

図1 非処方箋薬の非従来型供給方法

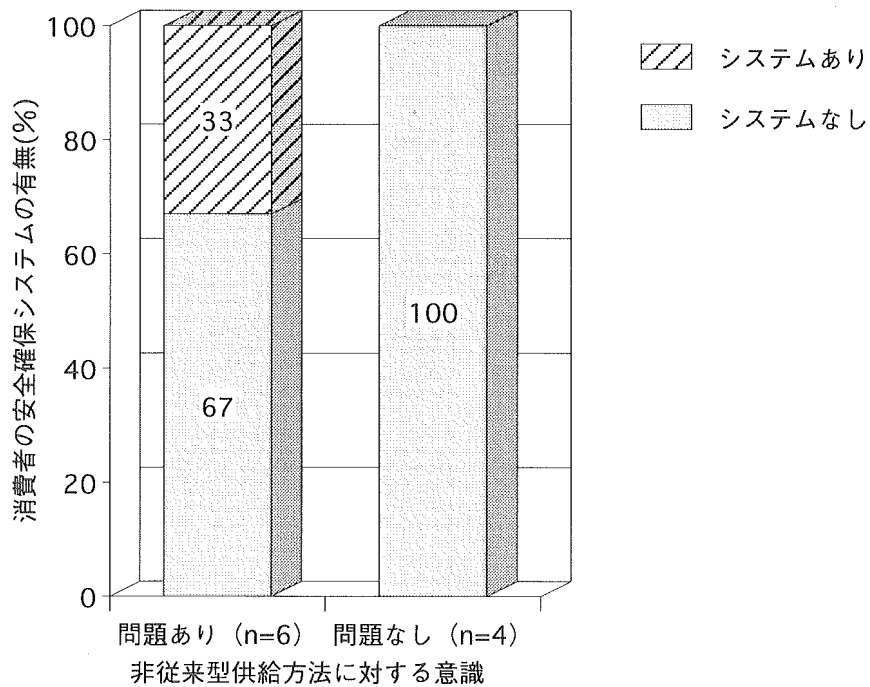


図2 非従来型供給方法に対する問題意識と消費者の安全確保システムの有無

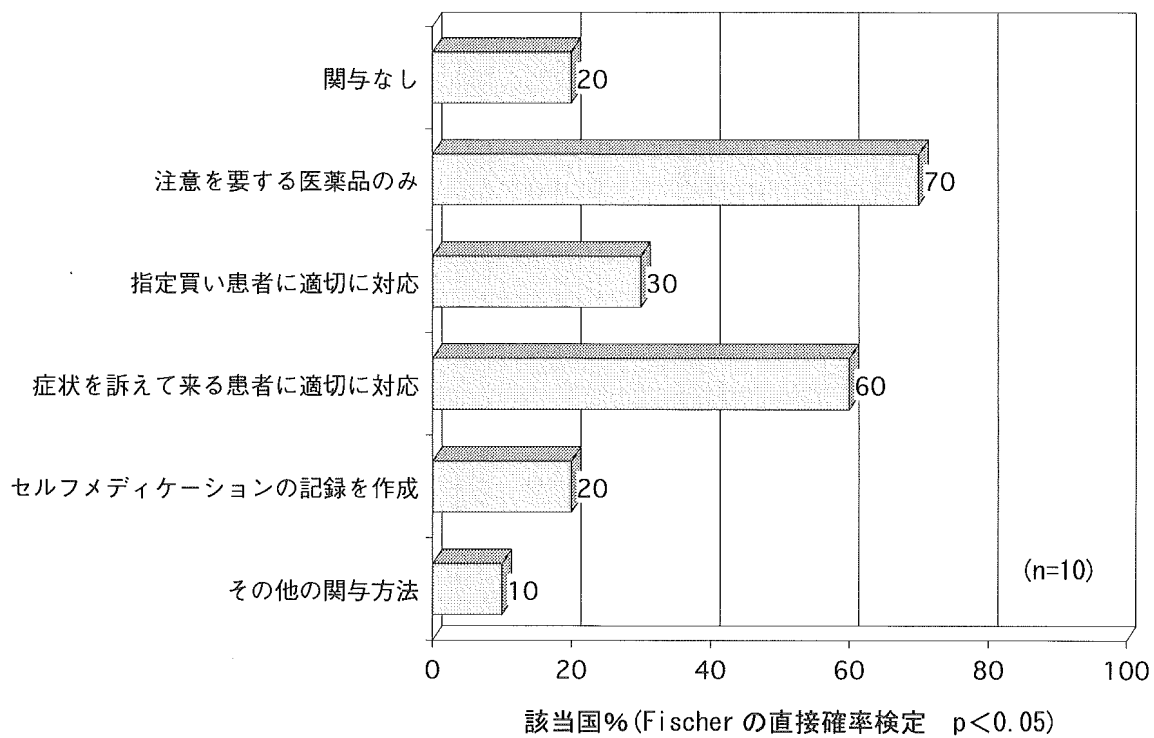


