Holding ourselves to the highest ethical standards

It is right for society to have high expectations toward companies when it comes to integrity and ethical behavior. At Novartis, we believe in transparency when it comes to fulfilling our commitment to uphold high ethical standards. We want to be open about where we are and what we still need to accomplish.

Klaus Moosmayer
Chief Ethics, Risk and Compliance Officer

2018 highlights

- Rolled out a new principles-based Professional Practices Policy to guide our interactions with stakeholders, including healthcare professionals, healthcare organizations, patients and patient groups
- Experienced a 54% reduction in the number of reported complaints of fraud and professional practices in the sales force in 2018 versus 2017
- Launched a newly harmonized Risk Assessment and Monitoring Process
- Strengthened the Integrity & Compliance function and conducted 220 country visits
- Elevated the role of Chief Ethics, Risk and Compliance Officer to the Executive Committee of Novartis

Key challenges

- Addressing questions regarding our business practices and our involvement with Essential Consultants
- Standardizing the implementation of sales force fixed and variable pay across countries
- Managing risk across an organization of more than 125,000 people that sells products in 155 countries
Why is it important? If Novartis is to be a trusted leader in changing the practice of medicine, we need to be an institution that holds the respect and confidence of society. The pharmaceutical industry has lost much goodwill in recent years due to a variety of real or perceived ethical and legal lapses. We are committed to continuing to build trust with patients, physicians and other stakeholders; it is critical to delivering on our purpose as well as long-term financial performance. We always need to keep in mind our responsibility to society, and we aim to consistently meet its increasing expectations.

Our approach and performance

We care about our people, patients and customers, and commit to the highest ethical standards in what we do. As part of the company’s cultural transformation, we are continuing to strengthen the tone from leaders, support constructive principles-based discussions, and improve the decision-making of our associates. This is a journey that we began several years ago, and over the past year, we have made further progress.

In late 2017, we announced a new principles-based policy on interactions with our stakeholders, including healthcare professionals, healthcare organizations, patients and patient groups: the Professional Practices Policy (P3). This officially came into force enterprise-wide on March 1, 2018, replacing the previous divisional compliance policies (with the exception of Alcon). P3 encourages ethical decision-making by helping our associates navigate areas of ambiguity by first asking themselves five simple questions, starting with whether they are putting patients first. We operate in a highly regulated industry, so guidance and rules still exist, but we believe this approach enables professional judgment across all activities, driving personal accountability for behaviors.

Since 2016, we have adjusted the ratio of fixed to variable total compensation for our sales force to help ensure that the target variable component is a maximum of 35% of total compensation, on average across all countries. To receive any form of variable compensation, each employee, including the sales force, must perform to a minimum standard with regard to our Values and Behaviors, which include acting with integrity. For our sales force, in particular, 20% of target variable pay is based on demonstration of our Values and Behaviors. We are in the process of implementing these standards in every country in which Novartis operates. Ultimately, no sales representative will receive the variable compensation unless he or she meets expectations with respect to our Values and Behaviors.

So far, the rollout of the new incentive system has shown positive results. Across divisions, there was a 54% reduction in the number of reported complaints of fraud and professional practices in the sales force in 2018 compared to 2017. Additionally, 223 complaints (88 of higher risk and 135 of lower risk) were investigated. Of these, 65% were substantiated misconduct allegations for 2018 (compared to 63% in 2017). A higher-risk complaint applies to a senior leader or manager, potentially disruptive reputational impact, sexual harassment, discrimination, retaliation and financial significance.

When hiring and promoting associates, we are also increasingly taking ethical competencies into account to help ensure that there are no known issues for a particular individual before he or she is brought into – or promoted within – the organization.

P3 PRINCIPLES

Novartis has adopted a single set of ethical principles that should be applied in daily decision-making by all Novartis associates.

