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LABELLING COMPLIANCE OF OVER-THE-COUNTER MEDICINES WITH NATIONAL REGULATIONS

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1. INTRODUCTION

Many people treat a headache, a cold or heartburn without ever speaking to a doctor or a pharmacist. They pick a box from a shelf, read what is printed on it, and decide how much to take. That makes the label the main safety tool for non-prescription medicines, and a more important one than for products dispensed with oral counselling [1]. Self-medication also brings clear public health benefits when it is done well, from relief of minor ailments to savings for health systems, a point made in discussions of the

Abstract

Labels on over-the-counter medicines are often the only written guidance a consumer reads before taking a product. This review summarises published work on what national and regional regulations require on such labels, how compliance has been audited, which deficiencies are reported most often, and what is known about consumer comprehension. It also covers dosing devices, pictograms and readability testing. The literature indicates that formal compliance and real understanding are separate things, that dosing and active-ingredient information cause most of the documented problems, and that audit methods are poorly standardised. No new audit data are reported, and the conclusions rest on regulatory documents and studies by others.

rise of self-medication [2].

National regulators therefore specify in considerable detail what has to appear on an outer carton, an inner container and a leaflet.

Requirements include the product name, active substances and strength, dose and directions, warnings, expiry date, batch number, storage conditions and the name of the marketing authorisation holder [3, 4, 5]. Compliance with these rules is checked at authorisation, by inspection and, in some countries, by retrospective surveys of products on the market. Whether a label meets the letter of the rules is one question. Whether an ordinary buyer can use it correctly is another, and the literature on OTC labels spends much of its energy on the gap between the two [6, 7].

This review draws on regulatory texts, published audits and comprehension studies to describe what compliance means in practice, how it has been measured, and which problems recur. It is a narrative synthesis and does not report an audit of its own or any new data. The focus is on oral solid and liquid products sold without prescription, with analgesics, antipyretics, cough and cold remedies and antacids as the commonest examples. Findings from the United States, Europe, the United Kingdom and India are used as illustrations because each has a distinct regulatory tradition, although the underlying human factors problems are similar everywhere [5, 8, 9, 10].

2. REGULATORY REQUIREMENTS FOR OTC LABELLING

In the European Union, Directive 2001/83/EC sets out the particulars required on the outer packaging and immediate container, and the contents of the package leaflet, for all human medicines [3]. Directive 2004/27/EC added the requirement that the name of the medicine be expressed in Braille on the outer packaging and that the leaflet be legible, clear and easy to use, with the results of consultations with target patient groups taken into account [4]. A separate guideline on readability describes type size, layout and wording, and recommends that the leaflet be tested with volunteers [8]. Member states then apply these rules through national law and add language requirements.

In the United States, the Drug Facts format arose from a 1999 rule that standardised the order and wording of OTC labelling. The

label has headed sections for active ingredient, purpose, uses, warnings, directions, other information and inactive ingredients, set in a specified type size with bullets and boxed warnings [5]. The idea was to give consumers a familiar layout, comparable to the nutrition facts panel on food. The Food and Drug Administration has also issued guidance on label comprehension studies for nonprescription products, setting out how sponsors should test whether consumers understand key messages before a switch from prescription status [11].

In the United Kingdom, the Medicines and Healthcare products Regulatory Agency (MHRA) publishes best practice guidance on labelling and packaging, which stresses clear differentiation between products, prominent display of the active ingredient and strength, and avoidance of look-alike packaging within a range [9]. India controls what may be claimed on a medicine label through the Drugs and Magic Remedies (Objectionable Advertisements) Act, which treats labels and wrappers as advertisements and prohibits misleading claims of cure for specified diseases and conditions, while licensing provisions add the statutory particulars that must appear on the pack [10]. Many countries adopt parts of the European or American models, and so the basic content is broadly familiar even when details differ.

Regulatory frameworks differ in what they do about the OTC category itself. Some countries have a defined list of non-prescription substances, others allow pharmacy-only or general sale status on the basis of risk, and some leave a good deal of discretion to the licensing authority. Discussions of the rise of self-medication make the same point: once a doctor or pharmacist is no longer involved, the information on the pack becomes the main means of managing risk, so it must state the indication, dosage and precautions and say when to seek medical advice [2]. The WHO criteria for ethical promotion add that claims on labels and in advertising should be reliable, accurate, truthful and not misleading [12].

The representative findings in table 1 are arranged under the headings used in this

review, from regulatory elements to audit methods, reported deficiencies and improvement strategies. As the distribution in fig. 1 shows, the published literature has concentrated on deficiencies and comprehension, while descriptions of audit methods and of the effectiveness of regulatory enforcement are fewer. That imbalance matters because it is hard to compare reports of non-compliance from different countries when each team has used its own checklist, its own sample of products and its own definition of what counts as an error.

