NOVARTIS

Audit program and regulatory inspections

To maintain compliance with our quality and safety standards and to support the continuous improvement of our QMS, Novartis has a robust and independent audit program that covers the product lifecycle. The audit program is governed by global procedures and covers Novartis internal sites and functions as well as suppliers. The scope of each audit depends on the type of operations conducted. The frequency of audits is based on activities performed and applicable risk assessments. The Novartis quality audit program normally conducts more than 900 audits per year covering internal functions, sites and external suppliers in areas including Good Manufacturing Practice (GMP), Good Clinical Practice (GCP), Good Laboratory Practice (GLP) and pharmacovigilance. An annual audit plan is established to take into account audit frequency and assessed risks. Audits are performed by certified auditors. The subsequent audit report is reviewed and approved independently and distributed to the auditee (internal function, manufacturing site or external supplier) who is responsible for submitting a corrective and preventative action plan which, upon agreement, is implemented. The audit is closed when all actions in the plan have been completed.

We regularly participate in regulatory inspections to help ensure the highest quality in our operations in development, manufacturing and distribution. Health authorities, including the European Medicines Agency (EMA), Swissmedic and the US Food and Drug Administration (FDA), carried out the following inspections in the last three years. We conduct thorough investigations whenever there is any evidence of deviation from these standards, or if we detect failures in our processes. We take corrective and other measures where applicable, including proactively notifying health authorities.

Report on Nonfinancial Matters (915 KB) ESG Data Summary (229 KB)