図3 非処方箋薬供給時の薬剤師の関与

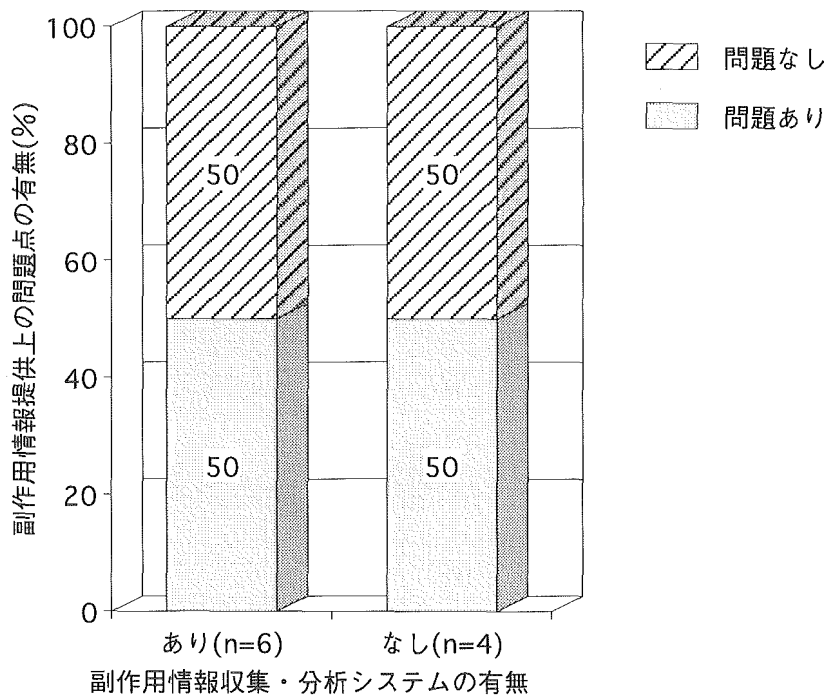


図4 非処方箋薬の副作用情報収集・分析システムと副作用情報提供に対する問題意識の有無

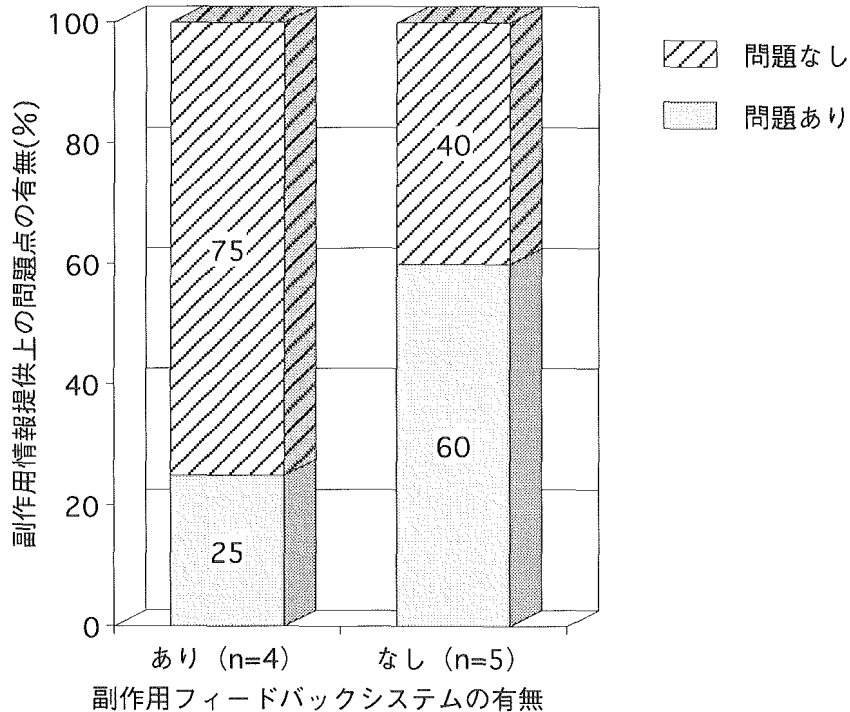


