UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 16, 2017

MYLAN N.V.
(Exact Name of Registrant as Specified in Charter)

The Netherlands	333-199861	98-1189497
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

Building 4, Trident Place Mosquito Way, Hatfield, Hertfordshire	AL10 9UL
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: +44 (0) 1707-853-000

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2 (b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4 (c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR 230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR 240.12b-2).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 1.01. Entry into a Material Definitive Agreement.

On August 17, 2017, Mylan N.V. (the "Company") announced that its subsidiaries, Mylan Inc. and Mylan Specialty L.P. (together, "Mylan"), have signed an agreement with the U.S. Department of Justice ("DOJ") and two relators finalizing the Medicaid drug rebate settlement, which the Company had previously announced on October 7, 2016, for $465 million (the "Settlement Agreement").

As previously disclosed, the Settlement Agreement resolves claims relating to the classification of EpiPen® Auto-Injector and EpiPen Jr® Auto-Injector (collectively, "EpiPen® Auto-Injector") for purposes of the Medicaid Drug Rebate Program. The question in the underlying matter was whether the EpiPen® products were properly classified with the Centers for Medicare and Medicaid Services ("CMS") as a non-innovator drug under the applicable definition in the Medicaid Rebate statute and subject to the formula that is used to calculate rebates to Medicaid for such drugs. EpiPen® Auto-Injector has been classified with CMS as a non-innovator drug since before Mylan Specialty L.P. acquired the product in 2007 based on longstanding written guidance from the federal government.

The Settlement Agreement provides for resolution of all potential Medicaid rebate liability claims by the federal government, as well as potential claims by certain hospitals and other covered entities that participate in the 340B Drug Pricing Program. The Settlement Agreement allocates money to the Medicaid programs of all 50 states and establishes a framework for resolving all potential state Medicaid rebate liability claims within 60 days. In connection with the settlement, Mylan also has entered into a Corporate Integrity Agreement (the "CIA") with the Office of Inspector General of the Department of Health and Human Services ("OIG-HHS") which has a five-year term and which requires, among other things, that an independent review organization annually review various matters relating to Mylan and the Medicaid drug rebate program.

Neither the Settlement Agreement nor the CIA contains an admission or finding of wrongdoing. Mylan Specialty L.P. will reclassify EpiPen® Auto-Injector for purposes of the Medicaid Drug Rebate Program and pay the rebate applicable to innovator products effective as of April 1, 2017. As disclosed in our Quarterly Report on Form 10-Q filed on August 9, 2017, in anticipation of the Settlement Agreement being finalized, the Company has accrued the higher rebate amount since April 1, 2017.

The foregoing descriptions of the Settlement Agreement and the CIA are not complete and are qualified in their entirety by reference to such agreements, which have been available on the DOJ and OIG-HHS websites, respectively, and which are attached to this Form 8-K as Exhibits 10.1 and 10.2, respectively, and are incorporated by reference in this Form 8-K.

Item 7.01. Regulation FD Disclosure.

On August 17, 2017, the Company issued a press release announcing its entry into the Settlement Agreement and the CIA. A copy of that press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and incorporated by reference in this Item 7.01. The information contained in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed "filed" with the Securities and Exchange Commission nor incorporated by reference in any registration statement filed by the Company under the Securities Act of 1933, as amended.

Forward-Looking Statements.

This report and the attachments include statements that constitute "forward-looking statements" which are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including statements in the press release about the Company's commitment to providing patients in the U.S. and around the world with access to medicine, and that the Company looks forward to continuing to deliver on this mission. Because such statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to: any changes in or difficulties with our inventory of, and our ability to manufacture and distribute, EpiPen and our other products; the effect of any changes in our customer and supplier relationships and customer purchasing patterns; other changes in third-party relationships; the impact of competition; changes in the economic and financial conditions of the businesses of the Company; the scope, timing, and outcome of any ongoing legal proceedings and the impact of any such proceedings on our business; any regulatory, legal, or other impediments to our ability to bring our products to market; actions and decisions of healthcare and pharmaceutical regulators, and changes in healthcare and pharmaceutical laws and regulations, in the United States and abroad; our ability to protect our intellectual property and preserve intellectual property rights; other uncertainties and matters beyond the control of management; and the other risks detailed in the Company's filings with the Securities and Exchange Commission. The Company undertakes no obligation to update these statements for revisions or changes after the date of this release.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
10.1	Settlement Agreement with the U.S. Department of Justice and two relators finalizing the Medicaid drug rebate settlement, dated August 16, 2017.
10.2	Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Mylan Inc. and Mylan Specialty L.P., dated August 16, 2017.
99.1	Press release dated August 17, 2017.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

MYLAN N.V.

Date: August 21, 2017

By: /s/ Kenneth S. Parks
Kenneth S. Parks
Chief Financial Officer

EXHIBIT INDEX

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99.1	Press release dated August 17, 2017.

Exhibit 10.1

SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General ("OIG-HHS") of the Department of Health and Human Services ("HHS"), Mylan Inc. and Mylan Specialty L.P. (collectively, "Mylan"), and Relators identified in the cases listed in Paragraph B of the Recitals to this Agreement ("Relators") (hereafter collectively referred to as "the Parties"), through their authorized representatives.

RECITALS

A. Defendant Mylan Inc. is a corporation incorporated in Pennsylvania with its principal offices in Canonsburg, Pennsylvania. Mylan Inc., through its subsidiaries, manufactures, markets, and sells pharmaceuticals. Mylan Inc. acquired Dey Pharma, L.P. ("Dey") as a wholly-owned subsidiary in 2007, and changed Dey's name to Mylan Specialty L.P. in 2012 (collectively referred to hereafter as "Mylan Specialty"). Defendant Mylan Specialty L.P. is a Delaware limited partnership with its principal place of business in Morgantown, West Virginia, and is a wholly-owned subsidiary of Mylan Inc. At all relevant times, Mylan Specialty has owned the exclusive rights to sell EpiPen® and EpiPen Jr.® products, identified by National Drug Codes 49502-0500-01, 49502-0500-02, 49502-0501-01, and 49502-0501-02, (collectively, "EpiPen") in the United States.

B. On July 29, 2016, sanofi-aventis US LLC ("Sanofi") filed a *qui tam* action in the United States District Court for the District of Massachusetts captioned *United States, et al. ex rel. sanofi-aventis US LLC v. Mylan Inc., et al.*, No. 16cv11572-ADB, pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b), and filed an amended *qui tam* complaint on August 4, 2016. On December 8, 2016, Ven-A-Care of the Florida Keys, Inc. ("Ven-A-Care") filed a *qui tam* action in the Southern District of New York captioned *United States, et al. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Mylan Inc., et al.*, No. 16-CV-9484

(JGK), and an amended *qui tam* complaint on January 3, 2017. On January 19, 2017, Ven-A-Care's *qui tam* action was transferred to the District of Massachusetts under the same caption and later assigned Case No. 17-10140-ADB. Ven-A-Care and Sanofi are collectively referred to herein as "Relators" and Sanofi's and Ven-A-Care's *qui tam* complaints are collectively referred to as the "Civil Actions." Relators allege, *inter alia*, that Mylan misclassified EpiPen as a "noninnovator multiple source" drug, rather than as a "single source" drug, for Medicaid Drug Rebate Program purposes and underpaid rebates owed to the Medicaid Program for EpiPen as a result of this misclassification.

C. The United States contends that (1) Mylan submitted or caused to be submitted claims for payment to the Medicaid Program, 42 U.S.C. §§ 1396-1396w-5 ("Medicaid") for EpiPen; (2) Mylan Specialty entered into a Rebate Agreement with the Secretary of HHS in exchange for Medicaid's coverage of EpiPen; and (3) under the Rebate Agreement and 42 U.S.C. § 1396r-8 ("Rebate Statute"), Mylan Specialty was required to submit pricing information on a quarterly basis to the Centers for Medicare and Medicaid Services ("CMS") regarding EpiPen and pay quarterly rebates to Medicaid, per unit of EpiPen dispensed to Medicaid beneficiaries.

D. The United States contends that it has certain civil claims against Mylan from July 29, 2010 to March 31, 2017. Specifically, the United States contends that Mylan Specialty knowingly submitted false statements to CMS and/or to State governments that incorrectly classified EpiPen as a "noninnovator multiple source" drug, as opposed to a "single source" or "innovator multiple source" drug, as those terms are defined in the Rebate Statute and Rebate Agreement. The United States further contends that Mylan Specialty was required to report a Best Price, as that term is defined in the Rebate Statute and Rebate Agreement, for all "single source" and "innovator multiple source" drugs, but that Mylan Specialty did not report a Best

Price for EpiPen. The United States asserts that, as a result, Mylan (1) caused to be submitted false claims relating to the classification of EpiPen for Medicaid rebate purposes; (2) underpaid rebates to Medicaid for EpiPen; and (3) overcharged certain entities (hereinafter known as the "340B Covered Entities") that participated in the 340B Drug Pricing Program, 42 U.S.C. § 256b, which is part of the Public Health Service Act, 42 U.S.C. §§ 201-300ggg-92. The alleged conduct set forth in this Paragraph constitutes the "Covered Conduct" for purposes of this Agreement. No statements by Mylan prior to the Effective Date of this Agreement as to the settlement of this matter shall be construed as denying the Covered Conduct.

E. Each Relator claims entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to that Relator's reasonable expenses, attorney's fees and costs.

F. Mylan has entered into, or will be entering into, separate settlement agreements, described in Paragraph 1.b below (the "Medicaid State Settlement Agreements"), with the states (the "Medicaid Participating States") in settlement of the conduct released in those separate Medicaid State Settlement Agreements.

In consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Mylan shall pay to the United States, the Medicaid Participating States, and the 340B Covered Entities, collectively, the sum of four hundred sixty-five million dollars ($465,000,000), plus interest accruing at an annual simple rate of 1.625% from October 6, 2016, and continuing until and including the day of payment (collectively, the "Settlement Amount"), as specified in Subparagraphs (a) through (c) below. The Settlement Amount shall constitute a debt immediately due and owing to the United States, the Medicaid Participating States, and the

340B Covered Entities on the Effective Date of this Agreement. This debt shall be discharged by payments to the United States, the Medicaid Participating States, and the 340B Covered Entities as follows:

a. No later than ten business days after the Effective Date of this Agreement, Mylan shall pay the sum of two hundred thirty-one million seven hundred sixty-four thousand dollars ($231,764,000), plus accrued interest as set forth above (the "Federal Settlement Amount"), to the United States by electronic funds transfer pursuant to written instructions to be provided by the United States.

b. Mylan shall pay to the Medicaid Participating States the sum of two hundred thirteen million nine hundred thirty-six thousand dollars ($213,936,000), plus accrued interest as set forth above (the "State Settlement Amount"), pursuant to the terms of the Medicaid State Settlement Agreements that Mylan has entered into or will enter into with the States. In the event one or more of the States do not sign a Medicaid State Settlement Agreement, the portion of the State Settlement Amount shall be reduced by the amount allocable to such State or States, and that amount shall not be owed and, if previously paid into escrow by Mylan, shall be returned to Mylan.

c. As provided in written instructions by the United States, Mylan shall pay the sum of nineteen million three hundred thousand dollars ($19,300,000) to the 340B Covered Entities, plus accrued interest as set forth above (the "340B Settlement Amount"). The 340B Settlement Amount shall be paid into an escrow account with a national banking institution (the "340B Deposit Account") no later than ten business days after the Effective Date of this Agreement and shall be deemed to accrue interest as set forth above. The 340B Settlement Amount shall be distributed as follows:

(1) Within 180 days of the Effective Date of this Agreement, Mylan shall issue a report to the United States which (a) documents the amounts needed to pay each 340B Covered Entity for any alleged overcharges that were caused by the claims in the Covered Conduct (including each entity's proportionate share of accrued interest) and (b) contains the underlying calculations used to arrive at such amounts.

