

**UNITED STATES OF AMERICA**  
**Before the**  
**SECURITIES AND EXCHANGE COMMISSION**

**SECURITIES EXCHANGE ACT OF 1934**  
**Release No. 78730 / August 30, 2016**

**ACCOUNTING AND AUDITING ENFORCEMENT**  
**Release No. 3798 / August 30, 2016**

**ADMINISTRATIVE PROCEEDING**  
**File No. 3-17517**

**In the Matter of**

**ASTRAZENECA PLC**

**Respondent.**

**ORDER INSTITUTING CEASE-AND-DESIST PROCEEDINGS PURSUANT TO SECTION 21C OF THE SECURITIES EXCHANGE ACT OF 1934, MAKING FINDINGS, AND IMPOSING A CEASE-AND-DESIST ORDER**

**I.**

The Securities and Exchange Commission (“Commission”) deems it appropriate that cease-and-desist proceedings be, and hereby are, instituted pursuant to Section 21C of the Securities Exchange Act of 1934 (“Exchange Act”), against AstraZeneca PLC (“AZN” or “Respondent”).

**II.**

In anticipation of the institution of these proceedings, Respondent has submitted an Offer of Settlement (the “Offer”) which the Commission has determined to accept. Solely for the purpose of these proceedings and any other proceedings brought by or on behalf of the Commission, or to which the Commission is a party, and without admitting or denying the findings herein, except as to the Commission’s jurisdiction over it and the subject matter of these proceedings, which are admitted, Respondent consents to the entry of this Order Instituting Cease-and-Desist Proceedings Pursuant to Section 21C of the Securities Exchange Act of 1934, Making Findings, and Imposing a Cease-and-Desist Order (“Order”), as set forth below.

### III.

On the basis of this Order and Respondent's Offer, the Commission finds<sup>1</sup> that:

#### **SUMMARY**

These proceedings arise out of violations of the internal controls and recordkeeping provisions of the Foreign Corrupt Practices Act (the "FCPA") by AZN and its wholly-owned subsidiaries in China and Russia. Through at least 2010, AZN failed to devise and maintain a sufficient system of internal accounting controls relating to the interactions of its China and Russia subsidiaries with government officials, the vast majority of whom were health care providers ("HCPs"), at state-owned and state-controlled entities in China and Russia. Sales and marketing staff, along with multiple levels of management at the two AZN subsidiaries, designed and authorized several schemes to make improper payments of gifts, conference support, travel, cash and other benefits to HCPs to reward or influence their purchases of AZN pharmaceuticals. In addition, employees in the China subsidiary made cash payments to local officials to reduce or avoid fines that were levied against the China subsidiary. AZN falsely recorded all of the improper payments by its China and Russia subsidiaries as bona fide business expenses in its consolidated financial statements.

#### **RESPONDENT**

1. AZN is a global biopharmaceutical company incorporated in the U.K. and headquartered in London. Throughout the relevant period, AZN's American Depositary Shares have been registered with the Commission pursuant to Section 12(b) of the Exchange Act and publicly traded on the New York Stock Exchange (NYSE: AZN), as well as the London and Stockholm Exchanges. AZN files annual and quarterly reports as required under Section 13 of the Exchange Act and Rules thereunder.

#### **OTHER RELEVANT ENTITIES**

2. AstraZeneca (Wuxi) Trading Co. Limited ("AZ China") is a wholly-owned subsidiary of AZN and was responsible for AZN's sales and marketing functions in China during the relevant period.

3. AstraZeneca UK Limited is a wholly-owned subsidiary of AZN and had a representative office in Russia through which AZN operated in Russia prior to 2007.

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<sup>1</sup> The findings herein are made pursuant to Respondent's Offer of Settlement and are not binding on any other person or entity in this or any other proceeding.

4. OOO AstraZeneca Pharmaceuticals is a wholly-owned subsidiary of AZN through which it has operated in Russia since 2007. (AstraZeneca UK Limited's representative office in Russia and OOO AstraZeneca Pharmaceuticals are referred to individually or collectively herein as "AZ Russia.")

## FACTS

### *Improper Conduct at AZ China*

5. From 2007 until 2010, AZ China sales staff made numerous improper payments in cash, gifts and other items to HCPs as incentives to purchase or prescribe AZN pharmaceuticals. Sales and marketing team members, including managers within various business units at AZ China, designed and implemented the improper payment schemes. The HCPs who received the improper incentives worked for various government entities in several regions throughout China.

6. Between at least 2006 and 2009, certain AZ China sales staff and their managers maintained written charts and schedules that recorded the amount of forecasted or actual payments of maintenance fees, gifts, entertainment and other expenses that AZ China would make per month or year in numerous regions throughout China. In some cases, the payments referenced gifts, entertainment and other expenses to individual physicians, and in other cases, maintenance fees to a particular hospital or medical department, as designated by an individual physician. AZ China sales staff management approved these payments with the expectation that the HCPs would increase purchases of AZN products during the corresponding period, or favorably influence the inclusion of AZN products on formulary or reimbursement drug listings.

