# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# **FORM SD**

## SPECIALIZED DISCLOSURE REPORT

# **NOVARTIS AG**

(Exact name of the registrant as specified in its charter)

Switzerland

(State or other jurisdiction of incorporation or organization)

1-15024

(Commission File Number)

98-0363351

(IRS Employer Identification No.)

Lichtstrasse 35 4056 Basel, Switzerland

(Address of principal executive offices)

Karen L. Hale Chief Legal Officer Tel.: 011-41-61-324-1111

(Name and telephone number, including area code, of the person to contact in connection with this report.)

Check the appropriate box to indicate the rule pursuant to which this form is being filed, and provide the period to which the information in this form applies:

☑ Rule 13p-1 under the Securities Exchange Act (17 CFR 240.13p-1) for the reporting period from January 1 to December 31, 2020.

## **Section 1. Conflict Minerals Disclosure**

## **Item 1.01 Conflict Minerals Disclosure and Report**

In accordance with Rule 13p-1 under the Securities Exchange Act of 1934 Novartis has filed this Specialized Disclosure Report (Form SD) and the associated Conflict Minerals Report. Both reports are posted and publicly available at the Novartis corporate website: www.novartis.com.

## Item 1.02 Exhibit

The Conflict Minerals Report is attached as Exhibit 1.01.

## Section 2. Exhibits

## **Item 2.01 Exhibits**

Exhibit No. Description

1.01 Conflict Minerals Report as required by Items 1.01 and 1.02 of this Form.

## **SIGNATURES**

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

## **NOVARTIS AG**

By: /s/ Harry Kirsch

Name: Harry Kirsch

Title: Chief Financial Officer, Novartis Group

By: /s/ Karen L. Hale

Name: Karen L. Hale

Title: Chief Legal Officer, Novartis Group

Date: June 1, 2021

## **Conflict Minerals Report of Novartis AG**

#### Overview

This is the Conflict Minerals Report for Novartis AG and its consolidated affiliates for calendar year 2020 in accordance with Section 1502 of the Dodd-Frank Wall Street Reform and Consumer Protection Act ("Section 1502") and Rule 13p-1 under the Securities Exchange Act of 1934 ("Rule 13p-1"). Unless the context requires otherwise, the words "we," "our," "us," "Novartis," "Group," "Company," and similar words or phrases in this Conflict Minerals Report refer to Novartis AG and its consolidated affiliates. We have performed a Reasonable Country of Origin Inquiry ("RCOI") on the conflict minerals that were in our supply chain between January 1 and December 31, 2020, to determine whether these conflict minerals were sourced from the Democratic Republic of Congo or adjoining countries (the "Covered Countries") or came from recycled or scrap sources. The conflict minerals covered by these rules are: tin, tantalum, tungsten and gold (collectively the "Conflict Minerals").

As of the date of this filing, Novartis is a multinational group of companies specializing in the research, development, manufacturing and marketing of a broad range of innovative pharmaceuticals and cost-saving generic medicines. Our purpose is to reimagine medicine to improve and extend people's lives. We use innovative science and technology to address some of society's most challenging healthcare issues. We discover and develop breakthrough treatments and find new ways to deliver them to as many people as possible. Novartis products reach nearly 800 million people globally and we are finding innovative ways to expand access to our latest treatments. About 110,000 people of more than 140 nationalities work at Novartis around the world. Our vision is to become the most valued and trusted medicines company in the world. Our strategy is to build a leading, focused medicines company powered by advanced therapy platforms and data science.

As of the end of 2020, the Group comprised two global operating divisions: Innovative Medicines: innovative patent-protected prescription medicines; and Sandoz: generic pharmaceuticals and biosimilars. We also separately report the results of Corporate activities.

Our Innovative Medicines Division researches, develops, manufactures, distributes and sells patent-protected medicines. Innovative Medicines is organized into two global business units: Novartis Oncology and Novartis Pharmaceuticals. The Novartis Oncology business unit is responsible for the commercialization of products in the areas of cancer and hematologic disorders. The Novartis Pharmaceuticals business unit is organized into the following global business franchises responsible for the commercialization of various products in their respective therapeutic areas: Immunology, Hepatology and Dermatology; Ophthalmology; Neuroscience; Cardiovascular, Renal and Metabolism; Respiratory; and Established Medicines.

