

What's in it for me?

▶ You are contributing to extending the safety knowledge of medicines that could be used to minimise risks to patients in the future. In return for your assistance we offer a small contribution to your admin costs.



Why is the form so detailed?

▶ These studies are now undertaken in order to satisfy part of the regulatory requirement for risk management of medicines. The regulator (the MHRA or the European Medicines Agency, EMA) often specifies which aspects of the medicine should be investigated further post-marketing, resulting in the need for detailed aggregate information on characteristics of patients, risks and prescribing patterns.

What happens to the results of these MPEM research studies?

▶ A DSRU study report is sent to the MHRA, EMA and the company which manufactures the medicine. Study data add to the ongoing benefit risk evaluation for the product and can contribute to changes in the product label. The DSRU publishes its studies in peer-reviewed journals.

GP Masterclass – Effective Prescribing

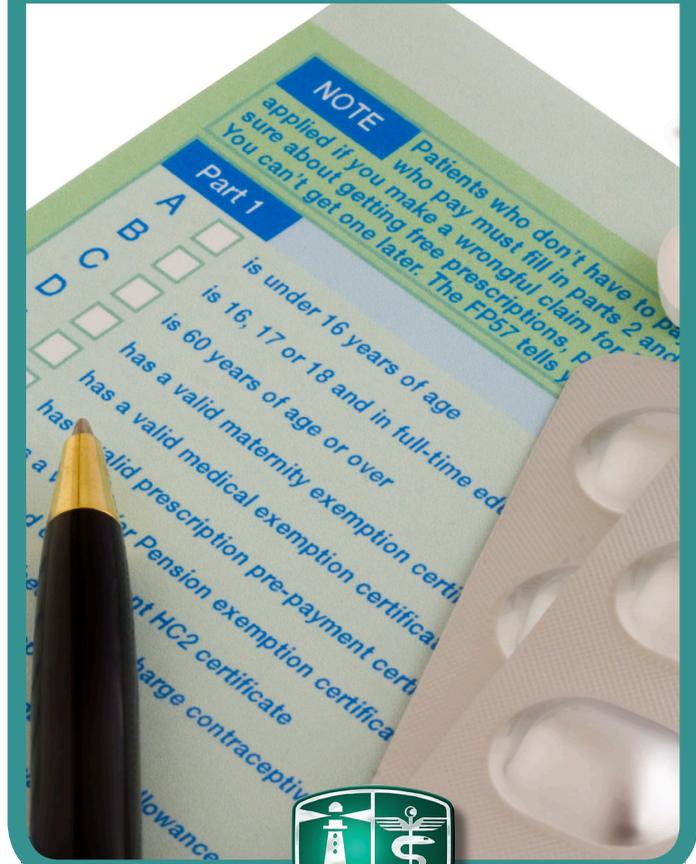
▶ Our GP Masterclass in effective prescribing is an educational day for GPs, looking at various aspects of effective prescribing, accredited by the RCGP. Organised twice a year in different locations, these Masterclasses are a chance to think more about your prescribing decisions and to hear from the experts. There will be opportunities for discussion and professional interaction.

To view our calendar of Masterclasses, visit <http://www.dsru.org/courses/course-calendar/>



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Quick Guide to the DSRU and MPEM



Drug Safety Research Unit

What is the DSRU?

- ▶ The Drug Safety Research Unit (DSRU) is an independent academic unit and registered charity.
- ▶ The DSRU aims to protect NHS patients from unwanted adverse effects of newly marketed medicines.
- ▶ The DSRU was established in 1981 and is based in Southampton.

What is Modified Prescription-Event Monitoring (MPEM)?

- ▶ The method (derived from Prescription-Event Monitoring) is a national system for monitoring the safety of medicines prescribed in primary care, established by the DSRU.



Why has this MPEM form been sent to me?

- ▶ You have received this form because you have prescribed a medicine that the DSRU is studying.

Do I have to complete it?

- ▶ No, but we very much hope you will. The GMC¹ urges GPs to respond to requests for data from the DSRU. The DSRU has completed over 120 PEM and MPEM studies since 1981 based on data provided by thousands of GPs across England who have completed and returned our questionnaires.



References:

- 1: General Medical Council, 2013, "Good Practice in Prescribing and Managing Medicines and Devices".
- 2: Further information about Section 251 approval is available at www.hra.nhs.uk/about-the-hra/our-committees/section-251/.

Do I need to ask the patient's consent?

- ▶ No. DSRU has approval under Section 251² of the NHS Act 2006 to use patient information without consent for the purpose of conducting these drug safety studies. Application for this approval involves thorough examination of the DSRU's information security procedures and approval is subject to annual review and rigorous annual information governance requirements.

I have already completed a Yellow Card report so why reply to you?

- ▶ The Yellow Card Scheme has a different purpose and is a passive scheme used to report suspected adverse drug reactions (ADR) to any drug, vaccine or medical device to the Medicines & Healthcare products Regulatory Agency (MHRA). MPEM provides a complementary system that actively and systematically collects drug utilisation and safety outcome data. Even if a Yellow Card has already been submitted for an ADR we still require you to return the form.