If you previously purchased Matas Medicare Vaginal Tablets, you may also have discovered that they are no longer available. When we lost the right to claim that the product is effective against bad odor and candida in the vagina, Matas chose to stop market their version of LadyBalance's vaginal tablet when the stock was sold out. It is permitted to market the product without claims in relation to illness, but actual approval for this activity cannot be obtained, therefore Matas was afraid to go this route. All other sales channels – including pharmacies – have chosen to continue with the product. The product in various forms of packaging is available on our own website ladybalance.dk.

New product – LadyBalance Mini Vaginal Tablet
Ladybalance Mini is a slimmer version of the classic lactose tablet. 0.8g instead of 1.2g - still divisible. The product consists of white sugar tablets with a neutral smell. Easy to place in the vagina, where they give you a clean and fresh smell within less than a day. Your body tells you how much you should use.
The product is suitable for women who find the normal tablet too large and would prefer to avoid breaking the tablet. And for those women for whom even half a normal tablet is too much. So far, it is only available in an aluminum bag (corresponding to a refill) with 30 pcs.

Why can't we write that it works?

The Danish authorities decided in 2008 that if we state that the product can help problems with vaginal health, then it will need to follow the legislation for medical devices - and in group 2a, which requires that production, documentation and labeling is approved by an independent company (notified body). It wasn't easy, but we succeeded in 2009 and we kept the approval running until 2021.

The new legislation for medical devices applies from May 2021. It is much more demanding on many points, therefore many notified bodies have given up their approval. This also applied to the Danish company (Presafe), which had previously certified LadyBalance. In return, they offered that we could be transferred to their Norwegian parent company, DNV. We applied for this, but received the answer that the Norwegian authorities do not do not consider the product a medical devices. Therefore, the certification could not be transferred to a Norwegian company. There was (and is) a great shortage of certifying bodies, so it was not possible to find an alternative.

At that time, we gave up being re-approved under the old legislation (the one we were approved for 2 times previously), but we were met with very rigid and new requirements and horrible invoices, so we actually chose to give up this re-approval. At the end of the day, we wouldn’t have a certification anyway.

The companies that received re-approval and have a supplier of certification could now continue to use the old legislation until 2024. As there are still major problems with the system, the EU has recently decided that this transitional arrangement will be extended until 2027. But unfortunately we lost that opportunity.

Dialogue with i.a. authorities made it clear that it is legal to market the product as long as it is not claimed that it has an effect in relation to diseases. Then it will typically fall under the legislation for chemical products. For this type of product (like so many others) there is no approval system - you cannot therefore

get a fine certificate that you meet the requirements. It is up to the company itself to assess whether it meets the requirements of the legislation. However, we have received good help from experts in the field.

It's a bit of a strange situation - we can't change the history. Today, we are not allowed to mention diseases in the product description. But it is relevant to keep in archive the newsletters from the years when the product was approved.

To complete the history, I want to emphasize that the lack of approval is not caused by problems with the product. Over the years, more than one million packs of the product have been used - and there has never been a serious incident - that is, cases where the user became seriously ill. One of the silly requirements, that we would not fulfill, was that we had not carried out toxicological tests with the active substance - lactose. It can be mentioned that the substance in the chemical legislation is on a list of substances that are considered tested and harmless to a degree, where they do not have to meet the generally applicable requirements for chemical substances. Lactose is not exactly an unknown substance for the female body either.

That it works - we primarily have the users' statements about. As well as a clinical test - but since the test used 0.8 g tablets, it "obviously" cannot say anything about the effect of a 1.2 g tablet! But now we have the 0.8 g tablet for sale - there is documentation on it. There was a significant effect on the number of Gardnerella vaginalis – the classic cause of bacterial vaginosis. But since we cannot get a certification, we are not allowed to claim that it works.

We are therefore back to "mouth-to-ear" spreading the good story about how to keep the vagina in top condition. If you know someone who could benefit from using LadyBalance vaginal tablets, you need to tell them about the possibility. Please send her the link www.ladybalance.dk.