Original pack dispensing as standard practice

Purpose
To review the issues around original pack dispensing and whether the Society should support original pack dispensing as standard practice.

Strategic Objective
Improve patient safety and enable pharmacists to comply with the legislation requiring them to issue patient information leaflets from the marketing authorisation holder at the time of dispensing items to the public.

Recommendations
The Practice Committee recommends
i. that the Society issue a formal statement supporting the introduction of original pack dispensing for primary and secondary care as standard practice unless it is not in the best interest of the patient;

ii. that the Society work with other pharmacy and stakeholder organisations to influence the DH to change the current regulations relating to original pack dispensing for community pharmacy and to redirect funding to support implementation of original pack dispensing in hospitals.

1. Background
It is a legal requirement that when a medicine is dispensed or supplied that a patient information leaflet (PIL) is supplied which was produced by the marketing authorisation (MA) holder unless all the required patient information is included on the immediate or outer packaging. (Medicines supplied in a hospital are exempt from this requirement, although the leaflet should be available in the pharmacy or on the ward for use by a patient who requests it.)

The most up-to-date leaflet for the product should always be supplied. Product information does change and it is important that patients receive the right version. Pharmacists must still supply the PIL from the MA holder even if a medicine is being used for an off-licence indication i.e. being used outside of licensed indication.

It is important that patients have access to the appropriate information leaflet so that they understand how to take their medicine, are aware of any side effects, interactions, contraindications and are informed of any storage requirements.

Pharmacists are unable to comply with the requirement to supply an appropriate PIL as a significant number of items (45% estimated) are still dispensed from broken bulk or split packs in Great Britain. In a significant number of instances the pharmacist has problems in supplying the appropriate PIL from the MA to give out with the dispensed medicine. We are unusual in the European Union in maintaining this practice; in most countries original pack dispensing is standard practice.
Pharmacists have problems with accessing appropriate PILs. In theory they can access them via the Electronic Medicines Compendium at www.emc.medicines.org.uk, but this website does not have a comprehensive list of PILs but for many community pharmacists it is not a practical option. Other proposals that have been put forward include contacting manufacturers to supply additional leaflets, and photocopying. Again, these suggestions are not generally practical for community pharmacists as both add an further potential for error to the process, while downloaded or photocopied versions may be of reduced quality (loss of detail, colour, legibility) leading to difficulties for the patient in reading and understanding the information.

Pharmacists are currently not reimbursed for supplying original packs unless the quantity on the prescription matches that of the original pack, or the item is available as a calendar or some other “special” pack.

All of these issues can lead to pharmacists breaking the law, as they have no other option.

2. Benefits of original pack dispensing as standard practice
Dispensing original packs as standard practice would significantly reduce the problem of being unable to supply an appropriate PIL at the point of dispensing.

The benefits of original pack dispensing include:

- Patients receiving medication that is in appropriate packaging, with relevant information including a PIL. The supply of medication in standard white cartons (this is normal practice for dispensing of part blister packs), which must increase the risk of confusion for patients, would be reduced. The National Patient Safety Agency is looking at package design from a patient and healthcare professional perspective.

- Braille readers being able to gain more information on all their medicines when Braille is introduced on original packs (we recognise that most visually impaired people are unable to read it Braille).

- Retention of batch number and expiry date information on all medicines supplied to patients, as cutting blister strips will cease. This has a number of other benefits: some patients are unable to pop tablets out from part strips or have swallowed the part strip rather then popping out the tablet, causing gastric intestinal bleeds.

- Medicines provided in the patient-friendly packs companies have spent a significant amount of time and resource to design and test.

- A reduction in repackaging into child resistant containers which some patients, especially the elderly, have problems in trying to open to access their medicines. As a consequence, there will be a reduction in the significant number of reports where patients have attended hospitals following accidents with knives and spanners that were being used to open packaging of dispensed medicines.

- Fewer steps in the dispensing process may mean less opportunities for errors, and an improvement in efficiency - an important factor to take into consideration for many community pharmacies.

- The facilitation of the introduction of automation, which could again reduce the number of errors that occur in the dispensing process.
3. Where original pack dispensing is not appropriate
There are certain medications where the risks of issuing more than the amount required by a patient outweigh the benefits of original pack dispensing. These include substances that may be abused, or cytotoxic agents where precise dosing are required. These account for a relatively small number of prescriptions.

It may also be necessary for the pharmacist to supply medication in systems that help the patient to take the medication appropriately e.g. monitored dose systems. It is also recognised that there are additional problems for veterinary medicines as the necessary range of original packs are not available at the present time.

4. Factors impacting on the introduction of original pack dispensing

4.1 Patient safety
Patient safety is high on the government’s agenda. Patients need to be able to access the necessary information to enable them to take their medication safely and be aware of any side effects and what to do should they occur. They also need to know what other medicines to avoid or when they should not take their medicine, and be directed to discuss these issues with a health professional. All of this information can be found in the PIL.

4.2 Medicines Act
Section 58 requires pharmacists to supply a medicine in accordance with a prescription. If an original pack is dispensed it may not be in accordance with the prescription. There needs to be agreement that this is possible.

Section 64 considers the nature and quality of the item dispensed. Again it is important that it is recognised that by dispensing an original pack this does not affect the nature of the item.

4.3 NHS terms of service
These would require amendment to allow dispensing of original packs so they are considered as special containers

4.4 Additional cost to the NHS
There would be some additional cost if items were rounded up to the nearest pack. The pharmaceutical industry does not have a standard month, and use both 28 and 30 days. Patients may therefore receive 28 days for some products and 30 days for others, leading to some wastage, but this is likely to be small compared to the total amount of medicine wastage. Council has previously agreed that the pharmaceutical industry should be encouraged to agree a standard for a month as being 28 days.

There would also be a “one off” cost that contractors would expect the NHS to pick up for writing off stock they could no longer use. This is likely to be less than a few years ago as more items are now available in original packs and there is a reduction in the number of large stock containers.

Original pack dispensing could be phased in over a period of time, perhaps several years, to reduce the cost to the NHS and the pharmaceutical industry (time to use up/write off stock)
4.5 Information Technology – Electronic transfer of prescriptions
Original pack dispensing would be facilitated if prescribers ordered in original pack quantities. Systems could be put in place that would facilitate this. With the proposed changes in IT for pharmacy and the introduction of electronic transfer of prescriptions processes could be built into any system to support and promote original pack dispensing.

4.6 Other organisations
It is thought that the other main pharmacy bodies would support the Society with a move towards original pack dispensing. It is known that the ABPI (Association of British Pharmaceutical Industries) would also support the Society. There is a need to gain support from the Department of Health (DH), Welsh Assembly Government (WAG) and Scottish Executive Health Department (SEHD)

5. Risk Implications
There are no risk implications for the Society in supporting this policy.

6. Resource Implications
Staff time would require to be allocated to progress discussions with DH, pharmacy bodies and other relevant stakeholders

7. Recommendation
The Practice Committee discussed the proposal and recommends
i. that the Society issue a formal statement supporting the introduction of original pack dispensing for primary and secondary care as standard practice unless it is not in the best interest of the patient.

ii. that the Society work with other pharmacy and stakeholder organisations to influence the DH to change the current regulations relating to original pack dispensing for community pharmacy and to redirect funding to support implementation of original pack dispensing in hospitals

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