# UNITED STATES DISTRICT COURT EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA

v.

)

TEVA PHARMACEUTICALS USA, INC.,

Defendant.

Criminal No. 2:20-cr-200-RBS(s)

Violations: 15 U.S.C. § 1 (conspiracy to restrain trade – 3 counts)

# **DEFERRED PROSECUTION AGREEMENT**

The United States Department of Justice, Antitrust Division ("United States") and TEVA PHARMACEUTICALS USA, INC. ("Teva USA" or the "Company"), a corporation organized and existing under the laws of Delaware, by and through its undersigned representative, pursuant to authority granted by its board of directors, enter into this Deferred Prosecution Agreement ("Agreement"), the terms and conditions of which are as follows:

# Criminal Indictment and Acceptance of Responsibility

1. Teva USA is charged in the Second Superseding Indictment (the "Indictment") in the case of *United States v. Teva Pharmaceuticals USA, Inc.*, 20-cr-200-RBS, filed in the United States District Court for the Eastern District of Pennsylvania. The Indictment charges Teva USA with the following three counts all in violation of the Sherman Antitrust Act,

15 U.S. C. § 1: (1) conspiring to suppress and eliminate competition with Glenmark

Pharmaceuticals Inc., USA, a generic drug company with its principal place of business in New Jersey; Apotex Corp., a generic drug company with its principal place of business in Florida; and other individuals, by agreeing to increase and maintain the prices of pravastatin and other generic drugs sold in the United States, from in or about May 2013 and continuing until at least

# Case 2:20-cr-00200-RBS Document 186 Filed 08/21/23 Page 2 of 46

December 2015; (2) conspiring to suppress and eliminate competition with Taro Pharmaceuticals U.S.A., Inc., a generic drug company with its principal place of business in New York, and other individuals, by agreeing to allocate customers and rig bids for, and stabilize, maintain, and fix prices of, generic drugs sold in the United States, from in or about May 2013 and continuing until at least December 2015; and (3) conspiring to suppress and eliminate competition with Sandoz Inc., a generic drug company with its principal place of business in New Jersey, and other individuals, by agreeing to allocate customers and rig bids for, and stabilize, maintain, and fix prices of, generic drug company with its principal place of business in New Jersey, and other individuals, by agreeing to allocate customers and rig bids for, and stabilize, maintain, and fix prices of, generic drugs sold in the United States, from at least as early as May 2013 and continuing until at least December 2015.

Teva USA hereby knowingly and voluntarily waives for the purposes of this Agreement and for the purposes of any charges by the United States arising out of the conduct described in the Statement of Facts (attached hereto as Attachment A and incorporated by reference into this Agreement) any objection with respect to venue in the United States District Court for the Eastern District of Pennsylvania, Speedy Trial Act, 18 U.S.C. §§ 3161-3174, and Federal Rule of Criminal Procedure 48(b). The United States agrees to defer prosecution of Teva USA pursuant to the terms and conditions described below.

2. Teva USA admits, accepts, and acknowledges that, under U.S. federal law, it is responsible for the acts of its officers, directors, employees, and agents that give rise to the facts set forth in the Statement of Facts. The Company admits, accepts, and acknowledges that the facts set forth in the Statement of Facts are true and accurate. Should the United States pursue the prosecution that is deferred by this Agreement, the Company agrees that it will not dispute the Statement of Facts set forth in this Agreement, and, in any such prosecution, the Statement of Facts shall be admissible as: (a) substantive evidence offered by the government in its case-in-

# Case 2:20-cr-00200-RBS Document 186 Filed 08/21/23 Page 3 of 46

chief and rebuttal case; (b) impeachment evidence offered by the government on crossexamination; and (c) evidence at any sentencing or other hearing. In addition, the Company agrees not to assert any claim under the United States Constitution, Rule 410 of the Federal Rules of Evidence, Rule 11(f) of the Federal Rules of Criminal Procedure, Section 1B1.1(a) of the United States Sentencing Guidelines ("USSG" or "Sentencing Guidelines"), or any other federal rule that the Statement of Facts should be suppressed or is otherwise inadmissible as evidence in any form. Neither this Agreement nor the Indictment is a final adjudication of the matters addressed in those documents.

# Parties to and Scope of the Agreement

Teva USA is organized under the laws of Delaware and headquartered in New
 Jersey. This Agreement binds Teva USA and the United States Department of Justice, Antitrust
 Division.

# Length of the Agreement

4. This Agreement is effective for a period (the "Term of the Agreement," or, the "Term") beginning on the date on which the Agreement is filed (the "Effective Date") and ending three (3) years from the Effective Date; provided, however, that Paragraphs 8 and 9, and 19-26, shall remain in effect until the penalty described in Paragraph 8 is paid in full. The Company agrees that in the event that the United States determines, in its sole discretion, that the Company, its parent, or any subsidiary (collectively, "affiliates") has violated any provision of this Agreement, an extension of the Term of the Agreement may be imposed by the United States, in its sole discretion, for up to one year, without prejudice to the United States' right to proceed as provided in Paragraphs 19–23 below. Any extension of the Term of the Agreement extends all provisions of this Agreement, including attachments, for an equivalent period, but

# Case 2:20-cr-00200-RBS Document 186 Filed 08/21/23 Page 4 of 46

does not extend the due dates for payments provided in Paragraph 8 below, or the terms of divestiture set forth in Attachment E, unless the United States gives the Company written notice to the contrary.

# **Relevant Considerations**

5. The United States enters into this Agreement based on the individual facts and circumstances of this case. Among the facts considered were the following:

(a) a conviction (including a guilty plea) likely would result in the Company's mandatory exclusion from participation in any federal healthcare programs under 42
 U.S.C. § 1320a-7 for a period of not less than five years, which would likely result in substantial consequences to the Company's customers and employees outside the federal health care programs;

(b) while Teva's parent company Teva Pharmaceutical Industries Ltd. entered into a deferred prosecution agreement with the Criminal Division in 2016 to resolve Foreign Corrupt Practices Act violations, and although the Department generally disfavors multiple deferred prosecution agreements, the resolution here is appropriate given that the matters at issue in the 2016 resolution did not involve recent or similar types of misconduct; the same personnel, officers, or executives; or the same entities; and in light of the extraordinary remedial measures required by paragraphs 12-15 of this agreement, the compliance requirements in paragraphs 16-18, and the Company's admission of wrongdoing in Attachment A;

(c) the Company has agreed to cooperate in the United States' ongoing prosecution into criminal antitrust violations among generic drug manufacturers;

# Case 2:20-cr-00200-RBS Document 186 Filed 08/21/23 Page 5 of 46

(d) the Company has agreed to engage an independent monitor to helpfacilitate, oversee, and report to the United States regarding the divestiture set forth inAttachment E of this Agreement;

(e) this Agreement can ensure that integrity has been restored to the
 Company's operations and preserve its financial viability while preserving the United
 States' ability to prosecute it should material breaches occur.

# Cooperation and Disclosure Obligations

6. The Company shall cooperate fully and truthfully with the United States in any and all matters relating to the current federal criminal investigation into violations of federal antitrust and related criminal laws involving the production and sale in the United States of generic pharmaceutical products, including the conduct described in this Agreement and the attached Statement of Facts, and other conduct under investigation by the United States, at any time during the Term, until the later of the date upon which all investigations and prosecutions arising out of such conduct are concluded, or the end of the Term (collectively "Federal Proceeding"). Federal Proceeding also includes any investigation, prosecution, litigation, or other proceeding regarding obstruction of, the making of a false statement or declaration in, the commission of perjury or subornation of perjury in, the commission of contempt in, or conspiracy to commit such offenses in any Federal Proceeding. The Company agrees that full, truthful, and continuing cooperation pursuant to this Paragraph will include the following:

(a) producing to the United States all documents, information, and other materials, wherever located, not protected under the attorney-client privilege or the workproduct doctrine, and with translations into English, in the possession, custody, or control of the Company or its affiliates, that are requested by the United States in its sole

#### Case 2:20-cr-00200-RBS Document 186 Filed 08/21/23 Page 6 of 46

discretion in connection with any Federal Proceeding or the payment of victim compensation pursuant to this Agreement, as well as providing to the United States a log of any responsive documents, information, and other materials that were not provided, including an explanation of the basis for withholding the materials, and bearing the burden of establishing the validity of any such an assertion;

(b) using best efforts to secure the full, truthful, and continuing cooperation of current and former officers, directors, employees, and agents of the Company as may be requested by the United States in its sole discretion. Such efforts will include making these persons available in the United States and at other mutually agreed-upon locations at the Company's expense for interviews and the provision of testimony in grand jury, trial, and other judicial proceedings in connection with the Federal Proceeding; and

(c) with respect to any information, testimony, documents, records or other tangible evidence provided to the United States pursuant to this Agreement, the Company consents to any and all disclosures to other governmental authorities, including federal, state, and local authorities, and those of a foreign government, of such materials as the United States in its sole discretion shall deem appropriate.