7. In numerous instances, AZ China sales staff submitted, and managerial employees knowingly approved, fake *fa piao* (tax receipts) for fraudulent reimbursements to generate cash that was used to make improper payments to HCPs.

8. Other methods were also used, such as establishing bank accounts in doctors' names as part of an improper payment scheme, or engaging a collusive travel vendor who submitted fake or inflated invoices to generate cash that could be used to funnel money to HCPs.

9. As a result of the deficient controls, AZ China employees were regularly reimbursed for submitted expenses despite inadequate supporting documentation.

10. Similarly, AZ China paid speaker fees to HCPs despite AZ China service contracts that were incomplete, containing no meeting date, venue, subject or fees associated with the particular speaker event. In some instances, the related speaker engagement was totally fabricated and never occurred. Additionally, sales and marketing team members were able to bypass formal approval procedures that required validation by a designated signatory in the company's electronic approval system.

11. In addition, in connection with inquiries by local Chinese government officials in 2008, AZ China employees made payments in cash to the local officials to get reductions or dismissals of proposed financial sanctions against the subsidiary.

### ***Improper Conduct at AZ Russia***

12. From at least 2005 until 2010, AZ Russia employees provided improper incentives to government-employed HCPs in connection with sales of AZN pharmaceutical products.

13. As was done by AZ China employees, AZ Russia employees created and maintained charts tracking the names of HCPs, the regions in which they practiced, their level of influence in making purchasing decisions for the respective entities where they worked and the manner in which they could be motivated to purchase AZN products through gifts, conference support and other means.

14. Employees at several levels of AZ Russia management directed or condoned their subordinates' practices of providing improper benefits to government-employed HCPs, which occurred in multiple regions where AZ Russia operates.

### **COOPERATION AND REMEDIAL EFFORTS**

15. AZN did not self-report its violations; nevertheless, the company provided significant cooperation to the Commission during the entire course of its investigation. AZN immediately took a cooperative posture and ensured that it consistently provided complete information in a timely manner. AZN voluntarily and timely disclosed information obtained during its own internal investigation, provided translations of key documents, and disclosed facts that the Commission would not have been able to readily and independently discover. AZN also kept the staff regularly informed of its ongoing remedial efforts throughout the course of the investigation.

16. AZN had begun independently remediating deficiencies in its compliance program prior to the Commission's investigation. The company incorporated information developed in the course of the Commission's investigation to further enhance its controls and compliance program. AZN made significant increases to both capital and human resources available to compliance at the corporate level and in the local markets. It has developed a centralized compliance program, revamped its internal controls and procedures, and placed key compliance personnel in high-risk local markets. Among the other improvements made are enhancements to AZN's policies governing interactions with HCPs and government officials, gifts, travel and entertainment, third-party engagements, meetings, congresses, and contributions. AZN also enhanced its anti-corruption training and audits. Additionally, AZN has taken various steps with regard to involved employees, including targeted training, reassignment to lower-risk areas of responsibility, voluntary separations, and dismissals.

### **LEGAL STANDARDS**

17. Under Section 21C(a) of the Exchange Act, the Commission may impose a cease-and-desist order upon any person who is violating, has violated or is about to violate any provision of the Exchange Act or any rule or regulation thereunder or any other person that is, was or would

be a cause of the violation due to an act or omission the person knew or should have known would contribute to such violation.

### ***Violations of the Books and Records and Internal Controls Provisions of the FCPA***

18. Section 13(b)(2)(A) of the Exchange Act, the books and records provision of the FCPA, requires every issuer with a class of securities registered pursuant to Section 12 of the Exchange Act “to make and keep books, records, and accounts, which, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the issuer.” 15 U.S.C. § 78m(b)(2)(A). As described above, AZN violated Section 13(b)(2)(A) when its subsidiaries mischaracterized improper payments as legitimate expenses in AZN’s books and records.

19. Section 13(b)(2)(B) of the Exchange Act, the internal controls provision of the FCPA, requires every issuer with a class of securities registered pursuant to Section 12 of the Exchange Act to “devise and maintain a system of internal accounting controls sufficient to provide reasonable assurances that (i) transactions are executed in accordance with management’s general or specific authorization; (ii) transactions are recorded as necessary (I) to permit preparation of financial statements in conformity with generally accepted accounting principles or any other criteria applicable to such statements, and (II) to maintain accountability for assets; (iii) access to assets is permitted only in accordance with management’s general or specific authorization; and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences.” 15 U.S.C. § 78m(b)(2)(B).