Our Sandoz Division develops, manufactures and markets finished dosage form medicines as well as intermediary products including active pharmaceutical ingredients. Sandoz is organized globally into three franchises: Retail Generics, Anti-Infectives and Biopharmaceuticals. In Retail Generics, Sandoz develops, manufactures and markets active ingredients and finished dosage forms of small molecule pharmaceuticals to third parties across a broad range of therapeutic areas, as well as finished dosage form anti-infectives sold to third parties. In Anti-Infectives, Sandoz manufactures and supplies active pharmaceutical ingredients and intermediates — mainly antibiotics — for internal use by Retail Generics and for sale to third-party customers. In Biopharmaceuticals, Sandoz develops, manufactures and markets protein- or other biotechnology-based products, including biosimilars, and provides biotechnology manufacturing services to other companies.

## **Reasonable Country of Origin Inquiry**

In accordance with Section 1502 and Rule 13p-1, we performed an RCOI on Conflict Minerals that were in our supply chain between January 1 and December 31, 2020, to determine whether these Conflict Minerals were sourced from the Covered Countries or came from recycled or scrap sources. As a result of the RCOI process, we concluded in good faith that during 2020 we had reason to believe that certain of the products that we manufactured or contracted to manufacture contained Conflict Minerals, but that we were unable to determine whether the Conflict Minerals originated in the Covered Countries or came from recycled or scrap sources.

#### **Products**

We reviewed for Conflict Minerals content all categories of materials either necessary to the production of our products or necessary to the products' functionality. In accordance with SEC Staff Guidance with respect to Rule 13p-1, we excluded packaging materials from this review. Based on the review, the categories of our products that were determined to include Conflict Minerals or to include metals of undeterminable content requiring additional analysis were: syringes (used as delivery mechanisms for certain pharmaceutical products); and electronics and mechanical components used in advanced laboratory automation equipment.

#### **Due Diligence**

We designed our due diligence measures to conform in all material respects with the OECD Due Diligence Guidance for Responsible Supply Chains of Minerals from Conflict-Affected and High Risk Areas Third Edition (OECD 2016) (the "OECD Framework") and related Supplements.

As a purchaser, we are many steps removed from the mining of the conflict minerals and do not purchase raw ore or unrefined Conflict Minerals.

Our annual due diligence activities, which are in line with the OECD Framework, are summarized below.

## Step 1: Establish strong company management systems

- We have a Third Party Code of Conduct, which requires our third parties with whom we collaborate to comply with the law, to adhere to ethical business practices, and to observe our standards and requirements concerning human rights, labor rights, health, safety and environmental sustainability, anti-bribery, animal welfare, responsible minerals, quality, trade sanctions and management systems. Specifically with respect to Conflict Minerals, our Third Party Code of Conduct requires third parties to help identify the source of Conflict Minerals in the products, components or materials supplied to Novartis (including the smelter or refiner where such Conflict Minerals were processed and the country of origin of the Conflict Minerals where possible through reasonable means); cooperate with Novartis in our due diligence process and in responding to our requests for information relating to minerals used in our products; provide, upon request, reasonable evidence of third parties' performance of similar due diligence with respect to any of their suppliers or sub-contractors involved in the production of the materials or products supplied to Novartis or any components of those materials or products; and work with Novartis to assess opportunities for alternative sources where Conflict Minerals are identified.
- Our Conflict Minerals Core Team ("Core Team") is responsible for the implementation and ongoing management of Conflict Minerals reporting activities, and the documentation and reporting of the results of the Conflict Minerals due diligence activities described in this and the next four steps.
- We have established an annual process to evaluate the products manufactured by our divisions, in order to identify and assess the presence and sources of Conflict Minerals in the supply chain, as set forth in further detail in Step 2 below.
- The Core Team uses standardized documentation to capture key decisions, processes and procedures used in gathering information related to the use of Conflict Minerals in our products, and to the sources of any such Conflict Minerals. We are required to retain such documentation in accordance with our corporate document retention policy.
- Novartis provides feedback mechanisms available to all interested parties to provide information or voice their concerns regarding our compliance with laws and regulations.

## Step 2: Identify and assess risks in the supply chain

• On an annual basis, we review the suppliers that provide materials used in manufacturing to identify potential sources of Conflict Minerals in our supply chain. The Core Team, working with each of our divisions, is responsible for determining the suppliers of materials that are necessary to the production or