7. In addition to the cooperation obligations described in Paragraph 6, during the Term of the Agreement, should the Company learn of or possess any evidence or allegation of conduct that may constitute a federal criminal antitrust offense or another federal criminal offense affecting the competitive process by the Company or its affiliates, or by any present or former officers, directors, employees, or agents during their employment at the Company or its affiliates, the Company shall promptly report such evidence or allegations to the United States. Any information that the Company thus discloses to the United States likely will include

# Case 2:20-cr-00200-RBS Document 186 Filed 08/21/23 Page 7 of 46

proprietary, financial, confidential, and competitive business information. Public disclosure of the information and reports could discourage cooperation, impede pending or potential government investigations, and thus undermine the United States' objectives in obtaining such reports. For these reasons, among others, the information and reports and the contents thereof are intended to remain and shall remain nonpublic, except as otherwise agreed to by the parties in writing, or except to the extent that the United States determines in its sole discretion that disclosure would be in furtherance of its discharge of its duties and responsibilities or is otherwise required by law.

### Monetary Penalty

8. The United States and the Company agree that the Company will pay a monetary penalty in the amount of \$225 million to the U.S. Crime Victims Fund. While the Company retains the option to pay the monetary penalty in full at any time during the Term, the Company must make incremental payments in at least the following amounts on the following schedule: \$22.5 million within seven (7) days of January 1, 2024 (the "first payment"); \$22.5 million on or before the first anniversary of the first payment (or the next business day following the anniversary); \$22.5 million on or before the second anniversary of the first payment (or the next business day following the anniversary); \$22.5 million on or before the third anniversary of the first payment (or the next business day following the anniversary); \$22.5 million on or before the third anniversary of the first payment (or the next business day following the anniversary); \$22.5 million on or before the third anniversary of the first payment (or the next business day following the anniversary); \$22.5 million on or before the third anniversary of the first payment (or the next business day following the anniversary); \$135 million on or before the fourth anniversary of the first payment (or the next business day following the anniversary). The Company and the United States agree that this penalty is appropriate given the facts and circumstances of this case, including the Relevant Considerations described in Paragraph 5. In light of the civil causes of action, and civil cases already filed against Teva USA, including the multidistrict litigation *In Re: Generic Pharmaceuticals Pricing Antitrust Litig.*, Case No. 2:16-

# Case 2:20-cr-00200-RBS Document 186 Filed 08/21/23 Page 8 of 46

md-2724, consolidated in the United States District Court for the Eastern District of Pennsylvania, this Agreement does not include any provision for restitution.

9. The penalty set forth in Paragraph 8 is final and shall not be refunded. Furthermore, nothing in this Agreement shall be deemed an agreement by the United States that \$225 million is the maximum penalty that may be imposed in any future prosecution in the event of a breach of this Agreement, and the United States is not precluded from arguing in any future prosecution that the Court should impose a higher penalty, although the United States agrees that under those circumstances, it will recommend to the Court that the penalty paid under this Agreement should be offset against any criminal penalty or fine the Court imposes as part of a future judgment. The Company acknowledges that no tax deduction may be sought, and agrees that no tax deduction will be sought, in the United States or elsewhere in connection with the payment of any part of this monetary penalty.

# Conditional Release from Liability

10. In return for the full and truthful cooperation of the Company as described in Paragraph 6, and compliance with all other terms and conditions of this Agreement:

(a) The United States agrees that, except as provided by this Agreement, it will not bring criminal charges against the Company for any act or offense committed before the Effective Date involving an antitrust conspiracy involving the production or sale in the United States of generic pharmaceutical products and as described in the Indictment and/or the Statement of Facts;

(b) This conditional release of liability does not provide any protection against prosecution for any individual;

# Case 2:20-cr-00200-RBS Document 186 Filed 08/21/23 Page 9 of 46

(c) Failure by the Company to comply fully with the Cooperation Obligations under Paragraph 6 will void the United States' agreement in Paragraph 10(a), and the Company may be prosecuted criminally for any federal crime of which the United States has knowledge; and

(d) The United States' agreement in Paragraph 10(a) does not apply to subornation of perjury (18 U.S.C. § 1622), false statements (18 U.S.C. § 1001), obstruction of justice (18 U.S.C. § 1503 *et seq.*), contempt (18 U.S.C. § 401–402), or conspiracy to commit such offenses. Its agreement in Paragraph 10(a) also does not apply to civil matters of any kind, any civil or criminal violation of the federal tax or securities laws or conspiracy to commit such offenses, or any crimes of violence.

## Related Administrative Proceedings

11. The Company understands that it may be subject to exclusion, suspension or debarment action by state or federal agencies based upon this Agreement, and that this Agreement in no way controls what action, if any, other agencies may take. However, the United States agrees that, if requested, it will advise the appropriate officials of any governmental agency considering such action of the fact, manner, and extent of the cooperation and remediation of the Company as a matter for that agency to consider before determining what action, if any, to take.

### Divestiture of Assets and Monitor

12. The Company agrees that, as a condition of this Agreement, it will divest the generic drug Pravastatin (sold by the Company under Abbreviated New Drug Application Nos. 076056 and 077793) as set forth in Attachment E.

13. The Company agrees that as a condition of this Agreement, it will retain a monitor

# Case 2:20-cr-00200-RBS Document 186 Filed 08/21/23 Page 10 of 46

to facilitate, oversee, and report on the divestiture described in Paragraph 12, as set forth in Attachment E.

# **Product Donations**

14. The Company agrees that, as a condition of this Agreement, it will donate, to one or more humanitarian organizations whose mission includes providing medication to those in need, Clotrimazole and Betamethasone Dipropionate (sold by the Company under Abbreviated New Drug Application No. 076002) and Tobramycin (sold by the Company under Abbreviated New Drug Application No. 091589) (collectively, the "Donation Products") during the period beginning on January 1, 2024 and ending on December 31, 2028 ("Donation Period"). The total value of these Donation Products shall be \$50,000,000, valued at the wholesale acquisition cost ("WAC") of such Donation Products as of the Effective Date. For the avoidance of doubt, the Company may donate more or less worth of either Donation Product, so long as the value of all donations made during the Donation Period total at least \$50,000,000 (valued at WAC as of the Effective Date).

15. In the event of a Force Majeure Event or other inability to donate the Donation Products during the Donation Period, the Company shall establish a commercially reasonable plan to resolve any inability to supply as quickly as reasonably possible using reasonable efforts which are consistent with accepted industry practices to resume performance as soon as practicable under the circumstances. For purposes of this Agreement, the term "Force Majeure Event" means any event reasonably beyond the control of the Parties, including wars, hostilities, revolution, riots, civil commotion, national emergency, unavailability of supplies, epidemics, fire, flood, earthquake, force of nature, explosion, terrorist act, embargo, or any act of God, or any law, proclamation, regulation, ordinance, or other act or order of any court or governmental authority.

# Corporate Compliance Program

16. In light of the conduct described in the Indictment and in the Statement of Facts, the Company represents that it has conducted a review of its compliance program and implemented compliance policies and procedures reasonably designed to prevent and detect antitrust violations.

17. The Company represents that it has implemented and will continue to implement compliance policies and procedures reasonably designed to prevent and detect antitrust violations throughout its operations, including those of its affiliates, agents, and joint ventures, and those of its contractors and subcontractors.

