1) Audit title

Van Hout, MC. (2014) A Pharmacy Process Audit of compliance to the South African Medicines Control Council Schedule 2 standards for supply of non-prescription codeine containing products, compliance to the Codeine Care Protocols and audit of training of pharmacy staff in how to comply with these standards and protocols. CODEMISUSED Project European Commission 7th Framework Programme, EU. Brussels.

2) Introduction

Codeine Care: A method to accurately screen and control the sale of codeine containing products in South Africa at pharmacy level[1]

Pharmacists are the custodians of medicine, and not merely traders in potentially harmful goods. However, the nature of the profession suggests that there is always risk involved in the treatment of patients or consumers with medication. It is the pharmacist's responsibility to see that he or she applies his or her thorough knowledge to weigh up the risk and benefit ratio of each individual treatment regimen for each patient or consumer, and to advise them accordingly. In the case of medicine (such as codeine) that is available in a pharmacy without a prescription from an authorised prescriber, the onus rests almost entirely on the shoulders of the pharmacist to ensure that the patient or consumer is given the correct advice, and that the most suitable medication is recommended for the particular ailment from which he or she suffers.

When a pharmacist dispenses potentially addictive or harmful medication, such as products containing codeine, the responsibility that he or she carries increases dramatically. The keeping of a Schedule 2 record is compulsory for all pharmacists in South Africa. However, it is limited in the extent to which it curbs the potential abuse and misuse of certain drugs. Therefore, it appears to be a somewhat futile exercise. The recorded information is only useful for repeat sales of a product in that particular

[1] Direct cite from Le Roux, K (2013). Marketing of CPS. Pharmaceutical Practitioner. *South African Pharmaceutical Journal*, 80,43-7.

pharmacy. Other pharmacies throughout South Africa do not benefit in any manner or form from the information, nor do the authorities ever use the collected information. The entire process is circumvented when individuals who are addicted to these products or substances supply false information to the pharmacist and carry out *"pharmacy hopping"*. In this way, they obtain their *"stash"* of medication from different pharmacies, and each pharmacist is unaware of previous or future purchases elsewhere. Therefore, identification of codeine misuse, abuse and addiction relies almost entirely on serendipity, as there is no effective communication structure between the authorities and the medicine suppliers. Even in the event of a pharmacist establishing the addiction or dependence of an individual, little can be achieved in the form of intervention, other than refusal of a sale. Unfortunately, the individual subsequently obtains the product from another pharmacy, or from a variety of pharmacies, in order to satisfy his or her need. The misuse of these products is an important consideration.

It has been observed that upscheduling of medication does little to stop the abuse or misuse of drugs from occurring, as was evident from the upscheduling of d-norpseudoephedrine in an attempt to prevent the manufacture of "*tik*" (crystal methamphetamine), and abuse of the drug itself. The upscheduling of codeine-containing products that are available for sale in a pharmacy for the treatment of minor ailments may well be seen as a possible next step in the regulation of substance abuse and misuse (see later update August 2014). It is suggested that this step could take place solely because of the perceived dependence-producing potential of the drug. If this were to occur, millions of people in South Africa would be deprived of a useful self-medication option with which to treat minor aliments because of the social problems of a minority group. These individuals would be forced to seek help from their doctors and would further burden an already overburdened healthcare system. In addition, they would need to pay the doctor's consultation fee in order to obtain a prescription for a codeine containing product that is currently available as an over-the counter product.

The Codeine Care Project

The management of codeine misuse and dependence requires a concerted effort between stakeholders, to include manufacturers, prescribers, pharmacists, wholesalers, treatment, law enforcement and drug education specialists. The South African '*Codeine Care Project'* was launched in June 2013 by the Community Pharmacy Sector (CPS) and The Pharmacy Society of South Africa (PSSA) to monitor and audit the sale and supply of codeine containing pharmaceuticals[12]). The project is funded by manufacturers as part of their social responsibility programmes, and aims to benefit the pharmaceutical industry by ensuring codeine use as directed and for the therapeutic purpose for which

