Information Design for Patient Safety
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Design guidance for the packaging of prescription medicines: secondary packaging (all types) and primary packaging (blister packs only)
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Foreword

Sir Liam Donaldson, Chief Medical Officer

In the Department of Health’s 2003 report, Design for Patient Safety, I offered a new perspective on improving patient safety and set out how we should be making use of the many opportunities for effective design in healthcare to address some of the safety challenges we are facing.

Concentrating on design for safer packaging of prescription medicines, this latest publication seeks to resolve some of the risks associated with medication error and, once again, draws attention to the need for an inclusive and systems-wide approach.

Ensuring the safety of patients must become a high visibility issue for anyone involved in the delivery of healthcare. This publication is a further contribution to the important work that is taking place in this field.
Introduction

Medication errors contribute significantly to the estimated 900,000 recorded adverse events occurring in the NHS every year.\(^1\) It is becoming increasingly clear that improved design could help reduce this figure and also improve medication compliance, in particular among older patients, where it is a considerable problem.

Prior to the publication of this document there has been limited formal guidance on best practice for visual form for designers and those involved in the production, regulation and purchase of medicines. This publication and the supporting research have been sponsored by the NHS National Patient Safety Agency. Its aim is to support and compliment the existing guidance and to help establish a benchmark in good design for the packaging of medicines.

This work is based on and developed from established guidance,\(^2,3,4\) which it supplements, using illustrations of bad and good practice based on real-life examples. The challenge for the pharmaceutical industry is to adopt a best practice approach that ensures, as a basic minimum, that vital information stays with medication until the actual moment when it is taken by the patient.

Information design for patient safety is the result of a year-long design research collaboration between the National Patient Safety Agency (NPSA) and the Helen Hamlyn Research Centre (HHRC) at the Royal College of Art, London. It builds on the Design for patient safety study commissioned by the Department of Health and the Design Council.
The approach was for the author to immerse herself in the world of medical packaging, through consultations with a wide range of stakeholders – including patients, pharmaceutical industry personnel, NHS agencies, nurses and pharmacists. Observational research was undertaken in key end-use environments, such as wards, pharmacies and patients’ homes. A collection of current medicine packages was assembled as part of the study, and an analysis was carried out of common problem factors for which design solutions were proposed.

**Scope**

Information design for patient safety focuses on the blister pack, the most common type of primary packaging for prescription medicines, the secondary packaging used to contain it, and the labelling attached to such packs in the pharmacy. The patient information leaflet and non-blower strip types of primary packaging, such as tablet bottles, are not addressed in this publication. However, as the design considerations and principles put forward deal with fundamental issues of legibility and the graphic organisation of information, they could easily be applied in other situations.

**Methodology**

This publication is the result of a study of labelling and packaging information from a design perspective, rather than a regulatory or human sciences perspective. The study was carried out over a one-year period by a post-graduate specialist in information and graphic design working to a brief set by the NPSA and the HHRC. Industry and NHS perspectives and concerns with regard to enhancing patient safety through better use of design were considered. Key research questions were: what constitutes good practice in information and graphic design in the context of medicine labelling and packaging; how can risks associated with medicine packaging be identified and designed out?

The approach was for the author to immerse herself in the world of medical packaging, through consultations with a wide range of stakeholders – including patients, pharmaceutical industry personnel, NHS agencies, nurses and pharmacists. Observational research was undertaken in key end-use environments, such as wards, pharmacies and patients’ homes. A collection of current medicine packages was assembled as part of the study, and an analysis was carried out of common problem factors for which design solutions were proposed.

**Design criteria**

Existing design guidance was reviewed and consultations were undertaken with members of the Design for patient safety team and expert graphic and information designers. This process resulted in a set of 24 key considerations and design criteria for primary and secondary packaging. The overall intention is not that this work should lead to mandatory guidance, but that it should encourage designers, manufacturers, purchasers and regulators to give due consideration to the design factors that can impact adversely on the safe use of medicines. It is also meant as a visual introduction to graphic and information design issues for non-specialists, who can benefit from a better understanding of the underlying factors and principles.

**The outcome**

The outcome is a fully illustrated set of design considerations with both good and bad examples. The purpose is to allow busy designers, purchasers and others with an interest in package legibility and comprehensibility to quickly and simply understand how and why good design can contribute to patient safety through the clear labelling of medicines.
The original intention had been to use photographs of poor design practice drawn from currently available examples, but this was felt to be counter-productive as it could be seen as singling out individual pack designs for criticism. Instead, anonymous generic pack designs were developed, based on real samples, and used to illustrate individual problems and good practice solutions.

This is further supported by a comprehensive checklist that follows the same sequence, in order to facilitate pack evaluation both during and after design. It should be stressed that the checklist is not intended to promote a ‘box ticking’ approach, but to ensure that those involved in design and evaluation give full and due consideration to each of the 24 factors and how they might collectively interact and impact on patient safety.

**Implementation**

This publication is not intended to inhibit or constrain designers and manufacturers, but to encourage good practice by drawing attention to key risk factors and issues. The illustrated designs are not meant to be prescriptive, nor single best solutions, but are indicative of the consistent application of good practice in information and graphic design, and the benefits it can deliver in terms of legibility and comprehension.

A design process that addresses each consideration and balances them against each other has the potential to deliver solutions that significantly reduce risk of error and enhance patient safety at no extra cost. This book is set out in a way that makes this process simple to put into action and readily verifiable via the checklist. Where significant changes are made, user research and evaluation is recommended, in line with the Medicines and Healthcare products Regulatory Agency (MHRA) guidance document. The checklist will help ensure that such testing is thorough and effective.

**Patient safety in the NHS**

Ensuring patient safety is becoming one of the most important challenges facing healthcare today. Prescription medicine is the most frequent treatment provided for patients by the National Health Service (NHS). General practitioners in England issue more than 660 million prescriptions every year; an estimated 200 million prescriptions are issued in hospitals and the average community pharmacy dispenses between 5,000 and 10,000 prescriptions every month. Not surprisingly, errors occur.

The NHS is a highly pressured, complex organisation in which the potential for error is ever present. In the UK it has been estimated that around 850,000 adverse incidents occur in the NHS each year, accounting for ten percent of hospital admissions at a cost to the taxpayer of approximately £2 billion. In 2000, around 1,200 patients in England and Wales died because of the adverse effects of medicines in therapeutic use in hospitals. The prevalence of medication errors in primary care is less certain. There is much anecdotal evidence of patients in the home environment failing to comply with prescription instructions, and this is particularly true of the elderly, where as many as 50 percent of those on medication do not take their medicine as intended. It is further estimated that 33 percent of medication errors can be attributed to confusion triggered by packaging and labelling.

A similar picture is seen in the United States: the US Institute of Safe Medication Practice (ISMP) receives between 1200-1500 reports of serious medication errors each year. Approximately 25 percent of
these are related to name confusion and 25 percent to labelling and packaging issues. The ISMP estimates that only one or two percent of serious errors are reported.\textsuperscript{13}

The history of design and patient safety in the NHS

In 2000, the findings of an expert group on learning from medical accidents in the NHS, chaired by the Chief Medical Officer, were published in the internationally acclaimed report \textit{An organisation with a memory}.\textsuperscript{14} The strategy proposal that resulted was based around a new national system for reporting, analysing and learning from adverse events involving NHS patients. Accepting all of the recommendations in the report, governmental plans were drawn up to implement this agenda and were announced in \textit{Building a safer NHS for patients}. The NPSA was established to take forward this strategy.