18. The Company further represents that it will continue to periodically review its antitrust compliance program and make any necessary adjustments and updates based on changes in the Company's operations, circumstances, legal developments, and industry practices, as set forth in Attachment C to this Agreement, and that the Company will report on its antitrust compliance program as set forth in Attachment D to this Agreement.

# **Deferred Prosecution**

19. In consideration of the undertakings agreed to herein by the Company, the United States agrees that any prosecution of the Company for the conduct set forth in the Indictment and the Statement of Facts be and hereby is deferred until the later of: 1) the Term of the Agreement expiring; or 2) the Company's paying in full the penalty amount set forth in Paragraph 8 of this Agreement.

20. The United States further agrees that if the Company fully complies with all obligations under this Agreement, the United States will not continue the criminal prosecution of Teva USA for the offenses described in Paragraph 1 of the Agreement and, at the conclusion of

#### Case 2:20-cr-00200-RBS Document 186 Filed 08/21/23 Page 12 of 46

the Term, this Agreement shall expire, except for, as relevant, the Cooperation Obligations set forth in Paragraph 6 of the Agreement and any remaining obligation to pay the penalty set forth in Paragraph 8 of this Agreement. Within thirty (30) days of the Company's paying in full the penalty amount set forth in Paragraph 8 of this Agreement, the United States shall seek dismissal with prejudice of the Indictment described in Paragraph 1 of the Agreement.

# Breach of Agreement

21. If the United States determines, in its sole discretion, that the Company has: (a) committed any felony offense under U.S. federal law subsequent to the Effective Date; (b) provided to the United States deliberately false, incomplete, or misleading information, including in connection with its disclosure of information about individual culpability; (c) failed to satisfy any Cooperation Obligations as set forth in Paragraph 6 of this Agreement; (d) failed to satisfy the requirements set forth in Attachments C, D, or E; or (e) otherwise failed to completely perform or fulfill any of the Company's obligations under this Agreement, regardless of whether the United States becomes aware of such a breach after the Term is complete, the Company shall thereafter be subject to prosecution for any federal criminal violation of which the United States has knowledge, including, but not limited to, the charges in the Indictment described in Paragraph 1, which may be pursued by the United States in the United States District Court for the Eastern District of Pennsylvania or any other appropriate venue. Any such prosecution may be premised on information provided by any source, including but not limited to the Company.

22. Any such prosecution relating to the conduct described in the Statement of Facts or relating to conduct known to the United States prior to the Effective Date that is not timebarred by the applicable statute of limitations on the Effective Date of this Agreement may be commenced against the Company, notwithstanding the expiration of the statute of limitations

#### Case 2:20-cr-00200-RBS Document 186 Filed 08/21/23 Page 13 of 46

between the Effective Date and the later of the expiration of the Term plus one year, or the full payment of the penalty described in Paragraph 8 plus one year. Thus, by signing this Agreement, the Company agrees that the statute of limitations with respect to any such prosecution that is not time-barred on the Effective Date of this Agreement shall be tolled for the later of the duration of the Term plus one year, or the full payment of the penalty described in Paragraph 8 plus one year.

23. In the event the United States determines that the Company has breached this Agreement, the United States agrees to provide the Company with written notice of such breach prior to instituting any prosecution resulting from such breach. Within thirty (30) days of receipt of such notice, the Company shall have the opportunity to respond to the United States in writing to explain the nature and circumstances of such breach, as well as the actions the Company has taken to address and remediate the situation, which the United States shall consider in determining whether to pursue prosecution of the Company.

24. In the event that the United States determines that the Company has breached this Agreement: (a) all statements made by or on behalf of the Company to the United States or to the Court, including the Statement of Facts, and any testimony given by any individual before a grand jury, a court, or any tribunal, or at any legislative hearings, whether prior or subsequent to this Agreement, and any leads derived from such statements or testimony, shall be admissible in evidence in any and all criminal proceedings brought by the United States against the Company; and (b) the Company shall not assert any claim under the United States Constitution, Rule 410 of the Federal Rules of Evidence, Rule 11(f) of the Federal Rules of Criminal Procedure, or any other federal rule that any such statements or testimony made by or on behalf of the Company prior or subsequent to this Agreement, or any leads derived therefrom, should be suppressed or

# Case 2:20-cr-00200-RBS Document 186 Filed 08/21/23 Page 14 of 46

are otherwise inadmissible. The decision whether any conduct or statement of any current or former director, officer, or employee, or any person acting on behalf of, or at the direction of, the Company, will be imputed to the Company for the purpose of determining whether the Company has violated any provision of this Agreement shall be in the sole discretion of the United States.

25. The Company acknowledges that the United States has made no representations, assurances, or promises concerning what sentence may be imposed by the Court if the Company breaches this Agreement and this matter proceeds to judgment. The Company further acknowledges that any such sentence is solely within the discretion of the Court and that nothing in this Agreement binds or restricts the Court in the exercise of such discretion.

26. On the date that the period of deferred prosecution specified in this Agreement expires, as set forth in Attachment F, the Company, by a corporate officer and General Counsel, will certify to the United States that the Company has met the disclosure obligations set forth in Paragraph 7 of this Agreement. Each certification will be deemed a material statement and representation by the Company to the executive branch of the United States for purposes of 18 U.S.C. §§ 1001 and 1519, and it will be deemed to have been made in the judicial district in which this Agreement is filed.

## Sale, Merger, or Other Change in Corporate Form

27. The Company agrees that, during the Term, if it undertakes any change in corporate form, including if it sells, merges, or transfers business operations that are material to the Company's consolidated operations, excluding the divestiture referenced in Attachment E, whether such sale is structured as a sale, asset sale, merger, or transfer, it shall provide notice to the United States at least sixty (60) business days prior to undertaking any such sale, merger, transfer, or other change in corporate form. Unless, after receiving the required notice from the

## Case 2:20-cr-00200-RBS Document 186 Filed 08/21/23 Page 15 of 46

Company of the transaction, the United States consents in its sole discretion that a specific transaction will not be subject to this provision, the Company shall include in any contract for sale, merger, or transfer a provision binding the purchaser, or any successor in interest thereto, to the obligations described in this Agreement. Unless the United States consents as described above, the purchaser or successor in interest must also agree in writing that the United States' ability to enforce all provisions of this Agreement, including to determine that it has been breached, is applicable in full force to that entity. The Company agrees that, unless the United States consents as described above, the failure to include these provisions in the transaction will make any such transaction null and void. The United States shall inform the Company within thirty (30) business days of receiving the Company's notification if it consents that the transaction(s) will not be subject to this provision, or if it determines that the transaction(s) will have the effect of circumventing or frustrating the purposes of this Agreement. If the United States does not respond to the Company's notification within thirty (30) business days, the transaction(s) at issue shall be deemed not to be subject to this provision and not to have the effect of circumventing or frustrating the purposes of this Agreement. If at any time during the Term the Company engages in a transaction(s) that has the effect of circumventing or frustrating the purposes of this Agreement, the United States may deem it a breach pursuant to Paragraphs 17-21 of this Agreement. Nothing herein shall restrict the Company from indemnifying (or otherwise holding harmless) the purchaser or successor in interest for penalties or other costs arising from any conduct that may have occurred prior to the date of the transaction(s), so long as such indemnification does not have the effect of circumventing or frustrating the purposes of this

Agreement, as determined by the United States in its sole discretion.

# Public Statements by the Company

28. The Company expressly agrees that it shall not, through present or future attorneys, officers, directors, employees, agents, or any other person authorized to speak for the Company or any affiliate, make any public statement, in litigation or otherwise, contradicting the acceptance of responsibility by the Company set forth above or as described in the Statement of Facts. Any such contradictory statement shall, subject to cure rights of the Company described below, constitute a breach of this Agreement, and the Company thereafter shall be subject to prosecution as set forth in Paragraphs 21–26 of this Agreement. The decision whether any public statement by any such person contradicting a fact contained in the Statement of Facts will be imputed to the Company for the purpose of determining whether it has breached this Agreement shall be at the sole discretion of the United States. If the United States reasonably determines that a public statement by any such person contradicts in whole or in part a statement contained in the Statement of Facts, the United States shall so notify the Company, and the Company may avoid a breach of this Agreement by publicly repudiating such statement(s) within five (5) business days after notification. The Company shall be permitted to raise defenses and to assert affirmative claims in other proceedings relating to the matters set forth in the Statement of Facts provided that such defenses and claims do not contradict, in whole or in part, a statement contained in the Statement of Facts. This Paragraph does not apply to any statement made by any present or former officer, director, employee, or agent of the Company in the course of any criminal, regulatory, or civil case initiated against such individual, unless such

# Case 2:20-cr-00200-RBS Document 186 Filed 08/21/23 Page 17 of 46

individual is speaking on behalf of the Company.