[2] Bateman, C. (2013). Is your prescribing serving a hidden addiction? *South African Medical Journal* 103, 359-61.
[1] Le Roux, K (2013). Marketing of CPS. Pharmaceutical Practitioner. *South African Pharmaceutical Journal*, 80,43-7.

they are intended. Available South African treatment data indicates combination codeine product abuse as secondary problematic substance and ranked second to benzodiazepine dependency, with primary over the counter/prescription medication abuse most common in females aged over 40 years, and secondary over the counter and prescription medication abuse most common in males over 40 years[3] On foot of rising treatment and pharmacy based concerns around codeine misuse and dependence, proactive efforts are now underway in South Africa to collect data in the SACENDU treatment data systems and in the National Household surveys (personal communication South African Medical Research Council, December 20th 2013).

Building on the need for national geographical and prevalence data recording and monitoring of the issue, the *'Codeine Care Project'* monitors national codeine dispensing by using The TrustaTAG™ compliance and counterfeit detection system. Two dimensional (2-D) barcodes on all codeine products packs are linked to a secure central database '*Misused Substance Database'* of all purchases of medication containing the active ingredient, codeine. Codeine is the first substance in this database, with intentions to include other commonly misused ingredients in the future. This computerised system will assist pharmacists to make an informed decision around the recommendation and sale of codeine, and has commenced real-time implementation on January 2nd 2014. Patient usage checks are conducted via an ordinary mobile phone, scanning kiosk, or through a webpage on the existing pharmacy dispensing system . The barcode is scanned prior to purchase and immediately indicates a live report of the consumption history of all scans from that customer in terms of when and where the customer last purchased codeine. A monthly threshold of 4g of codeine has been set, and all customers identified as potential misusers undergo pharmacist screening, consultation and referral to treatment.

Ultimately the *'Codeine Care Project'* intends to promote rational and responsible codeine use amongst the South African public and those involved in prescribing. Whilst empowering the role of pharmacists to fulfil their role as custodians of medicine with the support of modern TrustaTAG™ technology, the project is unique in that it provides all potential customers with a mechanism for the discrete access of information about the codeine product, by virtue of the customer scanning the barcode in the pharmacy with their basic feature phone or smart phone. They can inform their own decision to purchase the codeine product, and in the event of recognition of a problem with codeine, seek web assistance through dedicated referral lines, and links to national organisations such as Drug Wise (a campaign aimed at training pharmacists as Drug Wise counsellors) and Lifeline (a 24 hour

[3] Myers, B., Siegfried, N., & Parry, C.D. (2003). Over-the-counter and prescription medicine misuse in Cape Town--findings from specialist treatment centres. *South African Medical Journal*, 93, 367-370.

confidential crisis intervention service) . At the time of writing, the project has captured international interest, with the International Pharmaceutical Federation (FIP) requesting updating on its progress.

August 2014 Update on scheduling of Codeine

The South African Medicines Control Council is considering the rescheduling of acetyldihydrocodeine, codeine, dihydrocodeine and norcodeine. The reasons include the following:

1. the high abuse potential of codeine and codeine derivative products;
2. the limited clinical application of norcodeine and acetyldihydrocodeine containing products;
3. the global regulatory approach to codeine control.

Thus Council is considering implementing the following measures:

1. Schedule 2 listing

• Reducing the maximum quantity of codeine and dihydrocodeine per dosage unit from 20 mg to 10 mg and limiting the maximum daily dose to 80 mg and maximum treatment period to 5 days for oral solid preparations;

• Reducing the maximum quantity of codeine and dihydrocodeine per 5 ml dosage unit from 20 mg to 10 mg and limiting the maximum daily dose to 80 mg and maximum pack size to 100 ml for oral liquid preparations.

2. Schedule 3 listing

• Inclusion of a listing and inscription for codeine and dihydrocodeine for oral solid and liquid preparations exceeding the maximum quantity of active per dosage unit, i.e. 10 mg.

3. Schedule 6 listing

• Rescheduling of norcodeine and acetyldihydrocodeine from Schedule 2 to Schedule 6.

