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10 May 2006

Committee Secretary
Parliamentary Joint Committee on the Australian Crime Commission
Department of the Senate
PO Box 6100
Parliament House
Canberra ACT 2600

Dear Sir/Madam

Inquiry into the Amphetamines and Other Synthetic Drugs (AOSD)

Thank you for the opportunity to provide a submission to the Inquiry by the Parliamentary Joint Committee on the Australian Crime Commission into Amphetamines and Other Synthetic Drugs (AOSD).

Outlined in the attached submission are some of the activities taken and issues faced by community pharmacy in reducing the access to pseudoephedrine products for the illicit diversion to methamphetamine. You will note that we have responded only to those aspects of the terms of reference of the Inquiry where we have a particular interest from community pharmacy's perspective.

I trust that our submission is useful in assisting the Committee with its Inquiry into the Inquiry into Amphetamines and Other Synthetic Drugs (AOSD) and that our proposals will be reflected in your final recommendations. We look forward to hearing from you of the outcome of the Inquiry.

If you require further information or any clarification, please do not hesitate to contact me.

Yours sincerely

Wendy Phillips
Acting Executive Director

The Pharmacy Guild of Australia

**Submission to the Parliamentary Joint
Committee on the Australian Crime
Commission Inquiry into Amphetamines and
Other Synthetic Drugs (AOSD)**

May 2006



**The
PHARMACY
GUILD of
AUSTRALIA**

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Abbreviation Reference

AOSD	Amphetamines and Other Synthetic Drugs
Guild	The Pharmacy Guild of Australia
NDPSC	National Drugs and Poisons Schedule Committee
PSA	Pharmaceutical Society of Australia
PSE	Pseudoephedrine
QUM	Quality Use of Medicines

Introduction

The Pharmacy Guild of Australia is an employers' organisation servicing the needs of independent community pharmacies. It exists for the betterment of its members and to maintain community pharmacies as the most appropriate primary providers of health care to the community through optimum therapeutic use of drugs, drug management and related services.

Community pharmacy offers a highly accessible network of primary health care providers providing quality advice and service. Pharmacies exist in well spread out and accessible locations, are computerised and often operate over extended hours seven days a week in urban, rural and remote areas. On average each man, woman and child visits a community pharmacy 14 times each year, in metropolitan, rural and remote, hospital and indigenous community settings.

Purpose

The purpose of this submission is to inform the Parliamentary Joint Committee on the Australian Crime Commission Inquiry of steps taken and issues faced by community pharmacy in reducing the access to pseudoephedrine products for illicit diversion to methamphetamine.

Background

The production and consumption of Amphetamines and Other Synthetic Drugs (AOSD) in Australia has seen Australian pharmacies being targeted for supply of pseudoephedrine products to be diverted to methamphetamine 'speed' production in clandestine laboratories. This has been a major concern for The Pharmacy Guild of Australia (the Guild) which has been actively involved in the development of strategies to reduce the procurement of such products by so called 'pseudo runners'.

Pseudoephedrine (PSE) is an oral nasal decongestant drug available from Australian pharmacies without a prescription for the symptomatic treatment of the common head cold, influenza or hay fever. Originally, products with PSE as the sole active ingredient were targeted, but as supply of these products became more restricted, the combination products have since been heavily targeted. The most common of these combination products are 'Cold and Flu Tablets', the majority of which contain pseudoephedrine as one of a number of active ingredients.

As the demand for methamphetamine has increased, these medications have been in greater demand for its illicit production. Pharmacies and pharmacy wholesalers have, at times, been the target of ram raids for access to large quantities of pseudoephedrine products. But, a more common method is the use of 'pseudo runners' who target community pharmacies for the 'legitimate purchase' of pseudoephedrine products.

“Pseudo-runners” are individuals or groups who travel from pharmacy to pharmacy sourcing a number of pseudoephedrine-containing products. They are known to operate along pre-planned routes, visiting each pharmacy with different buyers. This practice has become more refined with time and the ‘runners’ have become more astute in obtaining the supplies from the pharmacy without arousing suspicion. It has also been reported that organisers involved in PSE diversion approach people on the street and pay them a fee to purchase PSE products from pharmacies. As a result, the pharmacy customers for PSE for illicit diversion are diverse and not from any particular background, age, race or socio-economic group. As such, it is very difficult for pharmacy staff to distinguish illicit customers from legitimate customers.