29. The Company agrees that if the Company or any affiliate issues a press release or holds any press conference in connection with this Agreement, the Company shall first consult the United States to determine: (a) whether the text of the release or proposed statements at the press conference are true and accurate with respect to matters between the United States and the Company; and (b) whether the United States has any objection to the release or proposed statements.

### Limitations on Binding Effect of Agreement

30. This Agreement is binding on the Company and the United States Department of Justice, Antitrust Division, but specifically does not bind any other component of the Department of Justice, other federal agencies, or any state, local or foreign law enforcement or regulatory agencies, or any other authorities. If the court refuses to grant exclusion of time under the Speedy Trial Act, 18 U.S.C. § 3161(h)(2), all the provisions of this Agreement shall be deemed null and void, and the Term shall be deemed to have not begun, except that the statute of limitations for any prosecution relating to the conduct described in the Statement of Facts shall be tolled from the date on which this Agreement is signed until the date the Court refuses to grant the exclusion of time plus six months, and except for the provisions contained within Paragraph 2 of this Agreement.

### **Definitions**

31. The term "including" means including but not limited to.

# <u>Notice</u>

32. Any notice to the United States under this Agreement shall be given by personal delivery, overnight delivery by a recognized delivery service, or registered or certified mail,

addressed to:

Director of Criminal Enforcement, Antitrust Division, U.S. Department of Justice, 950 Pennsylvania Ave NW Washington DC 20530

Any notice to the Company under this Agreement shall be given by personal delivery,

overnight delivery by a recognized delivery service, or registered or certified mail, addressed to

Brian Savage, SVP and General Counsel, Global Litigation Teva Pharmaceuticals USA, Inc., 400 Interpace Pkwy, Suite 3 Parsippany, NJ 07054

Notice shall be effective upon actual receipt by the United States or the Company.

# Entirety of Agreement

33. This Agreement, including Attachments A–F, sets forth all the terms of the

agreement between the Company and the United States. No amendments, modifications, or

additions to this Agreement shall be valid unless they are in writing and signed by the United

States, the attorney(s) for the Company, and a duly authorized representative of the Company.

21/2023 81 DATE: \_

WARR BY:

Brian Savage General Counsel Teva Pharmaceuticals USA, Inc.

BY:

David L. Axelro Ballard Spahr LLP Counsel for Teva Pharmaceuticals USA, Inc.

Respectfully submitted,

BY: Matthew W. Lunder Thomas Tynan

Michael Sawers Barry Joyce

Attorneys United States Department of Justice

Antitrust Division 450 Fifth Street NW, Ste 11300 Washington DC 20530 (202) 476-0275

Christine 4 Lon Men

Jacqueline C. Romero United States Attorney Eastern District of Pennsylvania

#### **COMPANY'S GENERAL COUNSEL'S CERTIFICATE**

I have read the Deferred Prosecution Agreement ("Agreement") and carefully reviewed every part of it with outside counsel for TEVA PHARMACEUTICALS USA, INC. (the "Company"). I understand the terms of this Agreement and voluntarily agree, on behalf of the Company, to each of its terms. Before signing this Agreement, I consulted outside counsel for the Company. Counsel fully advised me of the rights of the Company, of possible defenses, of the Sentencing Guidelines' provisions, and of the consequences of entering into this Agreement.

I have carefully reviewed the terms of this Agreement with the Board of Directors of the Company. I have advised and caused outside counsel for the Company to advise the Board of Directors fully of the rights of the Company, of possible defenses, of the Sentencing Guidelines' provisions, and of the consequences of entering into the Agreement.

No promises or inducements have been made other than those contained in this Agreement. Furthermore, no one has threatened or forced me, or to my knowledge any person authorizing this Agreement on behalf of the Company, in any way to enter into this Agreement. I am also satisfied with outside counsel's representation in this matter. I certify that I am the Senior Vice President and General Counsel for the Company and that I have been duly authorized by the Company to execute this Agreement on behalf of the Company.

Date: 8/21/2023

Teva Pharmaceuticals USA, Inc.

By:

rian Javage Brian Savage

Senior Vice President and General Counsel

#### **CERTIFICATE OF COUNSEL**

I am counsel for TEVA PHARMACEUTICALS USA, INC. (the "Company") in the matter covered by the Deferred Prosecution Agreement ("Agreement"). In connection with such representation, I have examined relevant Company documents and have discussed the terms of this Agreement extensively with the Company's General Counsel who has discussed the Agreement with the Board of Directors. Based on our review of the foregoing materials and discussions, I am of the opinion that the representative of the Company has been duly authorized to enter into this Agreement on behalf of the Company and that this Agreement has been duly and validly authorized, executed, and delivered on behalf of the Company and is a valid and binding obligation of the Company. Further, I have carefully reviewed the terms of this Agreement with the Company's General Counsel who has discussed the terms of this agreement with the Company's General Counsel who has discussed the terms of this agreement with the Company's General Counsel who has discussed the terms of this agreement with the Company's General Counsel who has discussed the terms of this agreement with the Company's General Counsel who has discussed the terms of this agreement with the Company's General Counsel who has discussed the terms of this agreement with the Company's General Counsel who has discussed the terms with the Board of Directors. I have fully advised the Company of its rights, of possible defenses, of the Sentencing Guidelines' provisions and of the consequences of entering into this Agreement. To my knowledge, the decision of the Company to enter into this Agreement, based on the authorization of the Board of Directors, is an informed and voluntary one.

Date: S/21/23

By:

Dávid L. Axelrod / Ballard Spahr LLP Counsel for Teva Pharmaceuticals USA, Inc.

#### Attachment A: Statement of Facts

A. From in or about May 2013 and continuing until in or about December 2015 ("the relevant period"), Teva Pharmaceuticals USA, Inc. ("Teva"), organized under the laws of Delaware, with its principal place of business in the Eastern District of Pennsylvania, was engaged in the manufacturing, marketing and/or sale of generic drugs. During the relevant period, Teva's Employee 1 was involved in the pricing and/or sale of generic drugs. As described below, Teva, through Employee 1, suppressed and eliminated competition for certain drugs by agreeing with competitors to refrain from submitting bids and offers to sell to certain customers.

B. Employee 1 had authority to cause Teva to submit certain bids or refrain from submitting certain bids for the sale of certain generic drugs. Employee 1 acquired information about launches and price increases from individuals working at other entities that manufactured and sold generic drugs; shared information with those individuals about Teva's plans for launches and price increases; and agreed with those individuals to refrain from submitting bids and offers to sell to certain customers, with the purpose of increasing and maintaining the price of generic drugs as described below.

C. In or about the summer of 2013, Teva learned through Employee 1 that Glenmark Pharmaceuticals Inc., USA ("Glenmark") and Apotex Corp. ("Apotex") both intended to increase the price of pravastatin. Through Employee 1, Teva agreed not to provide a bid to supply pravastatin to a national pharmacy that at that time was a customer of Glenmark's for pravastatin.

D. Similarly, in or about the summer of 2014, Ara Aprahamian, the Vice President of Sales and Marketing at Taro Pharmaceuticals U.S.A., Inc. ("Taro"), told Employee 1 that Taro

## Case 2:20-cr-00200-RBS Document 186 Filed 08/21/23 Page 23 of 46

intended to increase the price of clotrimazole and sought Teva's agreement in maintaining the price increase. Through Employee 1, Teva agreed not to provide a bid to supply clotrimazole to a wholesale drug distributor that at that time was a customer of Taro's for clotrimazole.

