Association of the British Pharmaceutical Industry (ABPI)

Legislative Consent Memorandum (LCM) on the Health Service Medical Supplies (Costs) Bill

As requested by the Scottish Parliament’s Health and Sport Committee (“the Committee”) this response focuses solely on those areas of the Health Service Medical Supplies (Costs) Bill (“the Bill”) that relate to the legislative competence of the Scottish Parliament, contained within Clause 6 of the Bill.

The Legislative Consent Memorandum

ABPI Scotland acknowledges the Scottish Government’s conclusion that the information powers in the Bill (to the extent that they relate to devolved matters) are in the best interests of NHSScotland. However, ABPI Scotland is concerned about some provisions contained within Clause 6 of the Bill, which are detailed below.

We further agree that a UK-wide application of this Bill is the most pragmatic approach, and will lead to the most streamlined and efficient process.

Clause 6 – Provision and disclosure of information

ABPI Scotland supports clarification of the scope of the legislation, including in Clause 6. Specifically, we would welcome greater clarity from the Department of Health on the additional information that will be required by them as a result of the Bill, in advance of the Bill receiving Royal Assent.

Current proposals

- The UK Government already collects information on sales and purchases of medicines from various parts of the health service medicines supply chain under a range of existing arrangements.
- The Bill will introduce additional requirements on all UK manufacturers, wholesalers, pharmacies and GP practices that dispense medicines, to record and submit the following information:
  - The price charged or paid by the producer for the products;
  - The price charged or paid for the delivery or other services in connection with the manufacturing, distribution or supply of those products;
  - The discounts or rebates or other payments given or received in connection with the manufacturing, distribution or supply of those products;
  - The revenue or profits accrued in connection with manufacturing, distribution or supply of those products;
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Concern with current proposals

- ABPI Scotland supports the Department of Health’s intention to bring all information requirements under a statutory footing in order to ensure the reimbursement system is run effectively.
- However, we are concerned that the Bill will require information from pharmaceutical companies which is beyond what is required to fulfil this aim.
- UK pharmaceutical companies already provide comprehensive information to the UK Government on profits they make at a company level. The Bill would require companies to allocate profit figures to individual products.
- The proposed information requirements potentially extend to a company’s global business and are therefore not required in order to achieve the UK Government’s policy intention.
- Information on payments made for distribution of individual products is not currently recorded by pharmaceutical companies at a product level. It would be extremely difficult for companies to share information at this level, with any information obtained likely to be estimated. Furthermore, such costs typically bear no relation to the cost of medicines to the NHS or reimbursement schemes, and are therefore unnecessary to achieve the aim of the Bill.
- As such, any information collected would be artificial, unreliable and highly complex to provide. Our members indicate that, in many cases, it would not be possible to provide product level data as might be required by the legislation.

Necessary clarification

- The Department of Health has published illustrative regulations alongside the Bill to aid with the legislative scrutiny. Whilst this is welcome, the legislation will still require companies to provide profit information at a product level.
- This lack of clarity is relevant to the proposed Legislative Consent Memorandum, as the Committee and the Scottish Parliament does not know what information, or from whom, will be requested as a result of the Bill.
- For example, Clause 9 of the Information Regulations state that all “English producers” must keep the following information re. all “English health service medicines” and produce it when requested by the Secretary of State:
  - names of buyer and seller
  - sales income actually received or the amount actually paid
  - quantity bought or sold
  - all discounts given or received and the terms on which they were made
- The broad definition of activities and companies (i.e. in connection with any manufacture, distribution or supply) in both this section of the regulations and the wording in the Bill itself, would capture any part of a company’s global supply chain.
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- ABPI Scotland would welcome clarification in the regulations that this information power only applies in the case of generic medicines, as per the intention of the Bill.
- Amending the regulations in this way would maintain the requirement that pharmaceutical companies keep company profit information, and remove the requirement to provide profit information at a product level.
- UK pharmaceutical companies already provide comprehensive information to the UK Government on profits they make at a company level. The proposed information powers would seemingly require allocation of profits to individual products, which would be artificial and unreliable as well as onerous and highly complex to provide.
- They would also ensure that data provided is specific to an individual company’s business with the NHS, rather than at an individual product level.
- ABPI Scotland does not believe that such clarifications would deter from achieving the UK Government’s policy intention to introduce a payment mechanism into the statutory scheme.