Reference:	FOI.12108.23
Subject:	Chitin/Chitosan
Date of Request:	3 July 2023

Your request and our response

Hywel Dda University Health Board (UHB) provides its response below.

1a. Is any of the product(s) purchased/used in your hospital contain Chitin/Chitosan (e.g. surgical sutures, materials in wound healing/tissue engineering/dentistry/drug delivery)?

√ Yes
☐ No

If the answer to Q1a is Yes then skip to Q2a.
If the answer to Q1a is No then:

1b. Do you plan on utilizing products containing Chitin/Chitosan in the next two years?

☐ Yes
☐ No

If the answer to Q1b is No, you may skip the rest of the questionnaire.
If the answer to Q1b is Yes, answer Q2a and then you may skip the rest of the questionnaire.

2a. What product(s) do you have in the hospital (or intend to purchase) that FOI.HywelDda@wales.nhs.ukcontains Chitin/Chitosan?

Under the Freedom of Information Act 2000 (FoIA), Hywel Dda University Health Board (UHB) can only provide information that it holds. Therefore, the UHB confirms that it has purchased Celox gauze, which contains Chitosan, during the 2022/23 financial year.

2b. For each product listed in response to Question Q2a, could you please provide the following details:

- The product's brand name:
  Celox Z fold gauze

- The purpose of the product and in which department it is used:
  Haemorrhage control used in the Emergency Department in Bronglais General Hospital.

- The approximate volume of the product used/purchased over the last financial year (1st April 2022 – 31st March 2023):
  Ten (10) packs were purchased, during the 2022/23 financial year.

3. Has the hospital received any complaints or filed any cases of side effects from using the Chitin/Chitosan product(s) mentioned above? If so, please provide detail of the following:
   a. Number of cases in years 2020, 2021, 2022 and 2023
   b. description of the most three common side effects
   c. Which product(s) caused the most commonly seen side effects

The UHB confirms that no complaints have been recorded on the UHB's DATIX Incident Reporting system, during the period from the 2020 calendar year to the date of your request.

Additionally, the UHB does not hold information on medicine or medical adverse events. This information would be held by the Medicines and Healthcare products Regulatory Agency (MHRA), who manage the yellow card scheme, which is a scheme used to collect, collate and investigate reports of suspected drug reactions.

Therefore, we suggest that you re-direct this part of your request to FOI_policy@mhra.gov.uk

4. Is there any limitation(s), certification(s), or regulatory requirement(s) that are bounded when utilizing Chitin/Chitosan in the hospital (i.e., ISO standards or Ethics, etc)? If so, please specify.

   The UHB confirms that there are no specific regulatory requirements over 'CE' marking.

   However, there are the following limitations:
   Do not apply over eyes.
   Do not use in abdominal wounds and wounds unamenable to pressure.
   Do not pack into body cavities.
   Device not intended for surgical use.

   Additionally, Product Instructions for Use (IFU), are available via the attached link:
   Celox-Rapid-1.5m-Z-Fold-CE-MTP-21-2066-English-May-22.pdf (celoxmedical.com)

5. Is the hospital currently or will be promoting any new products containing chitin or chitosan?

   The UHB confirms that it does not promote any products.