E. Finally, during the relevant period, after learning that Sandoz, Inc. ("Sandoz") intended to launch the sale of tobramycin inhalation solution ("tobramycin"), for which Teva was at that time the exclusive supplier, Employee 1 agreed to relinquish a national retail chain customer's tobramycin business to Sandoz by declining to bid for the sale of tobramycin and compete for the customer's tobramycin business.

F. During the relevant period, the generic drugs pravastatin, clotrimazole, and tobramycin, as well as payments for these generic drugs, all traveled in interstate commerce. Additionally, the business activities of Teva and its co-conspirators in connection with the production and/or sale of these generic drugs were within the flow of, and substantially affected, interstate trade and commerce.

#### Attachment B: Certificate of Corporate Board Resolutions

WHEREAS, Teva Pharmaceuticals USA, Inc. (the "Company") has been engaged in discussions with the United States Department of Justice, Antitrust Division ("United States") regarding issues arising in relation to the conduct described in Attachment A; and

WHEREAS, in order to resolve such discussions, it is proposed that the Company enter into a Deferred Prosecution Agreement with the United States dated August 21, 2023 ("Agreement"); and

WHEREAS, the Company's Senior Vice President and General Counsel, Brian Savage, and its Secretary, Brian Shanahan, together with outside counsel for the Company, have advised the Board of Directors of the Company of its rights, possible defenses, the Sentencing Guidelines' provisions, and the consequences of entering into such Agreement with the United States;

Therefore, the Board of Directors has RESOLVED that:

1. The Company (a) acknowledges the filed three-count Indictment charging the Company with 15 U.S.C. § 1; (b) waives for the purposes of this Agreement and for the purposes of any charges by the United States arising out of the conduct described in the Statement of Facts (attached as Attachment A and incorporated by reference into this Agreement) any objection with respect to venue and Speedy Trial Act, 18 U.S.C. §§ 3161-3174; (c) agrees to pay a monetary penalty in the amount of \$225 million to the United States Crime Victims Fund, as specified in the Agreement, with respect to the conduct described in Attachment A; (d) agrees to donate \$50 million in Donation Products as specified in the Agreement; and (e) agrees to accomplish the drug divestiture specified in Attachment E to the Agreement;

# Case 2:20-cr-00200-RBS Document 186 Filed 08/21/23 Page 25 of 46

2. The Company accepts and will comply with all of the terms and conditions contained in the Agreement and its attachments;

3. Senior Vice President and General Counsel of the Company, Brian Savage, is hereby authorized, empowered and directed, on behalf of the Company, to execute the Agreement substantially in such form as reviewed by this Board of Directors at this meeting with such changes as Senior Vice President and General Counsel of the Company, Brian Savage, may approve;

4. Senior Vice President and General Counsel of the Company, Brian Savage, is hereby authorized, empowered and directed to take any and all actions as may be necessary or appropriate and to approve the forms, terms or provisions of any agreement or other documents as may be necessary or appropriate, to carry out and effectuate the purpose and intent of the foregoing resolutions; and

5. All of the actions of Senior Vice President and General Counsel of the Company, Brian Savage, which actions would have been authorized by the foregoing resolutions except that such actions were taken prior to the adoption of such resolutions, are hereby severally ratified, confirmed, approved, and adopted as actions on behalf of the Company.

Date: 21 August 2023

By:

Brian Shanahan Secretary Teva Pharmaceuticals USA, Inc.

### Attachment C: Corporate Compliance Program

As part of the Deferred Prosecution Agreement between Teva Pharmaceuticals USA, Inc. (the "Company") and the United States Department of Justice, Antitrust Division ("United States") dated August 21, 2023 ("Agreement"), and to address any deficiencies in the Company's compliance program, including its policies, procedures, and internal controls relating to compliance with the Sherman Antitrust Act and other applicable antitrust laws and regulations, the Company agrees to continue to conduct, in a manner consistent with all of the Company's obligations under this Agreement, appropriate reviews of its existing policies, procedures, and internal controls.

Where necessary and appropriate, the Company agrees to modify its compliance program, including compliance policies and procedures designed to ensure the prevention and detection of antitrust violations. At a minimum, this should include the following elements:

- Design and Comprehensiveness. The Company has or will develop compliance policies and procedures reasonably designed to prevent antitrust violations. The policies and procedures should be integrated into the Company's business practices and reinforced through appropriate internal controls specifically tailored to the Company's business. The Company shall notify all employees that compliance with the policies and procedures is the duty of individuals at all levels of the company.
- Culture of Compliance. The Company's senior leadership as a whole, through words and actions, will work to foster a culture of compliance throughout the organization. Senior leadership across the organization are and will be held accountable for failures in the Company's antitrust compliance.

- 3. Responsibility for the Compliance Program. The Company will assign responsibility to one or more senior leaders in the company with sufficient background and competence in antitrust law for the implementation and oversight of the antitrust compliance program. Those responsible for the Company's antitrust compliance program will be provided with sufficient autonomy, authority, and seniority within the Company's governance structure to effectuate the compliance program.
- 4. Periodic Risk-Based Reviews. The Company will conduct periodic antitrust risk assessments to ensure that its antitrust compliance program, including internal controls, is tailored to the Company's individual circumstances. In undertaking such risk assessments, the Company will review its policies and procedures and make any necessary adjustments and updates based on changes in the Company's operations, circumstances, legal developments, and industry practices.
- 5. Training and Communication. The Company will develop an antitrust compliance training program tailored to the Company's specific antitrust risks and will periodically update the program to ensure that it reflects the Company's current antitrust policies and reporting procedures, and legal, technical, or marketplace developments. The audience, timing, frequency, form, and content of the Company's antitrust training should be commensurate with the Company's operations and circumstances. The Company should make certain that all relevant employees (regardless of management level or location) understand the antitrust training and when and how to report a possible antitrust violation. Training may include participation and compliance certifications as appropriate. The Company will also maintain detailed records of training and compliance-related communications.

- 6. Monitoring and Auditing. The Company will conduct regular monitoring and auditing of its antitrust compliance program to ensure that the program is fully implemented and followed. If the Company's monitoring and auditing functions detect potential violations, they will be reported to the Company's governing authority by the individual(s) responsible for the compliance program. The Company will also revise its policies, procedures, and internal controls as appropriate to reflect the results and findings of monitoring and audit activities.
- 7. Reporting and Guidance. The Company will implement an effective and confidential system for communication that employees may use to seek guidance, raise concerns, or report potential antitrust violations anonymously and confidentially without fear of retaliation. The system will be widely disseminated to all relevant employees and will be designed to respond promptly to all communications. The Company will maintain detailed records of any communications through this system and how those communications were addressed.
- 8. *Incentives and Discipline*. The importance of antitrust compliance will be reflected in the Company's employee evaluation, incentive, and compensation structure. The Company will discipline employees, managers, and senior executives as appropriate for antitrust compliance failures.
- Remediation. The Company shall have procedures in place to address failures in the Company's antitrust compliance program and to communicate changes in its polices to employees.

### **Attachment D: Compliance Reporting Requirements**

As part of the Deferred Prosecution Agreement between TEVA PHARMACEUTICALS USA, INC. (the "Company"), and the United States Department of Justice, Antitrust Division ("United States") dated August 21, 2023 ("Agreement"), the Company agrees that it will report to the United States about the Company's compliance program, including policies, procedures, and internal controls described in Attachment C. During the Term, the Company shall: (1) conduct an initial review and submit an initial report, and (2) conduct and prepare at least two (2) follow-up reviews and reports, as described below:

1. By no later than six months from the Effective Date of the Agreement, the Company shall submit to the United States a written report setting forth a description of the Company's remediation efforts to date (including those that took place prior to the Effective Date), its proposals reasonably designed to improve the Company's policies, procedures, and internal controls for ensuring compliance with the criminal antitrust laws, and the proposed scope of the subsequent reviews. The report shall be transmitted to Ryan Tansey, Chief, Washington Criminal I Section, Antitrust Division, U.S. Department of Justice, 450 Fifth St. NW, Suite 11300, Washington, DC, 20530. The Company may extend the time period for issuance of the report with prior written approval of the United States. The United States may respond to the report by requesting additional information and/or requesting that the Company take further action to improve its policies, procedures, and internal controls for ensuring compliance with the criminal antitrust laws.