- Research for the right reason
- Put patients first
- Fund responsibly
- Engage appropriately
- Act with clear intent

54%

Reduction in the number of reported complaints of fraud and professional practices in the sales force in 2018 vs. 2017
In 2018, we combined our risk management and compliance functions into a single organizational umbrella to provide the businesses with a better view of the risks we face as an organization, and how those risks could impact our ability to deliver on strategic priorities. This is expected to enable more effective risk management and mitigation efforts. We created the role of Chief Ethics, Risk and Compliance Officer to head the combined organization, and elevated this role to the Executive Committee of Novartis (ECN). In addition, the Chief Ethics Risk and Compliance Officer presents bi-annually to the Audit and Compliance Committee (ACC), and is free to request a closed session with the ACC and/or its Chair as needed. The Chief Ethics Risk and Compliance Officer also is a permanent attendee to the Risk Committee, and plays an active role with the Chair of that committee in shaping the Board agenda regarding risk.

In 2018, we launched our newly harmonized Risk Assessment and Monitoring (RAM) process within the Integrity & Compliance (I&C) function. This will enable us to have a more targeted approach to monitoring and auditing by focusing on key countries and activities where outliers have been detected, and aiming to prevent misconduct before it transpires. We started this journey in 2017 by working to consolidate the data available across Novartis, and in 2018, we launched an enhanced version of our I&C risk assessment dashboard, incorporating country risks and mitigation and monitoring plans in one central place. From 2019 onward, we will further develop our companywide enterprise risk management process to ensure that we move to a single and integrated risk approach throughout Novartis, fully supported by online tools and data analytics. The harmonization of this process is another example of simplification, helping our local teams identify and manage risk effectively.

We are also using digital technology to help bring ethical standards closer to our associates on a daily basis. We have developed an ethics app that consolidates our global integrity and compliance information, which is then available for download onto associates’ mobile devices wherever they are.

To help monitor and enforce our integrity standards, we have continued to build our I&C function, adding more than 100 people in recent years. The expanded team has increased the number of country visits to share learnings from across the organization, reaching about 220 in 2018. We also continue to invest in training for our associates, with

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**NEW RISK ASSESSMENT AND MONITORING PROCESS LAUNCHED**

In 2018, we launched a newly harmonized RAM process that will enable a more targeted approach.

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<tbody>
<tr>
<td>Novartis associates trained and certified on the Code of Conduct¹</td>
<td>116,884</td>
<td>114,913</td>
<td>110,774</td>
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<tr>
<td>Misconduct cases reported/allegations substantiated²</td>
<td>951 / 618</td>
<td>2,086 / 1,571</td>
<td>1,807 / 1,343</td>
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<td>BPO allegations per category (%)³</td>
<td></td>
<td></td>
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<tr>
<td>Fraud</td>
<td>51</td>
<td>50</td>
<td>46</td>
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<tr>
<td>Professional practices</td>
<td>31</td>
<td>29</td>
<td>36</td>
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<tr>
<td>Employee relations</td>
<td>36</td>
<td>32</td>
<td>27</td>
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<td>Conflict of interest</td>
<td>10</td>
<td>6</td>
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<tr>
<td>Information protection</td>
<td>4</td>
<td>5</td>
<td>3</td>
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<tr>
<td>Quality assurance</td>
<td>6</td>
<td>7</td>
<td>6</td>
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<tr>
<td>Research and development</td>
<td>1</td>
<td>2</td>
<td>2</td>
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<tr>
<td>Other</td>
<td>8</td>
<td>8</td>
<td>8</td>
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<tr>
<td>Dismissals and resignations related to misconduct⁴</td>
<td>311</td>
<td>803</td>
<td>669</td>
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¹ Active Novartis associates with email addresses, trained via e-learning
² The number of misconduct cases reported may change, as matters may be reassessed in the course of the case lifecycle. The number of substantiated allegations may change due to the fact that investigation reports with assessments are received on an ongoing basis, which potentially leads to a difference in numbers at a later stage.
³ One case can fall under several categories, so the total is greater than 100% and category figures total more than the stated number of cases. Investigation reports are received on an ongoing basis, which potentially leads to a reassessment of the allegation category and related figures.
⁴ The number of dismissals and resignations related to misconduct may change due to the fact that investigation reports are received and then reviewed for remedial actions on an ongoing basis, which potentially leads to a difference in numbers at a later stage.
high completion rates for our Code of Conduct training (98%), our P3 training (99%), as well as our anti-bribery course (91% after three months1).