The NPSA recognises the key role that design plays, in particular at the systems level, in delivering safer healthcare products and has recommended that action be undertaken to identify opportunities for improved patient safety through the effective use of design. This patient-centred systems level approach to designing pharmaceutical packaging and labelling builds on, and is further supported by, the recent Department of Health and Design Council report \textit{Design for patient safety}.\textsuperscript{15}

Design initiatives for medication labelling

Following the publication of \textit{Building a safer NHS for patients}, the Committee on Safety of Medicines established a working group on Labelling and Packaging of Medicines with a remit to advise on improvements to labelling and packaging to reduce medication errors. The working group reviewed published evidence and prepared a report, which was issued for circulation on 21 August 2001.\textsuperscript{16}

The consultation and review process resulted in the publication by the Medicines and Healthcare products Agency of \textit{Best practice guidance on the labelling and packaging of medicines},\textsuperscript{17} for implementation from 1 March 2003. This guidance document identified three common factors affecting all users of medicines – information, format and style – which it addressed in a series of criteria against which all applications submitted for assessment will be considered, with regard to their labelling components.

The guidance will be updated on a regular basis, and the objective is to promote improvements to medicine labelling that will add clarity to the information provided, and assist healthcare professionals, patients and carers to select the correct medicine and use it safely.

The NPSA recognise the need for a publication to address these issues in a form accessible to designers, purchasers, and other stakeholders, allowing them to appreciate the significance of a patient-centred approach to design. The visual guidance given in this publication is intended to build on and compliment the work of the RNIB, MHRA, EU and others who have drawn attention to the need for better packaging design for medication.

Design and patient safety

Following \textit{Building a safer NHS for patients}, the Department of Health and the Design Council commissioned a scoping study to deliver ideas and practical recommendations for a design approach to reduce medical error. The resulting report,\textsuperscript{18} supported by the Chief Medical Officer, stated that there was little evidence within the NHS of the value and significance of design, and concluded that the NHS would benefit greatly if it were to adopt modern thinking and practice with regard to designing for safety.
The report proposed a systems-based user-centred approach to healthcare design, with the aim of understanding patient and carer related issues in the context of complex interactions between many stakeholders, equipment, medications and environments. Workshops undertaken with stakeholders identified a wide range of actual and potential problems associated with medication and labelling. Particular emphasis was placed on reading and understanding, access and packaging, information and knowledge, communication and confusions between medicines.

Two issues were consistently identified by the Design for patient safety report and the MHRA guidance document. Firstly, end-use contexts, where the labelling and packaging of medication has to function – for example, in the pharmacy, patients’ homes, hospital wards, the workplace and other environments – must be considered. Secondly, the degradation of information – for example information printed on a blister pack is lost as pills are removed – must also be considered. Key to addressing both issues is the concept of user and patient-centred design; where the design is developed and evaluated with regard to the way different users interact with it and how this is affected by the various contexts within which that interaction takes place.

The importance of patient-centred design
There is a widespread assumption that human error is the inevitable cause of most adverse incidents within the healthcare environment, but there is little awareness of the extent to which design-related factors, such as poor visual information, cluttered labelling, or the similarity of names and packages can burden already pressured workloads and cause ‘user error’ to occur. Open reporting and discussion of errors and how they arise will aid the identification and elimination of avoidable causes of error and greatly assist in the development of better, safer designs.

In 2002, Alan Milburn, the then Secretary of State for Health, accepted the challenge to build a new culture within the NHS – a health service in which the emphasis is on trust and not blame, ‘where there is greater partnership between patients and professionals, where lines of accountability are clear and where there is openness about mistakes, where services are designed from the patients’ point of view and where safety for patients always comes first’.  

To implement these aims, it is necessary to understand the way patients and the range of healthcare professionals interact with healthcare environments, products and services. In the case of medication and its packaging, end-use contexts – such as patients’ homes and workplaces, pharmacies, hospital wards and care homes – are of particular importance. Design solutions that assist pharmacists to choose the correct pack from crowded shelves may not necessarily make it easy for a vision impaired older patient, for instance, to take the right medication at the right time. The challenge is to address multiple issues in a single design, and this is why user research is an essential component of patient-centred design, as emphasised in the MHRA guidance document.

It is also necessary that the packaging of medications prioritises patient issues – for example legibility and ‘openability’ – above industry concerns such as brand presence, especially where patient safety might be compromised. From this perspective, it is crucial that packaging designers, and the pharmaceutical companies that employ them, adopt best practice in graphic and information-design. It is also imperative that those who regulate and purchase medication within the NHS understand how good graphic design on pharmaceutical packaging can enhance patient safety, and also how poor design can lead to adverse incidents that compromise patient safety.
Inclusive design
Given the many different contexts in which healthcare is delivered, and the considerable range of sensory, physical, and mental capabilities of patients across the NHS, it is essential that design solutions address the diverse range needs and support patient safety in all situations. Achieving this requires the application of an inclusive design approach that seeks to understand and address the needs and capabilities of the widest range of users of a product or service. User research and an understanding of end-use contexts are central to this approach. Such an approach has been developed at the Royal College of Art, London, and the Engineering Design Centre at the University of Cambridge, along with other leading institutions and design consultancies. Inclusive design is increasingly adopted by major companies and design groups, who see both the design and commercial advantage, and is codified in a new British Standard BS 5000-6.

Critical users
Almost all the growth in the UK population in the last 100 years has been in the over 50 age group. By 2020, half the adult population of Europe will be over 50. Currently, half of the NHS medicines bill is spent on medication for older people. Furthermore, 50 percent of older people may not be taking their medicines as intended. Consequently it is imperative that design solutions understand the specific needs and capabilities of older people, in particular with regard to the legibility and clarity of critical information and instructions. There is a well recognised correlation between the age of the patient and the likelihood of experiencing sight difficulties. According to the Royal National Institute of the Blind (RNIB), there are over one million people registrable as blind or partially sighted in the UK. There are a further 700,000 people who have a sight problem which makes it difficult for them to read ‘standard print’. One in five people have difficulty reading packaging labels because the text is too small, and, in a study of older patients, as many as 38 percent were unable to read their dispensing labels.

Different activities in different contexts
An understanding of the activities of patients and healthcare professionals, as well as the contexts in which they interact, brings the problems designers need to address into focus. Medicines are regularly handled by a variety of people in a number of different circumstances, for example emergency situations, hospital wards, pharmacies and patients’ homes. In each of these contexts the environmental conditions vary enormously, for example lighting frequently affects the way packaging is perceived, influencing both legibility and colour differentiation.

In the pharmacy, identification, classification and differentiation are regular activities in the course of searching for pharmaceutical information. There are a number of less obvious activities that pharmacists also engage in – searching, locating, comparing, checking, scanning and remembering. However, the methodology used for identifying particular packaging in the pharmacy environment is significantly different from the activity of locating the same medicine in a patient’s home.

