IBA Molecular - CIS Bio International

R.N. 306-SACLAY

B. P. 32

91192 Gif-sur-Yvette Cedex

France

01 July 2019

Case no.: 2018092197

Our ref.: ebn/lho

Your ref.: DOS-CTD-0047/008 (T02-2018-9-VAR\_G)

E-mail: ebn@dkma.dk

Vasculocis, 10 mg, Kit for radiopharmaceutical preparation MA-no DK R1043

**Acceptance of the variation**

With reference to your variation application of September 2018, the Danish Medicines Agency accepts the changes detailed in the application:

II, B.I.a.1.e Change in the manufacturer relates to a biological active substance or a starting material/reagent/intermediate used in the manufacture of a biological/immunological product.

II, B.I.a.3.c The change requires assessment of the comparability of a biological/immunological active substance.

IB, B.I.a.4.b Addition of a new inprocess test and limits.

II, B.I.b.2.d Substantial change to or replacement of a biological/ immunological/immunochemical test method or a method using a biological reagent for a biological active substance.

**The grouped variation application journal no. 2018092197 is approved**.

**Regarding change of the product information**

If your variation application has impact on the labelling, package leaflet or summary of product characteristics, the Danish Medicines Agency has the following terms to the product's marketing authorization in compliance with section 9(1) of the Danish Medicines Act:

1. Revision of the labelling and package leaflet must be implemented within 12 months from the date of the summary of product characteristics revised by the Danish Medicines Agency or from today, if
   1. it appears from the current package leaflet that the newest package leaflet is available at www.indlaegsseddel.dk, and
   2. the revised package leaflet is uploaded to "DKMAnet-Package Leaflets" within three months from the date of the summary of product characteristics revised by the Danish Medicines Agency or from today.
2. If the conditions of 1a and 1b above are not fulfilled, the revised labelling and package leaflet must be implemented within six months from today.

Continuation of the marketing authorisation is subject to the fulfilment of the above-mentioned terms.

Please note that the Danish Medicines Agency has not assessed the layout of the packaging material, if submitted.

Revised package leaflets of marketed products must be uploaded to "DKMAnet-Package Leaflets", even if the package leaflet is not yet contained in the marketed packages, see section 1(3) of the Danish executive order on submission of package leaflets to the Danish Medicines Agency (Danish title: "Bekendtgørelse om indsendelse af indlægssedler til Lægemiddelstyrelsen").

In case the product is not marketed the revised package leaflet must be uploaded to "DKMAnet-Package Leaflets" as soon as the product is marketed, see section 1 and 2 of the Danish executive order on submission of package leaflets to the Danish Medicines Agency (Danish title: "Bekendtgørelse om indsendelse af indlægssedler til Lægemiddelstyrelsen").

Best regards



**On behalf of**

**Eva Rauhe Bækdahl**