3) Rationale

The audit centres on pharmacy compliance of the Medicines Control Council Schedule 2 standards for safe supply of non-prescription codeine containing products, and Codeine Care project protocols. The rationale for the audit is as follows;

1) Professional concern

A variation in professional practice across different pharmacies has been noted (i.e. delivery of patient information around safe use of codeine, adherence to medical advice and labelling, awareness of dependence and harm, pharmacist decisions or refusal to supply the product, counter staff awareness of the guidelines for safe supply of non-prescription codeine containing products. An increase in the number of reported adverse events has been reported (for example customers reporting medication overuse headache associated with codeine withdrawal, and customer requests for over the counter codeine for symptoms, whilst unaware of actual withdrawal)

2) High risk procedures/situations

The issue of codeine misuse, both therapeutic and non-therapeutic is an area where pharmacy risk management requires focus. The cost of *`getting it wrong`* has major consequences for the patient (pharmacy risk management, impact of co-prescribing and use of OTC codeine)

3) Financial considerations

Given the focus on retail conflicting with customer care, not all pharmacies employ the same level of stringency and customer care.

4) Practical considerations

The audit aims to measure practice compliance against national regulatory standards for safe supply. The audit is two-fold, auditing for compliance of standards and training audit of pharmacists and pharmaceutical assistants. Improvements included compliance, patient/customer care and evaluation of Codeine Care Care protocols in operation.

Codeine Care Project Objectives

The Consumer/Patient

 To find a cost effective, simple and efficient mechanism to promote the responsible use of pharmaceutical products containing codeine to the patient / consumer and to the healthcare professional in multiple languages.

 To provide the patient / consumer with all the necessary warnings regarding taking these medicines.

 To provide the patient / consumer a mechanism which is discreet but readily available through which he/she is able to access information and seek help through direct links to telephone numbers and email addresses of either the manufacturer involved, or that of the likes of Narcotics Anonymous.

 To provide the patient / consumer with the full Patient Information Leaflet (PIL) of the particular codeine containing product and all other necessary information and warnings required by the Consumer Protection Act, in their language of choice.

Pharmacy and in time Dispensing Doctors

 To provide a cost effective, efficient and simple mechanism to check/validate and track patient / consumer purchase of codeine containing products (both OTC and prescription).

 To provide the healthcare professional with the full PIL of the particular codeine containing product and all other necessary information required by the Consumer Protection Act on a mobile phone or alternatively emailed to him/her from the system via their mobile phone without the need to have access to an email account on the said mobile phone.

 To provide the mechanism through the dispensing vendors for the PIL TAG to be printed onto the dispensing labels currently printed and as such make it available on a mobile phone or through the information being emailed to the individual or to the pharmacist or other healthcare professional who in turn can print it out.

Pharmacy Council/Medicines Control Council/CPS

 To provide a SECURE central database of codeine usage.

 To provide SECURE live reports of all scans from consumers – providing geographical usage and prevalence without providing any confidential information such as names, etc.

 To provide a SECURE live report of all scans by pharmacists and pharmacist assistants.

4) The audit aim and objectives

The aim of the audit is ensure correct pharmacist compliance in adhering to the Medicines Control Council Schedule 2 standard for safe supply of non-prescription codeine containing products and Codeine Care project protocols (I – VI), so that public awareness of correct use of codeine and safe supply occurs in South African pharmacies.

The objectives of the audit are as follows;

1. To improve pharmacy practice with regard to supply of non-prescription products containing codeine occurs according to the Medicines Control Council schedule 2 standard for safe supply of non-prescription codeine containing products and Codeine Care project protocols.
2. To raise awareness among pharmacy staff (pharmacists, counter staff) that all sales of Schedule 2 medicines are required to be recorded in a Schedule 2 register. The Codeine Care Program is not a substitute for the details required to be recorded in terms of the Medicines and Related Substances Act.
3. To ensure that the pharmacist takes note of the Protocol provided that guides the implementation of the program at a pharmacy level. The Pharmacist will ensure the use of the Codeine Care Program in the pharmacy and that all staff empowered by legislation to dispense various schedules of codeine products are familiar with all aspects of the program.
4. To ensure that the pharmacist provides the patient / consumer with the full Patient Information Leaflet (PIL) of the particular codeine containing product and all other necessary information and warnings required by the Consumer Protection Act, in their language of choice.
5. The pharmacist and his/her staff limit their counselling of patients to that within the scope of practice of a pharmacist, and that s/he will not attempt to provide services that fall within the scope of experienced and trained substance abuse counsellors and professionals, and that referral contacts of reputable facilities and professionals are provided to patients or clients for all matters that fall outside of the basic counselling associated with the safe use of medicine.

