

## 6. Legal proceedings update

A number of Novartis subsidiaries are, and will likely continue to be, subject to various legal proceedings that arise from time to time. As a result, the Group may become subject to substantial liabilities that may not be covered by insurance. Litigation is inherently unpredictable and large verdicts do occur.

As a result, Novartis may in the future incur judgments or enter into settlements of claims that could have a material adverse effect on its results of operations or cash flow. See note 20 in the Group's Consolidated Financial Statements in the 2009 Annual Report for a summary of major legal proceedings. The following is a non-exhaustive list relating to some cases reported in the 2009 Annual Report and includes information as of the 2009 fourth quarter:

### Governmental investigations

In 2005 the US Attorney's Office for the Eastern District of Pennsylvania (the EDPA) served an administrative subpoena pursuant to the Health Insurance Portability and Accountability Act on Novartis Pharmaceuticals Corporation (NPC), a Novartis subsidiary. NPC has been cooperating with parallel civil and criminal investigations by the EDPA into allegations of potential off-label marketing and promotion of the epilepsy therapy *Trileptal* as well as certain payments made to healthcare providers in connection with this medicine. NPC recently entered into a plea agreement with the EDPA, which is contingent on court approval, to resolve criminal allegations. Pursuant to the plea agreement, NPC will plead guilty to a misdemeanor violation of the US Food, Drug and Cosmetic Act and pay a fine of USD 185 million. NPC is currently negotiating with the EDPA to resolve civil claims relating to *Trileptal*. In the fourth quarter of 2009, Novartis increased provisions relating to the EDPA's *Trileptal* investigations by USD 318 million. Total provisions at the end of 2009 relating to the EDPA's civil and criminal *Trileptal* investigations were USD 397 million.

NPC is also cooperating with an investigation by the EDPA regarding potential off-label marketing and promotion as well as payments made to healthcare providers in connection with five other products: *Diovan*, *Exforge*, *Sandostatin*, *Tekturna* and *Zelnorm*. Novartis is unable to assess with reasonable certainty the outcome of the investigation related to these five products or the amounts, which could be material, that it might be required to pay to resolve this investigation.

The US Attorney's Office for the Northern District of California in 2007 served an administrative subpoena pursuant to the Health Insurance Portability and Accountability Act covering several Novartis subsidiaries. The subpoena covered information regarding potential off-label marketing and promotion of *TOBI* (tobramycin), a treatment for patients with cystic fibrosis acquired through the purchase of Chiron Corporation in mid-2006. In September 2009, Novartis subsidiaries reached an agreement in principle with the US Department of Justice to pay USD 72.5 million to resolve all federal civil claims and state Medicaid claims relating to this investigation. Details of the agreement in principle are under discussion with relevant federal and state government offices.

In October 2009, the European Commission, together with the French competition authority, searched the French offices of Sandoz, alleging that Sandoz may have entered into anti-competitive price coordination practices with other generic pharmaceuticals companies and via the French trade association for generic pharmaceuticals companies. Sandoz is cooperating with the Commission and French authorities.

On January 12, 2010, the European Commission addressed a request for information to certain pharmaceutical companies, including Novartis International AG, asking them to submit copies of all of their patent settlement agreements as well as copies of all annexes, related agreements and amendments. The request covers patent settlement agreements concluded between originator and generic pharmaceutical companies in the period from July 1, 2008, to December 31, 2009, and