図5 非処方箋薬の副作用情報フィードバックシステムと副作用情報提供に対する問題意識の有無

薬剤師のプロトコール

顧客が薬剤師義務薬の特定の製品を求めて来た場合

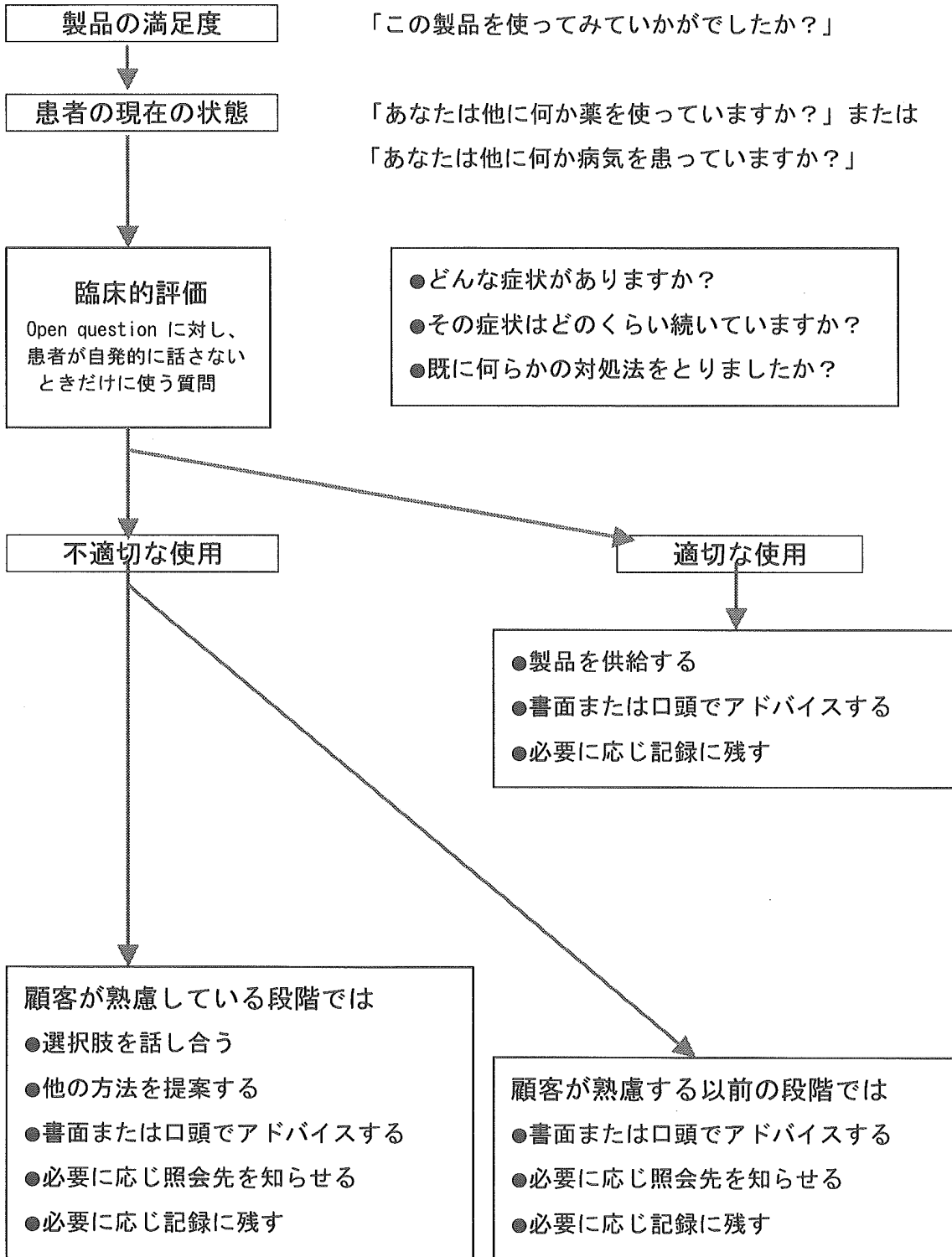


図6 薬剤師義務薬供給時の薬剤師のプロトコール その1⁵⁾ [オーストラリア]

