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Philips Respironics Consent Decree update

April 10, 2024

innovation you

Key takeaways

- Consent Decree provides clarity and a roadmap to demonstrate compliance and to restore the business; fully committed to meeting the requirements
- Primarily focuses on Philips Respironics' business operations in the US
- Must demonstrate continued compliance with the Current Good Manufacturing Practice requirements for medical devices, as incorporated in FDA's Quality System Regulation
- Will resume selling new CPAP or BiPAP sleep devices or other respiratory care devices in the US when relevant requirements are met
- The previously stated 2023-2025 Group financial outlook now takes the Consent Decree into account and remains unchanged

Background

- **June 2021:** Philips Respironics initiated a voluntary recall notification in the US/field safety notice outside the US for certain sleep and respiratory care devices related to the PE-PUR sound abatement foam in these devices[1,2].

- **August – November 2021:** The FDA conducted an inspection of Philips Respironics's facility in Murrysville, Pennsylvania (US), where these devices are manufactured and serviced.

- **November 2021:** following the inspection, the FDA provided a list of its observations (Form 483) to Philips Respironics with regards to its manufacturing practices. Philips Respironics submitted a comprehensive response and detailed action plan to the FDA.

- **July 2022:** Philips announced that the US Department of Justice, acting on behalf of the FDA, began discussions with Philips Respironics regarding the terms of a proposed Consent Decree.

- **January 2024:** Philips announced that it has agreed on the terms of a Consent Decree that primarily focuses on Philips Respironics' business operations in the US.

- **April 2024:** Consent Decree signed and approved by the relevant US court.

1. Completed 99% of remediation of sleep therapy devices; remediation of ventilators is ongoing | 2. During 2021-2023, Philips Respironics provided several test result updates that concluded that use of its sleep therapy devices is not expected to result in appreciable harm to health in patients; following ongoing communications with the FDA, Philips Respironics has agreed to implement additional testing to supplement current test data on PE-PUR foam. The FDA stated that current testing is extensive and conducted with independent parties and expressed no concerns with its validity or objectivity. Philips Respironics is in discussions with the FDA on the details of further testing.

Summary of the main terms of the Consent Decree (1/3)

- Primarily focuses on Philips Respironics' business operations in the US, including its facilities in Murrysville, New Kensington, Mount Pleasant and Pittsburgh in Pennsylvania ("Covered Respironics Facilities").

- Intended to resolve a complaint for an injunction based on alleged failures to comply with the FDA's Current Good Manufacturing Practice requirements and requirements for reporting corrections and removals.

- Philips Respironics' business operations must demonstrate continued compliance with the FDA's Current Good Manufacturing Practice requirements for medical devices as incorporated in the FDA's Quality System Regulation.

Summary of the main terms of the Consent Decree (2/3)

- Retain independent quality system experts to supervise the compliance improvement program in the Covered Respironics Facilities and Other Sleep and Respiratory Care facilities[1].

- Report to the FDA all actions taken to address all observations made by the experts and ensure the Covered Respironics Facilities and Other Sleep and Respiratory Care facilities are in compliance with the relevant requirements[2].

- Complete the rework, replacement, and refund activities in accordance with the Recall Remediation Plan as approved by the FDA.

- Retain testing and design experts to review and evaluate the testing of the new silicone sound abatement foam[3] and review the design of devices reworked as part of the recall.

1. Facilities (other than the Covered Respironics Facilities) at which Philips' Sleep and Respiratory Care business manufactures or services Sleep and Respiratory Care devices: Shenzhen (China) and Alajuela (Costa Rica) | 2. Detailed requirements are listed in the Consent Decree that can be found in the court docket: https://www.pawd.uscourts.gov | 3. Devices with the new silicone sound abatement foam have been subject to extensive testing in accordance with the applicable industry testing standards and may continue to be used in accordance with the instructions for use. Their use is not impacted by Consent Decree.

Summary of the main terms of the Consent Decree (3/3)

In the US:

- Will continue to service sleep and respiratory care devices already with healthcare providers and patients, and to provide accessories (including patient interfaces), consumables and replacement parts.
- Will resume sales of new CPAP or BiPAP sleep therapy devices or other respiratory care devices only when the relevant requirements are met.
- Agreed to disgorgement payments from sales of Medically Necessary Devices[1].Sales of Patient Interfaces (masks) and other consumables and accessories in the US are allowed under a separate exemption, which does not have a disgorgement requirement.
- Sales injunction and disgorgement payments to occur until Covered Respironics Facilities are in compliance with the relevant requirements and the rework, replacement, and refund activities are completed in accordance with the Recall Remediation Plan.

Outside the US:

- Will continue to provide new sleep and respiratory care devices, accessories (including patient interfaces), consumables, replacement parts and services, subject to certain requirements.
- It is common for Consent Decrees (including this one) to include requirements (e.g. controls and documentation) for exports to prevent reimportation of the medical devices into the US.

1. Medically Necessary Devices are listed in the Consent Decree (Appendix 2) that can be found in the court docket: https://www.pawd.uscourts.gov

Financials

- As announced on January 29, 2024, Philips
  - recorded a provision of EUR 363 million in Q4 2023 that relates to remediation activities, inventory write-downs and onerous contract provisions.
  - expects around 100 basis points of costs in 2024 that relate to remediation activities and disgorgement payments[1] for Philips Respironics sales in the US.

- The previously stated 2023-2025 Group financial outlook[2] of mid-single-digit comparable sales growth, low-teens Adjusted EBITA margin, and EUR 1.4-1.6 billion free cash flow now takes the Consent Decree into account and remains unchanged.

1. Agreed to disgorgement payments from sales of Medically Necessary Devices (10% of net revenue between entry of the Decree and December 31, 2024, 12% of net revenue between January 1, 2025, and December 31, 2025, thereafter 25% of net revenue.); Medically Necessary Devices are listed in the Consent Decree (Appendix 2) that can be found in the court docket: https://www.pawd.uscourts.gov; sales of Patient Interfaces (masks) and other consumables and accessories in the US are allowed under a separate exemption specific to those items, which does not have a disgorgement requirement | 2. Excludes the impact of ongoing litigation and the investigation by the US DoJ related to the Respironics field action.

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Appendix

What is a Consent Decree?

- A Consent Decree is an agreement negotiated between the government and a company to resolve a civil enforcement action as an alternative to litigation.
- Typically, a Consent Decree addressing alleged non-compliance with the Federal Food, Drug and Cosmetic Act (FDC Act) requires a company to take a series of actions, with defined milestones and deliverables, to assess and remedy alleged non-conformances.
- This usually includes undergoing third-party audits and implementing quality systems improvements.
- Generally, a Consent Decree also imposes restrictions on a company's ability to engage in certain FDA-regulated activities, which are lifted once certain obligations under the consent decree have been satisfied.

Note: follow the link to the Philips Respironics Consent Decree FAQ for additional details


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