

**FOI 23/910**

Dear

Many thanks for your correspondence, dated 24 November 2023, where you requested the following:

*The full product licence history for Relaxit Enema (PL 0009/0019, PL 0022/0150, PL 11138/0004 and PL 20074/0003).*

Relaxit (PL 00009/0019; Pharmacia Biotech Limited) was granted a Marketing Authorisation on 29/11/1977. The legal basis is not recorded in our electronic database. We may hold more information on this in our paper archives, which are held off-site and will take time to retrieve. Please let us know if you would like us to search further for the legal basis and this will be dealt with as a new request. The licence underwent a change of marketing authorisation holder to G D Searle and Company Limited (Relaxit Micro-Enema; PL 00022/0150) on 28/2/1994 and was subsequently cancelled.

Relaxit Micro Enema 5ml (PL 11138/0004; Crawford Pharmaceuticals Limited) was granted a Marketing Authorisation on 18/10/1995. This was an abridged simple application, granted under Dir Art 4.8a(i), cross-referring to PL 00022/0150, as the reference product. The licence then underwent a change of marketing authorisation holder to Crawford Healthcare Limited (Relaxit Micro Enema 5ml; PL 20074/0003) on 30/10/2006. The licence was subsequently cancelled on 26/9/2013.

We now consider this request closed. If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the Agency who has not previously been involved in your request. If you wish to pursue that option please email: [info@mhra.gov.uk](mailto:info@mhra.gov.uk)

After that, if you remain dissatisfied, you may write to the Information Commissioner at;

The Information Commissioner's Office  
Wycliffe House  
Water Lane  
Wilmslow  
Cheshire  
SK9 5AF

They will make a decision on whether or not we have interpreted the FOIA correctly in handling your request.

Yours sincerely

FOI Team