

EXPLANATORY MEMORANDUM TO
THE GENERAL PHARMACEUTICAL COUNCIL (AMENDMENT OF
MISCELLANEOUS PROVISIONS) RULES ORDER OF COUNCIL 2012

2012 No. 3171

1. This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty. This Order is also being laid before the Scottish Parliament.
2. **Purpose of the instrument**
 - 2.1 The General Pharmaceutical Council (GPhC) is the regulator for pharmacists, pharmacy technicians and registered pharmacies in Great Britain, ensuring that registrants adhere to standards and requirements for the safe and effective practice of pharmacy. This instrument amends the GPhC's rules relating to the composition of the Statutory Committees of the Council and connected matters. It also makes amendments to provisions about the functions and procedures of the Committees and about the procedures for applications relating to registration of pharmacists and pharmacy technicians, together with some consequential amendments.
3. **Matters of special interest to the Joint Committee on Statutory Instruments**
 - 3.1 None
4. **Legislative Context**
 - 4.1 The GPhC was established under the Pharmacy Order 2010 (2010/231). The GPhC has made the following rules under that Order: the General Pharmaceutical Council (Statutory Committees and their Advisers) Rules 2010 (scheduled to SI 2010/1616); the General Pharmaceutical Council (Fitness to Practise and Disqualification etc.) Rules 2010 (scheduled to SI 2010/1615), and the General Pharmaceutical Council (Registration) Rules 2010 (scheduled to SI 2010/1617). This instrument amends the aforementioned rules.
5. **Territorial Extent and Application**
 - 5.1 This instrument extends to and applies in Great Britain.

6. European Convention on Human Rights

6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

7.1 The proposed changes to the rules update and modernise existing provisions. In 2012, the GPhC consulted on proposals to amend the rules. These included amendments to the rules that would deliver administrative efficiencies at the GPhC, derived from lessons they have learned since being in operation since 2010. These include:

- increasing the maximum number of panellists to be allowed on statutory committees, to make sure there are enough panellists available and hearings can take place as soon as possible;
- allowing panellists to be members of both the Fitness to Practise Committee and Appeals Committee and for both committees to share the same list of reserve panellists, to provide greater flexibility and make sure panellists can maintain their skills. Conflicts of interest would be avoided by making sure that a panellist assigned to an appeals case had not been involved in any related Fitness to Practise proceedings;
- making the Council responsible for deciding policies regarding the criteria for referral of cases to the Fitness to Practise Committee and appropriate sanctions. The guidance documents produced by the Council would be used by the statutory committees when they make decisions in individual fitness to practise cases. The Investigating Committee and Fitness to Practise Committee have previously produced their own guidance;
- removing the role of the Appointments Committee in advising the Council about the competencies it considers appropriate for statutory committee members;
- providing for the Investigating Committee to notify the Registrar that the Council should consider bring criminal proceedings in certain cases;
- enabling a person to be appointed as a statutory committee member for a term that is less than 4 years;
- providing for the Council to determine the procedure for suspension or removal of a statutory committee member without having to receive a draft from the Appointments Committee first;
- reducing an unnecessary prohibition on someone who has acted as secretary to another committee from also acting as secretary to the Fitness to Practise Committee (provided the secretary has not acted as secretary to the Investigating Committee in connection with the same allegation);

- clarifying the rule regarding the quorum for the statutory committees;
- providing for the Chair to determine the detailed composition of the Appeals Committee at hearings;
- confirming that a member of the Fitness to Practise Committee who was involved in the making of an Interim Order in any case may not also sit at the full hearing of that case;
- removing the requirement for a legal adviser to be present at all meetings of the Investigating Committee and replacing that with a discretion so that the legal adviser is only present when needed;
- providing greater clarity as to who may be a representative at Fitness to Practise hearings;
- making changes to the requirements for identity checks for registration so it is more straightforward for applicants to provide the necessary identity documents, at the same time as making sure that identity documents are genuine.

Consolidation

7.2 There are no plans for consolidation of the GPhC's rules at this time. Informal consolidated texts of the rules are freely available to the public on the GPhC's website <http://www.pharmacyregulation.org/about-us/what-we-do/legislation/pharmacy-order-2010-and-rules> .

8. Consultation outcome

8.1 The GPhC published the rules in draft for public consultation across Great Britain for a period of 12 weeks from 19 April 2012. Twenty-two responses were received from a range of organisations and individuals. The responses showed broad support for the proposals. The GPhC has produced a report summarising the views expressed in response to the consultation and describing how these have been taken into account. This consultation report was approved by the GPhC's Council on 15 November 2012 and is available on its website: <http://www.pharmacyregulation.org/get-involved/consultations/our-previous-consultations> .

9. Guidance

9.1 Neither the Department of Health nor the Scottish Government has issued guidance in relation to these Rules. However, the GPhC plans to publicise the changes through its website and through its journal which is sent to all registrants.

10. Impact

- 10.1 The Rules have limited impact on businesses, charities, voluntary bodies or the public sector. They are intended to enable the GPhC to fulfil its existing regulatory functions under the Pharmacy Order 2010 more efficiently, while maintaining the quality of outcomes.
- 10.2 The GPhC has not prepared an Impact Assessment for these Rules. An Impact Assessment was prepared for the related Pharmacy Order 2010 (2010/231). This included the anticipated administrative and operating costs of the GPhC and is contained within the Explanatory Memorandum available at: http://www.legislation.gov.uk/uksi/2010/231/pdfs/uksiem_20100231_en.pdf.
- 10.3 The GPhC prepared an Equality Impact Assessment covering the measures which are being brought in by these Rules. This is available at <http://www.pharmacyregulation.org/get-involved/consultations/our-previous-consultations>. The equality impact of the proposals was further evaluated after consultation by the consultation report referred to in paragraph 8.1 above. It was not considered that the proposal will have adverse effect on any group sharing a characteristics protected by the Equality Act 2010.