Steps taken to reduce supply of and access to Pseudoephedrine products for illicit diversion

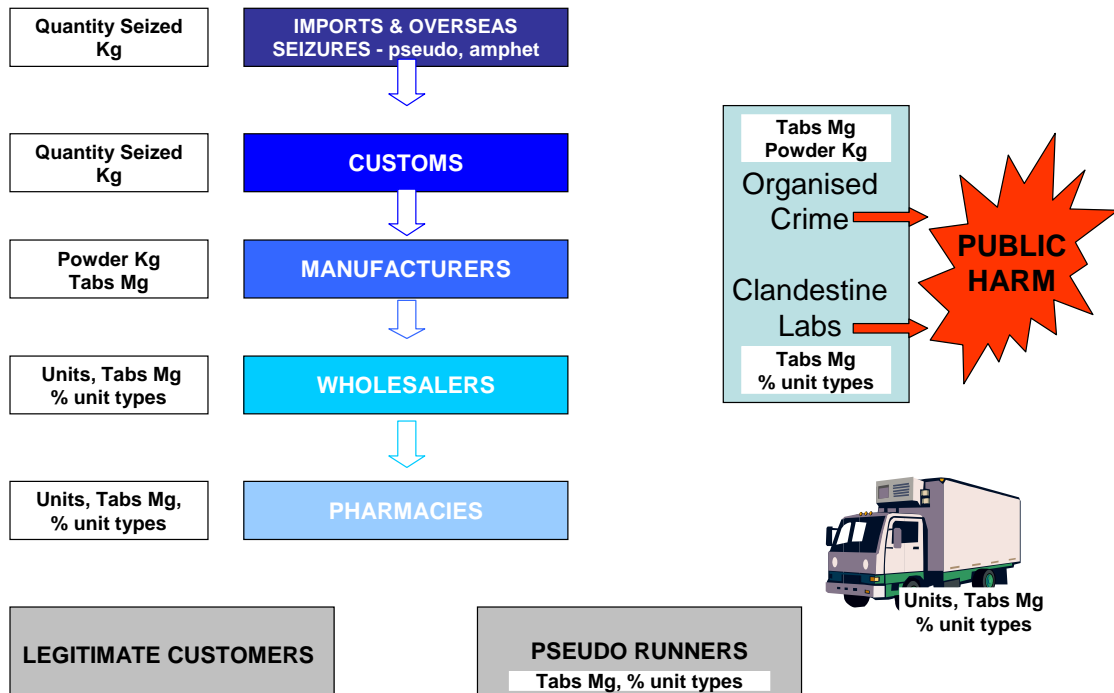
From the late 1990s, in an effort to reduce the diversion of PSE to methamphetamine, a number of strategies were used:

- All State and Territory Pharmacy Boards sent a letter to all registered pharmacists reminding them of their professional responsibilities in selling drugs such as PSE and providing professional advice on storage and supply of PSE products.
- State/Territory Pharmaceutical Services Branches commenced monitoring purchases of PSE tablets and initiated disciplinary action against those pharmacists supplying multiple packs of PSE tablets in quantities in excess of recognised therapeutic standards in line with Quality Use of Medicines (QUM).
- Drug companies reformulated PSE products in an effort to increase the difficulty of the extraction process of PSE, and discontinued production of larger sized packs of tablets with PSE as the sole active ingredient.
- A Pharmaceutical Industry Code of Conduct was developed in an effort to establish a common system of practice for marketing PSE products.

Since then, the Guild has been maintaining an oversight on this issue and the successes and problems of actions taken thus far. The Guild has participated in committees such as the National Working Group on the Prevention of the Diversion of Precursor Chemicals into Illicit Drug Manufacture and collaborated with other relevant parties, such as the Pharmaceutical Society of Australia (PSA) and the law enforcement agencies in developing strategies to increase the awareness of community pharmacy to the diversion of pseudoephedrine products, as well as implementing programs to reduce the illicit access to these precursor medications and to assist in the identification and arrest of the ‘pseudo runners’.

In an effort to develop an integrated approach to the problem, the Guild convened a workshop in 2005 with relevant stakeholders to discuss ways of quantifying and analysing the extent of diversion of precursor chemicals into illicit drug manufacture and measuring the impact of strategies to address this problem. The workshop participants observed that a whole of industry approach is required and that an integrated solution must be evaluated across all impacts. Currently there are lack of data from all levels of the supply chain and therefore it should be collated nationally as depicted below.

