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Ambiguous Risk Information in Over-the-Counter Chinese Patent Medicine Labels: A Content Analysis of 30 Package Inserts with Clinician Interpretations

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Abstract

Safety information on over-the-counter Chinese patent medicine package inserts is frequently summarised with the phrase "unclear"—*shang bu ming que*—yet little is known about how this ambiguity is distributed across label sections or how clinicians act on it. This study combined a structured content analysis of 30 over-the-counter package inserts with semi-structured interviews with six licensed physicians in China. Ambiguity concentrated in adverse-reaction sections: 20 of 30 inserts (66.7%) described adverse reactions as "unclear", compared with 9 of 30 (30.0%) for contraindications, and all nine contraindication-ambiguous inserts also had unclear adverse reactions. Specific drug-interaction information appeared on only 2 of 30 inserts, while 29 of 30 advised users to consult a physician or pharmacist. Actionable advice stratified into three intensity levels, from consultation alone to discontinuation plus medical care. Fewer than half of the inserts, 12 of 30, carried a dedicated special-population section; inserts with such a section covered all four special populations more often than those without, 66.7% versus 38.9%. Physicians read "unclear" as insufficient evidence rather than evidence of safety, and responded with cautious prescribing, supplementary information seeking, or simplified regimens. These results indicate where label regulation and risk communication for these products most need strengthening.

Keywords

Chinese patent medicine, package insert, ambiguous safety information, risk communication, content analysis

1. Introduction

Drug labels and package inserts are the primary written channel for communicating medication risks to patients and healthcare professionals. How clearly each section is worded shapes the way both groups interpret the content and, ultimately, the way medicines are used. Chinese patent medicines (CPM) occupy a special position in this landscape. Surveys of several hundred package inserts have repeatedly found that safety sections are incomplete, that adverse reactions and interactions are described as "unclear" (尚不明确), and that terminology is non-standard [1–3]. Recent evaluations of OTC medication inserts in China reach similar conclusions on readability and information quality [4], and investigations built on national drug databases show that the problem extends across drug categories, including paediatric products [5].

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A large body of work has documented what is missing from these labels, and a smaller body has examined how patients understand the missing information. Far less attention has been paid to the clinicians who prescribe CPM products and who must translate ambiguous wording into concrete decisions about prescribing, risk assessment, and patient communication. Physicians are the core decision-makers for CPM use; when a label states that adverse reactions are "unclear", the burden of interpretation falls on them. How they carry that burden in practice has remained largely undescribed.

We approach this gap by combining evidence at two levels. A structured content analysis of 30 OTC CPM package inserts establishes where ambiguous safety wording appears and what forms it takes; semi-structured interviews with six licensed physicians then show how that wording is read, and what clinicians do when a label withholds the information they need. Read together, the corpus supplies the textual context and the interviews supply the clinical response. The paper next places the study in the literature on labelling quality and risk interpretation, then describes the methods, reports findings at both the label and the interview level, and closes with implications for label regulation and risk communication.

2. Related Work

2.1 Quality of Safety Information on CPM Package Inserts

That safety information on these inserts is thin, vague, or non-standard is among the best replicated findings in the Chinese pharmacy literature, and the evidence takes several forms. Surveys of hospital and retail inserts — 580 from Jiaxing hospitals, 318 internal-medicine products from Xi'an pharmacies — repeatedly found safety items reduced to the single phrase "unclear" or left incomplete [1, 2]. A review of contraindication sections documented frequent divergence from the pharmacopoeia and pervasive non-specific wording [3], while readability testing of OTC inserts showed that even where the text exists, lay users may struggle with it [4]. Category-specific work points the same way: internal-medicine and non-injectable products display the same deficiencies [2, 5], and national drug-coding data reveal paediatric CPM inserts that often lack age-specific dosing, treatment duration, and adverse-reaction information altogether [5]. What this work has not yet done is follow the label into the clinic. Most of it stops at the text itself, leaving open how the public, or clinicians, actually make sense of such labels in real-world use.

2.2 Public Understanding of Risk Information on Drug Labels

Research on Western drug labels has shown that non-healthcare professionals frequently misunderstand the risk information presented to them. In a Thai outpatient survey, one quarter of patients reported a suspected adverse drug reaction, yet information leaflets were among the least used sources for confirming one [6]. In China, patients expect more information about adverse reactions than labels currently provide, and most want physicians to explain serious and common reactions directly [7]. Surveys of public perceptions of adverse drug reaction reporting in eastern and western China likewise reveal limited awareness of the reporting system and low confidence in recognising reactions [8]. For CPM labels specifically, patients struggle with traditional Chinese medicine terminology and tend to read the phrase "unclear" in the adverse-reaction section as an indication of safety [7]. Because patients are the direct users of these medicines, the extent of their understanding matters for treatment outcomes. Existing studies, however, have concentrated on non-professionals and have seldom involved clinicians, even though clinicians serve as the intermediate interpreters of label content in prescribing and consultation.