(2) Within 30 days of this report, Mylan shall cause checks drawn on the 340B Deposit Account to be issued to each 340B Covered Entity in the amounts determined; provided, however, that the total amount paid to all 340B Covered Entities shall not exceed the 340B Settlement Amount, plus interest accrued, and each 340B Entity shall receive its pro-rata share of the 340B Settlement Amount as determined by the report described in Paragraph 1(c)(1). If any checks issued to the 340B Covered Entities are not cashed within 180 days after the date of the check issuance, Mylan will notify the Civil Division of the United States Department of Justice of this fact within 10 business days after the expiration of the 180-day period after check issuance. Mylan agrees to transfer all remaining assets contained in the 340B Deposit Account (including any interest that has accrued) to the United States by electronic transfer within 5 days after receiving written instructions from the Civil Division of the United States Department of Justice.

2. Conditioned upon the United States receiving the Federal Settlement Amount from Mylan and as soon as feasible after receipt, the United States shall pay $38,767,136.50 to Sanofi by electronic funds transfer to Sanofi's counsel's client funds trust account, pursuant to written instructions to be provided by undersigned counsel for Sanofi.

3. Subject to the exceptions in Paragraph 6 (concerning excluded claims) below, and conditioned upon Mylan's full payment of the Settlement Amount, the United States releases Mylan from any civil or administrative monetary claim the United States has for the Covered

Conduct under the False Claims Act, 31 U.S.C. §§ 3729-33; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-12; the 340B Drug Pricing Program, 42 U.S.C. § 256b; the Medicaid Rebate Statute, 42 U.S.C. § 1396r-8; or any statutory provision for which the Civil Division of the Department of Justice has actual and present authority to assert and compromise pursuant to 28 CFR Part 0, Subpart I, .45(d); and the common law theories of payment by mistake, unjust enrichment, and fraud.

4.a. Subject to the exceptions in Paragraph 6 below, and conditioned upon Mylan's full payment of the Federal and 340B Settlement Amounts, each Relator, for itself and for its respective heirs, successors, attorneys, agents, and assigns, releases Mylan and all of its past, present, and future successors, predecessors, subsidiaries, divisions, departments, affiliates, directors, officers, agents, and employees, from any and all claims, demands, actions, suits, debts, damages, attorneys' fees and costs, losses, claims for payment of unpaid fees, requests for indemnity, and/or causes of action that have been brought or could have been brought, are currently pending or were pending, or are ever brought in the future, on behalf of the United States in any forum, arising out of or related in any way to the Covered Conduct or the Civil Actions, whether known or unknown, disclosed or undisclosed, asserted or unasserted, under or pursuant to any agreement, statute, regulation, common law, or equity.

4.b. Subject to the exceptions in Paragraph 6 below, and conditioned upon Mylan's full payment of the State Settlement Amount, each Relator, for itself and for its respective heirs, successors, attorneys, agents, and assigns, releases Mylan and all of its past, present, and future successors, predecessors, subsidiaries, divisions, departments, affiliates, directors, officers, agents, and employees, from any and all remaining claims, demands, actions, suits, debts, damages, attorneys' fees and costs, losses, claims for payment of unpaid fees, requests for indemnity, and/or causes of action that have been brought or could have been brought, are

currently pending or were pending, or are ever brought in the future, in any forum, arising out of or related in any way to the Covered Conduct or the Civil Actions, whether known or unknown, disclosed or undisclosed, asserted or unasserted, under or pursuant to any agreement, statute, regulation, common law, or equity, including without limitation any state-law claims in the Civil Actions and any claims that have been or could be asserted on behalf of a State (whether or not such State is a Medicaid Participating State as defined in this Agreement).

5. In consideration of the obligations of Mylan in this Agreement and the Corporate Integrity Agreement ("CIA") entered into between the OIG-HHS and Mylan and conditioned upon Mylan's full payment of the Settlement Amount, the OIG-HHS agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Mylan Inc. and Mylan Specialty L.P. under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in this Paragraph and in Paragraph 6 (concerning excluded claims), below. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude Mylan Inc. and/or Mylan Specialty L.P. from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 6, below.

6. Notwithstanding the releases given in Paragraphs 3 and 5 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:

a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);

b. Any criminal liability;

c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs;

d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

e. Any liability based upon obligations created by this Agreement;

f. Any liability of individuals;

g. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;

h. Any liability for failure to deliver goods or services due; and

i. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

7. Relators and each Relator's respective heirs, successors, attorneys, agents, and assigns shall not object to this Agreement but agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B). Conditioned upon receipt of the payments described in Paragraph 2, Relators and each Relator's respective heirs, successors, attorneys, agents, and assigns fully and finally release, waive, and forever discharge the United States, its agencies, officers, agents, employees, and servants, from any claims arising from the filing of the Civil Actions or under 31 U.S.C. § 3730, and from any claims to a share of the proceeds of this Agreement and/or the Civil Actions.

8. Mylan has agreed to pay the Relators' attorney's fees and costs in full satisfaction of any claim Relators may have for attorney's fees and costs under 31 U.S.C. § 3730(d) incurred in connection with the Civil Actions. Such payment shall be made within ten business days of

the Effective Date of this Agreement to the respective Relator's counsel, by electronic funds transfer pursuant written instructions to be provided by such Relator's counsel. Conditioned upon such payments, each Relator, for itself, and for each of its respective heirs, successors, attorneys, agents, and assigns, releases Mylan and all of its past, present, and future successors, predecessors, subsidiaries, divisions, departments, affiliates, directors, officers, agents, and employees, from any liability to Relators for expenses or attorney's fees and costs arising from the filing of the Civil Actions or under 31 U.S.C. § 3730(d).

9. Mylan waives and shall not assert any defenses Mylan may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. Nothing in this paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

10. Mylan fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Mylan has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct and the United States' investigation and prosecution thereof.

11. Mylan, for itself and for its respective heirs, successors, attorneys, agents, and assigns, fully and finally releases the Relators, and their past, present, and future successors, predecessors, subsidiaries, divisions, departments, affiliates, directors, officers, agents, attorneys

and employees, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Mylan has asserted, could have asserted, or may assert in the future against the Relators, or any of their past, present, and future successors, predecessors, subsidiaries, divisions, departments, affiliates, directors, officers, agents, attorneys and employees related to the Civil Actions or the Covered Conduct and the Relators' investigation and prosecution thereof.

12. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (*e.g.*, Medicare Administrative Contractor, fiscal intermediary, carrier), Medicaid, or any State payer, related to the Covered Conduct; and Mylan agrees not to resubmit to any Medicare contractor, Medicaid, or any State payer any previously denied claims related to the Covered Conduct, agrees not to appeal any such denials of claims, and agrees to withdraw any such pending appeals.

13. Mylan agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.20547; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Mylan, its present or former officers, directors, employees, shareholders, and agents in connection with:

(1) the matters covered by this Agreement;

(2) the United States' audit(s) and civil investigation(s) of the matters covered by this Agreement;

(3) Mylan's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil investigation(s) in

connection with the matters covered by this Agreement (including attorney's fees);

(4) the negotiation and performance of this Agreement;

(5) the payment Mylan makes to the United States pursuant to this Agreement and any payments that Mylan may make to any Relator, including costs and attorney's fees; and

(6) the negotiation of, and obligations undertaken pursuant to the CIA to: (i) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and (ii) prepare and submit reports to the OIG-HHS

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program ("FEHBP") (hereinafter referred to as "Unallowable Costs"). However, nothing in Paragraph 13.a(6) that may apply to the obligations undertaken pursuant to the CIA affects the status of costs that are not allowable based on any other authority applicable to Mylan.

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Mylan, and Mylan shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Mylan or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Mylan further agrees that, within 90 days of the Effective Date of this Agreement, it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors,

and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Mylan or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. Mylan agrees that the United States, at a minimum, shall be entitled to recoup from Mylan any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Mylan or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Mylan or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Mylan's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

14. Mylan agrees to cooperate fully and truthfully in the event of any investigation relating to the Covered Conduct by the United States of individuals and entities not released in this Agreement. Upon reasonable notice, Mylan shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its best efforts to make available, and encourage, the cooperation of former directors, officers, and employees for

interviews and testimony, consistent with the rights and privileges of such individuals. Mylan further agrees to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in its possession, custody, or control concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf.

15. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 16 (waiver for beneficiaries paragraph), below.

16. Mylan agrees that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

17. Upon Mylan's payment of the Federal Settlement Amount and the 340B Settlement Amount as described in Paragraph 1, above, and Mylan's payments to the Relators described in Paragraph 8, above, the Parties shall promptly sign and file in each Civil Action a Joint Stipulation of Dismissal of the claims brought on behalf of the United States in the Civil Action with Prejudice, pursuant to the terms of this Settlement Agreement and pursuant to Rule 41(a)(1). Upon Mylan's payment of the State Settlement Amount as described in Paragraph 1, above, Mylan and the Relators shall promptly sign and file in each Civil Action a Joint Stipulation of Dismissal, with prejudice, of all remaining claims in the Civil Action, including any claims brought on behalf of a State, pursuant to the terms of this Settlement Agreement and pursuant to Rule 41(a)(1). These Joint Stipulations of Dismissal of all remaining claims in the Civil Actions shall be without prejudice as to any State on whose behalf a claim was brought

which is not a Medicaid Participating State as described in paragraph F, above, and with prejudice as to all Medicaid Participating States.