It is clear that the activities of users cannot be generalised. For instance, it is difficult to identify exactly where (and how) a patient will store medicine – in a bathroom cupboard, a bedside table drawer, on a kitchen shelf or a tray on a table. Most patients have individual and unique ways to identify, memorise and act upon critical dispensing information.
A virtuous circle
Vital information is gathered as each of these many circumstances is taken into account. Research by pharmaceutical companies and independent academics must address the variety of both best practices and worst cases of those handling and using pharmaceutical medicines in order to ensure that information on pharmaceutical packaging is accessible to the widest range of users.

One broader aim of this project is to create a virtuous circle in which design for patient safety is not regarded as a cost but as a means of product differentiation and a tool for commercial competitive advantage.

Safety first
This book sets out the safety challenges that need to be addressed, and outlines a new design-led approach to reducing the incidence of medication errors attributed to confusing, complex and unwieldy information design on packaging that is ineffective and, at worst, potentially dangerous to both medical staff, patients or both across the NHS.

Although the ideas in this study require further research, they provide the foundation for error to be designed out of information packaging in the NHS before accidents occur.

In the short term, this work can be seen as a step towards a safer, more cost-effective NHS. In the long term, it is hoped that it will contribute to the development of an international culture in which health service professionals take a conscientious and proactive approach to the design of healthcare products.

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4 Always read the leaflet: getting the best information with every medicine, Committee on Safety of Medicines, Working Group on Patient Information, The Stationary Office, 2005
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Stakeholder review panel

The stakeholder review panel was formed to ensure that this publication addresses a wide and representative range of issues. Each member has reviewed and responded to the publication.
Roger Coleman  
Co-founder and Co-director, Helen Hamlyn Research Centre  
Perhaps 50 percent of elderly patients fail to take their medication as intended. That is only part of the problem. Better designed packs, information leaflets and labels could significantly reduce the frequency and impact of medication errors – on the ward, in the home and in other care contexts. Failure to comply with simple, well-established graphic and information design principles is a big cause of error. Also, packaging designers and drug purchasers do not understand what can go wrong in end-use situations.

Steven Drewett  
Outpatient, Haematology & Oncology, Hammersmith Hospital  
After a long hospital treatment for Acute Leukaemia, I am recovering at home and am on a complex medication schedule. At one time I was prescribed over eight different medications simultaneously, each drug with particular intervals. My bathroom cupboard was overflowing with packaging. I think that clearer graphic design is an important issue and could really improve my medication experience and aid compliance.

Colum Menzies Lowe  
Head of Design and Human Factors, National Patient Safety Agency  
In my personal view, the adoption of good design is a critical factor in the future progression and development of healthcare in this country; design that is appropriately focused on end-user requirements and which aims to simplify the complexity of our current healthcare system. I believe that this publication goes a long way to setting out the guidelines for achieving this and is a must-read for all designers and manufacturers in medication packaging.

Professor David Cousins  
Head of Safe Medication Practice, National Patient Safety Agency  
Patient safety incidents can arise from look-alike and sound-alike medicine labelling and medicine names and confusing or unclear information. They may also arise if users find the medicine product physically difficult to handle or use as intended. Improving the design of medicine products to take into account the needs of the user is a very effective method to minimise patient safety incidents. Healthcare purchasers are increasingly preferring to purchase and use products that are safer to use in practice. I welcome this report to help improve the design of medicine products.

Wendy Harris  
Senior Pharmacist, National Patient Safety Agency  
Pharmacy practice and, in particular, the compounding and production of good quality, safe medicines, has changed dramatically since the days of Apothecaries and Chemist & Druggists. However, despite technological and pharmaceutical advancements, the focus on packaging has been almost exclusively maintained upon preserving the efficacy of the medicine. Whilst this is understandable, the needs of the user must be given a higher priority if they are to truly derive the maximum benefit from the medicines with the minimum opportunity for error.
The safe use of medicines is rapidly emerging as one of the biggest challenges to those wishing to enhance patient safety. Whilst the development of a drug is subject to rigorous research, its subsequent packaging and usability seems to have been largely ignored. This study goes some way to redressing this situation and will undoubtedly help draw attention to the need for, and principles of, effective information transmission through simple graphic design.

I believe ‘Information Design for Patient Safety’ will benefit health professionals from all sectors, and self-administering patients from all walks of life. While many of these packaging users are likely to be totally unaware of this document and its straightforward step by step approach to what can often can be an over-complicated subject, it will no doubt have a positive impact in their daily lives. Ill-conceived pack layout is not excusable. Inclusive design and user-testing will go a long way to help reduce ‘use error’ and improve medicine safety and administration. The direct benefits of this publication will be felt by packaging graphic designers and artworkers, who produce pack graphics on a daily basis, and who previously have been working blind as specific guidance was thin-on-the-ground or nonexistent.

The Royal Pharmaceutical Society supports 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. It is therefore important that the packaging, both primary and secondary, facilitates rather than hinders the safe and effective use of the product by the patient and dispensing by pharmacy. The product must be easy to identify and not confused with other products. The packaging must be kept to a minimum to reduce storage space, however, it must be a sufficient size to ensure all relevant information can be easily identified and read. To achieve this the importance of good design should not be underestimated.

These issues need addressing to ensure that medication packaging is much safer to use. The clear way the guidelines have been set out should make a big difference.
Jeff Willis  
**Deputy Head of Communication Art & Design Department, Royal College of Art**

To engage with a project such as this one, demands a patient, well informed, analytical and rigorous approach to graphic design. Firstly the designer has to be fully equipped with all the information in order to see and identify all the layers and complexities of information. The response has to be appropriate and have integrity, the recipients need is paramount and cannot be compromised. The design must communicate, it has to be controlled, tested and implemented with exacting attention to detail. We, as consumers, should not be aware of the designers struggle; the designer will remain modestly anonymous.

Careen Snadden  
**Technical Director, Almus Pharmaceuticals**

Patient safety is the collective responsibility of all stakeholders within the healthcare system. Developing an insight into how medicines are managed and handled throughout the entire healthcare chain is essential when working with designers, enabling the design and creation of pharmaceutical packaging that satisfies the needs of the diverse user groups. The pharmaceutical industry must place greater emphasis on developing user-focused packaging, ensuring not only the medicine, but the entire product delivers the necessary efficacy, quality and safety. Healthcare providers have the opportunity to positively influence patient safety through their purchasing decisions. Several examples of patient focused packaging are already in the market, and together with this comprehensive guidance report, should act as the catalyst for change.

Howard Stokoe  
**Principal Pharmacist, NHS Purchasing and Supply Agency**

The Chief Medical Officer’s report Building a safer NHS for patients: improving medication safety has established an NHS wide environment with clear patient safety objectives. NHS PASA is expected to assist in the delivery of these objectives as it works alongside hospital pharmacists to award contracts for medicines on behalf of the NHS in England. Guidance to manufacturers on clearer graphic design will supplement that provided by the MHRA to improve overall performance and in turn reduce risks to patients.

Brian Parkinson  
**Making Sense Design, co-facilitator of Designers in Health Network**

One of the areas where graphic design can make a significant positive difference to people’s lives is in the clear presentation of health information. Thoughtfully designed drug packaging can undoubtedly help to reduce medication errors and improve patients’ compliance. We need to shift the design emphasis from branding-led issues to making sure that information is clear and accessible. We need to show that, for minimal additional cost, pharmaceutical companies can markedly improve the experience of their customers.