薬剤師のプロトコール 顧客が症状を訴えて来た場合

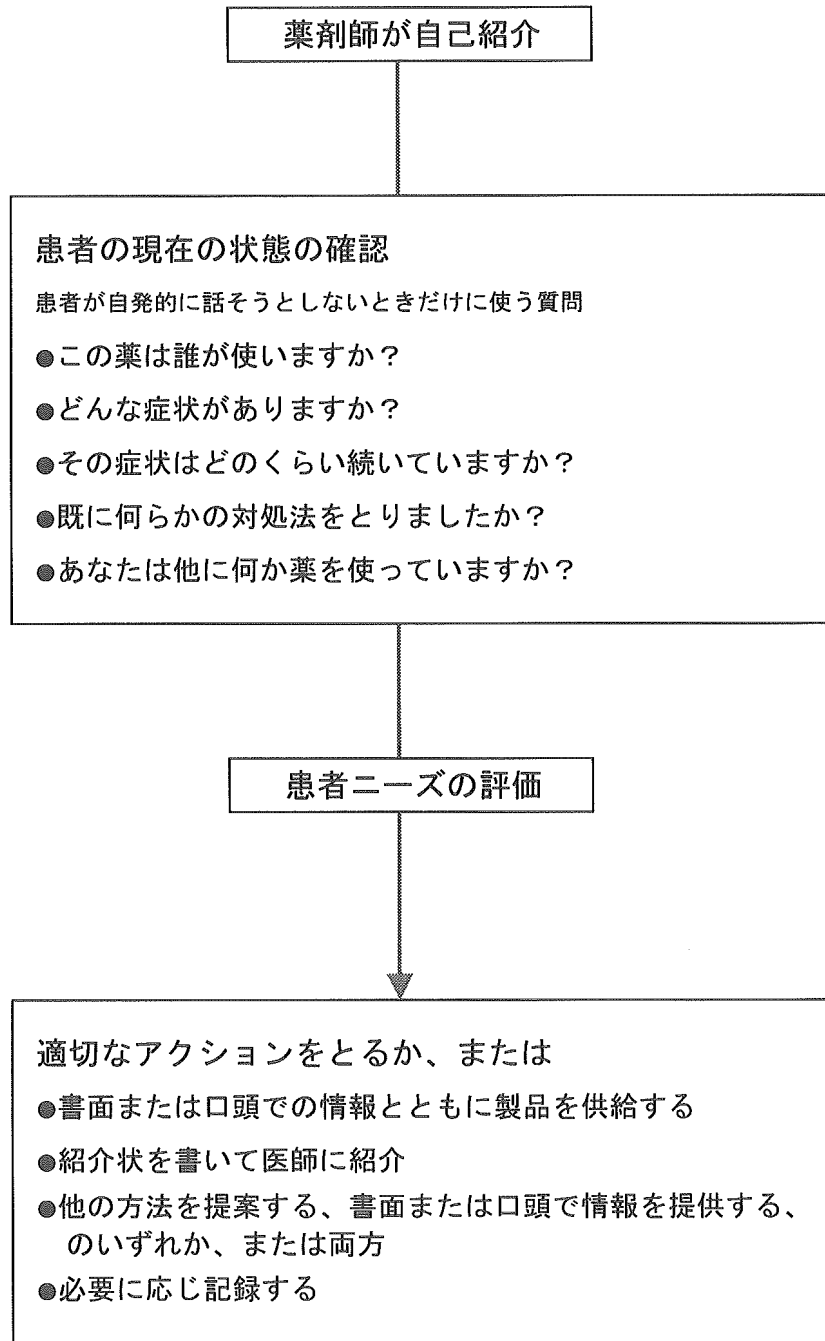


図7 薬剤師義務薬供給時の薬剤師のプロトコール その2⁵⁾ [オーストラリア]