18. Except as otherwise provided herein, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

19. Each party and signatory to this Agreement represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

20. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the District of Massachusetts. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

21. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

22. For the avoidance of doubt, and notwithstanding anything to the contrary herein, Mylan and Sanofi agree that neither this Agreement nor any release contained in this Agreement shall apply in any way to bar any claims or other relief by Sanofi against Mylan pending in *Sanofi-Aventis U.S. LLC v. Mylan Inc. and Mylan Specialty, L.P.*, 17-cv-02763 (D.N.J.) (and as transferred for pretrial purposes: *Sanofi-Aventis U.S. LLC v. Mylan Inc., et al.*, No. 17-CV-02452-DDC-TJJ (D. Kan.)) or *In re EpiPen (Epinephrine Injection, USP) Marketing, Sales Practices and Antitrust Litigation*, 17-md-02785-DDC-TJJ/MDL 2785 (D. Kan.), or any compulsory counterclaims by Mylan against Sanofi arising out of such claims.

23. The undersigned individuals and counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

24. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

25. This Agreement is binding on Mylan's successors, transferees, heirs, and assigns.

26. This Agreement is binding on each Relator's respective successors, transferees, heirs, and assigns.

27. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

28. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

DATED: 8/16/17

BY: /s/ Augustine M. Ripa
AUGUSTINE M. RIPA
NICHOLAS C. PERROS
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 8/17/17

BY: /s/ Gregg Shapiro
GREGG SHAPIRO
KRISS BASIL
Assistant United States Attorneys
United States Attorney's Office for the
District of Massachusetts

DATED: 8/16/17

BY: /s/ Lisa M. Re
LISA M. RE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

MYLAN INC. - DEFENDANT

DATED: 8/15/17

BY: /s/ Brian S. Roman
BRIAN S. ROMAN
Global General Counsel

DATED: 8/16/17

BY: /s/ Mitchell E. Zamoff
MITCHELL E. ZAMOFF
Counsel for Mylan Inc.

MYLAN SPECIALTY L.P. - DEFENDANT

DATED: 8/15/17

BY: /s/ Brian S. Roman
BRIAN S. ROMAN
Global General Counsel

DATED: 8/16/17

BY: /s/ Mitchell E. Zamoff
MITCHELL E. ZAMOFF
Counsel for Mylan Specialty L.P.

sanofi-aventis US LLC - RELATOR

DATED: 8/16/17

BY: /s/ Chan Lee
CHAN LEE
General Counsel North America, Sanofi US
sanofi-aventis US LLC

DATED: 8/16/17

BY: /s/ Robert M. Thomas, Jr. / SED
ROBERT M. THOMAS, JR.
Counsel for sanofi-aventis US LLC

DATED: 8/16/17

BY: /s/ Suzanne E. Durrell
SUZANNE E. DURRELL
Counsel for sanofi-aventis US LLC

Ven-A-Care of the Florida Keys, Inc. - RELATOR

DATED: 8/16/17

BY: /s/ John Lockwood, M.D.
JOHN LOCKWOOD, M.D.
Individually and as Vice President on behalf of
Ven-A-Care of the Florida Keys, Inc.

DATED: 8/16/17

BY: /s/ James J. Breen
JAMES J. BREEN
Counsel for Ven-A-Care of the Florida Keys, Inc.
and John Lockwood, M.D.

Exhibit 10.2

CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
MYLAN INC. AND MYLAN SPECIALTY L.P.

I. PREAMBLE

Mylan Inc. and Mylan Specialty L.P. (collectively "Mylan") hereby enter into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with this CIA, Mylan is entering into a Settlement Agreement with the United States.

Mylan represents that prior to the Effective Date of this CIA (as defined below), Mylan established a compliance program that includes, among other things, the appointment of a Corporate Compliance Officer, the development and dissemination of Mylan's Code of Business Conduct and Ethics, the establishment of written policies and procedures, a Disclosure Program, screening measures for Ineligible Persons, review and disciplinary proceedings, and regular training concerning Mylan's Code of Business Conduct and Ethics and policies and procedures.

Mylan shall continue the operation of its compliance program in accordance with the terms set forth below for the term of this CIA. Mylan may modify its compliance program as it deems appropriate, but at a minimum, Mylan shall ensure that during the term of this CIA, it shall comply with the obligations enumerated in this CIA.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Mylan under this CIA shall be five years from the effective date of this CIA. The "Effective Date" shall be the date on which the final signatory of this CIA executes this CIA. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

B. Sections VII, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) Mylan's final Annual Report; or (2) any additional materials submitted by Mylan pursuant to OIG's request, whichever is later.

C. The scope of this CIA shall be governed by the following definitions:

1. "Covered Persons" includes:

a. all owners of Mylan who are natural persons (other than shareholders who: (i) have an ownership interest of less than 5% and (ii) acquired the ownership interest through public trading);

b. all officers, directors, and employees of Mylan Inc. and Mylan Specialty L.P. and all employees of other Mylan entities, subsidiaries, or affiliates (including Mylan Pharmaceuticals Inc.) who perform any of the Government Pricing Functions (as defined below in Section II.C.4) on behalf of Mylan; and

c. all contractors, subcontractors, agents, and other persons who perform any of the Government Pricing Functions on behalf of Mylan.

2. "Relevant Covered Persons" includes all Covered Persons who engage in any of the Government Pricing Functions and all individuals who supervise Covered Persons who engage in any of the Government Pricing Functions.

3. "Government Reimbursed Products" refers to all products of all Mylan entities, subsidiaries, or affiliates (including Mylan Pharmaceuticals Inc.) that are: (a) marketed or sold by Mylan in the United States (or pursuant to contracts with the United States) and (b) reimbursed by Federal health care programs. The term Government Reimbursed Products shall include brand name products, generic products, and authorized generic products.

4. The term "Government Pricing Functions" refers to the collection, calculation, verification, or reporting of information for purposes of the Medicaid Drug Rebate Program (codified at 42 U.S.C. § 1396r-8), the Medicare Program (42 U.S.C. §§1395-1395hhh), and the 340B Drug Pricing Program (codified at 42 U.S.C. § 256b) (the 340B Program). Persons engaged in these functions include individuals whose job

responsibilities include the calculation and reporting of Average Sales Price (ASP), Average Manufacturer Price (AMP), Best Price, the 340B Program ceiling price, Average Wholesale Price (AWP), and all other information reported by Mylan and used in connection with the programs specified in this Paragraph.

III. CORPORATE INTEGRITY OBLIGATIONS

Mylan shall establish and maintain a Compliance Program that includes the following elements:

A. Compliance Responsibilities of Certain Mylan Employees and the Board of Directors.

1. *Compliance Officer*. To the extent not already accomplished, within 90 days after the Effective Date, Mylan shall appoint a Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be an employee and a member of senior management of Mylan Inc., shall report directly to the Chief Executive Officer of Mylan Inc. and shall not be, or be subordinate to, the General Counsel or Chief Financial Officer or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for Mylan. The Compliance Officer shall be responsible for, without limitation:

a. developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements;

b. making periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Mylan Inc. ("Board" or "Board of Directors") and shall be authorized to report on such matters to the Board of Directors at any time. Written documentation of the Compliance Officer's reports to the Board of Directors shall be made available to OIG upon request; and

c. monitoring the day-to-day compliance activities engaged in by Mylan as well as for any reporting obligations created under this CIA.

Any noncompliance job responsibilities of the Compliance Officer shall be limited and must not interfere with the Compliance Officer's ability to perform the duties outlined in this CIA.

Mylan shall report to OIG, in writing, any change in the identity or position description of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within five days after such a change.

2. *Compliance Committee*. To the extent not already accomplished, within 90 days after the Effective Date, Mylan shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., members of senior management with responsibility for relevant departments, such as government pricing and contracting, human resources, audit, and operations). The Compliance Officer shall chair the Compliance Committee and the Compliance Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of Mylan's risk areas and shall oversee monitoring of compliance-related audits and compliance investigations). The Compliance Committee shall meet at least quarterly. The minutes of the Compliance Committee meetings shall be made available to OIG upon request.

Mylan shall report to OIG, in writing, any changes in the composition of the Compliance Committee, or any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

3. *Board of Directors Compliance Obligations*. The Board (or a committee of the Board) shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements and the obligations of this CIA. The Board must include independent (i.e., non-executive) members.

The Board shall, at a minimum, be responsible for the following:

a. meeting at least quarterly to review and oversee Mylan's Compliance Program, including but not limited to the performance of the Compliance Officer and Compliance Committee;

b. submitting to OIG a description of the documents and other materials it reviewed, as well as any additional steps taken, such as the engagement of an independent advisor or other third party resources, in its oversight of the Compliance

Program and in support of making the resolution described below during each Reporting Period; and

c. for each Reporting Period of the CIA, adopting a resolution, signed by each individual member of the Board, summarizing its review and oversight of Mylan's compliance with Federal health care program requirements and the obligations of this CIA.

At minimum, the resolution shall include the following language:

> "The Board of Directors (or a committee thereof) has made a reasonable inquiry into the operation of Mylan's Compliance Program during the preceding twelve-month period including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, Mylan has implemented an effective Compliance Program to meet Federal health care program requirements and the obligations of the Corporate Integrity Agreement."

If the Board is unable to provide such a conclusion in the resolution, the Board shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement an effective Compliance Program at Mylan.

Mylan shall report to OIG, in writing, any changes in the composition of the Board, or any actions or changes that would affect the Board's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

4. *Management Accountability and Certifications*. In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Mylan employees (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable Mylan business unit is compliant with applicable Federal health care program requirements with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: (1) Chief Financial Officer; (2) Head of Commercial Finance – North America; (3) Head of Government Reporting; (4) Head of Finance, Global Integrated Services – North America; and (5) Director, Accounts Receivable.

For each Reporting Period, each Certifying Employee shall sign a certification that states:

> "I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of department or functional area], an area under my supervision. My job responsibilities include ensuring compliance with regard to the _____ [insert name of the department or functional area] with all applicable Federal health care program requirements, obligations of the Corporate Integrity Agreement, and Mylan policies applicable to [department or function], and I have taken steps to promote such compliance. To the best of my knowledge, the _____ [insert name of department or functional area] of Mylan is in compliance with all applicable Federal health care program requirements and the obligations of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by the United States."

If any Certifying Employee is unable to provide such a certification, the Certifying Employee shall provide a written explanation of the reasons why he or she is unable to provide the certification outlined above and the steps being taken to address the issue(s) identified in the certification.

B. Written Standards.

Within 90 days after the Effective Date, Mylan shall develop and implement written policies and procedures regarding the operation of its Compliance Program, including the compliance program requirements outlined in this CIA and Mylan's compliance with Federal health care program requirements (Policies and Procedures). Throughout the term of this CIA, Mylan shall enforce and comply with its Policies and Procedures and shall make such compliance an element in evaluating the performance of all employees. The Policies and Procedures shall be made available to all Covered Persons.