Table 1: Representative published findings on OTC medicine labelling, audit methods and comprehension

Topic	Reported finding	Ref.
EU legislation Directives 2001/83/EC and 2004/27/EC	Define labelling particulars, Braille on outer packaging and legible, user-tested leaflets	[3, 4]
US Drug Facts format	Standardised headed sections and type size to make OTC labels comparable	[5, 11]
UK and Indian provisions	Best practice guidance on differentiation and statutory content rules for labels	[9, 10]
Checklist audits	Measure presence of required statements, not whether the consumer can use them	[13, 14]
Consumer testing	Find-and-understand tests set a target proportion; closer to real behaviour	[8, 11]
Dosing directions	Missing maximum daily dose, unclear age bands and interval wording are frequent problems	[15, 16]
Duplicate active ingredients	Many adults fail to recognise the same drug in different products	[15]
Liquid dosing devices	Mismatched markings and units are linked to parental dosing errors	[17, 18]
Warning phrases	Common auxiliary warnings misunderstood, especially at low literacy	[6, 7]
Pictograms	Improve recall and reduce dosing errors if tested and culturally adapted	[19, 20, 21]

Topic	Reported finding	Ref.
Revised warning text	Plain-language wording and layout raised comprehension in a randomised comparison	[22]

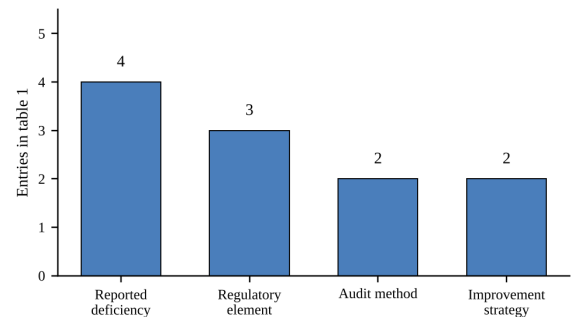


Fig. 1: Number of entries in table 1 by theme

A practical complication is the lifecycle of regulations. Labelling rules change as new safety information emerges, and products already on the market may carry older labels for months or years. A retrospective survey that finds missing statements may simply be looking at stock printed before a rule came into force. Studies that do not report manufacturing dates, or that do not state the version of the requirement against which products were assessed, are difficult to interpret [5, 8]. This is a recurring weakness in audit-style publications and deserves explicit mention in any critical appraisal.

3. AUDITING LABEL COMPLIANCE

Published compliance audits are mostly cross-sectional. Investigators collect a convenience or systematic sample of products from pharmacies, supermarkets and informal outlets, and score each label against a checklist derived from the applicable regulation. Items include whether the active ingredient and strength are stated, whether dosing directions are given by age, whether warnings, contraindications and storage statements are present, and whether batch and expiry details are legible. Scores are usually summarised as the proportion of products meeting each item or as an overall compliance percentage [13, 14]. The approach is inexpensive and transparent, but it measures presence of text, not usefulness.

Checklists vary in length and weight. Some treat every item as equal, so that the absence of a manufacturing address counts the same as the absence of a maximum daily dose.

Others weight items by safety importance, which is closer to the way a regulator or pharmacist would judge risk. The choice affects the results. A product can score very highly on an unweighted checklist and still omit the one statement that prevents overdose, and published audits seldom report both scores [13, 23]. Where weighting is used, the basis for it should be explained, ideally by reference to expert panels or established risk categories.

A second tradition tests the label with consumers. Following the approach used in the European leaflet readability work, participants are asked to find and explain specified items of information, and the proportion who can do so is compared with a target, often 90 per cent finding and 90 per cent of those understanding what they found [8, 13, 24]. Label comprehension studies for switching prescription products to OTC use a similar logic and are described in FDA guidance [11]. User testing is more demanding than a checklist, but it comes closer to answering the question that matters, which is whether people behave safely after reading the label.

Raynor and colleagues compared consumer medication information across the United States, Europe and Australia, assessing it against agreed quality criteria, and found marked differences in the content and format of leaflets between regions even for the same medicines [14]. A systematic review by Raynor and others examined the role and effectiveness of written information about medicines and concluded that, although written information is valued by patients, its design is often poor and its effect on outcomes uncertain [13]. These two sources are good starting points for anyone planning an audit because they show how comparisons across regulatory systems can be framed.

