Product recalls

Novartis maintains a comprehensive process across the entire company to assess quality defects and safety issues and whether a market action (such as a product recall) would be required. Any such occurring incident is escalated through an established company-wide quality assurance process that enables a prompt investigation and assessment by committees consisting of subject-matter experts, quality management, medical safety experts and regulatory responsible persons.

Conclusions from these committees are provided, with relevant documentation, including a safety assessment, to the competent responsible health authorities in impacted markets. Market actions, e.g., product recalls, will then be executed following an established process as agreed with and endorsed by the respective health authorities.

Novartis in Society Integrated Report 2024 (5 MB)

References:

1. Definition of Class I/II recalls is given on the FDA webpage: Recalls Background and Definitions

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1. https://www.novartis.com/about/quality/product-recalls
2. https://www.novartis.com/sites/novartis_com/files/novartis-integrated-report-2024.pdf
3. https://www.fda.gov/safety/industry-guidance-recalls/recalls-background-and-definitions#:~:text=Class%20I%20recall%3A%20a%20situation,adverse%20health%20consequences%20or%20death.