ROYAL PHARMACEUTICAL SOCIETY

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The Royal Pharmaceutical Society (RPS) is the professional body for pharmacists in Great Britain and the only body that represents all sectors of pharmacy. The RPS leads and supports the development of the pharmacy profession including the advancement of science, practice, education and knowledge in pharmacy. In addition, we promote the profession's policies and views to a range of external stakeholders in a number of different forums.

The RPS welcomes the opportunity to comment on this guidance and has collated responses from the Scottish, Welsh and English Pharmacy Boards as well as from RPS members themselves. The responses consider labelling but they mostly relate to packaging issues where there can be an impact on patient safety.

CHM developed a set of critical information which in their view should be located together on the pack in the same field of view. [Section 4.1]

Does this cover what in your view is essential at the point of selection and/or administration of medicines?

- ◉ Yes
- ○ No

Section 4.2 of the guidance considers how the critical information set is to be optimised for quick and accurate assimilation by the healthcare professional. Each aspect has its own best practice recommendations

If the guidance on placement and prominence of the name is adhered to does this provide sufficient assurance the medicine can be correctly identified in the pharmacy and other clinical areas?

- ◉ Yes
- ○ No

The guidance notes that in considering the strength of the product occasionally there will be a need for different ways of expressing this on the pack. It deals with the need for clarity when ranges of strengths are used and the need to spell out 'micrograms' in full on the label where there is space.

Are these provisions sufficient to enable accurate identification of the medicine?

- ◉ Yes
- ○ No

The route of administration should be described using positive messages and only standard abbreviations are acceptable.

Do you consider this to be sufficient?

- ◉ Yes
- ○ No

For most medicines available on prescription the dose and warnings will not usually appear on the labelling as this is not the purpose of the label. A separate guidance document covering specific warnings is available.
Does this section of the guidance provide sufficient detail to enable critical medicines to be suitably labelled?

- ◉ Yes
- ○ No

The guidance talks about the need for important information to appear prominently on the label.

Do you have examples of where this routinely does not happen and has resulted in harm?

- ○ Yes (please give examples) Guidance Note
- ○ No

The guidance discusses innovative packaging design and the judicious use of colour to help differentiate packs from each other either within a range of medicines or within a company portfolio.

Is this sufficient to enable safe selection and/or administration of medicines?

- ○ Yes
- ◉ No

Guidance note 4.4 states "consider the relative distinguishing features compared to other packs in a range" and "the primary aim of innovative design of packaging is to aid the identification and selection of the medicine"
Our members have commented on Almus, Teva, Crescent, Relon Chem and Actavis manufacturers' ranges where packaging does not aid identification and selection. See attached comments for details.

Small containers only need to have a limited set of information applied to the labelling.

Please provide examples of small containers where the labelling has been a factor in medication errors.

With reference to Guidance Not

Blister packs have very limited information applied to them and have to be kept within a fully labelled carton which will include all the statutory labelling particulars.

Please provide examples of blister strips where the labelling has been a factor in medication errors.

With reference to Guidance not

Please provide any additional information or examples not stated above which will add to the evidence needed to support additional labelling recommendations within the guidance.

With reference to Guidance not

Please tell us your role e.g. Medication Safety Officer, sector e.g. acute or primary care, and professional background e.g. nurse

Policy and Practice Pharmacist
Royal Pharmaceutical Society

If you wish to respond directly to a member of MHRA staff, please email patient.information@mhra.gsi.gov.uk

Please find below comments from RPS members which apply to the questions in the survey relating to small containers, blister packs and additional information with examples where applicable.

Small Containers

- **Guidance 5.1 -** The RPS agrees with this in principle but notes that small containers e.g. eye drops, are packaged in boxes where the application of the dispensing label without covering critical information is impossible. In these instances, additional labels in the form of clear plastic 'flags' have been used to add to the container along with the dispensing label so that all critical information is available for the patient. These had a mixed reception from patients with some instances of patients saying they have caused more harm to their eye by inadvertently sticking the plastic flag in their eye.
- **Guidance 5.3 -** The RPS supports innovative packaging of small containers e.g. the use of concertina style labelling which would allow the dispensing label to be applied to the original packaging.

Blister Packs

- **Guidance 6.2 –** RPS agrees that all blister packs should be readily identifiable and remain consistently so even after 'popping', regardless of the number of doses 'popped'. This is vitally important for carers as well as patients.
- **Guidance 6.5 -** RPS agrees that packs must be supplied in multiples of 7. 28 day blister packs should be produced rather than 30 day packs thus eliminating the need to cut blister strips leaving many cut blisters which are difficult to identify and may not have an expiry date or batch number. Days of the week should be on blister pockets and foil where possible to aid compliance.
- **Guidance 6.5 –** RPS noted that many Parallel Import calendar packs often have the days of the week in the language of the country of manufacture, which is confusing for patients and carers and therefore clear guidance on labelling and packaging must be given here within the guidance.

Packaging

- **Guidance 4.4 –** This guidance note states "The primary aim of innovative design of packaging is to aid in the identification and selection of the medicine" The RPS agrees with this in principle and notes there are numerous examples of where similar packaging has been a factor in medication errors. The Twitter page https://uk.pinterest.com/calangley1445/medication-with-similar-packaging-design/ has thousands of examples from leading generic brand manufacturers showing different medication with similar packaging leading to near miss incidents. Almus, Teva, Crescent, Relon Chem and Actavis manufacturers are all cited as examples of packaging concerns e.g. Almus Co-tenidone 50 and Felodipine 5 are in exactly the same box.
- **Guidance 4.5 –** The RPS notes that this relates to the labelling of a pack supplied against a prescription, however some manufacturers provide a space for the dispensing label on a box in which is found a tub which has no child resistant closure. Some medicines have no outer packing. This means the medication has to be decanted into a bottle with a child resistant closure and therefore the loss of the original packaging with all the regulatory requirements. E.g. Teva Promazine 25mg (no outer pack and no child resistant cap), Camcolit 400mg (no outer packaging and no child resistant cap). Further measures here may be warranted within the guidance.

OTC packaging

- **Guidance 7.3 –** This guidance note relates to labelling of OTC medicines. The RPS asks that there is more accurate advice on OTC medicines on when to seek medical advice from either the Pharmacist or the GP.