2.3 Professional Interpretation of Ambiguous Risk Information

Studies of healthcare professionals show that they, too, face systematic difficulties in interpreting risk information on drug labels. An exploratory survey among health care professionals found that package-leaflet statements about adverse drug reactions were often misread, with frequency statements confused with causal claims [9]. In Germany, although the federal institute standardised the wording of side-effect probabilities, doctors, pharmacists, and lawyers still interpreted terms such as "common" and "rare" in ways that deviated from the regulatory definitions [10]. Physician-oriented research adds that responses to risk information depend on how it reaches them: patient reports of adverse effects are often discounted unless they match a recognisable pattern [11], and the quality of information in patient-submitted reports differs from that of

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professional reports in ways that affect follow-up [12]. Pharmacists in Central China report positive attitudes toward adverse drug reaction monitoring combined with limited practice [13].

The nature of ambiguity in CPM labels differs from this Western literature. In Western labels, ambiguity lies in the gap between probability wording and its interpretation, whereas in CPM labels it consists of a substantial absence of safety information — adverse reactions, contraindications, or interactions marked simply as "unclear" [1, 3]. The analytical frameworks developed for probability wording presuppose that data exist to be interpreted, so they transfer poorly to a setting of missing information. Studies on CPM safety have so far addressed the awareness of physicians that information is missing [14] without examining how they interpret and act on the ambiguous wording in routine practice. The present study addresses this gap by pairing a descriptive analysis of CPM labels with semi-structured interviews on how clinicians read, and respond to, ambiguous risk information.

3. Methodology

3.1 Study Design

The study combines textual analysis with clinical interviews in a qualitative-led mixed-methods design. At the textual level we coded the safety sections of 30 unique OTC CPM package inserts; at the clinical level we interviewed six licensed physicians about how such labels are read and acted on. Each strand feeds the other. The coded corpus documents the forms, distribution, and specificity of ambiguous safety information, and the interviews examine what that ambiguity means for prescribing, risk assessment, and patient communication. Figure 1 summarises the two strands and where they are brought together.

3.2 Label Corpus and Sampling

Inserts entered the corpus if they were OTC products, carried sufficiently complete labelling information, and bore on the study's focus in safety communication; 30 unique Chinese patent medicines met these criteria. The resulting sample size of 30 matches what a single coder could extract, code, and cross-check in depth within the study period, and it sits within the range of comparable insert surveys, from several dozen to several hundred inserts [1, 2], while still spanning a variety of dosage forms and therapeutic categories typical of OTC CPM use. For every included medicine, the safety-related sections of the label — adverse reactions, contraindications, drug interactions, special populations, and precautions — were extracted verbatim for structured analysis. No personally identifiable or patient-level data were involved at any stage.

3.3 Label Coding and Analysis

Coding used a predefined framework applied to the safety-information sections of each insert. The core variables were factual. They recorded whether adverse reactions or contraindications were explicitly described as "unclear" (尚不明确); whether the interaction section named a drug or drug class together with a concrete consequence, rather than offering a generic warning; whether users were referred to a physician or pharmacist; whether special-population information sat in a separate section; and whether the label gave actionable advice, such as seeking medical care or stopping the medicine. Stop-medication advice counted only when discontinuation was stated as a directive action, not merely mentioned in passing.

Analysis was descriptive throughout and carried out in Microsoft Excel: frequencies and percentages for the coded variables, plus selected cross-tabulations — for instance, ambiguity across label sections and the link between information architecture and special-population coverage. No inferential tests were run; the aim is to characterise the sampled corpus rather than to test hypotheses. Every count was then checked back against the original label text in a second, contextual pass. That pass examined how ambiguous wording, professional referral, and actionable advice were combined within individual labels, and contrasting cases were compared to separate the specificity of risk information from the specificity of recommended actions.

3.4 Participants and Semi-Structured Interviews

Six licensed physicians made up the interview panel. Five practised otolaryngology and one breast surgery; their clinical experience spanned roughly one to fifteen years. Recruitment proceeded through convenience

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and snowball sampling, with eligibility limited to physicians currently in practice who read, or make clinical decisions involving, Chinese patent medicines.

