



Elanco Denmark ApS.
Lautrupvang 12, 1.th
2750 Ballerup
Denmark
www.elanco.dk

Statens Legemiddelverk
Postboks 240 Skøyen
0213 Oslo

14 August 2023

Withdrawal of application dossier for marketing authorisation of Imvixa in Norway – national procedure – [REDACTED]

Dear Madam/Sir,

On 9 September 2022, Elanco applied for a national marketing authorisation in Norway for the product Imvixa. The application was validated on 31 October 2022, and the day 110 assessment report and the day 110 list of questions were received on 17 February 2023.

Following a clarification meeting with the NoMA assessment team on 14 March 2023, Elanco applied for a three-month clock-stop extension which was granted by NoMA. The deadline for submitting the responses to the list of questions is 17 August 2023.

After further review of the assessment report and the feedback shared by NoMA at the meeting in March 2023, and under the current circumstances, Elanco has decided to withdraw the application.

Thank you in advance for acknowledging our withdrawal request.

In case of any questions, please do not hesitate to contact me [REDACTED]

Best regards,

[REDACTED]