Integrated Solution – Data Required



In trying to find a solution to this problem, suggestions have been made to re-schedule pseudoephedrine in order to make it less accessible, and even to remove the product from the market altogether. This approach has been supported by the State and Territory Police Authorities and State and Territory drug regulators. Phenylephrine, a medication from the same class of drugs as pseudoephedrine, has been touted as a suitable alternative to PSE in the treatment of nasal congestion, and therefore used to promote the removal of pseudoephedrine from the market without causing any significant void in medical treatment.

The National Drugs and Poisons Schedule Committee (NDPSC) discussed at its meetings between June and October 2005 the re-scheduling of pseudoephedrine products in an effort to further reduce access of the criminal element to this class of drugs. As a result, all pseudoephedrine products were rescheduled from 1 January 2006 to the Schedule 3 (Pharmacist Only) category and as of 1 April 2006, pharmacists can only issue limited quantities of pseudoephedrine products without a prescription. Such rescheduling ensures that every sale of a pseudoephedrine product is monitored by a pharmacist. In addition to this, some State regulations require every sale of pseudoephedrine to be recorded, along with details of the customer purchasing it.

While final judgement on the matter of rescheduling is made by the NDPSC, the Guild has acknowledged the seriousness of the issue and has supported the NDPSC's recommendation which would assist in stopping the flow of such products to illegal laboratories.

The Guild has agreed to a number of schedule changes for PSE products, acknowledging that this should reduce the accessibility to the products by illicit customers. However, it has strongly opposed the total removal of pseudoephedrine from the market. Although phenylephrine is a medication with similar indications to pseudoephedrine and was previously marketed in Australia until the 1980s, it has low oral bioavailability due to irregular absorption and first-pass metabolism. As such, the effectiveness of oral dose forms varies from patient to patient and some patients find it completely ineffective. In comparison, pseudoephedrine has a much higher oral bioavailability and has better absorption as it does not suffer the first-pass metabolism of phenylephrine. As such, it does provide a reliable and highly effective medication for use and recommendation by health professionals and, for this reason, the Guild believes pseudoephedrine should remain available and accessible to consumers.

The Guild also believes that the community pharmacies within Australia have the professional capabilities to ensure that pseudoephedrine is predominantly used for its proper indications in line with QUM protocols. Community pharmacy has adopted and worked effectively with the professional programs developed by the Guild to curb access to PSE for illicit diversion. Such programs have included:

Project Pseudo

In March 2005, responding to these concerns and to ensure the responsible retailing of pseudoephedrine products in pharmacy, the Guild launched 'Project Pseudo', which aimed to maintain access to these medications by legitimate customers in line with Quality Use of Medicines principles whilst restricting access by criminals and illicit runners. Project Pseudo included a set of guidelines on the wholesale purchasing, storage and sale of pseudoephedrine products by community pharmacies. This has since developed into the 'Pseudo watch' campaign.

Pseudo Watch

Pseudo Watch is an awareness strategy to educate pharmacy staff and consumers about the extent and possible dangers of drug runners, posing as genuine customers, purchasing and diverting pseudoephedrine into methamphetamine.

In December 2005, as part of the Pseudo Watch campaign, the Guild sent out a Pseudoephedrine Awareness Kit to all community pharmacies. This kit contained information, such as posters, brochures, stickers and feedback forms for consumers and pharmacy staff, in order to make the new regulations and increased security surrounding pseudoephedrine sales easier. In collaboration with the Australian Law enforcement agencies, this kit included a 'Suspicious Pseudoephedrine Request Pad' to allow pharmacies to expediently fax details of suspicious customers to State/Territory Police.

Along with the distribution of the Awareness Kit, the Guild collaborated with the PSA for the presentation of Information Workshops to take place in all States and Territories. These workshops were designed to supply information to pharmacists and pharmacy staff regarding the Pseudo Watch campaign and what procedures staff should follow to comply with the principles and guidelines of the campaign.

The majority of feedback received by the Guild from pharmacies regarding this campaign has been positive. This is reinforced by comments from Crimestoppers who feel the response has been excellent and the reporting system very effective as it provides substantial detail for report.

