Department of Health & Social Care

Sarah Wilkinson
Chief Executive
NHS Digital
1 Trevelyan Square
Boar Lane
Leeds
LS1 6AE

18 June 2018

Dear Sarah,

Sales and Purchases of Unbranded Generic Medicines and Special Medicinal Products Directions 2018

I am writing to provide Directions to the Health and Social Care Information Centre, known as and hereafter referred to in these Directions as NHS Digital.

These Directions are given in exercise of the powers conferred by sections 254(1) and (6), 260(2)(d), 261(2)(e), 274(1)(d) and (2) and 304(9), (10) and (12) of the Health and Social Care Act 2012[1] (the Act) and Regulation 32 of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013[2] (the Regulations).

In accordance with section 254(2)(b) of the Act, the Secretary of State considers that it is in the interests of the health service in England for these Directions to be given.

These Directions are to be known as the **Sales and Purchases of Unbranded Generic Medicines and Special Medicinal Products Directions 2018** and come into effect on 1st July 2018. This aligns with the date on which the Health Service Medical Supplies (Costs) Act 2017 comes into force.

Pursuant to sections 254(1) and 254(6) of the Act, NHS Digital is directed to establish an information system for the collection or analysis of information about sales and purchases of unbranded generic medicines and special medicinal products from manufacturers, wholesalers and importers to be known as the **Sales**

and Purchases of Unbranded Generic Medicines and Special Medicinal Products Information System.

The purpose of this information system is to collect sales and purchase information to inform the reimbursement prices of community pharmacies and for other purposes listed in s264A(3) of the NHS Act 2006 (as amended by the Health Service Medical Supplies (Costs) Act 2017).

Under 254(1) NHS Digital is directed to collect and analyse the data items as set out in Annex 1, but to only publish analysis of the data collected where a separate instruction has been issued by the Secretary of State.

In accordance with section 260(2)(d) of the Act, NHS Digital is directed not to publish the data obtained by complying with these Directions.

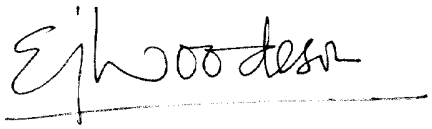
Pursuant to section 274(1)(d) and (2) of the Act and regulation 32(1) of the Regulations, NHS Digital is further directed to exercise the following additional systems delivery functions of the Secretary of State:

- the development and operation of IT applications, IT infrastructure and IT systems as would assist NHS Digital to provide the **Sales and Purchases of Unbranded Generic Medicines and Special Medicinal Products Information System** and minimise the burden on data providers.

In accordance with regulation 32(2)(a) of the Regulations, the Secretary of State may make payments to NHS Digital for things done in the exercise of the systems delivery functions described in these Directions.

In accordance with section 254(5) of the Act, NHS Digital has been consulted before these Directions have been given.

Yours sincerely



Liz Woodeson
Director, Medicines and Pharmacy

Annex 1

Information to be collected

Information will be collected on a defined list of unbranded generic medicines and a defined list of special medicinal products that will be comprised of all products listed in the Drug Tariff and any products that are being considered for inclusion in any Drug Tariff. For each type of medicine (generics and specials) DHSC will provide NHS Digital with a list of products every quarter.

The following information about each product will be collected:

- Volumes sold/bought
- Total sales income/amount paid net of discounts/rebates
- Any discount/rebates that cannot be attributed to the product

In the case of special medicinal products, more detailed information about the type of manufacture and available Drug Tariff formulations will also be collected.