

PSA Consultation on draft Rulemaking guidance

Royal Pharmaceutical Society Response

1. Do you think our guidance will help regulators exercise their rulemaking powers effectively?

In our guidance we outline principles to help regulators to use their rulemaking powers in a way which prioritises public protection and ensures a good practice approach to making rules (see 4.1-4.3 of the draft rulemaking guidance). The following questions relate to these principles:

2. Do you think that the principles outlined are the right ones?

- **Yes**
- No
- Don't know

3. Do you have any comments to make on the principles listed or any additional principles to suggest?

The principles listed seem appropriate to ensure a robust process of good rule-making and are key to providing consistency across regulators. However, it is not clear how regulators will be assessed against these principles, or how they may be challenged on the way they set rules.

The principles and guidance do not necessarily add much in terms of good practice. They are a high-level overview and helpfully remind regulators of their duties in terms of consultation etc. Over time, the guidance should be built upon to include deep-dives into good practice around rule-making.

In our guidance we give advice on ensuring consistency between different regulators' processes and avoiding unjustifiable difference (see 6.1 – 6.11 and Annex A of the draft rulemaking guidance). The questions below relate to this section:

4. Do you think that the guidance on consistency between regulators (avoiding unjustifiable difference) is helpful?

- **Yes**
- No
- Don't know

5. Do you have any comments to make on this section of the guidance?

In terms of holding a register, this is mainly an administrative task, although complex, and could be done centrally for all healthcare professionals, although different criteria will apply for the different professions.

In terms of the other functions of a regulator, such as, determining standards of education and training for registration; providing advice about standards of conduct and performance; and administering procedures relating to misconduct and fitness to practise, we would be concerned if these were undertaken by a regulator other than the GPhC for the pharmacy profession as other regulators would not have the thorough understanding of the pharmacy profession that the GPhC have

In our guidance we give advice on consulting on rules and associated guidance/policies (see 7.1-7.12 of the draft rulemaking guidance). The following questions relate to this section:

6. Do you think that the guidance on consultation is helpful?

- **Yes**
- No

- Don't know

7. Do you have any comments to make on this section of the guidance?

Regulators should be required to assess the impact of proposed changes to their rules, processes, and systems before they are introduced. However, once the impact assessment has been undertaken, a report should be published by the regulator and any changes consulted on within a specified time frame. An established time frame as to when this will apply, in terms of regulators setting their own rules and standards, needs to be made explicit. Having the ability as a regulator to set out how they operate, and what their own governance structure should be, enables flexibility in times of emergency and this has been demonstrated with some of the changes enabled during the coronavirus-19 pandemic e.g., revalidation.

In our guidance we give advice on governance for approval of rules and associated guidance/policies (see 8.1-8.4 of the draft rulemaking guidance). The following questions relate to this section:

8. Do you think that the guidance on governance is helpful?

- Yes
- No
- Don't know

9. Do you have any comments to make on this section of the guidance?

The approval process for making rules will change with the current final decision making body replaced in the future with a unitary board. Therefore, the route to approve and adopt rules will change as the decisions will be made by the unitary board for approval (rather than council and exec) so there are still some unknowns on the impact of regulatory reform on rulemaking by regulators.

The following questions relate to the impact of our guidance:

10. Please set out any impacts that our guidance would be likely to have on you and/or your organisation, or considerations that we should take into account when assessing the impact of the proposals.

11. Are there any aspects of these proposals that you feel could result in different treatment of, or impact on, groups or individuals based on the following characteristics as defined under the Equality Act 2010?

- Age
- Disability
- Gender reassignment
- Marriage and civil partnership
- Pregnancy and maternity
- Race
- Religion or belief
- Sex
- Sexual orientation
- Other (please specify)
- Yes
- No

- **Don't know**

If you have responded 'yes' about any of the above, please provide further details, explain why and what could be done to change this.