- functionality of products that contain one or more Conflict Minerals, or contain metal of undeterminable content.
- Suppliers of the items identified as containing Conflict Minerals or metals of undeterminable content are designated as "In Scope" for the RCOI.
- As part of this annual process, we offer Conflict Minerals training for In Scope suppliers and require them to complete a webbased survey based on the Conflict Minerals Reporting Template version 6.01 ("CMRT") from the Responsible Minerals Initiative ("RMI").
- To help encourage the highest level of compliance, we make multiple attempts to get responses from all In Scope suppliers.
- We review the information provided by each supplier to determine the completeness of each supplier's responses, and note certain points of information, including whether the supplier has a policy regarding conflict minerals and whether they source any Conflict Minerals from the Covered Countries.
- We review aggregate supplier CMRT responses as well as company statements made by suppliers regarding the status of Conflict Minerals in their supply chain in order to summarize key findings regarding risks in the supply chain. The Core Team meets regularly to review progress.
- We conduct a review of smelter/refinery information provided in the supplier surveys to determine the actual number of unique smelters/refiners identified by its suppliers and whether each has been audited by a third party or presents a "red flag" as defined by the OECD Framework. To make the determination of each smelter/refiner's conflict status, we rely upon information provided by RMI. RMI conducts an industry-standard Responsible Minerals Assurance Program ("RMAP"), in which it certifies smelters/refiners worldwide by conducting an independent audit to validate company-level management and sourcing processes for responsible mineral procurement. RMI makes available to the public the list of smelters/refiners that it has certified as "Conformant", which identifies smelters/refiners that are in conformance with the RMAP assessment protocols and that bear the highest level of Conflict Minerals responsible sourcing certification set by RMI.
- Smelters/refiners with the RMI "re-audit in progress" designation are also considered to be RMAP Conformant during the period in which this designation is assigned.
- Smelters/refiners that carry the RMI "Active" designation are in the process of being audited by RMI to determine whether they can be certified as Conformant. Smelters and refiners are identified as Active in the RMAP once they have submitted a signed Agreement for the Exchange of Confidential Information (AECI), an Auditee Agreement, and a Due Diligence Checklist.
- A smelter or refiner is deemed by RMI as "Known" if it was not Conformant or Active but is listed on the CMRT Smelter Reference List. The status information reflected in this report is current as of April 30, 2021.
- Based on the process described above, the results our due diligence for 2020 were as follows:
  - a. In Scope Suppliers (all were surveyed):149
  - b. Responses received: 91
  - c. Unique Smelters/Refiners Identified: 291
  - d. Conformant Smelters/Refiners Identified: 234
  - e. Active Smelters/Refiners Identified: 8
  - f. Known Smelters/Refiners Identified: 49

## Step 3: Design and implement a strategy to respond to identified risks

- We continue to encourage supplier conformance with the Conflict Minerals section of the Novartis Third Party Code of Conduct
- We have established the capability to routinely store, maintain, and retrieve the key data that was collected as part of due diligence, should it be required to demonstrate reasonable efforts for compliance.
- As part of our review of compliance activities, we will assess our processes in order to determine whether additional actions are required in the future.

## Step 4: Carry out independent third-party audit of smelter/refiner's due diligence practices

• In accordance with the OECD Framework, we monitor industry actions and the results of independent third-party audits of the due diligence performed by smelters and refiners. Given the nature of our

business, the associated costs, and the current lack of transparency in our global supply chain, we are not in a position to conduct our own audits of smelters and refiners.

## Step 5: Report annually on supply chain due diligence

• In accordance with Section 1502 and Rule 13p-1, we annually summarize the activities and results of our due diligence with regard to Conflict Minerals in this Conflict Minerals Report, which is filed with our Form SD.

### Risk Mitigation and Future Due Diligence Measures

We will look to improve our due diligence process by considering measures aimed at increasing Supplier responses to our RCOI in terms of accuracy, timeliness and completeness.

#### **Determination**

Consistent with the OECD Framework, our efforts to determine the countries of origin, the facilities, and the mines or locations of origin of necessary Conflict Minerals used in the manufacture of our products consisted of the due diligence activities described above. In response to these due diligence activities, certain In Scope suppliers provided us with no information about their smelters and refiners, certain other In Scope suppliers provided only a partial list of their smelters and refiners, and certain other In Scope suppliers provided us with a complete list of their smelters and refiners.

Based on the information from our In Scope suppliers that provided us with names of smelters and refiners in their supply chain, we have determined the following information with respect to the facilities used to process Conflict Minerals:

- There were at least 291 unique smelters used by In Scope Suppliers in 2020
- Of those identified smelters, 234 were certified as being Conformant by RMI (as of April 2021)

Because the information that we obtained from the In Scope suppliers was incomplete, other than as set forth above with respect to the Conflict Minerals that were either necessary to the production of our products or necessary to the products' functionality, we were unable to determine the countries of origin of the Conflict Minerals or the facilities used to process them.