A semi-structured interview guide explored physicians' engagement with CPM labelling. The guide covered participants' clinical backgrounds and use of CPM products, their interpretation of the phrase "unclear" in the adverse-reaction and contraindication sections, the influence of clear versus ambiguous safety information on prescribing decisions, responses to non-specific interaction statements, and the accessibility of special-population information. Concrete examples of wording taken from the sampled labels were incorporated into the guide to anchor the discussion in realistic labelling scenarios.

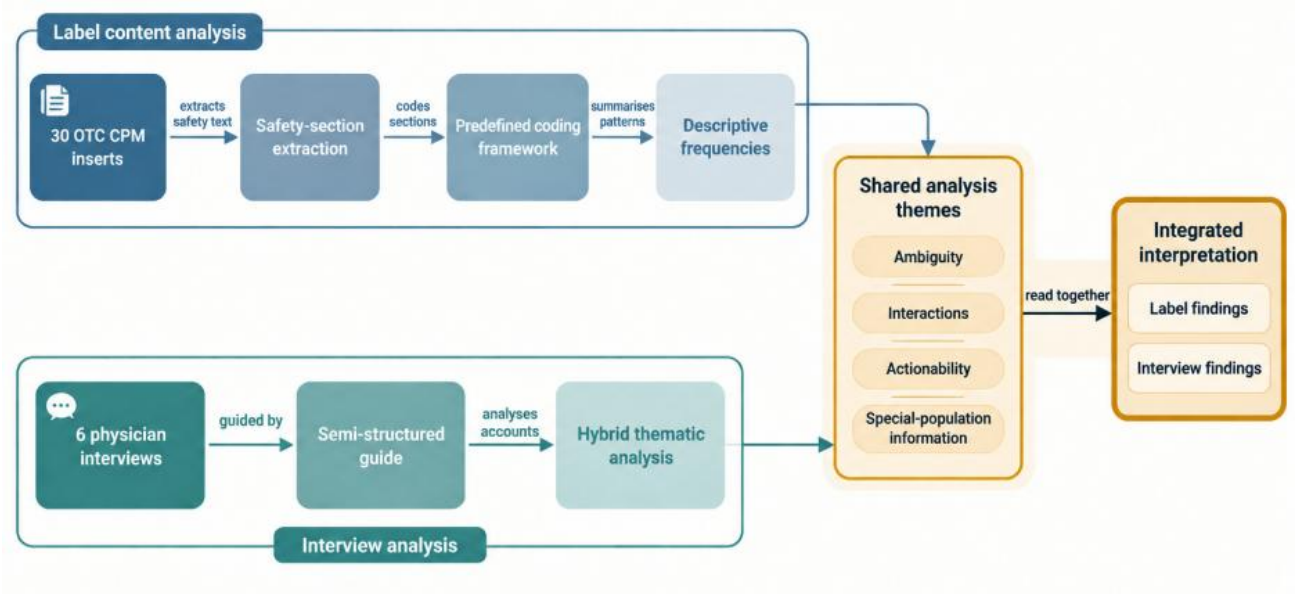
3.5 Interview Data Analysis

Interview transcripts were coded thematically, moving between deduction and induction. Broad domains came first, taken from the research questions and the interview guide: how ambiguous safety wording is interpreted, how it shapes prescribing, uncertainty about interactions, special-population information, patient communication, and where physicians turn for supplementary information. Codes within each domain emerged from what participants actually said. Cross-interview comparison then grouped these codes into patterns — recurring similarities, differences, and decision strategies — and the coded material was checked repeatedly against the transcripts so that themes stayed anchored in participants' own accounts.

3.6 Ethics

Participation was voluntary and based on informed consent. Interviews were anonymised at the point of transcription, and no identifiable patient information was collected or used. The label corpus consisted of publicly available package inserts of marketed products. Participants are reported with anonymised identifiers (P1–P6) throughout.

Figure 1: Overview of the mixed-methods design. The label strand (left) codes the safety sections of 30 OTC Chinese patent medicine inserts into descriptive frequencies; the interview strand (right) analyses semi-structured interviews with six physicians thematically. The strands are integrated at the interpretation stage, where label-level ambiguity patterns are read against clinicians' accounts



4. Research Findings

The findings draw on the two data sources described above: the structural analysis of the 30 OTC CPM package inserts and the interviews with six practising clinicians. Results are presented thematically, integrating patterns observed at the label level with how clinicians interpret and manage ambiguous safety information in practice. Table 1 consolidates the descriptive counts across the four themes.