At a minimum, the Policies and Procedures shall address appropriate ways to conduct Government Pricing Functions in compliance with all applicable Federal health care program requirements. This includes (a) gathering, calculating, verifying and reporting the data and information reported to the Centers for Medicare & Medicaid Services (CMS) and/or the State Medicaid Programs in connection with the Medicaid Drug Rebate Program, the Medicare program, and as otherwise required by Federal or state government requirements and directives; and (b) the appropriate classification of drugs as Single Source, Innovator Multiple Source, or Non-Innovator Multiple Source

drugs for purposes of the Medicaid Drug Rebate Program. These Policies and Procedures shall require at a minimum that Mylan properly consider all price concessions and all service, administrative, or other fees (including those paid to group purchasing organizations, wholesalers, and distributors) in its calculation of prices and information reported to CMS and/or to State Medicaid programs in accordance with the requirements of the then-applicable laws, regulations, and program guidance issued by CMS to all participants in the Medicaid Drug Rebate Program.

At least annually (and more frequently, if appropriate) Mylan shall assess and update, as necessary, all the Policies and Procedures. Any new or revised Policies and Procedures shall be made available to all Covered Persons. All Policies and Procedures shall be made available to OIG upon request.

C. Training and Education.

1. *Training Plan*. Within 90 days after the Effective Date, Mylan shall develop a written plan (Training Plan) that outlines the steps Mylan will take to ensure that: (a) all Covered Persons receive adequate training regarding Mylan's CIA requirements and Compliance Program and the applicable Federal health care program requirements, including the requirements of the Anti-Kickback Statute, and (b) all Relevant Covered Persons receive adequate training regarding: (i) Mylan's systems and processes relating to Government Pricing Functions; (ii) all applicable Federal health care program requirements relating to Government Pricing Functions; and (iii) Mylan's systems for gathering relevant data and calculating, verifying, and reporting information to CMS and/or the State Medicaid Programs for purposes of the Medicaid Drug Rebate Program, the Medicare Program, or any other Federal or state government price reporting requirement.

The Training Plan shall include information regarding the following: training topics, categories of Covered Persons and Relevant Covered Persons required to attend each training session, length of the training session(s), schedule for training, and format of the training. Mylan shall furnish training to its Covered Persons and Relevant Covered Persons pursuant to the Training Plan during each Reporting Period.

2. *Board Member Training*. Within 90 days after the Effective Date, each member of the Mylan Board of Directors shall receive at least two hours of training. This training shall address the corporate governance responsibilities of board members and the responsibilities of board members with respect to review and oversight of the Compliance Program. Specifically, the training shall address the unique responsibilities of health care industry Board members, including the risks, oversight areas, and strategic

approaches to conducting oversight of a health care entity. This training may be conducted by an outside compliance expert hired by the Board and should include a discussion of OIG's guidance on Board member responsibilities.

New members of the Board of Directors shall receive the Board member Training described above within 30 days after becoming a Board member or within 90 days after the Effective Date, whichever is later.

3. *Training Records*. Mylan shall make available to OIG, upon request, training materials and records verifying that Covered Persons, Relevant Covered Persons, and Board members have timely received the training required under this section.

D. Review Procedures.

1. *General Description*.

a. *Engagement of Independent Review Organization*. Within 90 days after the Effective Date, Mylan shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform the reviews identified in this Section III.D. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

b. *Retention of Records*. The IRO and Mylan shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Mylan) related to the Government Pricing Function Review.

2. *Government Pricing Functions Review*. The IRO shall assess Mylan's systems, processes, policies, and procedures relating to Mylan's Government Pricing Functions (Government Pricing Functions Review) and shall prepare a Government Pricing Functions Review Report, as outlined in Appendix B to this CIA, which is incorporated by reference.

3. *Additional Items Review*. In addition to the Government Pricing Functions Review, OIG may, in its discretion, require a review by the IRO of up to three additional areas or practices of Mylan identified by OIG relating to Government Pricing

Functions (hereafter "Additional Items") and prepare an Additional Items Review Report, as outlined in Appendix B.

4. *Independence and Objectivity Certification*. The IRO shall include in its report(s) to Mylan a certification that the IRO has: (a) evaluated its professional independence and objectivity with respect to the reviews required under this Section III.D; and (b) concluded that it is, in fact, independent and objective in accordance with the requirements specified in Appendix A. The IRO's certification shall include a summary of all current and prior engagements between Mylan and the IRO.

E. Risk Assessment and Internal Review Process.

To the extent not already accomplished, within 90 days after the Effective Date, Mylan shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with its Government Reimbursed Products. The risk assessment and internal review process shall require compliance, legal and department or business unit leaders, at least annually, to (1) identify and prioritize risks, (2) develop internal audit work plans related to the identified risk areas, (3) implement the internal audit work plans, (4) develop corrective action plans in response to the results of any internal audits performed, and (5) track the implementation of the corrective action plans in order to assess the effectiveness of such plans. Mylan shall maintain the risk assessment and internal review process for the duration of the CIA.

F. Disclosure Program.

To the extent not already accomplished, within 90 days after the Effective Date, Mylan shall establish a Disclosure Program that includes a mechanism (e.g., a toll free compliance telephone line) to enable individuals to disclose to the Compliance Officer or some other person who is not in the disclosing individual's chain of command any identified issues or questions associated with Mylan's policies, conduct, practices, or procedures with respect to a Federal health care program requirement believed by the individual to be a potential violation of criminal, civil, or administrative law. Mylan shall appropriately publicize the existence of the Disclosure Program and the disclosure mechanism (e.g., via periodic e-mails to employees, or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. The Disclosure Program also shall include a requirement that all of Mylan's Covered Persons shall be expected to report

suspected violations of any Federal health care program requirements to the Compliance Officer or other appropriate individual designated by Mylan. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that it obtains all necessary information to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, Mylan shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or designee) shall maintain a disclosure log and shall record each disclosure in the disclosure log within two business days of receipt of the disclosure. The disclosure log shall include a summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews.

G. Ineligible Persons.

1. *Definitions*. For purposes of this CIA:

a. an "Ineligible Person" shall include an individual or entity who:

i. is currently excluded from participation in any Federal health care programs; or

ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded.

b. "Exclusion List" means the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available through the Internet at http://www.oig.hhs.gov).

2. *Screening Requirements*. Mylan shall ensure that all prospective and current Covered Persons are not Ineligible Persons by implementing the following screening requirements.

a. Mylan shall screen all prospective Covered Persons against the Exclusion List prior to engaging their services and, as part of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Ineligible Persons.

b. Mylan shall screen all current Covered Persons against the Exclusion List within 90 days after the Effective Date and on a monthly basis thereafter.

c. Mylan shall maintain a policy requiring all Covered Persons to disclose immediately if they become an Ineligible Person.

Nothing in this Section III.G affects Mylan's responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by excluded persons. Mylan understands that items or services furnished, ordered, or prescribed by excluded persons are not payable by Federal health care programs and that Mylan may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Mylan meets the requirements of Section III.G.

3. *Removal Requirement*. If Mylan has actual notice that a Covered Person has become an Ineligible Person, Mylan shall remove such Covered Person from responsibility for, or involvement with, Mylan's business operations related to the Federal health care program(s) from which such Covered Person has been excluded and shall remove such Covered Person from any position for which the Covered Person's compensation is paid in whole or part, directly or indirectly, by any Federal health care program(s) from which the Covered Person has been excluded, at least until such time as the Covered Person is reinstated into participation in such Federal health care program(s).

4. *Pending Charges and Proposed Exclusions*. If Mylan has actual notice that a Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Covered Person's employment or contract term, Mylan shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary, or the accuracy of any claims submitted to any Federal health care program.

H. Notification of Government Investigation or Legal Proceeding.

Within 30 days after discovery, Mylan shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Mylan conducted or brought by a governmental entity or its agents involving an allegation that Mylan has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Mylan shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceeding, if any.

I. Reportable Events.

1. *Definition of Reportable Event*. For purposes of this CIA, a "Reportable Event" means anything that involves:

a. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program requirements for which penalties or exclusion may be authorized;

b. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a; or

c. the filing of a bankruptcy petition by Mylan.

A Reportable Event may be the result of an isolated event or a series of occurrences.

2. *Reporting of Reportable Events*. If Mylan determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Mylan shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists.

3. *Reportable Events under Section III.I.1.a and III.I.1.b*. For Reportable Events under Section III.I.1.a and b, the report to OIG shall include:

a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions, or other conduct giving rise to the Reportable

Event; the period during which the claims, transactions, or other conduct occurred; and the names of entities and individuals believed to be implicated, including an explanation of their roles in the Reportable Event;

b. a statement of the Federal criminal, civil, or administrative laws that are probably violated by the Reportable Event;

c. the Federal health care programs affected by the Reportable Event;

d. a description of the steps taken by Mylan to identify and quantify any Overpayments relating to the Reportable Event; and

e. a description of Mylan's actions taken to correct the Reportable Event and prevent it from recurring.

If the Reportable Event involves an Overpayment, within 60 days of identification of the Overpayment, Mylan shall repay the Overpayment, in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and 42 C.F.R. §§ 401.301-305 (and an applicable CMS guidance) and provide OIG with a copy of the notification and repayment. For purposes of this Section III.I, an Overpayment means any funds that Mylan receives or retains under any Federal health care program to which Mylan, after applicable reconciliation, is not entitled under such Federal health care program.

4. *Reportable Events under Section III.I.1.b*. For Reportable Events under Section III.I.1.b, the report to OIG shall include:

a. the identity of the Ineligible Person and the job duties performed by that individual;

b. the dates of the Ineligible Person's employment or contractual relationship;

c. a description of the Exclusion List screening that Mylan completed before and/or during the Ineligible Person's employment or contract and any flaw or breakdown in the screening process that led to the hiring or contracting with the Ineligible Person;

d. a description of how the Ineligible Person was identified; and

e. a description of any corrective action implemented to prevent future employment or contracting with an Ineligible Person.

5. *Reportable Events under Section III.I.1.c*. For Reportable Events under Section III.I.1.c, the report to OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program authorities implicated.

IV. SUCCESSOR LIABILITY

In the event that, after the Effective Date, Mylan proposes to: (a) sell any or all of its business, business units, or locations (whether through a sale of assets, sale of stock, or other type of transaction) relating to Government Reimbursed Products, or (b) purchase or establish a new business, business unit, or location relating to Government Reimbursed Products, the CIA shall be binding on the purchaser of any business, business unit, or location and any new business, business unit, or location (and all Covered Persons at each new business, business unit, or location) shall be subject to the applicable requirements of this CIA, unless otherwise determined and agreed to in writing by OIG.