6. The pharmacist shall ensure that the patient (purchaser) of codeine are informed about the program using the information provided by CPS, and that prior to recording, the patient consents to his/her details to be included into the program and that such consent is confirmed by means of a signature in the pharmacy's Schedule 2-book or any other register or form designated by the pharmacist for this purpose.
7. The pharmacist undertakes to accurately record all data on the program, including the patient's consent, or to indicate if a person did not provide consent (in which case no personal details are recorded at all). If the pharmacist falsely records- consent or - any other information, such false recording will not only constitute a violation of the applicable ethical- and legal provisions, it will also constitute fraud, and CPS, when this comes to its attention, may report such recording to any appropriate authority it deems fit.
8. Based on the information provided by the program, the pharmacist will exercise his/her judgement in taking appropriate steps in dispensing, or prior to dispensing a codeine-product to the patient, such as counselling the patient or referring the patient to an appropriate service provider. The pharmacist may also choose to make a note on the particular patient and any circumstances that may warrant use in excess of the maximum indicated.

5) The type of audit

The audit is a process audit and has two components, the pharmacist compliance in adhering to the Medicines Control Council schedule 2 standard for safe supply of non-prescription codeine containing products and Codeine Care project protocols (A), and the training of pharmacy staff in how to comply with these standards and project protocols (B).

6) The audit team

The audit team consists of the Audit Facilitator responsible for running the audits and providing the training (Part B), expert consultation with the Community Pharmacy Sector of the South African Pharmaceutical Society, and administration support (data input and administration support).

7) The standard statement

Audit Standard A: All customers requesting non-prescription medicinal products containing codeine will be consulted, advised and supplied the product according to the Medicines Control Council schedule 2 standard and Codeine Care project protocols for safe supply of non-prescription codeine containing products.

Audit Standard B: Staff will score 70% of above following training in how to supply non-prescription medicinal products containing codeine according to the Medicines Control Council Schedule 2

standard for safe supply of non-prescription codeine containing products and Codeine Care project protocols.

8) Evidence base

Medicines Control Council Schedule 2

I. All sales of Schedule 2 medicines are required to be recorded in a schedule 2 register. The Codeine Care Program is not a substitute for the details required to be recorded in terms of the Medicines and Related Substances Act.

Codeine Care Project Protocols

II. The Pharmacist takes note of the Protocol provided that guides the implementation of the program at a pharmacy level. The Pharmacist will ensure the use of the Codeine Care Program in the pharmacy and that all staff empowered by legislation to dispense various schedules of codeine products are familiar with all aspects of the program.

III. The Pharmacist will ensure that in working with and on the Codeine Care Program, s/he and his/her staff limit their counselling of patients to that within the scope of practice of a pharmacist, and that s/he will not attempt to provide services that fall within the scope of experienced and trained substance abuse counsellors and professionals, and that referral contacts of reputable facilities and professionals are provided to patients or clients for all matters that fall outside of the basic counselling associated with the safe use of medicine.

IV. The Pharmacist shall ensure that the patient / consumer is provided with the full Patient Information Leaflet (PIL) of the particular codeine containing product and all other necessary information and warnings required by the Consumer Protection Act, in their language of choice.

V. The Pharmacist shall ensure that the patient (purchaser) of codeine are informed about the program using the information provided by CPS, and that prior to recording, the patient consents to his/her details to be included into the program and that such consent is confirmed by means of a signature in the pharmacy's schedule 2-book or any other register or form designated by the pharmacist for this purpose.

VI. The pharmacist undertakes to accurately record all data on the program, including the patient's consent, or to indicate if a person did not provide consent (in which case no personal details are recorded at all). If the pharmacist falsely records- consent or - any other information, such false recording will not only constitute a violation of the applicable ethical- and legal provisions, it will also constitute fraud, and CPS, when this comes to its attention, may report such recording to any appropriate authority it deems fit.

