

VYGORIS

London, March 28th, 2019

To whom it may concern,

In relation to the recent debate occurring in the Netherlands, Vygoris Limited would like to clarify its position on the mitomycin supply.

Vygoris Limited (formerly named Substipharm Limited) has acquired the Product Mitomycin and its associated trade marks from SEP (Speciality European Pharma, UK based) in April 2017.

We are the Marketing Authorisation holder of this product distributed in the Netherlands by our partner Eurocept.

Back then SEP was using the active substance source coming from Hisun (legally, as Hisun had a valid GMP certificate at the time). As soon as Hisun lost its relevant GMP status, no new order were placed with Hisun. The Dutch inspectorate granted permission for Hisun API which was still in stock, to prevent shortages for the market. The condition was met that this batch was tested extensively and no impurities were found. Later Vygoris has switched its sourcing to another supplier (Sicor).

In parallel, Vygoris has made a lot of effort to register a third source of active substance in order to have more choices at its disposal so we wouldn't be linked to the first two sources in case further issues arise.

This third source (with a CEP and GMP approved) is the one that we currently use and we are planning to do so in the future.

Vygoris Limited doesn't use and will not use any mitomycin Hisun active substance in its finished product for any market (let alone the Netherlands).

Finally it is important to note that Vygoris has been very open and transparent with the **IGJ (Netherlands Health Inspectorate)** and has updated IGJ every step of the way in order to secure a safe and validated source of active substance for the Dutch patients, resulting with zero out of stock situation of our product in the Netherlands.

With Warm Regards



Philippe Beaupere
Managing Director UK
Vygoris Limited