2. The Company shall undertake at least two follow-up reviews, and the Company shall submit to the United States a written report setting forth a description of each follow-up review. The follow-up reviews and reports shall incorporate comments from the United States

# Case 2:20-cr-00200-RBS Document 186 Filed 08/21/23 Page 30 of 46

on the Company's prior reviews and reports, to further monitor and assess whether the Company's policies, procedures, and internal controls are reasonably designed to detect and prevent violations of the criminal antitrust laws.

3. The first follow-up review and report shall be submitted to the United States by no later than one year after the initial report is submitted to the United States. The second follow-up review and report shall be submitted to the United States no later than thirty days before the end of the Term.

4. The reports likely will include proprietary, financial, confidential, and competitive business information. Public disclosure of the reports could discourage cooperation and impede pending or potential government investigations, and thus undermine the objectives of the reporting requirement. For these reasons, among others, the reports and the contents thereof are intended to remain and shall remain non-public, except as otherwise agreed to by the parties in writing, or except to the extent that the United States determines in its sole and reasonable discretion that disclosure would be in furtherance of the United States' discharge of its duties and responsibilities or is otherwise required by law.

5. The Company may extend the period for submission of any of the follow-up reports with prior written approval of the United States.

### **Attachment E: Divestiture and Monitor**

As part of the Deferred Prosecution Agreement between TEVA PHARMACEUTICALS USA, INC. (the "Company") and the United States Department of Justice, Antitrust Division ("United States") dated August 21, 2023 ("Agreement"), the Company agrees that it will divest the generic drug pravastatin and retain a Monitor (the "Monitor") to facilitate, review, and report on the Company's efforts to complete this divestiture.

# I. **DEFINITIONS**

As used in this Attachment E:

1. "Divestiture Assets" means all rights, title, and interest in and to all assets solely and exclusively related to the Divestiture Products, as defined below, to the extent legally transferable, as well as any non-exclusive licenses necessary to facilitate the divestiture; and

2. "Divestiture Products" means the products manufactured, marketed, sold, owned, and/or controlled by the Company as of the Effective Date pursuant to Abbreviated New Drug Application Nos. 076056 and 077793, and any supplements, amendments, or revisions thereto.

# II. COMPANY'S DIVESTITURE OBLIGATIONS

1. The Company shall use best efforts to divest the Divestiture Assets as expeditiously as possible, and until the divestiture is complete, shall take no action that would jeopardize the completion of the divestiture required by this Attachment E, including any action that would impede the permitting, operation, or divestiture of the Divestiture Assets.

 The Company shall use best efforts to ensure that supply to the market of Divestiture Products is not diminished, lessened, or compromised during the process described in this Attachment E.

# Case 2:20-cr-00200-RBS Document 186 Filed 08/21/23 Page 32 of 46

3. Within three months of the Effective Date of the Agreement, the Company shall use best efforts to select, as described in section IV of this Attachment E, a third-party purchaser (the "Third-Party Purchaser") that is acceptable to the United States, in its sole discretion, and that, in the United States' sole judgment, has the intent and capability, including the necessary managerial, operational, technical, and financial capability, to compete effectively in the manufacture, production, and sale of the Divestiture Products.

4. Following the United States' approval of the proposed Third-Party Purchaser, the Company shall use best efforts to enter into a binding agreement with such Third-Party Purchaser ("Divestiture Agreement") within six months of receiving such approval. The Divestiture Agreement may not be consummated until the United States, in its sole discretion, has provided written notice that it does not object, as described in section IV of this Attachment E. The Divestiture Agreement must include the transfer of assets sufficient for the Third-Party Purchaser to compete effectively in the manufacture, production, and sale of the Divestiture Products.

5. The Divestiture Agreement shall include terms that (a) facilitate the Third-Party Purchaser's marketing and sale of the Divestiture Products in the United States as expeditiously as possible, (b) facilitate the expeditious transfer, from the Company to the Third-Party Purchaser (or a contract manufacturer of the Third-Party Purchaser's choosing), of all technology needed to manufacture the Divestiture Products, and (c) obligate the Company to supply the Divestiture Products to the Third-Party Purchaser at a reasonable price, until such technology transfer has been completed, and the Third-Party Purchaser (or the contract manufacturer of its choosing) can manufacture the Divestiture Products.

# Case 2:20-cr-00200-RBS Document 186 Filed 08/21/23 Page 33 of 46

6. The Company shall use best efforts to assist the Third-Party Purchaser to obtain all necessary licenses, registrations, and permits to operate the Divestiture Assets, including to manufacture, produce, and sell the Divestiture Products. Until the Third-Party Purchaser obtains the necessary licenses, registrations, and permits, the Company shall provide Third-Party Purchaser with the benefit of the Company's licenses, registrations, and permits to the fullest extent permissible by law. However, the Company and the Third-Party Purchaser will each pay for their own expenses incurred in facilitating the divestiture of the Divestiture Assets. The Company, pursuant to the terms of its National Drug Rebate Agreement for the Medicaid Drug Rebate Program, will continue to be responsible for price reporting and rebates for Divestiture Products that are labeled with the Company's labeler code.

7. From the Effective Date of the DPA, and until the divestitures required by this Attachment E have been accomplished, the Company shall take all actions necessary to operate, preserve, and maintain the full economic viability, marketability, and competitiveness of the Divestiture Assets.

8. Unless the United States otherwise consents in writing, divestiture pursuant to this Attachment E shall include all relevant Divestiture Assets and shall be accomplished in such a way as to satisfy the United States, in its sole discretion, that (a) the Divestiture Assets can and will be used by the Third-Party Purchaser as part of a viable, ongoing business to manufacture and sell the Divestiture Products and (b) the divestiture to Third-Party Purchaser will remedy the competitive harm alleged in the Indictment.

9. Once the Company has effectuated the divestiture contemplated by this Attachment E, the Company shall not sell any Divestiture Products (or any other generic pravastatin) in the United States for five (5) years following the date the divestiture is

### Case 2:20-cr-00200-RBS Document 186 Filed 08/21/23 Page 34 of 46

effectuated, except that after the divestiture is effectuated, the Company may continue to sell any remaining inventory of Divestiture Products it has on hand until such inventory is depleted.

# **III. SELECTION AND INSTALLATION OF MONITOR**

1. The Company shall install the Monitor, and shall reach agreement on the Monitor's terms and conditions of engagement and compensation, following the process set forth below. Prior to beginning work, the parties shall ensure that the Monitor consents to be bound by the applicable provisions of this Attachment E.

2. The Company shall retain the Monitor until the later of (a) the completion of the divestiture of the Divestiture Assets (including transfer by the Company to the Third-Party Purchaser of the technology needed to manufacture the Divestiture Products, if necessary), or (b) the appointment of a Divestiture Trustee as contemplated by this Attachment E (the "Monitorship Term").

3. Within fourteen (14) days of the Effective Date, the Company shall propose to the United States a pool of three (3) qualified candidates to serve as Monitor. The Monitor candidates shall have, at a minimum, the following qualifications: (a) demonstrated expertise in the role of serving as monitor for divestitures of pharmaceutical products in competition matters as required by the Federal Trade Commission requirements and applicable industry regulations; (b) the ability to access and deploy resources as necessary to discharge the Monitor's duties as described below; and (c) sufficient independence from the Company to ensure effective and impartial performance of the Monitor's duties as described below.

4. At the time the Company recommends the pool of Monitor candidates, the Company shall provide the United States a written certification that each of the Monitor

# Case 2:20-cr-00200-RBS Document 186 Filed 08/21/23 Page 35 of 46

candidates is not an employee or agent of the Company and holds no interest in, or has no relationship with, the Company, or any of its attorneys, officers, directors, employees, or agents.