Idris Hughes  
**Community Pharmacist, Author www.patientpacks.com**

The right medicine can effect a cure, the wrong medicine could result in tragedy. A spoonful of good graphic design helps the right medicine ‘go down’. Poor packaging design is a direct cause of confusion and it can cause errors. Every nurse, carer, pharmacist and doctor knows the huge effort it takes to avoid error in medicine selection. We deserve all the help we can get in making sure that we get it right. This publication deserves to become a yardstick for good packaging design; it will help make sure that the pharmaceutical industry gets it right.
Dispensing and administration errors as a result of wrong drug selection do occur, especially in busy healthcare environments. Similar packaging is one of the contributory risk factors. An illustrated guide outlining design solutions for packaging and labelling to minimise risk in all steps of the medicines use process is a valuable tool. In particular it contributes directly towards the all-important goal of ensuring patient safety as outlined in the Department of Health report, *Building a safer NHS for patients*.

Grant Courtney
**Strategic Development Manager, GlaxoSmithKline**
This publication offers design considerations that promise to further the understanding and awareness of designing for patient safety and aid those involved in pack development.

At GlaxoSmithKline, we constantly strive to improve patient safety through the design of our products and packaging. This must start with an understanding of the principles of good design practice, and to continually embrace new ideas and emerging technologies that may offer further opportunities to achieve this goal.

GlaxoSmithKline – one of the world’s leading research-based pharmaceutical and healthcare companies will continue to place a high priority on improving our pack design and enhancing patient safety.

Jan MacDonald
**Medicines and Healthcare products Regulatory Agency**
Clear labelling of medicines is critical to their safe use. The Committee on Safety of Medicines has reviewed labelling practice and published guidance which cover the factors which should be taken into account when designing labelling for all medicines. MHRA recognises that our work and that of the CSM has been widely reflected in this document. Our hope is that all the available guidance will continue to be used innovatively by those designing medicines labelling to assist in preventing medication errors in the future.

James Ward
**Senior Research Associate, Engineering Design Centre, University of Cambridge**
Much has been done in recent years to highlight the link between sub-standard design of packaging and labelling, and medication error. Designers of medicines packaging and labelling must now make design for safety a top priority. However, with the current absence of precise guidance on what constitutes good practice, it is difficult to make effective improvements. This document provides clear advice, in an accessible format, and is most helpful in filling the gap in this much needed area.

Matt Kennedy-Martin
**Head of Government Relations, Design Council**
Effective design thinking should provide both the patient and medical professional with an effective, efficient and - most importantly - safe experience whilst within the healthcare setting. Unfortunately, the reality today falls significantly short of this potential. Focusing on a particular problem area, this report makes a significant contribution towards overcoming this challenge.
Design recommendations for prescription medicine packaging
When using medication, patients and healthcare professionals do not usually recognise individual design elements but perceive all visual stimuli simultaneously. Thus, when approaching the design of pharmaceutical packaging, it is important to recognise that a single design element, such as colour, cannot be evaluated without taking other visual elements – for example, packaging dimensions, location, storage, typography, corporate identity of the manufacturer – into account. Individual issues must not be judged in isolation as each visual element impacts upon another. The author asks that each design element presented in this publication be treated as an intrinsic part of a whole, where it is interconnected with, and dependent upon, the consideration of the others.

Wherever possible, the terminology is in keeping with the MHRA publication *Best practice guidance on the labelling and packaging of medicines* and the European Commission publication *A guideline on readability of the label and package leaflet of medicinal products for human use*.

**Notes on illustrations**

During the course of this project a large variety of drug packaging has been studied. The illustrations of packaging in this publication are displayed full size. The illustrations present the issues through the construction of anonymous drug packaging, which in this context removes the focus from specific brand manufacturers. It is not the intention here to single out particular companies for criticism but to better understand the issues that impact on patient safety today.
The term secondary packaging describes the outer package of a pharmaceutical product. It is the housing for the primary packaging. This packaging does not make contact with the medicine.
Dispensing label

Allocation of 70 x 35mm white space for dispensing label

Issue
For prescription medicines, pharmacists are required to produce a label that exactly repeats the prescriber's instructions. This label is then attached to the secondary packaging. In the absence of an allocated space on secondary packaging, dispensing labels are frequently placed over the manufacturer’s text, with two results. Firstly, the label can obscure the manufacturer's information including medicine name and strength. Secondly, the underlying text can show through the label making the prescription instructions difficult to read.

Recommendation
Secondary packaging should provide a clearly designated space for the dispensing label. This should be a white space in which there is no text or image of any kind. Dispensing label dimensions vary, but a minimum of 70 x 35mm space is suggested as this is the most common size for dispensing labels.

Effective use of design recommendation

Generic Name 10 mg

Each tablet contains ingredient 0mg. Also contains ingredient.

For oral administration. Take as directed by your doctor.

Please read enclosed leaflet carefully.

Store below 25°C in a dry place. Protect from light.

Keep out of sight and reach of children.
Dispensing label

Repetition of the generic name and strength of medicine above the space provided for the dispensing label

**Issue**

In the pharmacy, the prescription is read, the medicine is picked from the shelf, the medicine type and dosage are checked against the prescription, and the dispensing label is produced and printed by the dispensary system and then attached to the secondary packaging. Occasionally, due to human error, the dispensing label and medicine name on the secondary packaging may be mismatched.

**Recommendation**

The generic name and strength of the medicine should be located directly above or beside the space provided for the dispensing label. This will allow pharmacy staff to easily check that the medicine description on the dispensing label correctly matches that on the secondary packaging. For example, ensuring that the generic medicine name, form, variant and strength on the secondary packaging are the same as the generic medicine name, form, variant and strength on the dispensing label.
Faces of the packaging

Placement of critical information in the same field of view on at least three non-opposing faces

Recommendation
A standard packaging box has six faces on which information can be displayed. The critical information – medicine name, variant, strength, form and number of tablets or capsules – should appear in the same field of view on at least three non-opposing faces of the secondary packaging. In practical terms, this means that one of the top or bottom faces, one of the side faces, and one of the end faces should display the information. If it is feasible to display a product description on more than three non-opposing faces ease of use would be enhanced.
Design recommendations for secondary packaging

Faces of the packaging
Presentation of information for manoeuvrability

Recommendation
The text on every face of the secondary packaging, excluding the ends, should be oriented in the same direction. When the information is presented in this way, continuous rotation and legibility is enabled; the user, be they pharmacist or patient, is not required to flip the pack in order to read the front and back.

Effective use of design recommendation

Ineffective use of design recommendation
Hierarchies of information

Use of blank space on secondary packaging to emphasise critical information

Issue
Where secondary packaging is cluttered with text and images, it may be difficult for the patient to recognise important information or for the healthcare professional to positively identify the correct packaging.

Recommendation
Blank space can be used to great effect and to emphasise the critical information, for example medicine name and strength. This is essential for safe administration.
Hierarchies of information

Emphasis of generic medicine name

**Issue**
Where patients have different brands of the same medication, they may confuse the brand and generic names of a medicine. This may lead them to take multiple dosages of the same medication. This risk is especially high where the brand name receives more emphasis than the generic name.