If, in advance of a proposed sale or a proposed purchase, Mylan wishes to obtain a determination by OIG that the proposed purchaser or the proposed acquisition will not be subject to the requirements of the CIA, Mylan must notify OIG in writing of the proposed sale or purchase at least 30 days in advance. This notification shall include a description of the business, business unit or location to be sold or purchased, a brief description of the terms of the transaction and, in the case of a proposed sale, the name and contact information of the prospective purchaser.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report.

Within 120 days after the Effective Date, Mylan shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A.1, and a summary of other noncompliance job responsibilities the Compliance Officer may have;

2. the names and positions of the members of the Compliance Committee required by Section III.A.2;

3. the names of the members of the Board of Directors who are responsible for satisfying the obligations referenced in Section III.A.3;

4. the names and positions of the Certifying Employees required by Section III.A.4;

5. a list of the Policies and Procedures required by Section III.B;

6. the Training Plan required by Section III.C.1 and a description of the Board of Directors training required by Section III.C.2 (including a summary of the topics covered, the length of the training and when the training was provided);

7. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A; and (d) a certification from the IRO regarding its professional independence and objectivity with respect to Mylan;

8. a description of the risk assessment and internal review process required by Section III.E;

9. a description of the Disclosure Program required by Section III.F;

10. a description of the Ineligible Persons screening and removal process required by Section III.G;

11. a list of all of Mylan's locations in the United States (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers;

12. a description of Mylan's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and

13. the certifications required by Section V.C.

B. Annual Reports.

Mylan shall submit to OIG a report on its compliance with the CIA for each of the five Reporting Periods (Annual Report). Each Annual Report shall include, at a minimum, the following information:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer, a current list of the Compliance Committee members, a current list of the Board members who are responsible for satisfying the Board of Directors compliance obligations, and a current list of the Certifying Employees;

2. the dates of each report made by the Compliance Officer to the Board (written documentation of such reports shall be made available upon request);

3. the Board resolution required by Section III.A.3 and a description of the documents and other materials reviewed by the Board, as well as any additional steps taken, in its oversight of the Compliance Program and in support of making the resolution;

4. a list of any new or revised Policies and Procedures developed during the Reporting Period;

5. a description of any changes to Mylan's Training Plan developed under Section III.C and a summary of any Board of Directors training provided during the Reporting Period;

6. a complete copy of all reports prepared pursuant to Section III.D and Mylan's response to the reports, along with corrective action plan(s) related to any issues raised by the reports;

7. a certification from the IRO regarding its professional independence and objectivity with respect to Mylan;

8. a description of any changes to the risk assessment and internal review process required by Section III.E, including the reasons for such changes;

9. a summary of the following components of the risk assessment and

internal review process during the Reporting Period: work plans developed, internal audits performed, corrective action plans developed in response to internal audits, and steps taken to track the implementation of the corrective action plans. Copies of any work plans, internal audit reports, and corrective action plans shall be made available upon request;

10. a summary of the disclosures in the disclosure log required by Section III.F that relate to Federal health care programs or Government Reimbursed Products, including at least the following information: a description of the disclosure, the date the disclosure was received, the resolution of the disclosure, and the date the disclosure was resolved (if applicable). The complete disclosure log shall be made available to OIG upon request;

11. a description of any changes to the Ineligible Persons screening and removal process required by Section III.G, including the reasons for such changes;

12. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.H. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

13. a summary of Reportable Events (as defined in Section III.I) identified during the Reporting Period;

14. a description of all changes to the most recently provided list of Mylan's locations (including addresses) as required by Section V.A.11; and

15. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications.

1. *Certifying Employees*. In each Annual Report, Mylan shall include the certifications of Certifying Employees as required by Section III.A.4;

2. *Compliance Officer and Chief Executive Officer*. In the Implementation Report and each Annual Report, Mylan shall include the following

individual certifications by the Compliance Officer and the Chief Executive Officer that:

a. to the best of his or her knowledge, except as otherwise described in the report, Mylan is in compliance with the requirements of this CIA; and

b. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful.

3. *Medicaid Drug Rebate Certification*. In the Implementation Report and each Annual Report, the Chief Financial Officer must provide the Medicaid Drug Rebate certification set forth in Appendix C.

D. Designation of Information.

Mylan shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. Mylan shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:

Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, S.W.
Washington, DC 20201
Telephone: (202) 619-2078
Facsimile: (202) 205-0604

Mylan:

Thomas J. Pirozzi
Head of Global Compliance Operations and
Chief Compliance Officer, North America
1000 Mylan Boulevard
Canonsburg, PA 15317
Telephone: (724) 514-1800

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. Upon request by OIG, Mylan may be required to provide OIG with an electronic copy of each notification or report required by this CIA in searchable portable document format (pdf), in addition to a paper copy.

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may conduct interviews, examine and/or request copies of or copy Mylan's books, records, and other documents and supporting materials and conduct on-site reviews of any of Mylan's locations, for the purpose of verifying and evaluating: (a) Mylan's compliance with the terms of this CIA and (b) Mylan's compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by Mylan to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, and/or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Mylan's owners who are natural persons (other than shareholders who: (i) have an ownership interest of less than 5% and (ii) acquired the ownership interest through public trading), employees, contractors, and directors who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Mylan shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Mylan's owners, employees, contractors, and directors may elect to be interviewed with or without a Mylan representative present.

VIII. **DOCUMENT AND RECORD RETENTION**

Mylan shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and to compliance with this CIA for six years (or longer if otherwise required by law) from the Effective Date.

IX. **DISCLOSURES**

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Mylan prior to any release by OIG of information submitted by Mylan pursuant to its obligations under this CIA and identified upon submission by Mylan as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Mylan shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. **BREACH AND DEFAULT PROVISIONS**

Mylan is expected to fully and timely comply with all of its CIA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Mylan and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Mylan fails to establish, implement or comply with any of the following obligations as described in Section III:

a. a Compliance Officer;

b. a Compliance Committee;

c. the Board of Directors compliance obligations;

d. the management certification obligations;

e. written Policies and Procedures;

f. training and education of Covered Persons, Relevant Covered

Persons, and Board Members;

g. a risk assessment and internal review process;

h. a Disclosure Program;

i. Ineligible Persons screening and removal requirements;

j. notification of Government investigations or legal proceedings; and

k. reporting of Reportable Events.

2. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Mylan fails to engage and use an IRO as required by Section III.D, Appendix A or Appendix B.

3. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Mylan fails to submit a complete Implementation Report, Annual Report, or any certification to OIG in accordance with the requirements of Section V by the deadlines for submission.

4. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Mylan fails to submit any IRO Review report in accordance with the requirements of Section III.D, Appendix A, and Appendix B.

5. A Stipulated Penalty of $1,500 for each day Mylan fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Mylan fails to grant access.)

6. A Stipulated Penalty of $50,000 for each false certification submitted by or on behalf of Mylan as part of its Implementation Report, any Annual Report, additional documentation to a report (as requested by OIG), or otherwise required by this CIA.

7. A Stipulated Penalty of $1,000 for each day Mylan fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Mylan stating the specific grounds for its determination that Mylan has failed to comply fully

and adequately with the CIA obligation(s) at issue and steps Mylan shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the date Mylan receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1- 6 of this Section.

B. Timely Written Requests for Extensions. Mylan may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Mylan fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three days after Mylan receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. *Demand Letter*. Upon a finding that Mylan has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Mylan of: (a) Mylan's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter*. Within 10 days after the receipt of the Demand Letter, Mylan shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event Mylan elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Mylan cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment*. Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by OIG in the Demand Letter.

4. *Independence from Material Breach Determination*. Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Mylan has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA.

1. *Definition of Material Breach*. A material breach of this CIA means:

a. repeated violations or a flagrant violation of any of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;

b. a failure by Mylan to report a Reportable Event, take corrective action, or make appropriate refunds, as required in Section III.I;

c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or

d. a failure to engage and use an IRO in accordance with Section III.D, Appendix A, and Appendix B.

2. *Notice of Material Breach and Intent to Exclude*. The parties agree that a material breach of this CIA by Mylan constitutes an independent basis for Mylan's exclusion from participation in the Federal health care programs. The length of the exclusion shall be in OIG's discretion, but not more than five years per material breach. Upon a determination by OIG that Mylan has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Mylan of: (a) Mylan's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure*. Mylan shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

a. the alleged material breach has been cured; or

b. the alleged material breach cannot be cured within the 30 day period, but that: (i) Mylan has begun to take action to cure the material breach; (ii) Mylan is pursuing such action with due diligence; and (iii) Mylan has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30 day period, Mylan fails to satisfy the requirements of Section X.D.3, OIG may exclude Mylan from participation in the Federal health care programs. OIG shall notify Mylan in writing of its determination to exclude Mylan (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of Mylan's receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, Mylan may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to Mylan of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Mylan shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter. The procedures relating to the filing of a request for a hearing can be found at http://www.hhs.gov/dab/divisions/civil/procedures/divisionprocedures.html.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether

Mylan was in full and timely compliance with the obligations of this CIA for which OIG demands payment and (b) the period of noncompliance. Mylan shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Mylan to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Mylan requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review*. Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be whether Mylan was in material breach of this CIA and, if so, whether:

a. Mylan cured such breach within 30 days of its receipt of the Notice of Material Breach; or

b. the alleged material breach could not have been cured within the 30 day period, but that, during the 30 day period following Mylan's receipt of the Notice of Material Breach: (i) Mylan had begun to take action to cure the material breach within that period; (ii) Mylan pursued such action with due diligence; and (iii) Mylan provided to OIG within that period a reasonable timetable for curing the material breach.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Mylan only after a DAB decision in favor of OIG. Mylan's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Mylan upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Mylan may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. Mylan shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Mylan, Mylan shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision*. The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

XI. EFFECTIVE AND BINDING AGREEMENT

Mylan and OIG agree as follows:

A. This CIA shall become final and binding on the date the final signature is obtained on the CIA.

B. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA.

C. All requirements and remedies set forth in this CIA are in addition to and do not affect: (1) Mylan's responsibility to follow all applicable Federal health care program requirements or (2) the government's right to impose appropriate remedies for the failure to follow applicable Federal health care program requirements.

D. The undersigned Mylan signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatories represent that they are signing this CIA in their official capacity and that they are authorized to execute this CIA.

E. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Electronically-transmitted signatures shall constitute acceptable, binding signatures for purposes of this CIA.

ON BEHALF OF MYLAN INC. AND MYLAN SPECIALTY L.P.

/Thomas J. Pirozzi/	8/15/17
Thomas J. Pirozzi Head of Global Compliance Operations and Chief Compliance Officer, North America Mylan Inc.	DATE

/Mitchell E. Zamoff/	8/16/17
Mitchell E. Zamoff Adam K. Levin Hogan Lovells US LLP Counsel for Mylan Inc. and Mylan Specialty L.P.	DATE

ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

/Lisa M. Re/ — 8/16/17

LISA M. RE — DATE
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

/Mary E. Riordan/ — 8/16/17

MARY E. RIORDAN — DATE
Senior Counsel
Office of Inspector General
U.S. Department of Health and Human Services

/Nicole Caucci/ — 8/14/17

NICOLE CAUCCI — DATE
Senior Counsel
Office of Inspector General
U.S. Department of Health and Human Services

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.D of the CIA.

