McNeil Sweden AB
Att: Bina Azhar
Box 4007
169 04 Solna

Solna, 12 july 2019

Request for termination regarding Voltaren 23,2 mg/g gel claim

Hereby we, GlaxoSmithKline Consumer Healthcare A/S ("**GSK**"), inform you that although your request was directed to an incorrect GSK legal entity, we have received the letter from McNeil Sweden AB sent on 2019-07-02 regarding Voltaren 23,2 mg/g gel (the "**Product**"). We understand you are challenging whether the claim 'relieves joint pain up to 12 hours' has a factual basis in the SmPC for the Product as required under article 102 of the Ethical Rules for the Pharmaceutical Industry in Sweden (LER). This challenge is based on your assertion that the SmPC of the Product does not include information regarding the duration of pain relief.

We take Swedish and European ethical codes of conduct very seriously, as they are aligned to GSK values and principles.

The relevant section of the LER (Article 102) states:

> *The summary of product characteristics (SPC) that has been adopted for a medicinal product constitutes the factual basis for information about the medicinal product.*

"Relieves joint pain up to 12 hours"

GSK does not agree with your challenge and reasoning, as we believe that factual basis for the claim "Relieves joint pain up to 12 hours" is sufficiently established in SmPC for the Product. The posology section of the SmPC for Voltaren 23.2 mg/g explicitly states twice daily application (see below). The purpose of the posology section is to give guidance on the needed dose and the needed frequency of dosage to get the targeted pain relief.

Adults and adolescents over the age of 14

Voltaren gel is applied to the painful or inflamed area twice daily and gently rubbed into the skin. The amount of gel is adjusted to the size of the affected area: 2-4 g Voltaren gel (5-10 cm gel strand) is sufficient to treat a surface of 400-800 cm². The maximum daily dose is 8 g of gel.

The posology of Voltaren 23,2 mg/g gel is based on a randomised, placebo-controlled clinical study (n=242) in patients with acute ankle sprain, where pain on movement at day 5 (primary efficacy variable) was reduced by 23.2 mm vs placebo ($p<0.0001$) in those treated twice daily. As those using Voltaren 23,2 mg/g twice daily applied this in the morning and in the evening, the authors concluded that "two applications per day (morning and evening) suffice to exert a therapeutic effect that could last for up to 12 h" (Predel, et al. 2012).
The claim "Relieves joint pain up to 12 hours" communicates to consumers that to benefit from the Product each day (i.e. up to 24 hours) they will need to apply the Product twice-daily (morning and evening). The duration of efficacy and the required dosage are inextricably linked. The posology information in the SmPC is therefore the clear and obvious factual basis for the maximum duration of efficacy.

Finally, "Relieves joint pain up to 12 hours" claim for Voltaren 23.2 mg/g gel has been present in our marketing materials for the last five years with no concerns voiced by competitors, the MPA or IGN, or consumer. This is a clear indication that the claim aligns with consumer expectations of the Product and is accepted as properly substantiated, truthful and not misleading.

We therefore reject your assertion that the claim does not have a factual basis in the SmpC.

Advertising claims made for Ipaflex 200 mg naproxen

Related to McNeil's approach on claims substantiation and posology of Ipaflex 200 mg naproxen capsule (see below) one might question, if it is in line with LER article 104.3 which states:

exaggerated claims about a medicinal product's properties or effects may not be made. It may not be implied that a medicinal product or an active substance has any special benefit, quality or property if this cannot be verified

GSK questions McNeil's substantiation for "one capsule relieves pain up to 12 hours" in patients with muscle and back pain in your TV copy and marketing materials (example below) for Ipaflex 200 mg naproxen.

Ipalfex 200 mg naproxen SmPC declares in section 5, Pharmacodynamic characteristics in quite broad manner: "Clinical data shows that the pain relief effect can last up to 12 hours after intake of 220 mg naproxen sodium".

Adults and adolescents from the age of 12:

One capsule every 8 to 12 hours.
If necessary, 2 capsules may be taken as an initial dose, followed by an additional capsule after 12 hours if symptoms persist.
A maximum of 3 capsules per day.

When looking at the data available in the Clinical Overview for Naproxen Sodium 220 mg submitted to MPA, evidence is mostly bibliographic and is derived for formulations as well as dosages different from that in Ipaflex 200 mg naproxen. Efficacy of various conditions are described, but the analgesic response to the study drug was not evaluated in the patient's rating pain relief at 12 h in muscle pain or back pain, the conditions presented in the copy (e.g. back pain, muscle pain). We therefore query whether the claim "one capsule relieves pain up to 12 hours" made by you in respect of Ipaflex 200 mg naproxen for muscle and back pain is indeed supported and in accordance with LER article 104.3.

Dr Kate (Ekaterina) Fabrikant, DMD, PhD
Area Medical Director Nordics-Benelux
GlaxoSmithKline Consumer Healthcare A/S
Hemvärnsgatan 9, 171 54 SolnaEmail kate.x.fabrikant@gsk.com