**Recommendation**
The generic name on the secondary packaging should be presented consistently in large point size, preferably 16 point or larger.
Name of medicine

Use of Tallman lettering to emphasise the difference between look-alike and sound-alike medicine names

Issue
Confusion of similar medicine names can lead to the misadministration of a medication. Look-alike and sound-alike names, similar in spelling, number of letters and word shape, can be easily mistaken for one another. The possibility for error increases where medicines are stored alphabetically and therefore appear next to each other on a shelf. Pharmacists, medical practitioners and patients can easily make mistakes by selecting and administering the wrong medicine where the difference between similar medications has not been emphasised.

Recommendation
Tallman (capital) lettering should be used to highlight those sections of similar medicine names that contain the characteristic of the medicine (e.g. ChlorproMAZINE and ChlorproPAMIDE). This increases the likelihood of similar products being distinguished from one another.
Strength of medicine

Differentiation between strengths of the same medicine

Issue
Where the strength of a medicine is not clearly displayed, different strengths of the same medicine may be mistakenly selected. This is especially important considering that, in all other respects, secondary packaging from the same manufacturer’s range is likely to be identical.

Recommendation
The strength of the medicine should be clearly defined. The difference between various medicine strengths can be made clear through use of typeface, type weight, colour and shape.
Strength of medicine

Elimination of numbers with trailing zeros

**Issue**
Where numbers with a trailing zero (e.g. .0 following a whole number) are used, there is a possibility that a healthcare professional will fail to see the decimal point and dispense a tenfold overdose (e.g. 50mg could be administered instead of 5.0mg).

**Recommendation**
Whole numbers should be used at all times, where possible. Different strengths of the same medicine should be expressed in the same manner, such as 250mg, 500mg, 750mg. The use of decimal points should be avoided wherever possible.
**Typography**

**Use of type size**

**Recommendation**
Minimum type size recommended for use on secondary packaging is 12 point, however 14 point is more accessible for patients with sight difficulties. The generic medicine name should be in 16 point or larger.
Typography

Use of sentence case

**Issue**
Capital letters and italicised text are harder to read than sentence case (e.g. This is an example of sentence case). This is because letter shape plays an important role in the identification of words.

**Recommendation**
Capitals for generic medicine names (other than selective Tallman lettering, see page XX) brand names and bodies of text should be avoided. Italic type should not be used where there is an alternative method of emphasis available (e.g. use of bold type). Sentence case (i.e. upper and lowercase) should be used at all times.
Typography

Use of sans serif typefaces

Issue
The choice of typeface is important to legibility. Simulated handwriting and ornate typefaces are difficult to read. Serif typefaces are ideal for large bodies of text such as books and newspapers, where the serifs aid the reader in following and recognising lines of text at speed. They are not suitable for medication packaging, where clarity, accuracy and legibility must be paramount.

Recommendation
A clear and legible sans serif typeface, such as Arial, Helvetica or Univers, should be used.
Typography

Use of bold or semi-bold type

Issue
Where type is lightweight, legibility is reduced. Patients, especially those who are partially sighted, prefer bolder type.

Recommendation
Lightweight type should be avoided. Bold or semi-bold type should be used.
Typography

Elimination of condensed typefaces

**Recommendation**
Condensed typefaces reduce legibility and should be avoided.
Typography

Use of leading and kerning

Issue
Leading (the spacing between lines) and kerning (the spacing between individual letters) significantly affect the legibility and clarity of text.

Recommendation
Leading should be used for clarity and ease of legibility (e.g. 12 point text on 16 point leading). Lines of text should not be squashed closely together. Letterspacing should not be condensed or stretched. Kerning should only be adjusted when necessary as an aid to legibility.
Typography

Use of alignment

Issue
Alignment affects the legibility and clarity of text. It is important that a regular amount of space occurs between each word.

Recommendation
Fully justified text should be avoided, as this can result in irregular word spacing. Text should be aligned to the left margin to make it easier to find the beginning of each line.
Typography

Use of unbroken blocks of text

Issue
Fitting text around or over images or logos breaks the flow of information and reduces legibility.

Recommendation
Bodies of text should remain unbroken. Images or logos should be placed at the beginning or end of the relevant text.
Typography

Creation of strong contrast between type and background colour

Issue
Many patients, especially those who are partially sighted, struggle to read information when there is insufficient contrast between the background and the typography.

Recommendation
The type colour should strongly contrast with the background colour. Strongly coloured type (e.g. black, dark blue) should be placed on a lightly coloured background (e.g. white, pale pink, pale yellow).
Notes on the use of colour

Colour can be an important factor in helping the correct identification, classification and differentiation of medicines, but it also can cause many problems. Colour can, for example, be used to reduce the similarity in appearance between two confusable medicines, or differentiate between different strengths of the same medicine within a manufacturer’s range. Colour can also be used as an additional safeguard to complement the use of style, font and type size. But there is serious concern that both pharmacists and patients could begin to rely too much on colour association, leading to the possibility of an incorrect selection. Other serious difficulties to be taken into account when using colour include the incidence of colour blindness, the difference in appearance of a colour in different lighting conditions, and individual perceptions of colour.

Errors with the application of a single colour across a manufacturer’s range

The application of one colour across a whole manufacturer’s range of products results in entirely different medicines becoming difficult to distinguish. This problem is compounded when medicines with similar names are stored next to one another. Also, differing medicine strengths from the same manufacturer’s range are often placed next to one another on the dispensary shelf contributing to an already complex dispensing environment. There is also a problem when different medicines of the same colour packaging are co-prescribed to patients, especially the elderly, leading to an increased risk of incorrect selection and consequent administration of the wrong medicine.

Colour coding

Colour coding is the systematic application of colour to aid in the classification and identification of medicine products. A colour coding system allows people to memorize a colour and match it to its function. The fundamental problem with colour coding is that it allows the opportunity for a shortcut to identification of a medicine without reading the label. The policy of colour coding is not supported on grounds of safety for three reasons. Firstly, no colour coding system could positively differentiate between all 12,000 medicines authorised in UK. Secondly, in the absence of a nationally or internationally agreed colour code, any UK system could become a barrier to trade. Thirdly, where a user has a condition such as colour blindness, it cannot be assumed that they will interpret colour in the same way as others. One exception is the medicine Warfarin, which has a universal colour coding system (strengths of 1mg are brown, 3mg are blue, 5mg are red).

Colour differentiation

Colour differentiation is favoured above colour coding. Colour differentiation is the means by which colour is used to make certain features on the package stand out or to help distinguish one item from another. The colour itself has no meaning. Colour differentiation can highlight strength differences within a range or help distinguish different products across ranges. It is important that there is no pattern in the colour scheme; the colours should not indicate anything.
Design recommendations for secondary packaging

Colour

Judicious use of colour differentiation

Issue
Colour differentiation should be approached with care. Consideration should also be given to an awareness of the use of colour across the prescription medicine market.

Recommendation
Colour coding should be eliminated. The judicious use of colour differentiation can help distinguish products in a manufacturer’s range, particularly between different strengths of the same medicine. Opposing, meaningless colours should be used to distinguish similar named medicines within a manufacturer’s range. An awareness of users with limited colour perception should also be developed.

Effective use of design recommendation

Ineffective use of design recommendation
Design recommendations for primary packaging

The term primary packaging describes the inner package of a pharmaceutical product. It is the housing for the medication. This packaging makes contact with the medicine. In this publication the blister strip is the only primary packaging considered.
Blister strip

Use of non-reflective foil to prevent glare

Issue
Blister strips are commonly sealed with reflective foil. Glare can easily be caused by the reflection of light on the foil. This can greatly reduce the legibility of the information printed on the foil. Legibility is most severely affected where lightly coloured lettering or lightweight font is used on a reflective foil.

