

Since this article was brought to the attention of the European Medicine Agency, the mention of Lapp lactase deficiency was modified to “total lactose deficiency”. See https://www.ema.europa.eu/en/documents/scientific-guideline/annex-european-commission-guideline-excipients-labelling-package-leaflet-medicinal-products-human_en.pdf

Racism in medical texts? The case of Lapp lactase deficiency

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In the great majority of patient information leaflets, the patients are informed that they might not tolerate the medicine if they have “Lapp lactase deficiency”. Where does the term come from? Is this about the Lapps? Shouldn’t we say “Sami lactase”? A beautiful case of language deficiency, demonstrating how the sole use of English in the scientific world can bias scientific progress. And what about warnings that some medicines are less active or less well tolerated by non-Caucasians?

This case was presented at the World Congress of the Fédération Internationale des Traducteurs, on August 4, 2014, in Berlin.

The intention of this presentation is to provide colleagues with the necessary arguments and references to convince the regulatory authorities that it might be dangerous to restrict the warning to just one type of lactase deficiency.

Conventions in medical leaflets

Medical leaflets are written according to strict rules, set by the European Medicines Agency (EMA) in Europe (and the FDA in America). Specific guidelines dictate the structure and layout, the phrasing and the terminology. Moreover, European guidelines dictate that legibility (or readability) should be tested. The translations have to follow the same rules. Since the beginning of this millennium, EMA has published templates for the leaflets in all the European languages. There are several kinds of leaflets: for human and veterinary medicine, for the general public (patient or animal owner) and for medical specialists. And for human medicines, there are even different templates for different registration procedures: centralized or decentralized. All these templates are revised regularly: more often so for human medicines than for veterinary medicines. The templates for the decentralized and centralized procedures for the registration of human medicines are almost identical, yet inconsistencies persist, even within documents. Logic would dictate that as the documents in one procedure are revised, the ones in the other would automatically follow, yet this does not happen. All this is, of course, a great frustration to the translators, who notice these inconsistencies and even errors. The different customers in the market have no way of judging the accuracy of the documents in all languages, so they tend to stick to the templates to the letter and even the comma, for fear that an official might reject their document and as a consequence, delay the whole registration process. Thus, the French documents contain grammatical errors, the German documents have spelling errors, etc. Not to mention that some translations are so very literal, that the language loses the “native-speaker” feel. On the optimistic note: the texts are slowly improving.

Where do the Lapps come in?

One stubborn error persists in all the version of the templates for human medicines. It seems to be a terminological problem, and it perpetuates itself, mainly because no one remembers its origin any more: Lapp lactase.

When a translator encounters such a term, he will start looking in two possible directions: is Lapp a person, after whom something is named, or an abbreviation? Or might it be connected to Lapp as an inhabitant of Lapland?

A search on the internet does not give much information, except that it confirms that Lapp does not refer to a scientist or an abbreviation, but to a population. Lapp lactase is the lactase found in the Lapp population – or is it?

Lapp lactase is never found on its own, it is always referred to as “Lapp lactase deficiency”. This raises the following question: are we talking about a deficiency of a type of lactase found in Lapps, or a type of lactase deficiency found in Lapps?

Actually, now that we know that Lapp refers to a population, I would like to mention that this population does not appreciate being referred to as Lapps: they now call themselves the **Sami**. They also do not appreciate being famous for a deficiency. Who likes to be deficient? For the rest of the article, I will stick to the term Lapp, though, and would like to ask the Sami reader to forgive that use. In no way do I intend to imply that the Sami are deficient. Even more: some deficiencies prove to be adaptations that improve the health of a population under certain circumstances. I will be giving the arguments to drop the use of “Lapp” altogether.

The warnings

In the EMA templates, one can read in the Summary of the Product Characteristics (the leaflet for medical personnel): *As this medicinal product contains lactose monohydrate as an excipient, patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.*”

The Patient Information Leaflet used to mention Lapp lactase as well, but fortunately the latest wording reads: *“If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.”*

What is lactase?

The explanation of lactose intolerance in Wikipedia is a good start. To summarise: lactose is a type of sugar found in milk. It is a chemical convention to give all sugars a name ending in –ose. Lactase is the enzyme that can digest lactose. Again, -ase is the conventional ending designating an enzyme.

A common characteristic of nearly all mammals is that we are raised with milk. Infants need to be able to digest lactose, and most do have this enzyme lactase. In fact, they would die without it. But as their diet changes to solid food, mammals in general lose this enzyme. Producing enzymes takes energy and it would be inefficient to continue spending energy for an enzyme one no longer needs. So, dear cat-lover, dog-owner or hedgehog enthusiast: feeding the animal milk will actually inconvenience the poor creature.

