



Press Information

October 11, 2017

Philips reaches agreement with the U.S. government on a consent decree focusing on the company's defibrillator manufacturing in the U.S.

Amsterdam, the Netherlands – Royal Philips (NYSE: PHG, AEX: PHIA) announced today that its subsidiary Philips North America LLC reached agreement on a consent decree with the U.S. Department of Justice, representing the Food and Drug Administration (FDA), related to compliance with current good manufacturing practice requirements arising from past inspections in and before 2015, focusing primarily on Philips' Emergency Care & Resuscitation (ECR) business operations in Andover (Massachusetts, U.S.) and Bothell (Washington, U.S.). The decree also provides for increased scrutiny, for a period of time, of the compliance of the other patient care businesses at these facilities with the Quality System Regulation. The decree will become effective once it is approved by the U.S. District Court for the District of Massachusetts.

Under the decree, Philips will suspend the manufacture and distribution of external defibrillators manufactured at these facilities, subject to certain exceptions, until FDA certifies through inspection the facilities' compliance with the Quality System Regulation. The decree allows Philips to continue the manufacture and distribution of certain automated external defibrillator (AED) models [1] and Philips will continue to service ECR devices and provide consumables and the relevant accessories, to ensure uninterrupted availability of these highly reliable life-saving devices in the U.S. Philips will also continue to export ECR devices once certain requirements have been met. Philips will continue to manufacture and distribute the products of the other patient care businesses at these facilities.

"We are committed to delivering high quality, innovative products and solutions, and we take this matter very seriously," said Carla Kriwet, Chief Business Leader Connected Care & Health Informatics at Royal Philips. "We are fully prepared to fulfill the terms of the decree, and we hope to resume the suspended defibrillator production in the course of 2018. Over the last years, we have made significant investments in our Quality Management System, with the change in our company-wide quality leadership and the launch of new standards and initiatives across all our businesses and markets. We will continue this program to further enhance our quality management throughout Philips."



Philips defibrillators currently in use by customers are recommended by Philips to remain in use, and should not be taken out of service as Philips has no reason to believe they pose a risk to patients. Philips is proud that its defibrillators save lives daily, with a high reliability record.

The full consent decree will be posted on Philips' website, along with information for users of Philips external defibrillators, describing how these products are impacted by the consent decree. Customers with questions not answered on Philips' website, can also contact Philips at + 1 800 263 3342 or via this [link](#).

Financial impact

As a consequence of the decree, Philips anticipates an EBITA impact of approximately EUR 20 million in the fourth quarter of 2017 and approximately EUR 60 million in 2018. These impacts relate primarily to the suspension of production, profit disgorgement payments, and incremental costs to prepare for and handle the regulatory inspections. These amounts will not impact Adjusted EBITA [2] in 2017 and 2018, respectively. The combined sales of the external defibrillator product lines affected by the terms of the decree was approximately EUR 35 million per quarter in 2016.

- [1] *Subject to limitations and conditions, Philips is permitted to continue manufacture and shipping of HeartStart HS1 AEDs (including HeartStart Home and HeartStart Onsite AEDs) in order to meet public health needs. Philips is also permitted to manufacture and ship devices under certain circumstances to customers who have standardized on Philips FR3 AED.*
- [2] *Adjusted EBITA is defined as income from operations excluding amortization of acquired intangible assets, impairment of goodwill and other intangible assets, restructuring charges, acquisition-related costs and other significant items.*

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About Royal Philips

Royal Philips (NYSE: PHG, AEX: PHIA) is a leading health technology company focused on improving people's health and enabling better outcomes across the health continuum from healthy living and prevention, to diagnosis, treatment and home care. Philips leverages

advanced technology and deep clinical and consumer insights to deliver integrated solutions. Headquartered in the Netherlands, the company is a leader in diagnostic imaging, image-guided therapy, patient monitoring and health informatics, as well as in consumer health and home care. Philips' health technology portfolio generated 2016 sales of EUR 17.4 billion and employs approximately 71,000 employees with sales and services in more than 100 countries. News about Philips can be found at www.philips.com/newscenter.

Forward-looking statements

This release contains certain forward-looking statements with respect to the financial condition, results of operations and business of Philips and certain of the plans and objectives of Philips with respect to these items. Examples of forward-looking statements include statements made about the strategy, estimates of sales growth, future EBITA, future developments in Philips' organic business and the completion of acquisitions and divestments. By their nature, these statements involve risk and uncertainty because they relate to future events and circumstances and there are many factors that could cause actual results and developments to differ materially from those expressed or implied by these statements.

This press release contains inside information within the meaning of Article 7(1) of the EU Market Abuse Regulation.