

Peptonic provides an update on Vernivia

Peptonic Medical AB (publ) (“Peptonic” or “the Company”) announces a regulatory update regarding Vernivia®. The Company has now finalised the relevant interim reports with its Notified Body, which constitutes a crucial step in the ongoing MDR process for updating the CE marking.

Vernivia is a unique, patented product targeting the major problem of bacterial vaginosis. Vernivia is the first clinically proven, antibiotic-free self-care treatment that provides rapid symptom relief, treats the vaginal infection and simultaneously stimulates the growth of protective lactobacilli. The product has very good clinical properties, which is also one of the reasons of why Peptonic merged with Pharmiva.

Vernivia was part of Pharmiva’s product portfolio and was CE-marked in accordance with the previous MDD (Medical Device Directive) regulations at the time of the merger between Pharmiva and Peptonic.

As a result of the merger and the transition to the new MDR (Medical Device Regulation) framework, the company has been unable to produce new units under the previous approval. To resume sales, CE marking in accordance with the MDR is required.

The transition to the MDR has affected all medical devices in the EU-regulated market and is therefore not unique to Peptonic. The aim is to raise safety standards for patients and users through stricter requirements for clinical evidence and traceability throughout the product’s lifecycle. Once the MDR approval process is complete, it will further strengthen the Company’s market position.

“– This is an important milestone for the company and for Vernivia’s future market potential. The fact that the interim reports with the Notified Body are now complete means we have taken a clear and significant concrete step forward. We are seeing a strong interest from the market, which confirms the need for the product. The focus going forward is on continuing the work as planned towards the CE marking following the MDR adaptation,” says Daniel Rudeklint, acting CEO of Peptonic Medical AB.

Vernivia is expected to be relaunched in the end of 2026 with sales starting early 2027 .

The company will provide further information when there are new significant developments in the ongoing regulatory process.

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Brief explanation — what is a Notified Body?

A Notified Body is an independent, accredited body that reviews technical documentation, quality systems and safety aspects of medical devices prior to CE marking under the MDR. The Notified Body carries out audits and assessments to ensure that the product meets the requirements of the regulations.

About Peptonic Medical AB

Peptonic Medical AB (publ) is a Swedish medical device company that develops and sells clinically proven self-care products for women’s intimate health. Under the VagiVital and Vernivia brands, the Company offers a non-prescription portfolio of effective and gentle products that help women understand, treat and prevent common

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gynaecological conditions. Peptonic's growth strategy is based on geographical expansion, particularly in the US and Europe, and on continuously strengthening the product portfolio through in-house product development and strategic acquisitions.

The Company has its headquarters in Stockholm, Sweden, and subsidiaries Peptonic Medical Inc. and Common Sense Marketing Inc. in the US. Peptonic Medical was founded in 2009 and has been listed on the Spotlight Stock Market since 2014.