薬剤師以外のスタッフのプロトコール

顧客が薬局義務薬の
特定の製品を求めて来た場合

この製品を使ってみて
いかがでしたか？

薬剤師に報告

What (以下の項目を確認)

使用者は？
使用期間は？
実際の症状は？
治療は

Stop (以下の項目を考慮)

症状は？
総合的に見て大丈夫か？
過量使用や乱用はないか？
薬剤師義務薬の方が
好ましいということはないか？

- W** Who is the patient ?
- H** How long
have they had symptoms ?
- A** Actual symptoms
- what are they ?
- T** Treatment for this or
any other conditions ?
- S** Symptoms ?
- T** Are you totally sure ?
- O** Overuse or abuse ?
- P** Pharmacist only ?

情報提供

薬剤師に必ず言ってください
製造者の指示に従ってください
書面で情報を提供する

GO

図 8 薬局義務薬供給時の薬剤師以外のスタッフのプロトコール その1⁵⁾

[オーストラリア]

薬剤師以外のスタッフのプロトコール

顧客が
症状を訴えて来た場合

(直ちに)薬剤師に報告

What (以下の項目を確認)

使用者は？
使用期間は？
実際の症状は？
治療は

Stop (以下の項目を考慮)

症状は？
総合的に見て大丈夫か？
過量使用や乱用はないか？
薬剤師義務薬の方が
好ましいということはないか？

情報提供

薬剤師に必ず言ってください
製造者の指示に従ってください
書面で情報を提供する

- W** Who is the patient ?
- H** How long
have they had symptoms ?
- A** Actual symptoms
- what are they ?
- T** Treatment for this or
any other conditions ?
- S** Symptoms ?
- T** Are you totally sure ?
- O** Overuse or abuse ?
- P** Pharmacist only ?

GO

図9 薬局義務薬供給時の薬剤師以外のスタッフのプロトコール その2⁵⁾

[オーストラリア]

