Sender: Emdoka bvba, John Lijsenstraat 16, B-2321 Hoogstraten

To all authorities involved in the application procedure of Tulatrixx

Procedure No.: EMEA/V/C/0005364

WITHDRAWAL OF APPLICATION OF TULATRIXX
Name of the VMP: **Tulatrixx**
Procedure No.: **EMEA/V/C/0005364**

Hoogstraten, April 1th, 2020

Dear Madam,
Dear Sir,

I would like to inform you that Emdoka bvba, at this point of time, has taken the decision to withdraw the application for Marketing Authorisation of:

A) Tulatrixx 25 mg/ml solution for injection for pigs
B) Tulatrixx 100 mg/ml solution for injection for cattle, pigs and sheep

which were intended to be used for .

A) Pigs: Treatment and metaphylaxis of swine respiratory disease (SRD) associated with Actinobacillus pleuropneumoniae, Pasteurella multocida, Mycoplasma hyopneumoniae, Haemophilus parasuis and Bordetella bronchiseptica sensitive to tulathromycin.
B) Cattle:Treatment and metaphylaxis of bovine respiratory disease (BRD) associated with Mannheimia haemolytica, Pasteurella multocida, Histophilus somni and Mycoplasma bovis sensitive to tulathromycin. Treatment of infectious bovine keratoconjunctivitis (IBK) associated with Moraxella bovis sensitive to tulathromycin.
Pigs:Treatment and metaphylaxis of swine respiratory disease (SRD) associated with Actinobacillus pleuropneumoniae, Pasteurella multocida, Mycoplasma hyopneumoniae, Haemophilus parasuis and Bordetella bronchiseptica sensitive to tulathromycin.
Sheep:Treatment of the early stages of infectious pododermatitis (foot rot) associated with virulent Dichelobacter nodosus requiring systemic treatment.

Yours sincerely,

[redacted]

[redacted]