Recommendation
Non-reflective, matt, printed and coloured foils should be used to enhance readability and identification.
Blister strip

Clear presentation of medicine name and strength over individual pockets

Issue
It is important that the name and strength of the medicine be presented on the individual pockets of a blister strip. This is because, firstly, blister strips are removed from their secondary packaging to access the medication, and occasionally the secondary packaging is discarded. Secondly, single blister pockets, which hold one dose of the medicine, are regularly cut from the strip leaving insufficient information. Thirdly, where the name and strength are printed on the blister as a whole, the text is damaged as the medication is removed for use, often making identification of the medicine difficult.

Recommendation
The name and strength of the medicine should appear over each pocket. Where this is impossible due to the small size of the pocket, the information should be repeated in a pattern which covers the entire strip. Careful consideration should be taken to preserve the name and strength of the medicine until the last dose of medication is removed from the blister strip.
Blister strip

Creation of a strong contrast between type and background colour

Issue
In many cases, the legibility of the information printed on a blister strip is reduced both by the nature of the foil material and the necessity of using a small type size. Where the foil material and small type size are combined with insufficient contrast between background and type, many patients, especially those who are partially sighted, struggle to read the information.

Recommendation
The type colour should strongly contrast with the background colour. For example, strongly coloured type (e.g. black, dark blue) should be placed on a lightly coloured background (e.g. white, pale pink, pale yellow). If text is reversed out of a background colour it is especially important that bold type is used.
Blister strip

Use of bold or semi-bold type

**Issue**
The combination of a small type size and a lightweight font on a foil background impairs the readability of information. Small type sizes are easier to read when set in a heavier weight font style.

**Recommendation**
Bold or semi-bold type should be used because it enhances legibility. Lightweight type should be avoided. It is important to note, however, that over enthusiasm for bold or semi-bold type can also impair the readability of type in very small sizes.
**Blister strip**

Identification of primary and secondary packaging through style

**Issue**
Where a complex medication schedule involves a large number of medicines, (particularly when the same medicine is prescribed in two or more strengths) patients must be able to easily identify which blister strip (primary packaging) belongs to which box (secondary packaging). Individual prescription instructions are presented on the dispensing label, which is attached to the secondary packaging. A patient may confuse primary and secondary packaging, especially when two or more products are used from the same manufacturer’s range, and in doing so may take the wrong medication or even overdose.

**Recommendation**
The primary and secondary packaging of a product should have an identical (or linked) distinctive visual style (e.g. through the use of colour).
Inclusive design

User testing

**Issue**
Without user research and an inclusive design process, manufacturers can be unaware of the complexities of the systems in which their products have to function and the potential for harm.

**Recommendation**
The diverse range of human abilities and needs should be taken into account when designing medicine packaging. Individual pharmaceutical companies should develop their own systematic approach to user testing, which should seek to understand and address the widest range of users. Special attention should be given to ‘critical’ users – those at the extremes of capability ranges – and also to ‘boundary’ cases where, for example, age-related capacity loss begins to compromise visual, cognitive or dexterous functions. See Appendix for an example of a method for user testing.

The way forward

Better pack design can make a significant and immediate contribution to patient safety, but the ultimate goal must be to consistently deliver the correct amount of the right medicine to the right patient at the right time. The challenge is to find ways to keep medication and the information the patient needs together and intact, right up to the moment when the medication is taken.

**Suggested issues for further research:**
- How design can assist patients on multiple medication schedules
- Whether the inclusion of information on the tablet itself contributes to patient safety
- Whether it is advisable to include a picture of the tablet on the secondary packaging
- The effect of matching machine-readable codes on packaging and dispensing labels
- Whether small products, especially ophthalmic products, should be packaged in larger packaging
- Whether the blister strip could accommodate a ‘header’ area set aside from the capsules where all critical information would remain intact
Information design checklist
### Name of medicine on secondary packaging

<table>
<thead>
<tr>
<th>Issue</th>
<th>Consideration</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identification</td>
<td>Is the critical information in displayed in the same field of view on at least three non-opposing faces?</td>
<td>42</td>
</tr>
<tr>
<td>Emphasis of critical information</td>
<td>Is blank space used to emphasise the medicine name?</td>
<td>46</td>
</tr>
<tr>
<td>Emphasis of critical information</td>
<td>Is the generic medicine name emphasised?</td>
<td>48</td>
</tr>
<tr>
<td>Differentiation</td>
<td>Is Tallman lettering used to emphasise the difference between look-alike and sound-alike medicine names?</td>
<td>50</td>
</tr>
<tr>
<td>Legibility and clarity</td>
<td>Is the medicine name set in 16pt size or larger?</td>
<td>56</td>
</tr>
<tr>
<td>Legibility and clarity</td>
<td>Is the medicine name set in sentence case?</td>
<td>58</td>
</tr>
<tr>
<td>Legibility and clarity</td>
<td>Is the medicine name set in a sans serif typeface?</td>
<td>60</td>
</tr>
<tr>
<td>Legibility and clarity</td>
<td>Is the medicine name set in bold or semi-bold type?</td>
<td>62</td>
</tr>
<tr>
<td>Legibility and clarity</td>
<td>Is the medicine name set in a non-condensed typeface?</td>
<td>64</td>
</tr>
<tr>
<td>Legibility and clarity</td>
<td>Are leading and kerning used effectively?</td>
<td>66</td>
</tr>
<tr>
<td>Legibility and clarity</td>
<td>Does any graphic or logo interfere with the medicine name?</td>
<td>70</td>
</tr>
<tr>
<td>Legibility and clarity</td>
<td>Is there a strong contrast between type and background colour?</td>
<td>72</td>
</tr>
</tbody>
</table>

### Strength of medicine on secondary packaging

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<thead>
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<tbody>
<tr>
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<td>Is the critical information in displayed in the same field of view on at least three non-opposing faces?</td>
<td>42</td>
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<tr>
<td>Identification</td>
<td>Are there any numbers with trailing zeros?</td>
<td>54</td>
</tr>
<tr>
<td>Differentiation and clarity</td>
<td>Is blank space used to emphasise the medicine strength?</td>
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<tr>
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<td>Is the medicine strength set in 16pt size or larger?</td>
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<td>Does any graphic or logo interfere with the medicine strength?</td>
<td>70</td>
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<tr>
<td>Legibility and clarity</td>
<td>Is there a strong contrast between type and background colour?</td>
<td>72</td>
</tr>
<tr>
<td>Differentiation and clarity</td>
<td>Is there clear differentiation between different strengths of the same medicine?</td>
<td>–</td>
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</table>
### All the critical information on secondary packaging
(medicine name, variant, strength, form and number of doses)

<table>
<thead>
<tr>
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<tr>
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</table>