5. The United States retains the right, in its sole discretion, to choose the Monitor from among the pool of candidates proposed by the Company. If, in its sole discretion, the United States determines that none of the candidates are qualified to serve as Monitor, or is not satisfied with the candidates proposed, the United States may request that the Company nominate additional candidates. In the event the United States rejects all proposed monitors, the Company shall propose an additional three (3) candidates within fifteen (15) calendar days after receiving notice of the rejection. This process shall continue until a Monitor acceptable to both parties has been chosen. If, during the Monitorship Term, the Monitor becomes unable to perform his or her obligations, or if the United States in its sole discretion determines that the Monitor cannot fulfill such obligations to the satisfaction of the United States, the United States shall notify the Company of such Monitor's release. Within fifteen (15) calendar days of such notice, the Company shall recommend a pool of three (3) qualified Monitor candidates from which the United States will choose a replacement using the process described above.

6. The Company shall install the Monitor within thirty (30) calendar days of the Government's selection of the Monitor.

7. The Monitor shall serve at the cost and expense of the Company pursuant to a written agreement, on terms and conditions, including confidentiality requirements and conflict of interest certifications, approved by the United States in its sole discretion.

 The Monitor may hire, at the cost and expense of the Company, agents and consultants that are necessary in the Monitor's judgment to assist with the Monitor's duties.
 These agents or consultants shall be solely accountable to the Monitor and will serve subject to

# Case 2:20-cr-00200-RBS Document 186 Filed 08/21/23 Page 36 of 46

the same terms and conditions, including confidentiality requirements and conflict-of-interest certifications, as the Monitor.

9. The compensation of the Monitor and agents or consultants retained by the Monitor must be on reasonable and customary terms commensurate with the individuals' experience and responsibilities. Within three business days of hiring any agents or consultants, the Monitor shall provide written notice of the hiring and the rate of compensation to the Company and the United States.

10. The Monitor shall account for all costs and expenses incurred.

# Monitor's Mandate

11. The Company may not object to actions taken by the Monitor in fulfillment of the Monitor's responsibilities on any ground other than malfeasance by the Monitor. Objections by the Company must be conveyed in writing to the United States and the Monitor within 10 calendar days of the Monitor's action that gives rise to the Company's objection.

12. The Monitor shall be responsible for assessing and monitoring the Company's compliance with the terms and conditions of this Attachment E to the Agreement. During the Monitorship Term, the Monitor will:

- *a.* evaluate the effectiveness of the Company's efforts to complete the divestiture detailed above;
- *b.* act in consultation with the United States;
- c. serve as an independent third party and not as an employee or agent of theCompany or the United States;

- d. enter into a non-disclosure or other confidentiality agreement with the
  Company related to materials and information received in connection with
  the Monitor's performance of the Monitor's duties;
- e. notify the Company and the United States, in writing, no later than 5 days in advance of entering into any agreement that creates a conflict of interest, or the appearance of a conflict of interest, including a financial, professional, or personal conflict; and
- *f*. report in writing to the United States concerning the Company's compliance with this Attachment E on a schedule as determined by the United States, and at any other time requested by the United States.

These tasks collectively represent the Monitor's "Mandate". This Mandate shall include an assessment of the Board of Directors' and senior management's commitment to the obligations in this Attachment E.

# Company's Obligations with Respect to the Monitor

13. The Company shall cooperate fully with the Monitor, and the Monitor shall have the authority to take such reasonable steps as, in his or her view, may be necessary to fulfill the Mandate. The Company shall provide the Monitor with access to all information, documents, records, facilities, and employees, as reasonably requested by the Monitor, that fall within the scope of the Mandate.

14. Neither the Company nor anyone acting on its behalf shall retaliate against the Monitor for any recommendations, reports, or disclosures the Monitor makes during the course of the Monitorship.

## Withholding Access

15. The parties agree that no attorney-client relationship shall be formed between the Company and the Monitor. In the event that the Company seeks to withhold from the Monitor access to information, documents, records, facilities, or current or former employees of the Company that may be subject to a claim of attorney-client privilege, the attorney work-product doctrine, or any similar legal privilege, or where the Company reasonably believes production would otherwise be inconsistent with applicable law, the Company shall work cooperatively with the Monitor to resolve the matter to the satisfaction of the Monitor.

16. If the matter cannot be resolved, at the request of the Monitor, the Company shall promptly provide written notice to the United States with a copy to the Monitor. Such notice shall include a general description of the nature of the information, documents, records, facilities or current or former employees that are being withheld, as well as the legal basis for withholding access. The United States may then consider whether to make a further request for access to such information, documents, records, facilities, or employees.

### Monitor's Coordination with the Company and Review Methodology

17. In carrying out the Mandate, to the extent appropriate under the circumstances, the Monitor shall coordinate with Company personnel, including in-house counsel, on an ongoing basis.

18. In undertaking the reviews to carry out the Mandate, the Monitor shall formulate conclusions based on, among other things: (a) inspection of relevant documents; and (b) meetings with, and interviews of, relevant current and, where appropriate, former directors, officers, employees, business partners, agents, and other persons at mutually convenient times and places.

# Contemplated Confidentiality of Monitor's Reports

19. The parties acknowledge that the Monitor's reports will likely include proprietary, financial, confidential, and competitive business information. Moreover, public disclosure of the reports could discourage cooperation, or impede pending or potential government investigations and thus undermine the objectives of the Monitorship. For these reasons, among others, the reports and the contents thereof are intended to remain and shall remain non-public, except as otherwise agreed to by the parties in writing, or except to the extent that the United States determines in its sole discretion that disclosure would be in furtherance of the United States' discharge of its duties and responsibilities or is otherwise required by law.

# IV. NOTICE OF PROPOSED DIVESTITURE

1. Within two business days following selection of a Third-Party Purchaser, the Company must notify the Monitor of the proposed Third-Party Purchaser. Such notice will include the name, address, and telephone number of each person not previously identified who offered or expressed an interest in or desire to acquire any ownership interest in the Divestiture Assets. The Company's selection of the Third-Party Purchaser will be subject to approval of the United States in consultation with the Monitor. If a divestiture trustee has been appointed, the divestiture trustee must notify the United States of the selection of a Third-Party Purchaser.

2. Within two business days following execution of a definitive agreement with the approved Third-Party Purchaser to divest the Divestiture Assets, the Company must notify the Monitor of the proposed divestiture, and provide a copy of the executed agreement. The executed agreement will be subject to approval of the Monitor in consultation with the United States. If the divestiture trustee is responsible for completing the divestiture, the divestiture

## Case 2:20-cr-00200-RBS Document 186 Filed 08/21/23 Page 40 of 46

trustee must notify the United States and the Company within two business days following the execution of a definitive agreement, and provide the agreement to the United States at that time.

3. After receipt of the notices required by the prior paragraphs of this section, the United States or Monitor may make one or more requests to the Company or the divestiture trustee for additional information concerning the proposed divestiture, the proposed Third-Party Purchaser, and other prospective Third-Party Purchasers. The Company or the divestiture trustee must furnish any additional information requested within 15 days of the receipt of each request.

4. Within 15 days after receipt of the notices required by Paragraphs 1 and 2 of this section, or within 15 days after the United States has been provided the additional information requested pursuant to Paragraph 3 of this section, whichever is later, the United States will provide written notice to the Monitor and the Company that states whether the United States objects to the proposed Third-Party Purchaser or any other aspect of the proposed divestitures. Without written notice that the United States does not object, a divestiture may not be consummated. If the United States provides written notice that it does not object, the divestiture may be consummated, subject only to the Company's limited right to object to the sale under the paragraph of this Attachment E governing right to object to a sale by a divestiture trustee. Upon objection by the Company, a divestiture by the divestiture trustee may not be consummated unless approved by the United States.

# V. FAILURE TO TIMELY DIVEST – DIVESTITURE TRUSTEE APPOINTED

1. If the Company has not, within the time periods specified above: (i) selected a Third-Party Purchaser that has been approved by the United States, (ii) entered into a Divestiture Agreement approved by the United States to effectuate the divestiture to the Acquirer, and/or (iii) divested all of the Divestiture Assets (including transfer by the Company to the Third-Party

## Case 2:20-cr-00200-RBS Document 186 Filed 08/21/23 Page 41 of 46

Purchaser of the technology needed to manufacture the Divestiture Products, if necessary) within thirty (30) months of the Effective Date of the DPA, the Company must immediately notify the United States of that fact in writing. Subsequent to such notification by the Company, the United States may seek through the Court, and the Company shall not oppose, the appointment of a divestiture trustee selected by the United States to effectuate the divestiture of any of the Divestiture Assets that have not been sold during the specified time periods (the "Divestiture Trustee"). Prior to beginning work, the parties shall ensure that the Divestiture Trustee consents to be bound by the applicable provisions of this Attachment E.