A. IRO Engagement

1. Mylan shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives the information identified in Section V.A.7 of the CIA or any additional information submitted by Mylan in response to a request by OIG, whichever is later, OIG will notify Mylan if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Mylan may continue to engage the IRO.

2. If Mylan engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, Mylan shall submit the information identified in Section V.A.7 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by Mylan at the request of OIG, whichever is later, OIG will notify Mylan if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Mylan may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Government Pricing Functions Review who have expertise in the collection, calculation, verification and reporting of drug pricing and other relevant information for purposes of the Medicaid Drug Rebate Program, the Medicare program, and other government programs (including the 304B Drug Pricing Program). More specifically, the assigned individuals shall have expertise in the collection, calculation, verification and reporting of Average Sales Price (ASP), Average Manufacturer Price (AMP), Best Price, the 340B Program ceiling price; Average Wholesale Price (AWP); and all other information reported by Mylan and used in connection with Federal health care programs.

2. assign individuals to design and select the samples for the Government Pricing Functions Review who are knowledgeable about appropriate statistical sampling techniques; and

3. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities

The IRO shall:

1. perform each Government Pricing Functions Review in accordance with the specific requirements of the CIA;

2. follow all applicable Federal health care program requirements in making assessments in each Government Pricing Functions Review;

3. request clarification from the CMS if in doubt about the application of a particular Medicaid drug rebate requirement, regulation, or policy;

4. respond to all OIG inquires in a prompt, objective, and factual manner; and

5. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. IRO Independence and Objectivity

The IRO must perform each Government Pricing Functions Review in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the United States Government Accountability Office.

E. IRO Removal/Termination

1. *Mylan and IRO.* If Mylan terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, Mylan must submit a notice explaining its reasons for termination or the reason for withdrawal to OIG no later than 30 days after termination or withdrawal. Mylan must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the IRO.

2. *OIG Removal of IRO.* In the event OIG has reason to believe the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify Mylan in writing regarding OIG's basis for

determining that the IRO has not met the requirements of this Appendix. Mylan shall have 30 days from the date of OIG's written notice to provide information regarding the IRO's qualifications, independence or performance of its responsibilities in order to resolve the concerns identified by OIG. If, following OIG's review of any information provided by Mylan regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify Mylan in writing that Mylan shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. Mylan must engage a new IRO within 60 days of its receipt of OIG's written notice. The final determination as to whether or not to require Mylan to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B

GOVERNMENT PRICING FUNCTIONS REVIEW

A. IRO Engagement, General Description

As specified more fully below, Mylan shall retain an IRO to perform reviews to assist Mylan in assessing and evaluating its systems, processes, policies, and procedures related to Mylan's Government Pricing Functions for Government Reimbursed Products as defined in Section II of the CIA (Government Pricing Functions Review). The Government Pricing Functions Review shall consist of the following components: a systems review (Systems Review); a transactions review (Transactions Review); a product classification review (Product Classification Review); and, if requested, an Additional Items Review as described more fully below. Mylan may engage, at its discretion, a single entity to perform all components of the Government Pricing Functions Review provided that the entity has the necessary expertise and capabilities to perform all components.

If there are no material changes in Mylan's systems, processes, policies, and procedures relating to Government Pricing Functions, the IRO shall perform the Systems Review as described below for the second and fourth Reporting Periods. If Mylan materially changes its systems, processes, policies, and procedures relating to Government Pricing Functions, the IRO shall perform an additional Systems Review for the Reporting Period(s) in which such changes were made. The additional Systems Review(s) shall consist of: (1) an identification of the material changes, and (2) a review of the systems, processes, policies, and procedures that materially changed. The IRO shall conduct the Transactions Review and the Product Classification Review for each Reporting Period of the CIA.

B. Government Pricing Functions Systems Review

The Government Pricing Functions Systems Review shall be a review of Mylan's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to Government Pricing Functions for Government Reimbursed Products. More specifically, the IRO shall review Mylan's systems, processes, policies, and procedures associated with the following (hereafter "Reviewed Policies and Procedures"):

1. The systems, processes, policies, and practices used by Mylan to classify its Government Reimbursed Products as Single Source Drugs, Innovator Multiple Source Drugs, or Non-Innovator Multiple Source Drugs for purposes of the Medicaid Drug Rebate Program;

2. The systems, processes, policies and practices used to determine which Mylan customers and classes of trade are included or excluded for purposes of calculating Average Manufacturer Price (AMP)[1] and Best Price;

3. The systems, processes, policies and practices used to determine whether and which particular transactions (e.g., sales, prices, discounts, rebates) are included in or excluded from AMP and Best Price calculations;

4. The systems, processes, policies, and practices (including those relating to transfer prices) used to determine the AMP and Best Prices for Government Reimbursed Products that are authorized generic drugs;

5. A review of Mylan's methodology for applying transactions to the AMP calculations and the Best Price determinations;

6. The flow of data and information by which price, contract terms (including discounts and rebates), and transactions with Mylan's customers are accumulated from the source systems and entered and tracked in Mylan's information systems for purposes of calculating AMP and for purposes of determining Best Price;

7. The systems, processes, policies and practices used in connection with the calculation and payment of additional rebate amounts due under 42 U.S.C. §§ 1396r-8(c)(2) and (c)(3) and applicable regulations and guidance (collectively hereafter "Additional Rebate Amounts");

8. A review of any Mylan inquiries to or communication with CMS regarding: (a) AMP calculations and reporting requirements pursuant to the Medicaid Drug Rebate Program, including requests for interpretation and guidance; (b) the classification of a drug as a Single Source Drug, Innovator Multiple Source Drug, or Non-Innovator Multiple Source Drug; (c) Best Price determinations and reporting requirements pursuant to the Medicaid Drug Rebate Program, including requests for interpretation and guidance; (d) Additional Rebate Amounts; and (e) any reporting obligations under the Medicaid Drug Rebate Program, including reporting of any product information (e.g., NDC information or baseline information about a product); and a review of any responses from CMS to any such inquiries or communications;

9. The controls and processes in place to examine and address Mylan internal system reports that require critical evaluation (such as reports of variations, exceptions, or outliers). This shall include a review of the bases upon which variations, exceptions, and

[1] For purposes of this Appendix B, references to AMP includes AMP for 5i drugs (i.e., inhalation, infusion, instilled, implanted, and injectable drugs) as referenced in 42 C.F.R. § 447.507.

outliers are identified and the follow-up activities undertaken to identify the cause of any variations.

C. Government Pricing Functions Systems Review Report

The IRO shall prepare a report based upon each Government Pricing Functions Systems Review performed (Systems Review Report). The Systems Review Report shall include the following items:

1. A description of the systems, processes, policies and practices in place to determine the classification of a Government Reimbursed Product as a Single Source Drug, Innovator Multiple Source Drug, or Non-Innovator Multiple Source Drug for purposes of the Medicaid Drug Rebate Program;

2. A description of the systems, processes, policies, and practices used to track, gather, and account for price terms, contract terms and transactions that are relevant to the calculation and reporting of AMP, Best Price, and Additional Rebate Amounts, including but not limited to:

a. The computer, software, applications, or other relevant systems (including the source systems and any other information systems, as applicable), used to track data for and to calculate and report AMP and Best Price;

b. The information input into Mylan's relevant computer or other systems used to calculate AMP and used to determine Best Price;

c. The system logic or decisional rationale used to determine which customers and classes of trade are included or excluded for purposes of calculating AMP and for purposes of determining Best Price;

d. The system logic or decisional rationale used to determine whether price and contract terms, discounts, rebates, and other relevant transactions are included or excluded when calculating AMP and when determining Best Price;

e. The systems, processes, policies, and practices (including those relating to transfer prices) relevant to the determination of AMP and Best Prices for Government Reimbursed Products that are authorized generic drugs;

f. The systems, processes, policies and practices used in connection with the calculation and payment of Additional Rebate Amounts; and

g. Mylan's policies and practices for examining Mylan internal system reports for variations that require critical evaluation, including the basis on which

variations, exceptions, or outliers are identified, and the follow up actions taken in response.

3. A description of the documentation, information, and systems reviewed, and the personnel interviewed, if any, including a description of the following:

a. Mylan's inquiries to and communications with CMS regarding the appropriate classification of a drug as a Single Source Drug, Innovator Multiple Source Drug, or a Non-Innovator Multiple Source Drug; the calculation of AMP; the determination of Best Price; Additional Rebate Amounts; and/or any reporting obligations; and any responses to those inquiries or communications;

b. Mylan's systems and practices for reporting AMP and Best Price to CMS as required by the Medicaid Drug Rebate Program;

c. the reasonable assumptions (as the term is used in the Medicaid Drug Rebate Agreement in place between Mylan and the Secretary of the Department of Health and Human Services (hereafter "Reasonable Assumptions")) relied upon by Mylan in making determinations relating to AMP and/or Best Price; and

d. Mylan's systems and practices for reporting any adjustments or additional information related to its AMP and Best Price submissions.

4. Observations, findings, and recommendations for any improvements to Mylan's systems, processes, policies, and practices relating to the Medicaid Drug Rebate Program.

D. Government Pricing Functions Transactions Review

1. AMP Transactions Review.

a. For each Reporting Period, the IRO shall randomly select a quarter during the Reporting Period. The IRO then shall select a sample of NDCs for Government Reimbursed Products (at the NDC-9 level) for which AMP was reported during the selected quarter and review a sample of the transactions that were taken into account in the AMP calculation. More specifically, the IRO shall review (i) all NDCs associated with EpiPen and any authorized generic version of EpiPen (collectively, "EpiPen NDCs"); (ii) 23 NDCs for Government Reimbursed Products that are Single Source Drugs or Innovator Multiple Source Drugs or 25% of the number of NDCs for such drugs, whichever is a larger number; (iii) 370 NDCs for Government Reimbursed Products that are Non-Innovator Multiple Source Drugs or 25% of the number of NDCs for such drugs, whichever is a larger number; and (iv) 14 NDCs for Government Reimbursed Products (apart from EpiPen) that are authorized generic products or 25% of

the number of NDCs for such drugs, whichever is a larger number. The NDCs associated with the drugs referenced in sections (ii) through (iv) above shall be randomly selected by the IRO and referred to hereafter as the "Selected AMP NDCs". The IRO shall review the EpiPen NDCs and the Selected AMP NDCs to test whether Mylan calculated and reported AMP in accordance with the Medicaid Drug Rebate Statute, regulations, and CMS guidance (collectively, "Medicaid Drug Rebate Program Requirements").

b. For purposes of the AMP Transactions Review, the following definitions shall be used:

(1) "Finalized Transaction Types" are defined as those transactions that are finalized at the time of the sale.