### Name and strength of medicine on primary packaging

<table>
<thead>
<tr>
<th>Issue</th>
<th>Consideration</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Legibility</td>
<td>Is the medicine name and strength clearly presented over individual pockets?</td>
<td>83</td>
</tr>
<tr>
<td>Legibility</td>
<td>Does the medicine name and strength remain visible when the blister strip has been partially used or cut?</td>
<td>83</td>
</tr>
<tr>
<td>Legibility</td>
<td>Is there a strong contrast between type and background colour?</td>
<td>86</td>
</tr>
<tr>
<td>Legibility</td>
<td>Is the medicine name set in bold or semi-bold type?</td>
<td>88</td>
</tr>
<tr>
<td>Identification</td>
<td>Is the blister strip clearly recognisable as belonging to its original secondary packaging?</td>
<td>90</td>
</tr>
</tbody>
</table>

### Brand names and the application of logos and corporate identities

<table>
<thead>
<tr>
<th>Issue</th>
<th>Consideration</th>
<th>Page</th>
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</thead>
<tbody>
<tr>
<td>Clarity and emphasis</td>
<td>Does the use of blank space emphasise critical information?</td>
<td>46</td>
</tr>
<tr>
<td>Clarity and emphasis</td>
<td>Is the generic medicine name emphasised more than the brand name?</td>
<td>48</td>
</tr>
<tr>
<td>Legibility</td>
<td>Is the brand emphasis on the communication of critical information?</td>
<td>–</td>
</tr>
<tr>
<td>Legibility</td>
<td>Does any type of pattern, logo or corporate identity obscure critical information in any way?</td>
<td>70</td>
</tr>
</tbody>
</table>
### Manoeuvrability and the dispensing label

<table>
<thead>
<tr>
<th>Issue</th>
<th>Consideration</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Legibility</td>
<td>Is there a 35 x 70mm white space allocated for the application of a dispensing label?</td>
<td>38</td>
</tr>
<tr>
<td>Identification in the pharmacy</td>
<td>Is the name and strength of the medicine repeated above or beside the space provided for the dispensing label?</td>
<td>40</td>
</tr>
<tr>
<td>Manoeuvrability</td>
<td>Is the information on the packaging designed for easy manoeuvrability?</td>
<td>44</td>
</tr>
</tbody>
</table>

### Judicious use of colour

<table>
<thead>
<tr>
<th>Issue</th>
<th>Consideration</th>
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</thead>
<tbody>
<tr>
<td>Differentiation</td>
<td>Is colour differentiation used judiciously?</td>
<td>76</td>
</tr>
<tr>
<td>Differentiation</td>
<td>Are all types of colour coding eliminated?</td>
<td>76</td>
</tr>
<tr>
<td>Differentiation</td>
<td>Is there any way in which the design or colour could be used as a shortcut to identification?</td>
<td>75</td>
</tr>
</tbody>
</table>

### Matching the primary and secondary packaging of one product

<table>
<thead>
<tr>
<th>Issue</th>
<th>Consideration</th>
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</thead>
<tbody>
<tr>
<td>Matching</td>
<td>Is the primary and secondary packaging of one product identifiable through style? What elements allow them to be matched together?</td>
<td>90</td>
</tr>
<tr>
<td>Matching</td>
<td>Is it possible to confuse or mix up the primary and secondary packaging with other medicines from the same manufacturer’s range? How can this be avoided?</td>
<td>–</td>
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</table>

### Inclusive design

<table>
<thead>
<tr>
<th>Issue</th>
<th>Consideration</th>
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<tbody>
<tr>
<td>Critical users</td>
<td>Have elderly or partially sighted users been considered?</td>
<td>92</td>
</tr>
<tr>
<td>User testing</td>
<td>Has the packaging been tested with critical users?</td>
<td>92</td>
</tr>
<tr>
<td>User testing</td>
<td>Has the packaging been tested in accordance with the company guidelines?</td>
<td>–</td>
</tr>
<tr>
<td>End-use context</td>
<td>Has consideration been given to likely end use contexts for the medication, especially where it is likely to be used by a specific group of patients or carers?</td>
<td>92</td>
</tr>
</tbody>
</table>
### Consideration of similar products

<table>
<thead>
<tr>
<th>Issue</th>
<th>Consideration</th>
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<tbody>
<tr>
<td>Differentiation and context</td>
<td>Does the packaging, especially in the pharmacy, adequately serve to distinguish it from other packaging?</td>
<td>–</td>
</tr>
<tr>
<td></td>
<td>Has a search been made for other commonly used packaging that are similar?</td>
<td>–</td>
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<tr>
<td></td>
<td>Are there products with similar or confusable names in the same manufacturer’s range? In what way are these differentiated?</td>
<td>–</td>
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<tr>
<td></td>
<td>How many strengths of the same medicine are there? In what way are they differentiated?</td>
<td>–</td>
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<tr>
<td></td>
<td>Has the pharmacy prescribing environment been considered?</td>
<td>–</td>
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<tr>
<td></td>
<td>Has the patients’ home environment been considered?</td>
<td>–</td>
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<tr>
<td></td>
<td>Is there an awareness of other brand manufacturers products? Could two products from different manufacturers cause confusion?</td>
<td>–</td>
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</table>
Acknowledgements

The author would like to thank Professor Roger Coleman and Professor Jeremy Myerson at the Helen Hamlyn Research Centre for their continual assistance and guidance on this project. Colum Lowe, Head of Design and Human Factors and Wendy Harris, Senior Pharmacist, Safe Medication Practice at the National Patient Safety Agency also gave unprecedented support. All the staff, patients and designers at all hospitals, pharmacies, homes and institutions that have been visited in the course of this research must be thanked for their time and effort. All the staff at the Helen Hamlyn Research Centre and the Communications department at the Royal College of Art are appreciated for their generous support. All of those who took part in the stakeholder review panel gave their time and expertise so generously. Appreciation must be given to the editor and readers of this publication, and to my family.

About the author

Thea Swayne graduated with an MA RCA in communication design at the Royal College of Art in 2004. She achieved a first class pass in Graphic Design at undergraduate level BA Hons at Central Saint Martins College of Art and Design in 2002. She has won many prizes, including the National Grid Transco Awards 2004. She is a freelance designer, living and working in London, whose clients have included The Guardian, The Future Foundation, Defra and the National Youth Orchestra.

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Brian Parkinson's personal website

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Medicines & Healthcare Products Regulatory Agency

www.nabp.net
National Association of Boards of Pharmacy (US)

www.npsa.nhs.uk
National Patient Safety Agency

www.patientpacks.com
Patient Packaging Audit

www.pharmacychoice.com
Pharmacy Choice

www.ppa.org.uk
Prescription Pricing Authority

www.rnib.org.uk
Royal National Institute of the Blind

www.rsa-design.net
Royal Society of Encouragement of the Arts, Manufacturers and Commerce, Medicine Safety Brief
**Typographic glossary**

This glossary has been put together to clarify the meaning of certain words used in this document concerning typographic design. Names in *italics* refer to other typographic glossary entries.

**alignment** Precise arrangement of letterforms upon a horizontal or vertical line.

**ascender** Part of a lowercase letter that projects above the *x height*. See also *descender*.

**bold** Type with thicker, heavier strokes than regular type. Type weight between bold and roman is called semi-bold.

**capital(s)** Letterforms of even height, larger than the corresponding lowercase letters, also called *uppercase* characters.

**character** An individual letter.

**clear print** A term used by RNIB to describe documents which utilise a minimum *type size* of 12 point, (although RNIB recommends 14 point to be accessible for more customers with sight problems). See also *large print*.