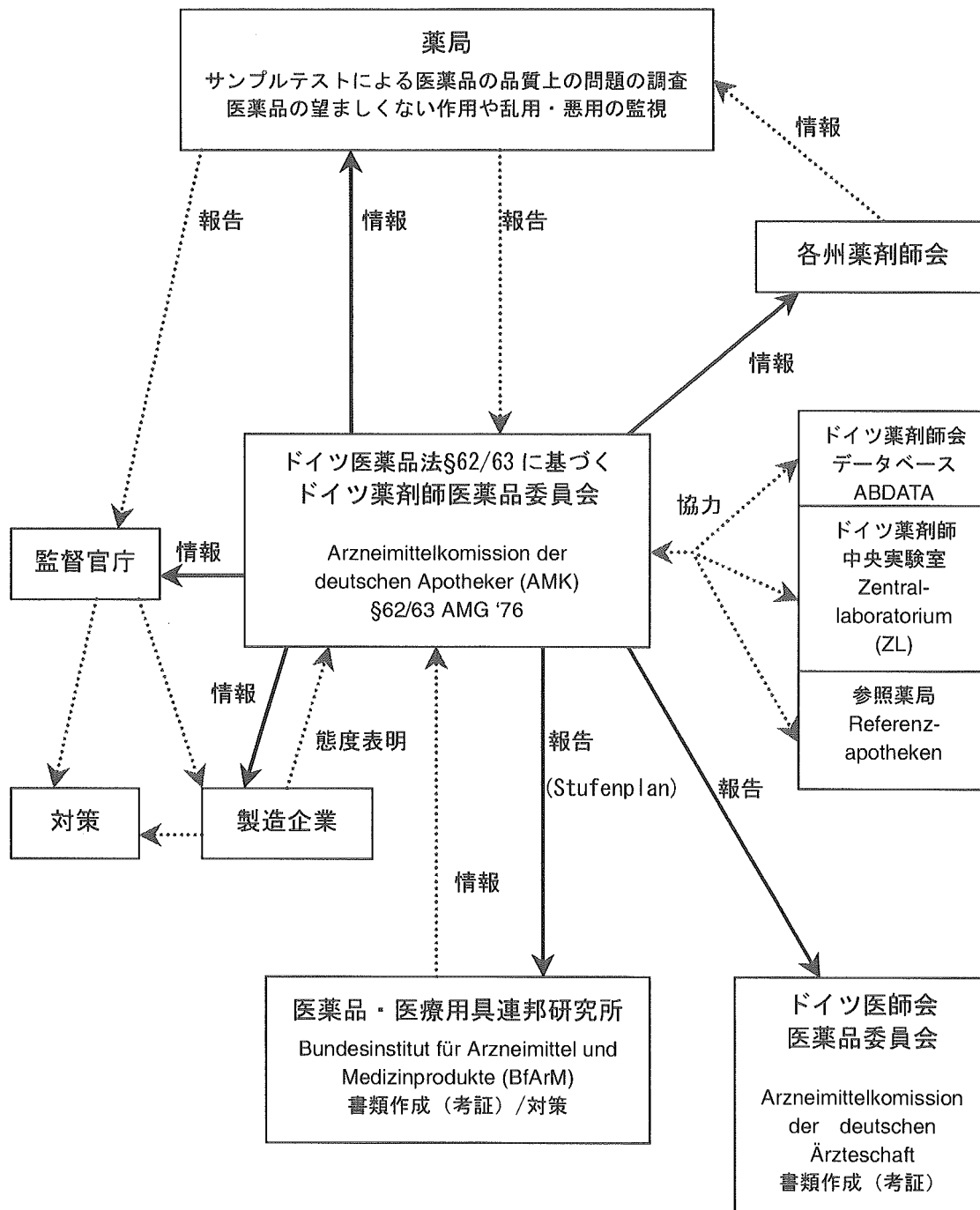


図 10 副作用等の情報の流れ¹⁵⁾ [ドイツ]

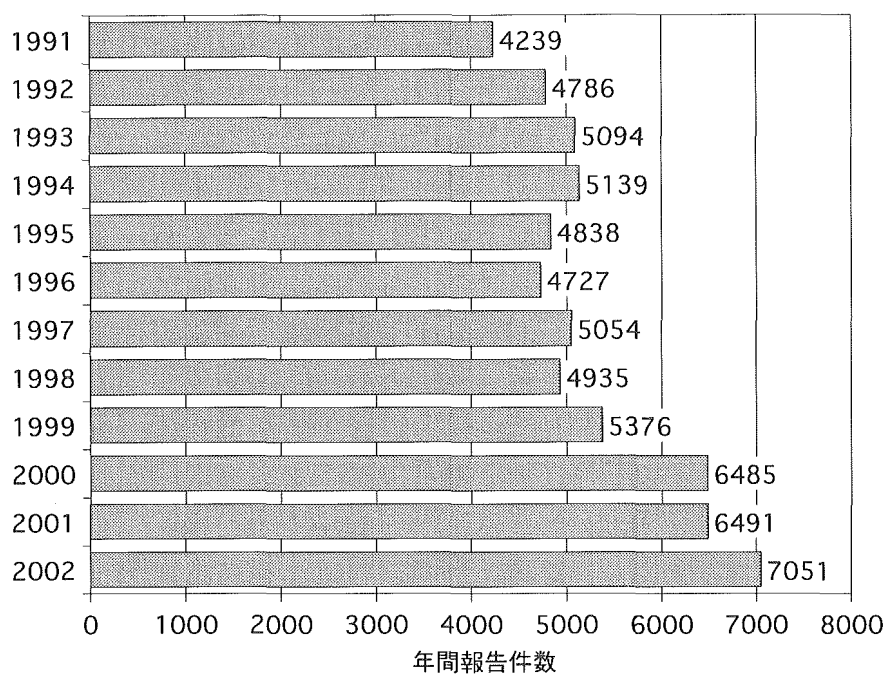


図 11 BfArM に対する副作用報告件数の推移¹⁵⁾ [ドイツ]

別紙 1
使用した調査票

Request for Cooperation with an Investigation Related to Non-prescription Medicines

August 31, 2003

Dear colleagues,

This cordially requests your cooperation with our investigation on the present situation related to non-prescription (OTC) medicines and/or self-medication practiced in your country including, especially, classification, distribution, professional involvement, and information management of Adverse Drug Reactions (ADRs).

BACKGROUND

In Japan, medicines are classified into two categories; namely prescription medicines (ethical drugs) and non-prescription medicines (OTC drugs). The former is subject to reimbursement under the national health insurance system, the latter is not at all. There is no category such as pharmacy medicines or pharmacist-only medicines.

