

DHSC: Proposed amendments to the Health Service Products (Provision and Disclosure of Information) Regulations 2018: consultation document

Consultation questions

About you

In what capacity are you responding to this survey?

- An individual sharing my personal views and experiences
- An individual sharing my professional views
- On behalf of an organisation

Questions for organisations

What is the name of your organisation? Royal College of Pharmacy

Where does your organisation operate or provide services? (Optional, select all that apply)

- England
- Wales
- Scotland
- Northern Ireland
- The whole of the UK
- Outside the UK

Which of the following best describes the work of your organisation?

- A manufacturer or supplier of health service products and/or appliances
- A wholesaler of health service products and/or appliances
- A supplier of health service products and/or appliances
- An organisation representing the pharmaceutical industry
- Other pharmaceutical or life science sector, please specify
- A provider of goods or services to the NHS
- Other private sector organisation, please specify
- An NHS organisation
- Research or education
- Other public sector organisation, please specify
- An organisation representing patients, the public and carers
- Other voluntary sector organisation, please specify Professional Leadership body for pharmacists and pharmaceutical scientists

If asked to specify, please provide further detail about the work of your organisation. (Optional, maximum 200 words)

Consultation proposals: reimbursement

DHSC proposes to introduce a provision to the information regulations that allows DHSC to routinely collect, on a quarterly basis, supply and purchase information on unbranded generic and special products, rather than relying on the current ad hoc provisions. This is with a view to adding the products to Part VIII of the Drug Tariff.

This would regularise the collection of data and allow for reimbursement prices to be considered for more products.

Do you agree or disagree with this proposal?

- Agree
- Neither agree nor disagree
- Disagree
- Don't know

DHSC proposes to introduce a provision to the information regulations that allows DHSC to routinely collect, on a quarterly basis, sales and volume data for branded and generic medicines in Category H of the Drug Tariff.

This would regularise the collection of data and allow for reimbursement prices to be considered for products in Category H of the Drug Tariff.

Do you agree or disagree with this proposal?

- Agree
- Neither agree nor disagree
- Disagree
- Don't know

DHSC proposes to introduce a provision to the information regulations to require producers of health service medicines to notify DHSC about any new health service medicines they place on the market.

This will ensure that the dm+d is updated accordingly and accurate reimbursement prices can be set in the Drug Tariff.

Do you agree or disagree with this proposal?

- Agree
- Neither agree nor disagree
- Disagree
- Don't know

DHSC also proposes to introduce a provision to the information regulations to require producers of health service medicines to notify DHSC about changes to any existing medicines (including price and pack size).

This will ensure that the dm+d is updated accordingly and accurate reimbursement prices can be set in the Drug Tariff.

Do you agree or disagree with this proposal?

- Agree

- Neither agree nor disagree
- Disagree
- Don't know

DHSC is proposing to include a provision in the information regulations that requires pharmacies acting in the capacity of a hub, as a supplier to community pharmacies providing NHS pharmaceutical services to record, to keep and provide information about their purchase, sale and supply of health service products that they supply to a 'spoke' business.

This will enable price setting for reimbursement and supply monitoring to reflect the whole supply chain where necessary.

Do you agree or disagree with this proposal?

- Agree
- Neither agree nor disagree
- Disagree
- Don't know

If you selected 'agree', do you agree or disagree that the best way to do this is by including hubs in the definition of a Category C purchaser as defined by regulation 15?

- Agree
- Neither agree nor disagree
- Disagree
- Don't know

In the information regulations, DHSC is proposing to define an invoice as 'any set of documentation that functions as an invoice for the purchase of any presentations, specifically enhanced delivery notes (which provide all the equivalent information of an invoice) and credit notes for purchases.'

This would be for the purpose of informing the margin survey and will provide clarity and ensure medicine margin calculations are based on accurate data.

Do you agree or disagree with this proposal?

- Agree
- Neither agree nor disagree
- Disagree
- Don't know

If you have any comments on the proposals in this section, please include them here. (Optional, maximum 800 words)

We support the proposals to encourage accurate and timely reporting with the aim to support the effectiveness and efficiency of the reimbursement arrangements, together with preventing medicines shortages and supporting DHSC to take mitigating action when they do occur. The principles align closely with some of the recommendations from our published report, [Medicines Shortages: Solutions for empty Shelves](#).

Some of these recommendations include;
Reiterate the legal and ethical responsibilities of the supply chain,

Review the Community Pharmacy Contractual Framework,
Earlier reporting of shortages by Marketing Authorisation Holders,
Enable greater data sharing to support planning and predict demand

Medicines reimbursement and the economics of the community pharmacy contract has been highlighted by community pharmacy organisations as a significant factor in increasing financial pressure on community pharmacies

To note from our engagement during the forming of our report, we heard that the use of price concessions and the system's responsiveness to price changes needed to be evaluated to establish how effective the pricing system is in mitigating the impact of price volatility on community pharmacies.

We are in broad support of the proposals, with an increase in collection of data on a more regular quarterly basis, if that helps ensure that community pharmacies are reimbursed fairly and appropriately for the medicines they dispense. In addition, through our report, we heard anecdotally of fluctuating prices in medicines to a degree where they are above drug tariff reimbursement, with price concessions not reflecting these prices in a timely manner, risking a perverse incentive to not supply medicines.

Wherever possible and to support manufacturers and suppliers, the collection of data must not be overly burdensome, manufacturers and suppliers already provide data as part of other schemes, including VPAG, and wherever possible this should be harmonised to support unnecessary duplication.