In the animal kingdom, humans take a special place: we defy such unwritten conventions and at some time in our evolution, we adapted to drink milk even in adulthood. We, that is – some of us. And so, in certain populations, we have continued to produce this enzyme – a condition which scientists call *lactase persistence*. And only recently have scientists realised that drinking milk is not as natural as we might think. In the second half of the last century, research started into lactase deficiency, which back then was considered as an exceptional condition. This research is preferably done in homogeneous populations. Chance designated the Lapps as a suitable population for the earliest research initiatives.

At that time, I happened to be a student of biology and I clearly remember seeing the titles of articles referring to the “Lapp lactase deficiency study”. Some years ago, a search on the internet still yielded some of these titles, but they can no longer be found, you will have to take my word for it – or search the literature of 1970-1990 on paper.

Four word technical designations

This will make it clear that the epithet “Lapp” actually belongs to “study” – and has nothing to do with lactase or deficiency.

Anyone translating from English will recognise the difficulty of technical designations made of four words. We have to find out – or decide – which of these words is the main term and which are to be considered as adjective(s). In this case, people who had no clue about the origin of the “Lapp lactase deficiency study” probably stuck to “Lapp” out of sheer ignorance, afraid to lose some information in translation.

Let it be established then, that “Lapp lactase” does not exist – since the population was studied for the very fact that they were deficient: they did not have it. They had a “lactase deficiency”.

Are there any other lactase deficiencies?

Of course – the lack of lactase is a normal state in adult mammals.

Have other populations been studied? Certainly, even Wikipedia mentions it and the list of the literature is quite long. Titles of lactase deficiency studies mention Australian aboriginal children; Thailand; South-East Asia; South African Bantus; Uganda and Orientals.

Actually, apparently, 75% of adults lose their lactase in adulthood, and in Africa and Asia this percentage can reach 90%. The opposite, lactose persistency, is found in people of European ancestry and in some populations in Africa, the Middle East and Southern Asia. Interestingly, this is the result of a mutation – and actually not one single mutation, but different mutations in the different populations.

The research also revealed that the loss of lactase is not always total: 44% of lactose-intolerant women regain the ability to digest lactose during a pregnancy.

Lactase deficiency is classified into three types:

- a genetic deficiency in adults, occurring in the majority of the world population, called primary lactase deficiency
- a deficiency caused by injury to the small intestine in infancy from disease, called secondary, acquired, or transient lactase deficiency
- a congenital deficiency that is present at birth, so even babies don't have the enzyme – as was found in the Lapp population.

So technically, the deficiency discovered in the Sami population is different from lactase deficiency in the majority of people.

Just to satisfy your curiosity: what happens to lactose-intolerant people if they happen to ingest lactose? Mostly abdominal bloating and cramps, flatulence, diarrhoea, nausea, borborygmi (rumbling stomach) and vomiting (particularly in adolescents), thirty minutes to two hours after ingestion. Humans have bacteria in their gut that can digest lactose, but that goes with an excessive production of gas and water. Some people can be assisted to digest lactose by eating yoghurt containing live bacteria. There are also some yeasts that can help digest lactose.

How does this affect patients worldwide?

Lactose is added as a bulking product to nearly all medicines that are presented as tablets. A lactose-intolerant patient taking such tablets might suffer from the side effects of lactose. A warning is certainly warranted. However, not only the Sami might suffer from these – any patient with any severe kind of lactose intolerance. It would be wiser to just erase “Lapp” and speak of “lactase deficiency” or even better: just use “lactose intolerance”. To a patient, the fact that he cannot digest a type of sugar will be more relevant than the reason (whether he has the enzyme or not).

Racism in medical texts

The use of “Lapp” has nothing to do with racism: it is a kind of fossil from the past. However, there is no need to stick with the term, it can be discarded. The elimination of this mysterious word would even improve the readability of the text.

The idea that medicine can be good for some populations and harmful to others may feel like an inconvenient truth. Many leaflets contain a warning that a medicine seems to be less effective for people of Japanese descent, or causes more side effects in people of African descent. There is no intention of racism, it is just a fact, of the same

order that some cosmetics look better on a darker skin than others, or that curly hair is rare among the people of the Far East. The need for warnings for non-Caucasians is a natural consequence of the fact that many medicines are developed in Western countries, and registered only when they prove to be safe to the populations of the registering countries. Later on, the unsuitability for those other populations is unfortunately discovered during the post-marketing vigilance. This raises a question of the possibility that Chinese medicines might be less effective on Caucasians for the same reason – if they were developed and tested on a Far Eastern population?

References:

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