As part of the Pseudo Watch campaign, funding was provided to Crimestoppers and the Victorian Police Drug Investigation team to implement the pseudoephedrine awareness strategy through television commercials. The Victorian Branch of the Pharmacy Guild is currently liaising with the police to develop several materials including a TV commercial and some print collateral. All these materials will be developed so as to be non state specific. They will become available for police and Crimestoppers in each state to distribute as they see fit, probably as community service announcements in the main stream media.

Project STOP

In November 2005, the Queensland Branch of The Pharmacy Guild of Australia initiated 'Project STOP'. This is a project developed by the Queensland Branch of the Guild in collaboration with the Queensland Police and the Queensland Department of Health to use the Epothecary database to track pseudoephedrine sales. It enables the movements of potential pseudoephedrine runners to be tracked and provides an online recording and reporting system giving pharmacists, police, and health authorities real-time access to suspicious pseudoephedrine reports.

Project STOP commenced in November 2005 and was implemented in a State-wide pilot of Queensland pharmacies and offered to every pharmacy in the State. There was a 70% uptake of the offer. The pilot involved the development and delivery of an eight-page welcome kit. The kit contained a plastic 'credit card' which carried the pharmacy's name and a unique identifying number. Pharmacists visited a website and entered the details from this card to activate their secure account.

A dedicated helpdesk was created and a '1300' number instigated to assist community pharmacists with any teething problems during the take-up phase. Seven road-shows were then held around the State where product demonstrations were provided. These road-shows generally resulted in an immediate increase in registrations. These road-shows, coupled with the '1300' number, ensured community pharmacy staff were well briefed about the project.

All Queensland pharmacies have been provided with broadband dial-up capabilities and on request for a PSE product, photo identification needs to be provided. The pharmacist then enters the network using their personal pharmacy identification code and records details of the customer's photo ID, as well as product details. The network then shows if there have been any sales to a person using this ID within a period of time determined by the Department of Health. The pharmacist records whether the sale is carried through, whether the sale is done under duress, or whether the sale has been refused. For customers of whom the pharmacist is suspicious, the database is set up to allow the pharmacist to enter the customer details from the photo ID as well as record a brief, visual description.

The Queensland Police have dedicated personnel who monitor the information provided to Project STOP from community pharmacies. They have the capability to look at the location of sales to observe trends and patterns and to check on details of suspicious customers provided by the pharmacists.

Since the pilot launch in November 2005, over 40,000 entries have been put through the system. This has included over 2,500 refusals of sale by pharmacists.

Project STOP is a stand-alone software program which allows the pharmacy to be able to report accurately on exactly what medications are being targeted and by using GPS (Global Positioning System) data is able to graphically demonstrate exactly where this activity is taking place.

In addition to ensuring that PSE products are being sold to legitimate customers, Project STOP has also enabled law enforcement agencies to track and identify 'pseudo runners'. Within the months of January to March 2006, Project Stop has resulted in:

- the generation of more than 100 Police investigative files;
- 12 offenders being arrested on 114 drug related charges together with six counts of trafficking;
- three illicit laboratories being detected, and
- a number of suspected 'runners' being summonsed to attend Australian Crime Commission Coercive Hearings.

The Pharmacy Guild of Australia (Queensland Branch) has been successful in securing funding from the Australian Government Attorney General's Department for the national roll out of Project STOP over a two-year period. The aim of this funding is to see the tool being made available to all of Australia's approximately 5,000 pharmacies.

A vital part of this scheme is the requirement of a pharmacist to record and report suspicious sales so police can consequently determine whether someone is purchasing trafficable quantities of pseudoephedrine products, and take appropriate enforcement action.

One issue to the roll out is implications of privacy guidelines on the ability of pharmacists to request identification for the recording of a sale of a non-prescription medication. It is the understanding of the Guild that the Attorney General's Department is approaching the National Privacy Commissioner with a view to being granted a public interest determination to allow pharmacists nationally to request relevant patient identification prior to the sale of pseudoephedrine products.

Current Queensland and NSW legislations require pharmacists to collect personal details prior to the sale of PSE products, however in other jurisdictions, there is uncertainty. The Guild believes that each State or Territory jurisdiction should have nationally consistent provisions in their legislations to enable pharmacists to perform their duties without contravening any privacy guidelines with regard to the supply of pseudoephedrine containing products.