20. As described above, AZN violated Section 13(b)(2)(B) of the Exchange Act by failing to devise and maintain a sufficient system of internal accounting controls relating to employee reimbursements, third-party vendors, speaker fees, conferences, gifts, travel and entertainment. AZN did not adequately enforce its corporate policy against making improper payments to government officials with respect to its subsidiaries in Russia and China. Although the company had a written policy that prohibited these unauthorized transactions, AZN did not employ reasonable controls to detect and prevent such improper payments. AZN failed to ensure that its Russia and China subsidiaries maintained accurate and complete recording of financial transactions referencing payments to government officials. These records never appropriately described the transactions, and were always inaccurate or incomplete, when the purpose of the payment involved an improper incentive to the government official. The company also did not employ reasonable measures to ensure that sponsorship activities involving government officials in China were appropriately approved through the company’s established electronic system by a pre-designated official in the country. Additionally, AZN did not provide adequate FCPA training to its sales and marketing employees in China and Russia who had routine interactions with government officials in the healthcare industry that posed a high risk for bribery and corruption. Furthermore, AZN did not employ reasonable due diligence and monitoring of third-party contractors engaged by its China and Russia subsidiaries, such as travel vendors who provided false invoices to the subsidiaries’ employees that facilitated the unauthorized use of corporate funds to improperly incentivize HCPs.

#### IV.

In view of the foregoing, the Commission deems it appropriate to impose the sanctions agreed to in Respondent AZN's Offer.

Accordingly, it is hereby ORDERED that:

A. Pursuant to Section 21C of the Exchange Act, Respondent AstraZeneca PLC cease and desist from committing or causing any violations and any future violations of Sections 13(b)(2)(A) and 13(b)(2)(B) of the Exchange Act [15 U.S.C. §§ 78m(b)(2)(A) and 78m(b)(2)(B)].

B. Respondent shall, within fourteen (14) days of the entry of this Order, pay disgorgement of \$4,325,000, which represents profits gained as a result of the conduct described herein, prejudgment interest of \$822,000, and a civil money penalty of \$375,000 to the Securities and Exchange Commission for transfer to the general fund of the United States Treasury, subject to Exchange Act Section 21F(g)(3). If timely payment of disgorgement and prejudgment interest is not made, additional interest shall accrue pursuant to SEC Rule of Practice 600, and if timely payment of a civil money penalty is not made, additional interest shall accrue pursuant to 31 U.S.C. § 3717. Payment must be made in one of the following ways:

- (1) Respondent may transmit payment electronically to the Commission, which will provide detailed ACH transfer/Fedwire instructions upon request;
- (2) Respondent may make direct payment from a bank account via Pay.gov through the SEC website at <http://www.sec.gov/about/offices/ofm.htm>; or
- (3) Respondent may pay by certified check, bank cashier's check, or United States postal money order, made payable to the Securities and Exchange Commission and hand-delivered or mailed to:

Enterprise Services Center  
Accounts Receivable Branch  
HQ Bldg., Room 181, AMZ-341  
6500 South MacArthur Boulevard  
Oklahoma City, OK 73169

Payments by check or money order must be accompanied by a cover letter identifying AstraZeneca PLC as a Respondent in these proceedings, and the file number of these proceedings; a copy of the cover letter and check or money order must be sent to Charles E. Cain, Deputy Chief, Foreign Corrupt Practices Act Unit, Division of Enforcement, Securities and Exchange Commission, 100 F Street, N.E., Washington, DC 20549-5648.

C. Amounts ordered to be paid as civil money penalties pursuant to this Order shall be treated as penalties paid to the government for all purposes, including all tax purposes. To preserve the deterrent effect of the civil penalty, Respondent agrees that in any Related Investor Action, it shall not argue that it is entitled to, nor shall it benefit by, offset or reduction of any award of compensatory damages by the amount of any part of Respondent's payment of a civil penalty in this action ("Penalty Offset"). If the court in any Related Investor Action grants such a Penalty Offset, Respondent agrees that it shall, within 30 days after entry of a final order granting the Penalty Offset, notify the Commission's counsel in this action and pay the amount of the Penalty Offset to the Securities and Exchange Commission. Such a payment shall not be deemed an additional civil penalty and shall not be deemed to change the amount of the civil penalty imposed in this proceeding. For purposes of this paragraph, a "Related Investor Action" means a private damages action brought against Respondent by or on behalf of one or more investors based on substantially the same facts as alleged in the Order instituted by the Commission in this proceeding.

D. Respondent acknowledges that the Commission is not imposing a civil penalty in excess of \$375,000 based upon its cooperation in a Commission investigation and related enforcement action. If at any time following the entry of the Order, the Division of Enforcement ("Division") obtains information indicating that Respondent knowingly provided materially false or misleading information or materials to the Commission, or in a related proceeding, the Division may, at its sole discretion and with prior notice to the Respondent, petition the Commission to reopen this matter and seek an order directing that the Respondent pay an additional civil money penalty. Respondent may contest by way of defense in any resulting administrative proceeding whether it knowingly provided materially false or misleading information, but may not: (1) contest the findings in the Order; or (2) assert any defense to liability or remedy, including, but not limited to, any statute of limitations defense.

By the Commission.

Brent J. Fields  
Secretary