Information Governance

27 December 2017 **Our Ref:** RFI 22176

Dear

Freedom of Information Act 2000
Information in Relation to Pharmaceutical Samples of Licensed Medicines

I am writing to confirm that the South Eastern Health & Social Care Trust (the Trust) has now completed its search for the information relating to the above which you requested on 5 December 2017.

A response to each of the questions raised has been provided by the Woman and Acute Child Health Directorate and is attached in Appendix A.

Under the terms of the legislation, if you are unhappy with this response you have the right to seek a review within the Trust in the first instance. If you wish to do so, please write to me at the address below.

If after such a review you are still unhappy with the response, you have the right to appeal to the Information Commissioner who will undertake an independent review. The Information Commissioner can be contacted at The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, SK9 5AF.

If you have any queries about this letter, please do not hesitate to contact me. Please remember to quote the reference number above in any future communications.

Yours sincerely

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L McAree (Miss)
Head of Information Governance &
Directorate Support

Q1) Please confirm if the Institution accepts pharmaceutical samples of licensed medicines (i.e. sample packs provided free of charge)?

A1. Yes for evaluation only, then a formulary request is required for consideration by the New Drugs Group.

Q2) If it does, please confirm whether the Institution also accepts "cold chain" samples? If it does, is there any restriction on pack size?

A2. The Trust has not accepted any 'cold chain' samples to date but would consider this. There is no restriction on pack size; however policy states small quantity, usually enough for 5–10 patients to allow evaluation.

Q3) Does the Institution have a formal policy relating to the receipt of samples in either of the above cases? If yes, please can you provide an electronic copy of this policy?

A3. Yes. Please see attached Section 1.4 from our medicines policy entitled 'Samples of Pharmaceutical Products'.

Q4) Excluding samples, are there any other circumstances or criteria under which the Institution would accept free of charge licensed medicines?

A4. Free of charge licensed medicines have been accepted as part of commercial agreements/patient access schemes whilst awaiting National Institute for Health and Care Excellence (NICE) guidance. The medicines are still subject to the Trust's Individual Funding Request (IFR) processes.

Extract from medicines policy entitled 'Samples of Pharmaceutical Products'.

1.4 Samples of pharmaceutical products

1.4.1 All pharmaceutical products to be used in the South Eastern HSC Trust must be issued through the Pharmacy Service.

1.4.2 A sample is defined as a small quantity of a pharmaceutical product provided to a health professional so that he/she may acquire experience in using it. A sample may only be provided to a health professional qualified to prescribe that particular product.

1.4.3 All samples must be licensed and have a UK marketing authorisation.

1.4.4 Samples of pharmaceutical products may only be supplied in response to a written request from a Consultant, clinical nurse specialist or professional head of department. The request should contain the following information:

- The clinical area in which the sample will be used
- The reason for requesting the sample
- Where the sample should be sent to
- The person who will receive and store the sample at ward/department level
- Confirmation that feedback will be given to the Pharmacy Services Manager (Downe and Lagan Valley Hospital - LVH) or the Pharmacy Procurement Lead (Ulster) once the sample has been used.
- The request must be sent to the Pharmacy Services Manager (Downe and LVH) or the Pharmacy Procurement Lead (Ulster) in writing or by e-mail

1.4.5 To ensure compliance with Product Liability Legislation, Medicines Act Regulations, Department of Health, Social Services and Public Safety (DHSSPS) now Department of Health guidelines and ABPI code, samples must not be left in clinical or administrative areas. All samples must be receipted and issued from the pharmacy department

1.4.6 The samples must be clearly labelled with details of the Consultant, clinical nurse specialist or professional head of departments who requested them.

1.4.7 To ensure that products can be traced in the event of a product safety recall, the pharmacy department will log the batch number and expiry date of each sample before sending them to the requesting member of staff. After a period of six months, any unused samples will be disposed of.

1.4.8 The request for and use of a sample does not indicate an intention to prescribe the product on a recurring basis. The Trust guidance for the acquisition of a new drug must be followed (see section 3.1.1) and appropriate funding streams secured.

1.4.9 Failure to respect the spirit of this guidance could result in the pharmaceutical company representative being denied access to the Trust facilities.