There is another category next to OTC drugs, which is unique to Japan. That is “quasi-drugs” which include medicated cosmetics, pesticides, sanitary items and the like. Manufacturing process of quasi-drugs is under control as rigid as that for OTC drugs. However, they are exempted rigid selling regulations and allowed to be sold by any person in the general retail stores because of their mild action. On the other hand, under the Pharmaceutical Affairs Law, all OTC drugs must be sold at pharmacies and so called druggists (four designated retail outlets).

RECENT CHANGES

Reflecting the social environment for relaxing regulations, a total of 15 groups of OTC drugs with relatively mild effects were shifted into the quasi-drug status in early 1999, being termed “newly designated quasi-drugs”, adding to the conventionally marketed quasi-drugs.

In addition, on June 27 this year, the Cabinet Meeting adopted “2003 Basic Policy for Economical/Financial Operations and Comprehensive Reform of Regulations” and decided all non-prescription medicines “with almost no safety problems” would be sold in general retail stores where there is no

pharmacist, after thorough examination during FY2003 (till the end of March, 2004) from the viewpoints of consumers' convenience and safety.

Japan Pharmaceutical Association (JPA) and other medical professional organizations are strongly opposed to the pharmaceutical retailing deregulation from the standpoint that professional involvement is essential for securing consumers' safety by ensuring proper use of medicines through provision of product information.

Today, it is an urgent task for Japanese pharmacists to grope for establishing ideal systems by which to allow access to non-prescription medicines coupled with their information. Under such circumstances, we have designed this investigation, which is to be favorably supported by the Ministry of Health, Labour and Welfare. We expect we can share the findings of the investigation with you hopefully in the next FIP Congress.

It would be very much appreciated if you could fill in attached questionnaire and send it back to us either by facsimile transmission or e-mail.

Investigators in charge:

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Chairman of International Affairs, JPA

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Please send your reply until the beginning of October

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For more information on Japanese medical care system in general, visit:

<http://www.pharma-outsourcing.com/pharmavision/medical/index.htm>

Your Country Status

* If pharmacies are organized on a state or province level rather than a national or federal level in your country, please indicate in the checkboxes below.

My answers are for the state/province for the whole country

Country: _____

State/Province: _____ (if applicable)

Country Population: _____ (or State/Province population if applicable)

Number of Community Pharmacies: _____

Number of Community Pharmacists: _____

Respondent

Your Name: _____

Organization/ Institution etc. to which you belong:

Contact: E-mail: _____

Tel: (Country Code +) _____

Fax: (Country Code +) _____

* Please be sure to fill e-mail address in case we need to ask you more details on your answer.

* If it is convenient for you, we will send this document (Microsoft Word 2001 file) to your e-mail address.

This questionnaire consists of 5 domains and 15 questions.

1. Classification of Non-prescription Medicines and Conventional Distribution

Q1-1. How many categories do you have into which non-prescription medicines are classified?

A. 2 3 more than 3 (_____ categories)

Q1-2. How many kinds of distributors, which are legally allowed to handle non-prescription medicines (e.g. pharmacy, druggist, retail store)?

A. 2 3 more than 3 (_____ kinds)

Q1-3. Please write down concrete names of the categories of medicines and kinds of distributors and indicate whether each category of medicine are allowed to sell (O) or not (X).

EXAMPLE

Distributors Categories	Pharmacy	Druggist
Unscheduled medicines	O	O
Pharmacy medicines	O	X
Pharmacist-only medicines	O	X

A.

Distributors Categories				

2. Unconventional Distribution of Non-prescription Medicines

Q2-1. Are the distance selling channels of non-prescription medicines mentioned below legally allowed (O) or not (X)?

As for an allowed channel, please indicate the requirements to be met if any.

A.

Channels	O/ X	Requirements
Mail order sales		
Telephone shopping		
Internet sales		
Other (_____)		

Q2-2. If you have channels mentioned Q2-1, is there any systems to secure consumers' safety ?

A. Yes --- Please describe below. No

Q2-3. Do you find any problem related to unconventional distribution channel of non-prescription medicines ?

A. Yes --- Please describe below. No

3. Professional Involvement

Q3-1. Please indicate the extent of pharmacists' involvement in providing non-prescription medicines in a majority of pharmacies.