(2) "Estimated Transaction Types" are defined as those transaction types that are sales, adjustments, and/or rebates that are available on a lagged basis.

c. The IRO shall review a sample of the transactions underlying the AMP calculation for each EpiPen NDC and each Selected AMP NDC, to test whether Mylan calculated and reported AMP in accordance with Medicaid Drug Rebate Program Requirements.

(1) The IRO shall select and review a sample of 50 AMP Finalized Transactions for each EpiPen NDC and each Selected AMP NDC and determine whether (a) the Finalized Transactions are supported by source documents and (b) the Finalized Transactions were included in or excluded from the AMP calculation for each EpiPen NDC and each Selected AMP NDC in accordance with Medicaid Drug Rebate Program Requirements.

(2) The IRO shall select and review a sample of 50 AMP Estimated Transactions for each EpiPen NDC and each Selected AMP NDC and determine whether: (a) the Estimated Transaction amounts were calculated in accordance with Medicaid Drug Rebate Program Requirements and were supported by relevant commercial arrangements or other source documents; and (b) the Estimated Transactions were included in or excluded from the AMP calculation for the EpiPen NDCs and Selected AMP NDCs in accordance with Medicaid Drug Rebate Program Requirements.

d. If the IRO identifies any Finalized Transactions or Estimated Transactions that are not supported by relevant commercial arrangements or other source documents or that were not included or excluded from Mylan's AMP calculation(s) in accordance with Medicaid Drug Rebate Program Requirements, Mylan shall be required to (1) adjust the applicable AMP calculation(s), resubmit the adjusted AMP to CMS, and pay any additional Medicaid rebate amounts that may be owed; and (2) perform a root cause analysis to determine the cause of each error identified by the IRO, and provide the findings of such root cause analysis to OIG, within 30 days following Mylan's receipt of the Government Pricing Transactions Review Report.

2. Best Price Transactions Review. For each Reporting Period, the IRO shall perform a review to test whether Mylan determined and reported Best Price for Government Reimbursed Products in accordance with Medicaid Drug Rebate Program Requirements. The Best Price Transactions Review shall consist of two parts:

a. Part One of the Best Price Transactions Review.

(1) For all of its Government Reimbursed Products that are Single Source Drugs and Innovator Multiple Source Drugs Mylan shall provide the IRO with a list of all Mylan customers who purchased or contracted for those products during a single quarter during the Reporting Period that has been randomly selected by the IRO. The IRO shall then randomly select a sample of 100 Mylan customers (Selected Customers) using the following methodology. The IRO shall categorize each Mylan customer as "large" or "small" based upon the total volume of sales of the contracted Medicaid rebate eligible NDCs to that Mylan customer during the selected quarter. The IRO shall randomly select 90 Mylan customers from the large customer category and 10 Mylan customers from the small customer category.

(2) For each of the "large" and "small" Selected Customers, the IRO's review shall cover the 20 NDCs (at the NDC-9 level) for which Mylan paid the largest amount (i.e., total dollars) of Medicaid rebates during the Reporting Period and 5 randomly selected other NDCs (collectively, the "Selected BP NDCs"). However, for purposes of determining the Selected BP NDCs, if Mylan paid less than $20,000 in Medicaid rebates during the Reporting Period for any randomly selected NDC, the IRO will replace that NDC with a randomly selected NDC for which Mylan paid at least $20,000 in Medicaid rebates for the Reporting Period.

(3) For each Selected Customer, the IRO shall identify all contracts with Mylan, any non-contract pricing terms offered by Mylan to the Selected Customer, and all corresponding Selected BP NDCs. The IRO shall determine whether all contract prices and any non-contract pricing terms for each Selected BP NDC were appropriately considered for purposes of determining Best Price in accordance with Medicaid Drug Rebate Program Requirements. To the extent that Mylan made available multiple price concessions in connection with the sale of a Selected BP NDC to a Selected Customer, the IRO shall determine whether the price concessions were appropriately considered for purposes of determining Best Price.

(4) Mylan also shall provide the IRO with information and documentation about all non-price-related arrangements or relationships initiated or in effect during the Reporting Period between Mylan and the "large" and "small" Selected Customers ("Other Arrangements"). These Other Arrangements could include, for example, grants provided to the Mylan customer or data or service fee arrangements entered into with the Mylan customer. The IRO shall review documentation and information about the Other Arrangements sufficient to identify the nature of the Other Arrangements, describe the terms of the Other Arrangements (including any amounts paid or other benefits conferred by Mylan in connection with the Other Arrangements and the time period of the arrangements), and identify any NDCs that were associated with the Other Arrangements. The IRO shall assess whether the Other Arrangements were appropriately considered for purposes of determining Best Prices for any NDCs associated with the Other Arrangements.

b. Part Two of the Best Price Transactions Review.

(1) For all of its Single Source Drugs and Innovator Multiple Source Drugs that are Government Reimbursed Products, Mylan shall provide the IRO with a listing of the 37 Medicaid rebate eligible NDCs (at the NDC-9 level) for which Mylan paid the largest amount (i.e., total dollars) of Medicaid rebates during the Reporting Period or 25% of the number of NDCs for such products, whichever is a larger number.

(2) For each of the NDCs identified in paragraph D.2.b(1), a listing of all unique prices paid to Mylan for the product that were lower than the reported Best Price for the single quarter randomly selected by the IRO as describe in paragraph D.2.a(1) above.

(3) For each unique price that was lower than the reported Best Price, the IRO shall review a minimum of 15 randomly selected transactions associated with each of these unique lower prices (or, if there are less than 15 such transactions, all such transactions) to determine whether each transaction was properly excluded from the determination of Best Price for the NDC in accordance with Medicaid Drug Rebate Program Requirements.

c. If the IRO's Best Price Transactions Review identifies (1) for any Selected Customers, any contract prices or non-contract terms that were not appropriately considered by Mylan for purposes of determining Best Price for the associated Selected BP NDCs; (2) any Other Arrangements with Selected Customers that were not appropriately considered for purposes of determining Best Price; or (3) any transactions associated with unique lower prices paid to Mylan that were not appropriately excluded from the determination of Best Price for a Medicaid rebate eligible NDC, then Mylan shall be required to (1) adjust the applicable Best Price determination(s), resubmit the adjusted Best Price to CMS, and pay any additional Medicaid rebate amounts that may be owed; and (2) perform a root cause analysis to determine the cause of each error identified by the IRO, and provide the findings of such root cause analysis to OIG, within 30 days following Mylan's receipt of the Government Pricing Transactions Review Report.

3. Additional Rebate Review.

a. For each Reporting Period, the IRO shall select a sample of NDCs at the NDC-9 level for Government Reimbursed Products and shall review Mylan's practices regarding Additional Rebate Amounts due for the NDCs. More specifically, the IRO shall review the items set forth below for 37 or 25% of the number of NDCs for Single Source and Innovator Multiple Source Drugs, whichever is a larger number; 369 or 25% of the NDCs for Non-Innovator Multiple Source Drugs, whichever is a larger number; and all the EpiPen NDCs. The NDCs for the Single Source and Innovator Multiple Source Drugs and the Non-Innovator Multiple Source Drugs shall be randomly selected for review.

b. For each NDC included in the Additional Rebate Review, the IRO shall evaluate whether the Base Date AMP reported by Mylan to CMS for the NDC was determined correctly in accordance with the Medicaid Drug Rebate Requirements.

c. For each NDC included in the Additional Rebate Review, the IRO shall assess whether the Additional Rebate Amount due was calculated correctly in accordance with Medicaid Drug Rebate Program Requirements.

d. If the IRO's Additional Rebate Review identifies: (1) any Base Date AMP that was not calculated in accordance with Medicaid Drug Rebate Requirements, Mylan shall be required to adjust the applicable Base Date AMP, resubmit the adjusted Base Date AMP to CMS and pay any supplemental Additional Rebate Amounts that may be owed; or (2) any Additional Rebate Amount due that was not calculated correctly, Mylan shall be required to adjust the applicable Additional Rebate Amount calculation and/or pay any supplemental Additional Rebate Amounts that may be owed. Mylan shall perform a root cause analysis to determine the cause of each error identified by the IRO, and provide the findings of such root cause analysis to OIG, within 30 days following Mylan's receipt of the Government Pricing Transactions Review Report.

4. AMP Transactions Review Report. For each Reporting Period, the IRO shall prepare a report based on its AMP Transactions Review. The report shall include the following information:

a. A detailed narrative description of the procedures performed and a description of the sampling unit and universe utilized in performing the procedures for each sample reviewed;

b. A full description of documentation and other information, if applicable, relied upon by the IRO in performing the AMP Transactions Review;

c. A description of Mylan's methodologies for calculating AMP (including for authorized generic drugs and for 5i drugs), including its methodologies for determining which customers, classes of trade, and types of transactions are included or excluded for purposes of calculating AMP;

d. description of all Reasonable Assumptions relied on by Mylan in connection with its calculation of AMP for the EpiPen NDCs and the Selected AMP NDCs;

e. For each EpiPen NDC and each Selected AMP NDC reviewed, the IRO shall identify (i) any Finalized Transactions or Estimated Transactions that it determined were not supported by relevant commercial arrangements or other source documents or were not included or excluded from Mylan's AMP calculation(s) in accordance with Medicaid Drug Rebate Program Requirements; (ii) the estimated financial impact of these transactions on Mylan's AMP calculation(s); and (iii) a description of actions taken by Mylan in accordance with Section D.1.d above; and

f. Any IRO recommendations for changes to Mylan's policies and procedures or methodologies to correct or address any weaknesses identified during the AMP Transactions Review.