Consultation proposals: availability and value for money

DHSC is proposing to amend regulation 29 so there are clear obligations to report any situation where supply might be reduced.

This will ensure that DHSC has sufficient notice of any potential shortages and will enhance DHSC's ability to manage supply issues, as currently not all potential issues are being reported.

Do you agree or disagree with this proposal?

- **Agree**
- Neither agree nor disagree
- Disagree
- Don't know

DHSC is proposing to introduce a requirement for companies to share information on products that can be used in the NHS (even if they are intended for retail sale) in the event a shortage is identified.

This will ensure that DHSC has a complete picture of the market and can better manage supply challenges. Do you agree or disagree with this proposal?

- **Agree**
- Neither agree nor disagree
- Disagree
- Don't know

DHSC is proposing to include a provision in the information regulations that enables DHSC to make ad hoc requests about marketing authorisation holders' stock position when there is no supply shortage or upcoming discontinuation.

This will enable DHSC to better respond to identified public health risks and minimise the effect of supply shortages on patients.

Do you agree or disagree with this proposal?

- **Agree**
- Neither agree nor disagree
- Disagree
- Don't know

DHSC is proposing to increase the scope of data that suppliers are required to provide when they anticipate a discontinuation or an upcoming supply shortage. The proposed scope of data would include current and future stock positions.

This will support future planning, horizon scanning and mitigation of supply risks.

Do you agree or disagree with this proposal?

- **Agree**
- Neither agree nor disagree
- Disagree
- Don't know

If you have any comments on the proposals in this section, please include them here. (Optional, maximum 800 words)

The amendment of regulation 29 so there are clear obligations to report any situation where supply might be reduced, could be supported by specific examples and scenarios to aid and support manufacturer reporting.

We are supportive of the requirement for companies to share information on products that can be used in the NHS (even if they are intended for retail sale) in the event a shortage is identified, to help DHSC to better manage supply challenges/spikes in demand. This would need to be proportionate and not unnecessarily burdensome for manufacturers and wherever possible done with timely forward planning e.g. asking for information on antibiotics pre the flu season – which is predictable.

We support the increased scope and frequency of data collection to ensure we have a system that is able to predict and respond to impending supply problems that may lead to shortages as early as possible to mitigate against them. Any changes must benefit patients, pharmacists and wider healthcare professionals involved in the prescribing and supply of medicines, to ensure there is greater visibility of the availability of medicines across the system. Additional data collection should be done in a proportionate manner to support compliance, without creating unnecessary burden on manufacturers.

Consultation proposals: improving the compliance regime

DHSC is proposing to replace the reference to 'NHS England online gateway' with a reference to the NHSBSA's data portal in the information regulations.

This will ensure the information regulations reflect the organisational changes that have taken place since they were first introduced.

Do you agree or disagree with this proposal?

- Agree

- Neither agree nor disagree
- Disagree
- Don't know

DHSC is proposing to amend the information regulations to define the specific delivery point for shortages and discontinuations to be reported.

This will provide further clarification and ensure the information regulations reflect current practice.

Do you agree or disagree with this proposal?

- Agree

- Neither agree nor disagree
- Disagree
- Don't know

DHSC is proposing to remove the requirement for DHSC to issue a compliance notice prior to imposing fines on companies that fail to comply with regulation 25(4) or 31(5) relating specifically to shortages, discontinuations or product information updates.

This will ensure faster, more effective responses to supply risks and allow for the dm+d to be updated to set accurate reimbursement prices.

Do you agree or disagree with this proposal?

- Agree
- Neither agree nor disagree
- Disagree

- Don't know

DHSC is proposing to reduce the frequency of the review of the information regulations to every 2 years.

This will enable adequate time for the information regulations to take effect and will enhance the quality of future evaluations.

Do you agree or disagree with this proposal?

- Agree

- Neither agree nor disagree
- Disagree
- Don't know

If you have any comments on the proposals in this section, please include them here. (Optional, maximum 800 words)

We are supportive of changes that improve compliance with reporting to mitigate against shortages and ensure adequate reimbursement for medicines and supports enforcement measures where necessary. Changes should be done with dialogue and collaboration with manufacturers, enforcement could be a tool, but a system that ensures early notification and is not overly onerous for manufacturers is important.

Changes must demonstrate a benefit for patients and healthcare professionals. Changes must not be overly burdensome on manufacturers and suppliers and encourage collaboration and compliance.

Impact of the proposals (file upload)

This section is intended to invite stakeholders to provide their own evidence to support the [impact assessment](#). If you would like to provide any qualitative and quantitative data on any of the proposed amendments, please do so here. (Optional)

Statutory duties

Several specific duties must be considered when proposing updates to the information regulations, including:

- duties under the NHS Act 2006
- the Family Test
- the environmental principles policy statement

DHSC considers the proposals will help ensure the Secretary of State for Health and Social Care continues to promote a comprehensive health service and that the proposed amendments support the efficient and effective operating of the reimbursement arrangements and is better positioned to prevent medicines shortages.

Do you agree or disagree with DHSC's initial conclusions about the impact that the proposed updates to the information regulations will have in terms of the statutory duties of the Secretary of State?

- Agree
- **Neither agree nor disagree**
- Disagree
- Don't know

Please explain your answer and provide evidence to support further development of our analysis. (Optional, maximum 500 words)

It is essential any changes are done through the lens of ensuring benefits for patients, pharmacists and other healthcare professionals involved in the prescribing and supply of medicines. We are broadly supportive of many of the proposals, and some we have not commented on, are more for other organisations (e.g. manufacturers) to comment on.