Impact of these Steps

The programs developed and implemented by the Guild and supported by pharmacy training by PSA have made a real impact in curbing sales of PSE products for illicit diversion. Pharmacy staff are acutely aware of these activities and have raised their professional standards to meet the demand for appropriate supply and storage of PSE products to reduce this practice. Pharmacies are reporting suspicious sales and requesting police assistance where appropriate. As mentioned above, Project STOP in particular allows real-time interaction with the police authorities to allow quick and reliable identification of possible ‘pseudo-runners’ and location of operation, and have resulted in a number of successful police interventions.

However, the new pseudoephedrine regulations have presented some problems within the pharmacy. Pharmacies have reported receiving some objections from consumers who have expressed frustration of being asked questions and are reluctant or are refusing to give their details/identification when buying common ‘cold and flu’ products. The Guild has received similar calls from consumers as well as pharmacist members advising of the consumer reaction regarding the new regulations surrounding pseudoephedrine. Reports within the media have also been critical about the red tape and additional personal information required of customers in order to purchase ‘cold and flu’ medication.

Within NSW, pharmacies have been required for several years to record and retain on the pharmacy premises customer details of purchases of PSE products. In October 2005, the NSW Branch of the Guild introduced a PSE-3 PAD¹ which allowed pharmacies to record patient details of PSE supply and retain such records on the pharmacy premises as per a prescription. A casual analysis of this by one of the pharmacy owners on the State Branch Committee showed that about 90% of PSE purchases were by customers from the local area and surrounding suburbs. This would be an indication that genuine customers are accessing the products than ‘pseudo-runners’. Of the remaining 10% of PSE customers, although not local, it cannot be taken as an indication that the customers are not genuine.

Another consequence to these actions taken thus far to curb the sales of PSE products for chemical diversion is that the change of pack size available for supply without prescription has resulted in an increase in cost to the consumer. The new pack size of 12 tablets of pseudoephedrine 60mg tablets has resulted in an increase in cost of daily dosing (i.e. three tablets per day) compared with the previous cost of a pack of 30 tablets. For those legitimate customers that have a need for longer courses of pseudoephedrine, they either need to return repeatedly to their pharmacy to purchase a small pack of tablets, or pay to see a doctor and get a script for a larger quantity. This in turn has the additional ‘dispensing fee’ costs attached to the purchase price.

¹ PSE-3 PAD Attachment 1

What needs to be done?

When examining the issue of PSE diversion for AOSD production, the Guild believes that it is important to focus on the benefits of cooperation and to continue bringing together law enforcement agencies with chemical technicians, manufacturing companies, consumer representatives and health professionals such as pharmacists. A whole of industry approach is needed. Whilst tighter controls of all parts of the supply chain, from manufacturing to distribution and finally pharmacy is needed, it must be recognised that this is a complex problem and needs an integrated solution with time to implement and educate all people involved, including consumers.

Pseudoephedrine products are useful and effective medications which should remain available to the public for legitimate purposes through community pharmacies, without the need of consumers either paying excessive prices for supply, or feeling they are being treated as suspicious because they are requesting such products. The reintroduction of oral Phenylephrine products to the Australian market, whilst offering a possible therapy alternative, does not provide one of equal efficacy for all consumers. Pharmacists are in a strong position to exercise responsible, professional judgment and, if deemed appropriate, supply pseudoephedrine products in accordance with therapeutic standards in line with QUM.

Allowing pseudoephedrine products to remain as non-prescription items for small quantities permits legitimate patients access to an effective medication without unduly increasing the cost burden for the consumer or for the Medicare Benefit Schedule (MBS), which would be the result if these products had been restricted to prescription only and required patients to consult a doctor in order to obtain the medication.

Community pharmacies have shown themselves interested in participating in programs developed to reduce access to PSE products for illicit diversion and have raised their professional standards accordingly for the storage and supply of PSE products, in line with the QUM guidelines. The Guild intends to continue collaborating with professional organisations such as the PSA, as well as law enforcement authorities and other relevant agencies, to continue to develop and implement such programs within community pharmacies with appropriate training to allow pharmacy staff to fulfil their professional and legal obligations without offending or alienating their clientele.

Community pharmacies need the continued support of the relevant government agencies and consumer organisations to assist them, by developing and implementing campaigns for dealing with this issue without hindering their business practice or creating secondary impacts by diverting the criminals to other channels of access, such as break-ins, use of force or conflict with staff. They also need the continued support of the law enforcement authorities to be able to act promptly and expediently on information provided by them. These in turn need the full support and backing of the State, Territory and Australian Governments.