We are already seeing early indications that our efforts are starting to pay off. For instance, in the last two years, we have seen a positive trend in “generally effective” internal compliance audits. Additionally, our whistleblower hotline continues to receive reports of suspected cases where employees may have failed to follow our ethical guidelines. While the proportion of substantiated allegations related to ethics and compliance matters remains stable (56% in 2018 compared to 55% in 2017), the number of reports received and the number of subsequently substantiated allegations have decreased. This overall decrease is attributed, in part, to a significant decrease in fraud cases in China and in employee relations cases in Alcon US and Innovative Medicines. At the same time, there has been an overall significant decrease in Alcon cases in general. We have also been undertaking a stricter initial assessment of incoming complaints than in the past, which has resulted in an increasing number of performance issues and minor policy violations being handled locally (+22% compared to 2017).

In 2018, the Business Practices Office (BPO) investigated 951 cases (454 of higher risk and 497 of lower risk) relating to misconduct, covering 1388 allegations. Out of these, 618 allegations (306 of higher risk and 312 of lower risk) were substantiated and resulted in 311 dismissals or resignations (157 for higher risk and 154 for lower risk).

However, the year was not without its challenges. Following the issue with Essential Consultants, when our political consultancy practices came into question, we took steps to improve oversight and help prevent similar matters in the future. We have strengthened the relevant contracting and due diligence processes; before Novartis engages political consultants, for example, we will secure an independent third-party due diligence report.

As an organization of more than 125,000 people that sells products in 155 countries around the world, we face a certain amount of risk. We will continue to increase our ability to manage risk and strengthen our three lines of defense. The first is associates engaging in principles-based decision-making and acting in every situation with strong ethics and integrity; the second is our Ethics, Risk and Compliance (ERC) function, strengthened in 2018. As of January 1, 2019, we have further strengthened the effectiveness of our third line of defense by bringing together Internal Audit, the BPO Office and Global Security (all complementary teams) into a new function called Novartis Business Assurance & Advisory (NBAA).

NBAA aims to provide a safe place for associates to speak up, drive fair and timely investigations, deliver value-adding audits and advisory engagements, and be an enabler of our culture. The BPO Office, renamed the SpeakUp Office, has been simplified. It continues to be a place where anyone can safely raise concerns about unethical behavior at Novartis. However, as of January 2019, it is focusing on significant cases while empowering local organizations to handle minor and day-to-day concerns to enable faster resolution. Global Security will be able to work even closer with the SpeakUp Office by investigating higher-risk cases while continuing to provide world-class protection for Novartis associates, patients, assets, brands and reputation. We expect these changes will improve how we manage risk at Novartis.

Commitment to transparency and disclosure

For many years, transparent reporting and disclosure has been a central part of our commitment to doing business responsibly. As the transparency landscape rapidly evolves, Novartis is keeping pace with developments and is committed to meeting new transparency requirements. We publish the Novartis in Society report (formerly our Corporate Responsibility Report) annually, and we will continue to publish the US Transparency and Patient Access Report, now renamed the Novartis in Society US report, on an annual basis.

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1 In 2018, our anti-bribery training campaign was launched in October. Final measurement will be available in May 2019.
Today, we disclose payments and other transfers of value made to healthcare professionals and organizations in Europe, in line with the European Federation of Pharmaceutical Industries and Associations (EFPIA) Disclosure Code and the MedTech Europe Code of Ethical Business Practice. We also encourage healthcare professionals to consent to individual disclosure as part of their commitment to medical integrity. Additionally, we disclose spend within the scope of transparency codes in Australia, Canada (voluntary disclosure), Israel, Japan and the US. These approximately 40 local reports are available on our website. We are working now to report in line with requirements in Saudi Arabia, South Korea, Indonesia, Brazil and Colombia. We are also working to implement appropriate internal processes and systems to disclose our numbers as regulations and the industry evolve.

Novartis also discloses monetary and non-monetary support to patient organizations around the globe by June 30 every year, in compliance with the Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organizations set by the EFPIA. These payments are also available on our website.

We fully support the publication of clinical study results. Our policy is to not withhold, veto or suppress data. We make every effort to comply with national and international standards for disclosure of clinical trial information, and we are committed to the timely disclosure of the design and results of all interventional clinical studies for innovative treatments in patients. Results are made publicly available, regardless of their outcome.

For more details, visit our website.

Photo: Physician-researcher Florencia Segal sits with patient James Mulcahy at Brigham and Women’s Hospital in Boston.