Kickback Statute](#) [6]

Accordion Type:

Collapsible

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Links

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[2] https://www.novartis.us/sites/www.pharma.us.novartis.com/files/n_int_056605.pdf

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