11. Regulating small business

- 11.1 GPhC registrants may operate, or be employed by, a small business but, as noted above, these Rules are intended to enable the GPhC to fulfil its functions more efficiently and should have limited, if any, impact on small businesses.
- 11.2 The GPhC has not prepared an Impact Assessment in relation to this, but the consultation on the Rules did not identify any concerns relating to the impact on small businesses.

12. Monitoring & review

- 12.1 The operation of the rules will be reviewed in three years. It will be also be monitored by the Professional Standards Authority for Health and Social Care as part of its ongoing annual review of the performance of the health regulators.

13. Contact

Keith Baggs at the Department of Health Tel: 0113 254 5791 or email: keith.baggs@dh.gsi.gov.uk can answer any queries regarding the instrument.

POLICY NOTE

THE GENERAL PHARMACEUTICAL COUNCIL (AMENDMENT OF MISCELLANEOUS PROVISIONS) RULES ORDER OF COUNCIL 2012

2012 No. 3171

1. The rules scheduled to and approved by this Order, amend General Pharmaceutical Council (GPhC) legislation relating to the composition of the Statutory Committees of the Council and connected matters. They also make amendments to provisions about the functions and procedures of the Committees and about the procedures for applications relating to registration of pharmacists and pharmacy technicians, together with some consequential amendments. These rules have been made by the GPhC in exercise of powers conferred by the Pharmacy Order 2010. The Order is subject to annulment in pursuance of a resolution of either House of Parliament or of the Scottish Parliament and is being laid simultaneously before both Parliaments by the Privy Council.

Background

2. While the provisions in the Pharmacy Order 2010 relating to the regulation of pharmacists and registered pharmacies by the GPhC are reserved to Westminster, those relating to the regulation in Scotland of pharmacy technicians fall within the legislative competence of the Scottish Parliament (see paragraph 3). Given that the Pharmacy Order 2010 set up an entirely new regulator for pharmacy, it was considered that Orders made under it should receive the additional scrutiny conferred by making them subject to annulment by either House of Parliament or the Scottish Parliament.

3. The Health Care and Associated Professions (Miscellaneous Amendments and Practitioner Psychologists) Order 2009 made provision for the extension of statutory regulation of pharmacy technicians to Scotland, thereby introducing the devolved component to the Pharmacy Order 2010. Provisions for a statutory register of pharmacy technicians in England and Wales were included in the Pharmacists and Pharmacy Technicians Order 2007, but were not commenced until 2009, when the respective provisions were commenced simultaneously for pharmacy technicians across Great Britain. There had been a longstanding policy objective to regulate pharmacy technicians across Great Britain (Northern Ireland has its own pharmacy regulator).

Policy Objectives

4. The changes proposed by this Order update and modernise existing provisions. In 2012, the GPhC consulted on proposals to amend its rules. These included amendments that would deliver administrative efficiencies at the GPhC, derived from lessons it has learned since being established in 2010. This instrument therefore amends the GPhC's rules relating to the composition of the Statutory Committees of the Council and connected matters. It also makes amendments to provisions about the functions and procedures of the Committees and about the procedures for applications relating to registration of pharmacists and pharmacy technicians, together with some consequential amendments.

5. Further details of the policy objectives of this Order are set out in the attached DH Explanatory Memorandum, in paragraph 7, headed "Policy background".

Consultation

6. The GPhC published the rules in draft for public consultation across Great Britain for a period of 12 weeks from 19 April 2012. Twenty two responses were received from a range of organisations and individuals. The responses showed broad support for the proposals. The GPhC has produced a report summarising the views expressed in response to the consultation and describing how these have been taken into account. This consultation report was approved by the GPhC's Council on 15 November 2012 and is available on its website: <http://www.pharmacyregulation.org/get-involved/consultations/our-previous-consultations>

Guidance

7. Neither the Department of Health nor the Scottish Government has issued guidance in relation to these Rules. However, the GPhC plans to publicise the changes through its website and through its journal which is sent to all registrants.

Impact Assessment and Financial Implications

8. The Rules have limited impact on businesses, charities, voluntary bodies or the public sector. They are intended to enable the GPhC to fulfil its existing regulatory functions under the Pharmacy Order 2010 more efficiently, while maintaining the quality of outcomes.

9. The GPhC has not prepared an Impact Assessment for these Rules. An Impact Assessment was prepared for the related Pharmacy Order 2010 (2010/231). This included the anticipated administrative and operating costs of the GPhC and is contained within the Explanatory Memorandum available at: http://www.legislation.gov.uk/uksi/2010/231/pdfs/uksiem_20100231_en.pdf

10. The GPhC prepared an Equality Impact Assessment covering the measures which are being brought in by these Rules. This is available at <http://www.pharmacyregulation.org/get-involved/consultations/our-previous-consultations>. The equality impact of the proposals was further evaluated after consultation by the consultation report referred to in paragraph 6 above. It was not considered that the proposal will have adverse effect on any group sharing a characteristics protected by the Equality Act 2010.

Monitoring and Review

11. The operation of the Rules will be reviewed in 3 years time. It will be also be monitored by Professional Standards Authority for Health and Social Care as part of its ongoing annual review of the performance of the health regulators.

Scottish Government Health Directorates
December 2012