**colour** In pure typography this usually refers to the overall tonal value of a typeface. However, in this context, colour refers to 1. the flat colour in a single tone that sits on the background of the packaging or in a specific shape, or 2. the colour given to a character or word.

**condensed type** Letterforms whose horizontal width has been compressed.

**design** The co-ordinated arrangement of all text matter so that it appears ordered and clear, fulfilling the requirements of the client in the particular context.

**descender** Part of a lowercase letter which projects below the baseline. Also see *ascender*.

**display type** Type sizes (usually 14 point and over) primarily used for headlines and titles.

**font** The design of alphabetical and numerical characters (including punctuation) having a particular and recognisable character. For example this font is called Frutiger. Also called *typeface*. Each font or typeface has its own visual properties. Other examples of well-known fonts include Futura, Helvetica, Times, Baskerville, etc.

**heading** Copy that has been given emphasis over other text, usually by a change in size, weight, spacing or alignment.

**italic** Letterforms having pronounced diagonal slant to the right. Used to give typographic emphasis to certain words.

**justified** The arrangement of text that is aligned with either a left- or right-hand margin, or with both. Fully justified text has lines of the same length that are perfectly aligned on right and left sides, achieved by altering the space between words.

**kerning** Adjusting (increasing or decreasing) the space between two adjacent letters to create a better visual fit. See also *letter spacing*.

**large print** Large print documents are produced in a larger-than-normal type size, typically around 16-22 point.

**leading** The spatial interval between lines.

**lettering** A term commonly misused for *typography*; most commonly applied to hand writing or craft-orientated penmanship. See *character*.

**letter spacing** A tightening up (or opening out) of the space between characters applied to complete lines or passages of text. Also known as tracking.

**levels** The organisation and design treatments of the text matter into clear and accessible headings, sub headings and paragraphs.
light weight The weight of a letter expressed typographically; of a lighter weight than roman or bold.

line length The measure of the length of a line of type.

line spacing See leading.

logo A sign or trademark.

lower case Small form of letters, not capitals, e.g. a, b, c, d etc; The opposite of capitals. They are typographically described in three parts: ascenders, e.g. h, l,descenders, e.g. j, g, y, and the x height.

margin The unprinted space surrounding type matter on a page.

numerals Arabic (1, 2, 3, 4, etc.) and roman (I, II, III, IV, etc.). Lining figures are when numerals are all same size, e.g. 12345; also non-lining figures when numerals are of differing heights, e.g. often in serif typefaces with descenders and ascenders.

point size The font size in the UK and US, usually given in points. The size does not refer to the visible size of a character but to the measurement of the body (see x height). The font size is usually expressed in points, e.g. 10 point (also expressed as 10pt.), 12 point, 18 point, etc. 1 point is equivalent to 0.351mm.

sans serif A category of typeface without serifs. Tends to be used for display purposes. For example Arial, Helvetica or Univers.

serif Small terminal strokes added to the end of the main stroke/line of a character, e.g Times is a serif typeface.

semi-bold See bold.

sentence case Headlines written with upper and lowercase characters, for example, ‘Ground floor this way’.

style A particular emphasis or character given to the text by the choice and family of the typeface and can include italic, bold, roman, condensed type, etc.

Tallman lettering A name given to capital lettering that is used to highlight sections of similar drug names that contain the characteristic of the drug (e.g. ChlorproMAZINE and ChlorproPAMIDE).

text In this context, the main body of written material. See also lettering.

trailing zeros A zero following a decimal point, e.g. 5.0, 7.00.

type size The size of characters measured in the point system. See point size.

type style The design applied by the designer to the text matter; includes choice of typeface, size, position, etc.

typeface The choice of a font related to the design of the material in question.

type family The complete range of variations of typeface design including fonts of roman, italic and bold, expanded, condensed and other versions. Also see style.

typography Originally related to the composition of printed matter from movable type. Now describes the design and process of the visual arrangement of text and pictorial matter by any system, today most commonly practised on computer. See also design.

unjustified text Text evenly arranged with either left or right hand edge of type left ragged. See also justified text.

uppercase The name for full capitals related to typographic design. See also capitals, Tallman lettering.

weight The lightness or heaviness of a typeface, which is determined by ratio of the stroke thickness to character height.

word spacing Adjustment of the spacing between words.

x height The height of lowercase letters, excluding ascenders and descenders. This is most easily measured on the lowercase letter x.
Appendix: Methods for user testing

Pharmaceutical companies should develop their own individual methods for user testing. Here is an example method developed from A guideline on the readability of the label and package leaflet of medicinal products for human use, European Commission, Brussels, Belgium, September, 1998:

Method
This investigation sets out to ensure, through user testing, that information on pharmaceutical packaging is legible for a wide range of stakeholders. To gain an accurate representation, it is recommended that the minimum number of participants that should be involved is 20. Manufacturers should decide how many more participants are appropriate to demonstrate the safety of their products. It is important to distinguish what combination of design elements work successfully as well any difficulties encountered.

Who should perform the testing?
Manufacturers should perform the testing and involve the designers in this process. In this way the designers will learn from the experience of the test and transfer this knowledge to future designs.

Who should be tested?
Critical users, i.e. those who are likely to have the most problems using the medication packaging and not necessarily those who have the illness the product treats, should be tested. Those at the extremes of capability ranges and ‘boundary’ cases – where age-related capacity loss compromise visual, cognitive or dexterous functions – would be suitable candidates.

Type of test
1. It is important to ask the participants to carry out their normal activities regarding reading the information on the packaging.
2. It is important to observe and document what they do carefully.
3. Ask them to note in their own words what they do.
4. Ask any questions that might extend the information gathered.
5. Ask specific questions about particular design elements, (or readability) of the packaging.

What to test?
Core questions to ask include:
1. Can the consumer find the information required quickly and easily?
2. Having found it, can they understand it and act appropriately?

Testing procedure
1. There are a number of core tasks that are critical for the safe use of pharmaceutical packaging and these can vary slightly from one product to another:
a. What is the information on the packaging used for?
b. How is the information used?
c. What are the undesirable effects of the information on the package?
2. No more than 15 questions should be compiled in a single document.
3. At least ten critical users should be recruited who are likely to have problems with information on packaging, for example, older patients.
4. One participant should be tested at a time, allowing at least half an hour for each person. More than one package could be tested on each participant. Note that testing that lasts more than 45 minutes may not be useful because the participant will tire.

5. The order of questions should be randomised and two questions concerning the same information should not be asked in the same sentence. If participants get confused, note how they try to deal with the difficulty.

6. When the participants find the information that has been asked of them, they will probably read out the information. They should be asked to put it into their own words and explain what it means. This will reveal whether they understand the information on the packaging or not. If this involves a physical activity such as mixing something together, they should be asked to do this and actually go through the procedure on the package.

7. If a consumer does not understand and asks a question, avoid giving the answer. Ask another question such as “What do you think it means?”.

8. After ten consumers have been tested, the data should be reviewed. Major faults with the information on the packaging should be becoming clear. At this stage, it is possible to redesign or rewrite the information before further testing.

9. Once satisfactory data has been obtained from ten consumers, a further ten should be tested. The objective is to have at least 16 consumers out of 20 able to answer each questions correctly. It may be necessary to clarify the performance of the questionnaire, which may include rewriting and remodelling the questions to achieve a better level of performance.