

**Patient Advocacy and Safety Conference**  
**15. November Brussels, Belgium**  
**European Parliament**

I would like to start by stating that I certainly am not against biosimilar, but I do mind that they don't have to undergo the same procedure in approval as applied to a generic product. One would not have to be a great chemist to understand that these medicines are very complex to manufacture. They cannot be COPIED. You can make something that is SIMILAR.

In a matter so complicated, I cannot understand that anyone dare to tone it down just to be a switch in product and not a switch in medication. I oppose on forced switching in well-treated patients. We are talking about patients who have been very sick for a very long period before they even will be introduced to biological treatment.

In April 2015 the Danish regional councils decided to switch all patients in treatment with Remicade on to the cheaper product Remsima from one day to the next.

The decision was obviously made based on EMA's and RADS (Danish Council of expensive hospital drugs) statements that they saw no obstacle in switching well-treated patients.

However, RADS wrote in its recommendations that you should not switch a patient if there was any medical reason against switching. This option took regional councils forthwith from specialists with their decision taken solely by economic reasons. Doctors who opposed against it, were told to find 5 nurses to let go then. Of course they had to do what they were told.

The specialists found this very difficult to explain to their patients, so in many cases they chose not to tell their patients about the switch. Afterwards, we saw a pattern. It was the strong patients, they avoided telling about the switch. I assume it was to avoid discussions with them. In cases where the patient was told about the switch or he or she found out later, they chose to say that Remicade was not in the hospital pharmacy shelves anymore, which was a direct lie.

4 to 5 months after the switch, we began to observe many posts on social media, and we (IBD Danish Association) received many direct inquiries from

well-treated patients who suddenly started having new side effects or even experienced relapse in their disease again.

We chose to implement a mini questionnaire survey via our social media.

Patients in biological treatment were asked to reply on:

Which medication they received.

Whether they, during the last months, had been better.

Whether they had developed side effects or disease had been erupting again.

Next they were asked to open their digital journal and check what medication they had received recently.

And then we had serious trouble. Here they found out, that they had been switched without that they were informed of this.

Some were informed but had just been told that it was the same medication only the name was changed. Naive patients were given an information leaflet on Remicade and treated with Remsima. A.s.o.

At this point 1782 patients with Crohn's or Ccolitis were treated with biologicals in Denmark. We got more than 100 responses with new side effects or even relapse. Nobody can claim that this happened as a result of some psychological impact due to the forced switch, since the patients did not know of it until now.

In Denmark patients are able to report on side effects themselves. These reports now account for 25% of all reports. Therefore, it is very important that patients know what they are treated with. From April 2015, and for the rest of the year, were almost no reports from either doctors or patients in treatment with Remsima, but many concerning Remicade. The drug nobody was treated with!!!!!!

The claim is that it is merely a switch in product and not a switch in medication.

How would you explain patients switched back on Remicade have a good effect, but got sick on Remsima?????????????????

Here my way of logic fails!!!!

We had meetings with almost all health politicians within the various parties. We ended with an audience with the same, along with the Minister of Health. Here we wanted an answer on whether it was legal not to inform patients about such a change in medication.

We wanted an answer from the Minister of Health, if she thought it was okay to switch well-treated patients. They agreed on the first matter, they even discussed if it bordered on a breach of human rights. About the switch, they followed the earlier mentioned Council's recommendations. However, now

the Minister of Health has requested a visit by me to a dialogue on biological and biosimilar treatment. A visit I certainly am looking forward too.

Subsequently, the government has decided to close down RADS and AMGROS (they agree on price on medication with the industry) and creating a Council of Medication. In addition to select medications that can be approved to be standard treatment, they also have to establish a form decision on which patients are to receive which treatment. There will be 2 patients participating in this council. I am 1 of 3 candidates in to be elected for this council.

My next concern in this thriller is the introduction of a so-called pharmacy model, and switching treatment once every year regarding which product is the cheapest.

A whistleblower contacted me to make me aware of that decision makers were making calculations on how much money they could save if they switched patients treated with completely different molecules, patients who already had failed treatment with Remicade, on to biosimilars.

According to a press release, this was stopped due to the disturbance that was created concerning this matter. The disturbance was that I wanted access to all minutes regarding this subject in all 5 regions.

I am familiar with the outcome of the Norswitch study, but I must say that I am astonished!!!!

Our Real life study tells a different story.

What is very sad in this story, is that patients have lost their trust in their doctors. You can destroy trust in just one night, but it takes years to build up again.

It is, in my world, still gambling with real life people.

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