Recommendations

The solution to this issue must be evidence based, accountable, credible and cost effective. It must be able to be enforced, monitored and measured from all levels of supply chain. Any programs must be feasible for pharmacy and for the law enforcement agencies to implement in both time and capability. The risk to benefit ratio of the solution must be justified and it must be consistent with the Quality Use of Medicines guidelines in accordance with the National Medicines Policy. And above all, it needs time to implement, to educate consumers, pharmacy staff and law enforcement personnel, and to evaluate.

Recommendation 1

That the solution to the issue must be evidence based, enforceable, measurable and feasible for pharmacy to implement and must be consistent with the Quality Use of Medicines guidelines and that required data regarding pseudoephedrine diversion is collected from all levels of supply chain.

The Guild believes that the Project STOP and Pseudo Watch campaigns at pharmacy level meet many of the above mentioned criteria and would like to see Project STOP operating within all States and Territories of Australia in the near future. To do this, each State or Territory jurisdiction should have provisions to their legislation enacted to allow pharmacists to perform their duties without breaching any privacy issues. It is recommended that there be consistency between all States and Territories with regard to the storage and supply of PSE products.

Recommendation 2

That each State or Territory jurisdiction should have nationally consistent provisions in their legislations to enable pharmacists to perform their duties without breaching any privacy issues and with regard to the storage and supply of pseudoephedrine containing products.

The Pharmacy Guild of Australia will be working with the Pharmaceutical Society of Australia to promote participation by and education of the majority of pharmacy staff within the States and Territories as they take up the recommended projects. The Guild believes that the recent schedule changes to pseudoephedrine products, Project STOP and pharmacy education programs in line with the Pseudo Watch campaign, should see a reduction in access to pseudoephedrine products through pharmacy channels for illicit diversion while maintaining access to necessary medicines by genuine consumers with appropriate level of regulation. An appropriate Schedule for pseudoephedrine containing medicines is Schedule 3 (Pharmacist Only Medicine).

Recommendation 3

That a practical best practice pharmacy model that facilitates access to necessary medicines by genuine consumers with appropriate level of regulation while preventing the diversion of chemical precursors be supported.


The Guild will continue to provide consumer education at the pharmacy level to advise pharmacy customers that the reasons for the increased need for consumer detail is to discourage the diversion of PSE for illicit purposes, but extra support from appropriate government agencies and consumer organisations is also required. The majority of sales of PSE products within pharmacies are by legitimate customers for proper indications, and these customers need to be reassured that they are not the intended target of these campaigns, but rather the illicit ‘pseudo-runners’ are.

Recommendation 4

That a national awareness campaign through community pharmacy and ongoing public relations activities be funded.

Conclusion

The Pharmacy Guild of Australia is committed to addressing the seriousness of the problem effectively by implementing a practical model in pharmacy to handle the sale of pseudoephedrine-based products. For a number of years, the Guild has worked with law enforcement agencies to prevent the misuse of pseudoephedrine for illicit drugs manufacture and is willing to work with Government to implement any new strategies to achieve a nationally consistent community pharmacy pseudoephedrine plan.


Ask your PHARMACIST
PSE-3 PAD

Date _____

Type of ID _____

ID No. _____

Product Requested _____


Name of Patient/Purchaser _____

Address _____

Postcode _____

Pharmacist Signature _____

This pad must be retained in the pharmacy as a record of purchase for 2 years
 For re-orders, please phone Janenne Wilson on 02 9467 7140
 or Janelle Quinn on 02 9467 7137


Ask your PHARMACIST

	YES	NO
Is this for you?	<input type="checkbox"/>	<input type="checkbox"/>
Have you used this before?	<input type="checkbox"/>	<input type="checkbox"/>
If yes, was it effective?	<input type="checkbox"/>	<input type="checkbox"/>
Have you tried any other medications to treat your symptoms?	<input type="checkbox"/>	<input type="checkbox"/>
Are you taking any other medication?	<input type="checkbox"/>	<input type="checkbox"/>
Do you have any medical conditions?	<input type="checkbox"/>	<input type="checkbox"/>
Are you pregnant or breast feeding?	<input type="checkbox"/>	<input type="checkbox"/>

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