2. After the appointment of a Divestiture Trustee by the Court, only the Divestiture Trustee shall have the right to sell the Divestiture Assets. The Divestiture Trustee shall have the power and authority to accomplish the divestitures to a third-party purchaser acceptable to the United States, in its sole discretion, at a commercially reasonable price and on commercially reasonable terms, and shall have other powers as the Court deems appropriate. The Divestiture Trustee shall have the power and authority to ensure that the Divestiture Assets can and will be used by the Third-Party Purchaser as part of a viable, ongoing business in the manufacture, production, and sale of the Divestiture Products, in order to remedy the competitive harm alleged in the Indictment. The parties acknowledge and agree that the Divestiture Trustee shall be empowered to sell the Divestiture Assets as quickly as reasonably possible.

3. The Company may not object to a sale by the Divestiture Trustee on any ground other than malfeasance by the Divestiture Trustee. Objections by the Company shall be conveyed in writing to the United States and the Divestiture Trustee within 10 calendar days after the Divestiture Trustee has provided the notice of proposed divestiture.

# Case 2:20-cr-00200-RBS Document 186 Filed 08/21/23 Page 42 of 46

4. The Divestiture Trustee shall serve at the cost and expense of the Company pursuant to a written agreement, on terms and conditions, including confidentiality requirements and conflict of interest certifications, approved by the United States in its sole discretion.

5. The Divestiture Trustee may hire at the cost and expense of the Company any agents or consultants, including investment bankers, attorneys, and accountants, that are reasonably necessary in the Divestiture Trustee's judgment to assist with the Divestiture Trustee's duties. These agents or consultants will be accountable solely to the Divestiture Trustee and will serve subject to the same terms and conditions, including confidentiality requirements and conflict-of-interest certifications, as the Divestiture Trustee.

6. The compensation of the Divestiture Trustee and agents or consultants hired by the Divestiture Trustee must be reasonable in light of the value of the Divestiture Assets and based on a fee arrangement that provides the Divestiture Trustee with incentives based on the price and terms of the divestiture and the speed with which it is accomplished. If the Divestiture Trustee and the Company are unable to reach agreement on the Divestiture Trustee's compensation or other terms and conditions of engagement within 14 calendar days of the appointment of the Divestiture Trustee by the Court, the United States, in its sole discretion, may take appropriate action, including by making a recommendation to the Court. Within three business days of hiring an agent or consultant, the Divestiture Trustee shall provide written notice of the hiring and rate of compensation to the Company and the United States.

7. The Divestiture Trustee shall account for all monies derived from the sale of the Divestiture Assets sold by the Divestiture Trustee and all costs and expenses incurred. Within 30 calendar days of the divestiture of the Divestiture Assets by the Divestiture Trustee, he/she shall submit that accounting to the Court for approval. After approval by the Court of the Divestiture

#### Case 2:20-cr-00200-RBS Document 186 Filed 08/21/23 Page 43 of 46

Trustee's accounting, including fees for unpaid services and those of agents or consultants hired by the Divestiture Trustee, all remaining money shall be paid to the Company and the trustee will then be terminated.

8. The Company shall use best efforts to assist the Divestiture Trustee to accomplish the required divestiture. Subject to reasonable protection for trade secrets, other confidential research, development, or commercial information, or any applicable privileges, the Company shall provide the Divestiture Trustee and agents or consultants retained by the Divestiture Trustee with full and complete access to all personnel, books, records, and facilities of the Divestiture Assets. The Company also shall provide or develop financial and other information relevant to the Divestiture Assets that the Divestiture Trustee may reasonably request. The Company shall not take any action to interfere with or to impede the Divestiture Trustee's accomplishment of the divestiture.

9. The Divestiture Trustee shall maintain complete records of all efforts made to sell the Divestiture Assets, including by filing monthly reports with the United States setting forth the Divestiture Trustee's efforts to accomplish the divestitures required by this Attachment E. The reports shall include the name, address, and telephone number of each person who, during the preceding month, made an offer to acquire, expressed an interest in acquiring, entered into negotiations to acquire, or was contacted or made an inquiry about acquiring any interest in the Divestiture Assets and must describe in detail each contact.

10. If the Divestiture Trustee has not accomplished the divestitures required by this Attachment E within six months of appointment, the Divestiture Trustee shall promptly provide the United States with a report setting forth: (1) the Divestiture Trustee's efforts to accomplish the required divestitures; (2) the reasons, in the Divestiture Trustee's judgment, why the required

## Case 2:20-cr-00200-RBS Document 186 Filed 08/21/23 Page 44 of 46

divestitures have not been accomplished; and (3) the Divestiture Trustee's recommendations for completing the divestitures. Following receipt of that report, the United States may make additional recommendations to the Court. The Court thereafter may enter such orders as it deems appropriate to carry out the purpose of this Attachment E and its Order, which may include extending the trust and the term of the Divestiture Trustee's appointment by a period requested by the United States.

11. The Divestiture Trustee shall serve until divestiture of all Divestiture Assets is completed or for a term otherwise ordered by the Court.

12. If the United States determines that the Divestiture Trustee is not acting diligently or in a reasonably cost-effective manner, the United States may recommend that the Court appoint a substitute Divestiture Trustee.

# VI. OTHER PROVISIONS

1. If, prior to complying with the provisions of this Attachment E, the Company sells or otherwise disposes of all or substantially all of its assets or of business units that include the Divestiture Assets, the Company must require any purchaser to be bound by the provisions of this Attachment E.

2. The Company may not reacquire any part of or any interest in the Divestiture Assets for five (5) years following the date the divestiture is effectuated without prior authorization of the United States.

# **Attachment F: Certification**

To: United States Department of Justice Antitrust Division Attention: Washington Criminal I section

Re: Deferred Prosecution Agreement Disclosure Certification

The undersigned certify, pursuant to Paragraph 26 of the Deferred Prosecution Agreement filed on August 21, 2023 in the U.S. District Court for the Eastern District of Pennsylvania, by and between the United States Department of Justice, Antitrust Division ("United States") and Teva Pharmaceuticals USA, Inc. ("Company") dated August 21, 2023 ("Agreement"), that the undersigned are aware of the Company's disclosure obligations under Paragraph 7 of the Agreement and that the Company has disclosed to the United States any and all evidence or allegations of conduct required pursuant to Paragraph 7 of the Agreement ("Disclosable Information"). This obligation to disclose information extends to any and all Disclosable Information that has been identified through the Company's compliance program, whistleblower channel, internal audit reports, due diligence procedures, investigation process, or other Company sources and processes. The undersigned further acknowledge and agree that the reporting requirement contained in Paragraph 7 and the representations contained in this certification constitute a significant and important component of the Agreement and the United States' determination whether the Company has satisfied its obligations under the Agreement.

The undersigned hereby certify, respectively, that they are the Executive Vice President (North American Commercial) of the Company and the General Counsel of the Company, and that each has been duly authorized by the Company to sign this Certification on behalf of the Company.

# Case 2:20-cr-00200-RBS Document 186 Filed 08/21/23 Page 46 of 46

This Certification shall constitute a material statement and representation by the undersigned and by, on behalf of, and for the benefit of, the Company to the executive branch of the United States for purposes of 18 U.S.C. § 1001, and such material statement and representation shall be deemed to have been made in the Eastern District of Pennsylvania. This Certification shall also constitute a record, document, or tangible object in connection with a matter within the jurisdiction of a department and agency of the United States for purposes of 18 U.S.C. § 1519, and such record, document, or tangible object shall be deemed to have been made in the Eastern District of Pennsylvania.

By:

Date:

Sven Dethlefs Executive Vice President (North American Commercial) Teva Pharmaceuticals USA, Inc.

By:

Date:

Brian Savage Senior Vice President, General Counsel Teva Pharmaceuticals USA, Inc.