Sampling remains a weak point. Studies drawing products from a handful of pharmacies in one city cannot represent the national market, and informal outlets that sell loose tablets or repackaged goods are usually excluded because they have no labels to assess. Where unlicensed products are included, the results can look dramatically worse, but the comparison with licensed

products is not like for like. Inter-rater agreement, a basic requirement for any checklist-based study, is mentioned in only some publications. Pilot testing of the checklist and double scoring of a subset of labels would improve credibility at little cost.

4. REPORTED DEFICIENCIES AND THEIR CONSEQUENCES

Across the audits and observational reports, the commonest deficiencies concern dosing. Directions are given as a single dose with no maximum daily amount, age bands are overlapping or missing for children, intervals between doses are unclear, and units are inconsistent between the label and the measuring device. The consequences are not trivial. Paracetamol, known as acetaminophen in North America, is the standard illustration, since unintentional overdose by repeated dosing or by taking several products that contain the same ingredient is a recognised cause of liver injury [15, 16]. Lee described the picture from the US Acute Liver Failure Study Group and argued for clearer labelling and public education [16].

Wolf and colleagues studied how adults with differing health literacy interpreted the label of OTC products containing acetaminophen and found that many could not correctly identify the maximum daily dose or recognise that different products contained the same active ingredient [15]. The study is an important reminder that the presence of a warning on a label does not guarantee that it is read. Active ingredient names are usually printed in small type on the back of a pack, whereas the brand name and the symptom claim dominate the front. A consumer picking a cold remedy and a headache tablet can therefore take the same drug twice without noticing [15, 23].

Warnings fare no better. Studies of prescription drug warning labels by Wolf, Davis and colleagues showed that many patients misunderstood common auxiliary phrases such as take with food or do not take with dairy products, and that comprehension depended strongly on literacy [6, 7]. Improved wording and layout, tested in a randomised comparison, raised comprehension substantially [22]. Although

those studies concerned prescription labels, the same principles apply to OTC warnings, which tend to be long, written in dense paragraphs, and positioned according to the order a regulator prefers and not according to what a consumer needs first [5, 22].

Children's medicines have attracted particular attention. Liquid products are often supplied with cups, syringes or spoons whose markings do not match the dose in the directions, and parents commonly make errors when converting between millilitres, teaspoons and tablespoons. Yin and colleagues showed that parents' medication administration errors were associated with the dosing instrument and with health literacy [17], and later work found that the unit of measurement used in instructions influenced the frequency of dosing errors [18]. A pictogram-based intervention reduced dosing errors in a randomised trial of caregivers of young children [21]. These findings point to the whole pack, not just the printed text, as the object of regulation.

Other reported problems are less dangerous but still relevant. Claims on the front of a pack may be stronger than the evidence in the leaflet allows, brand extensions with different active ingredients appear in near-identical packaging, and language requirements are not always met in multi-lingual markets. In some audits, expiry dates and batch numbers were missing, unclear or printed in a way that wears off. Look-alike, sound-alike confusion is a known concern for prescribed medicines and applies equally on the shelf [3, 9]. Individually minor, these issues add up to a poorer experience of self-care and weaken trust in the information supplied.

Cough and cold products deserve a separate comment because many are combinations, with an analgesic, a decongestant, an antihistamine and sometimes a cough suppressant in one formulation. Consumers choose them by symptom and not by ingredient, so the label has to carry the burden of explaining what is inside and why two products should not be combined. Reports from the United States led to restrictions on use in young children, and labels there were revised to reflect this, though the evidence behind the change came from poison control

and adverse event reports and not from label audits [5, 16, 25]. The episode shows how labelling can lag behind safety information.

5. COMPREHENSION, LITERACY AND DESIGN

Health literacy provides the link between label design and behaviour. Sørensen and colleagues reviewed definitions and models and described it as knowledge, motivation and competence to access, understand, appraise and apply health information [26]. Paasche-Orlow and Wolf set out causal pathways from limited literacy to poor outcomes, including difficulty reading labels and instructions [27]. The Institute of Medicine called attention to the scale of the problem and recommended that medication labels be standardised and written for people with limited literacy [28, 29]. Since OTC users are by definition a general public, the label should be written for the least skilled reader and not the typical one.

Literacy is not only a matter of reading ability. Numeracy, the capacity to interpret quantities such as a dose of two tablets every four to six hours to a maximum of eight in 24 hours, is a separate skill and often a weaker one. The collection edited by Schwartzberg and colleagues brings together the evidence that a large share of adults in developed countries struggle with everyday health tasks of this kind [30]. OTC labels that rely on arithmetic, for example conversions between age bands and doses by body weight, are therefore likely to be misread by the people who need clear guidance most, and the Institute of Medicine workshop on standard labels reached a similar view [28, 29].