A. (Almost) No involvement

In case providing non-prescription medicines to be taken care (e.g. switched OTC drugs) pharmacists are actively involved

Pharmacists always provide non-prescription medicines to consumers who designate products they want according to a defined structured process

Pharmacists always respond to consumers who have requests for their minor ailments by counseling and refer to doctors or decide not selling if necessary

Pharmacists keep a record of their involvement in self-medication for each consumer/patient.

We involve in more effective way than ways above-mentioned --- Please describe below.

Q3-2. Is there any CPD program sponsored by professional organizations to improve pharmacists' contribution only on provision of non-prescription medicines and counseling skills for self-care ?

A. Yes --- Please describe below. No

Q3-3. Is there any system or program for pharmacy staffs except pharmacists to enhance their understanding of non-prescription medicines and to make them appropriate referral to pharmacists if necessary.

A. Yes --- Please describe below. No

Q3-4. Do you think consumers well recognize pharmacists' contribution to appropriate provision of non-prescription medicines and their self-care ?

A. Yes --- Please describe simulating factors for your success below.

No --- Please describe obstacles to achievement below.

4. Information Management of ADRs

Q4-1. Is there any system either national or professional organization level to collect and analyze suspect/ probable cases of ADRs related to non-prescription medicines?

A. Yes --- Please describe below with number of reported cases if possible.

No

Q4-2. Is there any system either national or professional organization level to feedback information on ADRs related to non-prescription medicines based on collected suspect/ probable cases, reports in relevant biomedical journals or warnings by authorities of other countries ?

A. Yes --- Please describe below. No

Q4-3. How do pharmacists in majority of pharmacies provide consumers of information on possible ADRs related to the products (non-prescription medicines) they are going to take ?

A.

Q4-4. Do pharmacists in majority of pharmacies have any problems or difficulties in providing information on ADRs related to non-prescription medicines ?

A. Yes --- Please describe below. No

5. Your Opinion on the Pharmaceutical Retailing Deregulation

Q5-1. Do you agree or disagree with the decision of the Japanese Cabinet on the retailing deregulation of OTC drugs we mentioned in the cover page?

A. Agree Disagree --- Please describe your reason/opinion below.

Thank you very much for completing this questionnaire.

別紙 2
調査票に対する 10 か国の回答

注) 別紙2については、他の資料による補足をすることなく回答者の記載のまま和訳した。

1. 非処方箋薬の分類と供給方法（従来型のもの）

■設問

Q1-1. 非処方箋薬はいくつのカテゴリーに分類されていますか？

A. 2 3 3より多い (_____ カテゴリー)

Q1-2. 法的に非処方箋薬の取り扱いが認められている供給者は何種類ですか？
(例：pharmacy, druggist, retail store)

A. 2 3 3より多い (_____ 種類)

Q1-3. 医薬品のカテゴリーと、各々の取り扱いが認められた供給者の名称を具体的に記載してください。

例：

カテゴリー \ 供給者	薬局	薬店
一般販売薬	○	○
薬局義務薬	○	×
薬剤師義務薬	○	×

A.

カテゴリー \ 供給者				

■回答一覧

回答国	Q1-1 非処方箋薬のカテゴリー	Q1-2 医薬品販売業の種類
オーストラリア	3	2
デンマーク	3	2
フランス	2	1
ドイツ	2	2
イギリス	2	3<
アメリカ	1	3<
インドネシア*1	5(1)	5(1)
韓国	1	1
マレーシア	2	2
台湾*2	10(2)	2(1)

*1 Q1-1、Q1-2とQ1-3の回答が一致しない

*2 “カテゴリー”の概念の違いによるもので、Q1-1が2、Q1-2が1と思われる

■具体的な記載内容

Q1-1

非処方箋薬のカテゴリーについて補足があった国の記載（3か国）。

フランス

フランスの非処方箋薬には2つのカテゴリーがある。

- ・社会健康保険制度（social health insurance system）で償還されるもの
- ・社会健康保険制度で償還されないもの

マレーシア

薬剤師義務薬（pharmacist-only: POM）と一般販売薬（General Sales :GSL）

台湾

1. 解熱・鎮痛薬
2. 感冒薬
3. 鎮咳・去痰薬
4. 抗ヒスタミン薬
5. 眼科用薬
6. 消化器官用薬
7. 鎮暈薬
8. 外皮用薬
9. 駆虫薬
10. 浣腸