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4.1 Ambiguity

Ambiguity was not spread evenly across safety sections; it gathered in the adverse-reaction section. Of the 30 inserts, 20 (66.7%) described adverse reactions as "unclear", against 9 (30.0%) for contraindications. The nesting is instructive: all 9 inserts with an unclear contraindication section also carried unclear adverse reactions, yet only 9 of the 20 adverse-reaction-ambiguous inserts went that far on contraindications. Clinicians, for their part, did not read "unclear" as reassurance. Five of the six participants tied the phrase to inadequate research or unreliable clinical data, and P5 put it plainly: unclear labelling does not make a drug look safer, it makes prescribing more uncertain, and therefore more cautious. How much this mattered differed from physician to physician. Four said they prefer drugs whose adverse reactions are spelled out, mainly because explicit text lets them anticipate risks and explain them to patients. One less experienced physician took a different view: provided the indication is appropriate and the patient falls outside contraindicated groups, whether adverse reactions are listed makes little difference to drug selection (P2). The senior participant leant more on accumulated clinical experience and trusted colleagues' insight than on label completeness (P1). Caution, in short, was the common response — but no common decision rule emerged.

4.2 Interactions

Specific interaction information was the exception rather than the rule: only 2 of 30 inserts named a particular interaction risk. Referral advice, by contrast, was nearly universal — 29 inserts told users to consult a doctor or pharmacist, and 28 of these did so while giving no specific interaction detail at all, in the manner of "may cause drug interactions" followed by an instruction to seek further advice. The two exceptions show that specificity and the referral recommendation are analytically independent. The insert for Fufang Ganmaoling Granules both identifies specific interaction risks and recommends consulting medical professionals, whereas the insert for Huoxiang Zhengqi Water warns specifically about alcohol-related interactions, including disulfiram-like reactions when combined with cephalosporin antibiotics, without generic referral language.

What clinicians did when interaction information was unclear fell into two broad responses: top up their knowledge from elsewhere, or steer around the uncertainty altogether. Sources mentioned included past prescription experience, senior colleagues, hospital information systems, pharmacists, online searches, and artificial intelligence tools. P1 said that for unfamiliar drugs they would consult colleagues, supervisors, or the pharmacy; P6 described consulting pharmacy staff and using AI-based search tools for additional reference information. Others simplified the regimen instead — P2 would discontinue one medication when lacking experience with a combination, while P3, P4, and P5 would avoid traditional Chinese medicines or switch to Western alternatives rather than prescribe with undetermined interaction risks.

4.3 Actionability

Every one of the 30 inserts told patients to seek professional consultation or guidance, and clear advice to seek medical care was also common. Stronger directives — stopping the medicine — appeared much less often. We graded action recommendations by intensity: consultation or guidance only; a clear recommendation to seek medical care; and, at the top, discontinuation plus medical care. Only four products sat at the bottom of this gradient — Zhibai Dihuang Pills, Xiongdan Powder, Pudilan Anti-inflammatory Oral Liquid, and Tianwang Buxin Pills — while six carried the highest level, advising both discontinuation and medical care: Niuhuang Jiedu Tablets, Huoxiang Zhengqi Water, Yin Qiao Heji, Sanjiu Weitai Granules, Yangwei Shu Granules, and Siji Cold Tablets. Discontinuation advice typically appeared alongside, or ahead of, the instruction to seek medical care. The interviews matched this pattern: P1, P2, and P5 each said that when a drug's adverse reactions are not yet defined, they tell patients to stop the medicine at once and return for a follow-up visit if side effects occur.

4.4 Special-Population Information

Fewer than half of the inserts (12/30) included a dedicated section for special populations; in most, information on these groups was scattered across sections. Information on pregnant women and children was commonly present — only two inserts lacked pregnancy information and one omitted children — but information on breastfeeding and elderly patients was less common, appearing in 19 and 20 inserts respectively.

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Fifteen inserts covered all four special-population groups, exactly half of the corpus. Coverage was associated with information architecture: among the 12 inserts with a dedicated section, 8 (66.7%) covered all four groups, compared with 7 of 18 (38.9%) among inserts without one. Four physicians stated that CPM labels should carry a separate special-population section; two of them linked its absence to concrete reading problems, with P5 noting the risk of omissions and P6 describing reading difficulty. Both P1 and P2 said that in practice they rely on empirical medication habits, using drugs generally recognised as safe on the basis of experience; P2 also highlighted the lack of clinical data on use in pregnant women.