5. Best Price Transactions Review Report. For each Reporting Period, the IRO shall prepare a report based on its Best Price Transactions Review. The report shall include the following information:

a. A detailed narrative description of the procedures performed and a description of the sampling unit and universe utilized in performing the procedures for each sample reviewed;

b. A full description of documentation and other information, if applicable, relied upon by the IRO in performing the Best Price Transactions Review;

c. A description/identification of the following: (i) the 100 Selected Customers included under Part One of the review; (ii) the number of contracts and a summary of the contract terms associated with each Selected Customer and the Selected BP NDCs, (iii) the Selected BP NDCs tested; (iv) the contract prices and non-contract pricing terms for each Selected BP NDC tested; and (v) a description of any supporting documentation reviewed;

d. A description of the IRO's system for identifying the "large" and "small" Selected Customers and documentation supporting the random selection of the customers;

e. For each Selected Customer, a description of the steps taken to determine whether all contract prices and non-contract pricing terms were appropriately considered in Mylan's determination of the Best Prices for the Selected Best Price NDCs in accordance with Medicaid Drug Rebate Program Requirements;

f. For any situations involving multiple price concessions in connection with the sale of a Selected BP NDC to a Selected Customer, a description of any instance in which the price concessions were not appropriately considered for purposes of determining Best Price;

g. For each Selected Customer, a list of any contract prices and/or noncontract pricing terms that were not properly included in or excluded from Mylan's Best Price determination for the applicable quarter during the Reporting Period;

h. For each Selected Customer, a description of the nature of all Other Arrangements in effect between Mylan and the customer, a description of the terms of all Other Arrangements (including any amounts paid or other benefits conferred by Mylan in connection with the Other Arrangements and the time periods of the arrangements), an identification of any NDCs that were associated with the Other Arrangements, a description of the documentation or information reviewed with regard to all Other Arrangements; and an identification of any Other Arrangements (and related NDCs) that were not appropriately considered for purposes of determining Best Price;

i. A list of: (a) the Medicaid rebate eligible NDCs with the highest rebates provided under paragraph D.2.b(1); (b) the Best Price reported by Mylan to CMS for the Medicaid Drug Rebate Program for each of the NDCs under review, and (c) a description of the underlying documentation supporting the random selection of the 15 transactions associated with each unique price lower than the reported Best Prices;

j. A description of the steps and the supporting documentation reviewed to assess the unique lower prices for each of the selected NDCs which were below the Best Prices reported by Mylan to CMS. If more than 15 transactions are associated with any of the unique lower prices, the IRO shall also identify how many such transactions exist for each unique lower price;

k. A list of any unique prices not properly excluded from Mylan's Best Price determination for any of the NDCs reviewed and the corresponding NDC for which the price was not properly excluded;

l. A description of Mylan's methodologies for calculating Best Price (including for non-authorized generic drugs and authorized generic drugs);

m. A description of all Reasonable Assumptions relied on by Mylan in connection with its calculation of Best Prices;

n. A description of the actions taken by Mylan in accordance with Section D.2.c above; and

o. Any IRO recommendations for changes in Mylan's policies, procedures and/or methodologies relating to Best Price to correct or address any weaknesses or deficiencies identified during the review.

6. Additional Rebate Review Report. For each Reporting Period, the IRO shall prepare a report based on its Additional Rebate Review. The report shall include the following information:

a. For each of the NDCs reviewed in the Additional Rebate Review, a listing of the Base Date AMP that Mylan reported to CMS for the NDC;

b. An identification of any NDC for which the IRO determined that an incorrect Base Date AMP was reported to CMS; an explanation of the IRO's rationale for such determination; an estimate of the financial impact of the incorrect Base Date AMP on the amount of Additional Rebate Amount due under the Medicaid Drug Rebate Program; and a description of the actions taken by Mylan in accordance with Section D.3.d above;

c. For each of the NDCs included in the Additional Rebate Review, an assessment of whether the Additional Rebate Amount due was calculated correctly in accordance with Medicaid Drug Rebate Program Requirements. For any NDCs for which the IRO determined the Additional Rebate Amount was not correct, the IRO shall identify the correct amount of the Additional Rebate and describe the actions taken by Mylan in accordance with Section D.3.d above;

d. A full description of documentation and other information, if applicable, relied upon by the IRO in performing the Additional Rebate Review;

e. A description of Mylan's methodology for calculating the Additional Rebate Amounts; and

f. Any IRO recommendations for changes to Mylan's policies and procedures or methodologies to correct or address any weaknesses identified during the Additional Rebate Review.

E. Product Classification Review.

1. At the end of the first Reporting Period, Mylan shall provide to the IRO a list of all its Medicaid-rebate eligible drugs (Mylan Medicaid Rebate Eligible Drugs). The list shall identify both the drug name and the drug classification (i.e., Single Source Drug, Innovator Multiple Source Drug, or Non-Innovator Multiple Source Drug) for purposes of the Medicaid Drug Rebate Program, along with any additional information that the IRO determines is necessary in order to evaluate the drug's product classification. The IRO shall review the product classification for each Mylan Medicaid Rebate Eligible Drug and identify any Mylan Medicaid Rebate Eligible Drug that the IRO determines is incorrectly classified. The IRO shall provide Mylan with a report (Product Classification Review Report) that identifies any Mylan Medicaid Rebate Eligible Drug that the IRO determined was incorrectly classified by Mylan, along with an explanation of the basis for the IRO's determination.

2. At the end of each subsequent Reporting Period, Mylan shall provide to the IRO a list of any drugs that became Mylan Medicaid Rebate Eligible Drugs during that Reporting Period or any existing Mylan Medicaid Rebate Eligible Drug for which Mylan changed the product classification during the Reporting Period, if any. The IRO shall review the product classification for the Mylan Medicaid Rebate Eligible Drugs described above in this paragraph and shall identify any drug that the IRO determines is incorrectly classified. The IRO shall provide Mylan with a Product Classification Review Report that identifies any Mylan Medicaid Rebate Eligible Drug that the IRO determined was incorrectly classified by Mylan, along with an explanation of the basis for the IRO's determination. Mylan shall include each annual Product Classification Review Report (and Mylan's response to each report) in the Annual Reports submitted to OIG in accordance with Section V.B of the CIA.

F. Review of Additional Items. As set forth in Section III.D of the CIA, for each Reporting Period, OIG at its discretion may identify up to three additional items for the IRO to review (hereafter "Additional Items"). No later than 90 days prior to the end of the applicable Reporting Period, OIG shall notify Mylan of the nature and scope of the IRO review to be conducted for each of the Additional Items. Prior to undertaking the review of the Additional Items, the IRO and/or Mylan shall submit an audit work plan to OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by OIG. The IRO shall include information about its review of each Additional Item in the Transactions Review Report (including a description of the review conducted for each Additional Item; the IRO's findings based on its review for each Additional Item; and the IRO's recommendations for any changes in Mylan's systems, processes, policies, and procedures based on its review of each Additional Item).

G. OIG Review of Proposed Work Plan. At least 60 days prior to the end of each Reporting Period, the IRO shall submit to OIG a work plan outlining the methodology for each element of the AMP Transactions Review, the Best Price Transactions Review, the Additional Rebate Review, and the Product Classification Review described above. OIG

shall have 30 days to provide any comments regarding the work plan; if no comments are provided, the IRO may proceed with the work plan as proposed.

APPENDIX C

MEDICAID DRUG REBATE CERTIFICATION

In accordance with the CIA entered into between Mylan and OIG, the undersigned Chief Financial Officer of Mylan Inc. hereby certifies the following to the best of my knowledge, information, and belief:

1. Mylan has in place policies and procedures describing in all material respects its methods for collecting, calculating, verifying and reporting the data and information reported to the Centers for Medicare and Medicaid Services (CMS) and/or the State Medicaid programs in connection with the Medicaid Drug Rebate Program (Medicaid Rebate Policies and Procedures);

2. the Medicaid Rebate Policies and Procedures have been designed to ensure compliance with Mylan's obligations under the Medicaid Drug Rebate Program;

3. Mylan's Medicaid Rebate Policies and Procedures were followed in all material respects in connection with the calculation of Average Manufacturer Price (AMP) and Best Price (BP) for Mylan's products for each of the following quarters and months:

_____ .

4. the AMPs and BPs reported to CMS in the above-listed time periods were calculated accurately and all information and statements made in connection with the submission of AMPs and BPs and in this certification are true, complete, current, and made in good faith.

_____
Signature
Chief Financial Officer of Mylan Inc.

_____
Printed Name

_____
Date

Exhibit 99.1

Mylan Finalizes Settlement Agreement on Medicaid Rebate Classification for EpiPen® Auto-Injector

HERTFORDSHIRE, England and PITTSBURGH, Aug. 17, 2017 /PRNewswire/ — Mylan N.V. (NASDAQ, TASE: MYL) today announced that its subsidiaries, Mylan Inc. and Mylan Specialty L.P., have signed an agreement with the U.S. Department of Justice ("DOJ") and two relators finalizing the Medicaid drug rebate settlement that the Company announced on Oct. 7, 2016 for $465 million.

The settlement resolves claims relating to the classification of EpiPen® Auto-Injector and EpiPen Jr® Auto-Injector for purposes of the Medicaid Drug Rebate Program. The question in the underlying matter was whether the EpiPen products were properly classified with the Centers for Medicare and Medicaid Services ("CMS") as a non-innovator drug under the applicable definition in the Medicaid Rebate statute and subject to the formula that is used to calculate rebates to Medicaid for such drugs. EpiPen Auto-Injector has been classified with CMS as a non-innovator drug since before Mylan acquired the product in 2007 based on longstanding written guidance from the federal government.

The settlement provides for resolution of all potential Medicaid rebate liability claims by the federal government, as well as potential claims by certain hospitals and other covered entities that participate in the 340B Drug Pricing Program. The settlement allocates money to the Medicaid programs of all 50 states and establishes a framework for resolving all potential state Medicaid rebate liability claims within 60 days. In connection with the settlement, Mylan also has entered into a Corporate Integrity Agreement with the Office of Inspector General of the Department of Health and Human Services. The settlement does not contain an admission or finding of wrongdoing. Mylan will reclassify EpiPen Auto-Injector for purposes of the Medicaid Drug Rebate Program and pay the rebate applicable to innovator products effective as of April 1, 2017.

Mylan CEO Heather Bresch commented, "As we said when we announced the settlement last year, bringing closure to this matter is the right course of action for Mylan and our stakeholders to allow us to move forward. Over the course of the last year, we have taken significant steps to enhance access to epinephrine auto-injectors, including bringing a solution to the fast-changing healthcare landscape in the U.S. by launching an authorized generic version at less than half the wholesale acquisition cost of the brand and meaningfully expanding our patient access programs. Mylan has always been committed to providing patients in the U.S. and around the world with access to medicine, and we look forward to continuing to deliver on this mission."

Mylan is a global pharmaceutical company committed to setting new standards in healthcare. Working together around the world to provide 7 billion people access to high quality medicine, we innovate to satisfy unmet needs; make reliability and service excellence a habit; do what's right, not what's easy; and impact the future through passionate global leadership. We offer a growing portfolio of more than 7,500 marketed products around the world, including antiretroviral therapies on which approximately 50% of people being treated for HIV/AIDS in the developing world depend. We market our products in more than 165 countries and territories. We are one of the world's largest producers of active pharmaceutical ingredients. Every member of our more than 35,000-strong workforce is dedicated to creating better health for a better world, one person at a time. Learn more at Mylan.com.

SOURCE Mylan N.V.

For further information: Nina Devlin (Media), 724.514.1968; Melissa Trombetta (Investors), 724.514.1813