Readability measures are often reported for leaflets. Formulae based on sentence length and syllable count provide a rough guide, but they have limits, since a short sentence packed with technical words can be harder than a long one in plain language. Nielsen's usability principles and the Australian guidance on writing about medicines emphasise structure, headings, short sentences, active voice and layout that lets the reader locate an item quickly [24, 31]. The European readability guideline recommends a minimum type size, adequate spacing and a

question-based structure for leaflets, which tests well with volunteers [8]. Such design principles are easy to state and surprisingly hard to apply under packaging space constraints.

Pictograms are a popular proposed solution. A review by Katz and colleagues found that pictorial aids generally improved patient comprehension and recall of medication instructions, especially for people with low literacy, although the benefit depended on pictogram quality and on local testing [19]. Dowse and Ehlers evaluated pharmaceutical pictograms in a low-literate South African population and showed that many symbols were poorly understood without explanation, and that comprehension rose when they were culturally adapted [20]. For OTC labels, where space is limited, a small number of well-tested symbols for warnings such as drowsiness, not for children and do not exceed the dose may be of most value.

Presentation of risk is another issue. Knapp and colleagues compared how side-effect frequencies were described and found that verbal descriptors such as common or rare led people to overestimate risk compared with numerical frequencies [32]. This has direct relevance to OTC leaflets, where lists of adverse effects can discourage use of a product, or alternatively lead readers to skip the section altogether. Layout cues, such as placing the warnings that need action first and the more general information afterwards, may serve readers better than listing all effects in the same format [8, 32]. Good practice in this area still relies on testing with real users.

6. IMPROVING LABELS: EVIDENCE AND LIMITATIONS

Several interventions have evidence behind them. Standardised formats such as Drug Facts make it easier to locate information, and consumers in label comprehension studies generally perform better on standardised layouts than on idiosyncratic ones [5, 11]. Testing the label with consumers before release, as required in Europe for leaflets, identifies problems that experts overlook [8, 13]. Simple dosing devices with markings matched to the label, and pictograms where appropriate, reduce measuring errors in

children [17, 18, 21]. None of these is expensive, but they require the manufacturer, regulator and pharmacist to take responsibility for use of the product and not simply its content.

The pharmacist's role in making the label work is easy to underestimate. At the counter, a short question about other medicines being taken and a reminder of the maximum daily dose can prevent most of the problems described above, and pharmacy staff are well placed to notice products whose labels are confusing [1]. Evidence that counselling at the point of sale improves outcomes for OTC purchases is thin, mainly because it is difficult to study, but the logic is persuasive. Professional bodies can also provide feedback to manufacturers and regulators about packaging that leads to repeated questions or mistakes, a channel that is not used as often as it could be [23].

The literature has gaps. Most comprehension research comes from the United States and Western Europe, with participants recruited in clinics and community venues, and the findings may not transfer to settings where literacy, languages and retail practices differ. Regulatory audits are scattered, use different checklists, and rarely follow products over time. Studies with patient outcomes are very few. Systematic comparison of regulatory systems is also lacking, so it is difficult to say whether one approach produces better labels than another [13, 14]. This is a field in which good descriptive work exists but cumulative evidence has not built up.

Future work could usefully agree on a core checklist for compliance audits, with safety-weighted items and defined scoring, and combine it with consumer testing of a sample of the same labels. Linking audit results to poison centre and pharmacovigilance data would help show which label features matter most. Regulators could publish enforcement outcomes so that researchers can see which deficiencies lead to action. Pharmacists, who are the last professional contact for many OTC purchases, can contribute by reporting label problems and by reinforcing key messages about maximum dose and duplicate ingredients [15, 16]. These steps are feasible

with existing resources.

7. CONCLUSION

Published regulations for OTC labelling are detailed and broadly similar across the European Union, the United States, the United Kingdom and India, covering identity, strength, directions, warnings and traceability [3, 5, 9, 10]. Audits against these rules tend to find that most statements are present but that dosing information, active ingredient visibility and warnings are the weak points [13, 15, 16]. Formal compliance is therefore a necessary but incomplete measure of whether a label protects the consumer.

Comprehension research shows that many people misread dose limits, duplicate ingredients and standard warnings, and that clearer wording, tested pictograms and matched dosing devices help [19, 21, 22]. Progress will depend on shared audit checklists with safety weighting, consumer testing alongside compliance scoring, and links to poisoning data [8, 11, 16]. Until such work is routine, a claim that a product is compliant should be read as a statement about its text and not about its safe use.

8. ABBREVIATIONS

OTC-Over-the-counter, WHO-World Health Organization, FDA-Food and Drug Administration, MHRA-Medicines and Healthcare products Regulatory Agency

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10. AUTHORS CONTRIBUTIONS

All the authors have contributed equally.

11. CONFLICT OF INTERESTS

Declared none

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