Table 1: Descriptive frequencies across the 30 OTC CPM package inserts, by theme.

Coded feature	n	%
Ambiguity		
Adverse reactions described as "unclear"	20	66.7
Contraindications described as "unclear"	9	30.0
Contraindication-ambiguous inserts that are also adverse-reaction-ambiguous	9/9	100.0
Adverse-reaction-ambiguous inserts that are also contraindication-ambiguous	9/20	45.0
Interactions		
Specific drug-interaction information	2	6.7
Advice to consult a physician or pharmacist	29	96.7
Consultation advice without specific interaction detail	28/29	96.6
Actionability		
Consultation or guidance only (lowest tier)	4	13.3
Clear advice to seek medical care (middle tier)	20	66.7
Discontinuation plus medical care (highest tier)	6	20.0
Special populations		
Dedicated special-population section	12	40.0
All four special-population groups covered	15	50.0
Four-group coverage, inserts with dedicated section	8/12	66.7
Four-group coverage, inserts without dedicated section	7/18	38.9

5. Discussion

5.1 Principal Observations

Three observations stand out from the paired analysis of labels and interviews. Ambiguity on OTC CPM inserts is not evenly distributed: it clusters in the adverse-reaction section, and an unclear contraindication section almost always coincides with an unclear adverse-reaction section, while the reverse does not hold. The near-universal referral advice, moreover, stands in for rather than complements substantive content: 28 of 29 inserts that advise consultation provide no specific interaction information. Information architecture is also associated with completeness — inserts with a dedicated special-population section covered all four groups at nearly twice the rate of those without one — and clinicians themselves report that the absence of such a section impedes their reading.

5.2 Comparison with Previous Studies

These label-level patterns are consistent with earlier Chinese insert surveys, in which "unclear" entries concentrate in safety sections and interaction information is scarce [1–3]. The interview findings extend that literature in a specific direction. Western studies of professional interpretation examine the gap between probability wording and its reading, in which doctors and pharmacists misjudge standardised frequency terms [9, 10]; the physicians here confronted an absence of information rather than ambiguous probabilities. Their dominant reading, that "unclear" signals insufficient evidence rather than safety, echoes the position of pharmacovigilance research on CPM, which treats missing safety data as the core obstacle to rational use [5, 14]. Their coping strategies — consulting colleagues, pharmacists, and increasingly AI-assisted search tools, or simplifying regimens — parallel the multi-source information behaviour observed among health professionals in other drug-safety contexts [11–13].

5.3 Implications

Two regulatory priorities follow from the label findings, at least as candidates worth regulators' attention: interaction sections that exist should say something specific, and special populations deserve a section of their

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own, since in this corpus architecture and coverage travelled together. The actionability gradient points to a third, subtler target — the strength of recommended actions, not just their presence. For prescribers, the practical lesson is quieter. When a label withholds interaction detail, the interpretive work shifts to supplementary channels, and the physicians here leaned on pharmacy colleagues, hospital information systems, and curated digital references to fill the gap.

5.4 Limitations

Several limitations qualify these observations without, we believe, undoing them. The corpus holds 30 inserts and the interview panel six physicians from two specialties, assembled by convenience and snowball sampling; the percentages characterise this sample, but the agreement between the textual patterns and the independent clinicians' accounts gives the themes some footing beyond any single source. Nothing here is inferential, so the link between a dedicated special-population section and fuller coverage is a pattern awaiting confirmation, not a causal claim. Self-reported practice is the norm in prescribing research, and here it matched the textual evidence closely enough to encourage confidence. One market context and OTC products define the scope; widening both is the natural next step, and the present results tell that next step where to look.

6. Conclusion

Pairing a structured content analysis of 30 OTC Chinese patent medicine package inserts with interviews of six licensed physicians, this study examined how ambiguous safety information is presented on labels and handled in clinics. The textual record shows ambiguity pooling in the adverse-reaction section, interaction information almost always missing in substance, referral advice almost universally present, and special-population coverage tracking the presence of a dedicated section. The interviews show physicians reading "unclear" as missing evidence rather than implied safety — and responding in different ways: more cautious prescribing, extra information seeking, or simpler regimens, not one uniform rule. Richer interaction statements, dedicated special-population sections, and better-calibrated action recommendations therefore stand out as directions for improving CPM risk communication, and the present results give future work with larger corpora and wider specialty coverage a concrete place to start.

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Conflicts of Interest

The authors declare no conflict of interest.

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