VII. Based on the information provided by the program, the pharmacist will exercise his/her judgement in taking appropriate steps in dispensing, or prior to dispensing a codeine-product to the

patient, such as counseling the patient or referring the patient to an appropriate service provider. The pharmacist may also choose to make a note on the particular patient and any circumstances that may warrant use in excess of the maximum indicated.

9) The sample

Part A: A process audit of pharmacy compliance in the safe supply of non-prescription codeine containing products according to the Medicines Control Council Schedule 2 standards and the Codeine Care Project Protocols

All pharmacies registered in South Africa (4338 chains see http://www.pharmcouncil.co.za/B_Statistics.asp) will be advised that during one calendar month, a test shopper may visit their site, and request to purchase codeine using various scenarios in their pharmacies. These test shoppers will complete the data collection sheet to audit compliance. A stratified random sampling of every 10th pharmacy in each province will be audited by a test shopper requesting to purchase over the counter codeine. Test shoppers will present with a variety of scenarios to request codeine and inclusive of legitimate requests, inappropriate use, requesting codeine products by name, suspected misuse for intoxication purposes, suspected misuse for therapeutic purposes, suspected misuse for opiate withdrawals, suspected pharmacy hopping, lack of patient awareness of other forms of pain management and lack of patient awareness of codeine related harm.

Part B: A process audit of increase in knowledge around the safe supply of non-prescription codeine containing products according to the Medicines Control Council Schedule 2 standards and the Codeine Care Project Protocols

A stratified randomised listing of pharmacists (13371 see http://indicators.hst.org.za/healthstats/283/data) and pharmaceutical assistants (14,281 http://www.pharmcouncil.co.za/B_Statistics.asp) registered in South Africa (male/female/province) A stratified randomised listing of pharmacies will partake in 1 day training provided by the Audit Facilitator and requested to complete the data collection sheet to assess knowledge of the Medicines Control Council Schedule 2 standards and the Codeine Care Project Protocols at Time 1 before training, and Time 2 after training. Stratification will occur via job type (pharmacist/pharmaceutical assistant), gender and province, with every 10th case per subgroup sampled.

9) Data collection

The audit instruments will be piloted with a group of pharmacists (n=10) not partaking in the audit.

10) Ethical considerations

All participants will be provided with an information sheet outlining the purpose of the audit, will provide written consent to partake in the audit and be assured complete anonymity, that neither they

nor their pharmacy be identified in the final report. Data will be stored on a password protected computer and only accessed by the author. Dissemination of the findings will be approved by the Lead Audit Facilitator and the South African Pharmaceutical Society prior to release.

11) Dissemination of findings

The findings will be collated and presented in a report. Findings will be presented to a group of pharmacists to see if they are surprised or dispute findings. It is envisaged that two journal publications will present data relating to Part A and B respectively.

12) Timetable

Month	1	2	3	4	5	6	7	8	9
	Design and piloting of instruments Circular Email advising of the audit Sampling frame finalised.								
Audit A	Recruitment and training of test shoppers	Audit Test Shopper	Audit Test Shopper	Analysis of data					Report Dissemination
Audit B				Audit Time 1	Delivery of Training	Delivery of Training	Audit Time 2	Analysis Of data	Report Dissemination

13) Resources required

Administration support, travel and subsistence for logistics.

Part A: A process audit of pharmacy compliance in the safe supply of codeine according to the Medicines Control Council Schedule 2 and the Codeine Care Project Protocols

Standard A: All customers requesting non-prescription medicinal products containing codeine will be consulted, advised and supplied the product according to the PSNI Guidelines (I-VI) for safe supply of non-prescription codeine containing products.					
Criteria	**Target**	**Allowable exceptions**	**Definitions**	**Evidence base ***	**Location**
Criterion 1) All sales of Schedule 2 codeine containing medicines are required to be recorded in a schedule 2 register.	100%	None.	N/A	Medicines Control Council Schedule 2 and the Codeine Care Project Protocols	In the test customer's record sheet for each pharmacy.
Criterion 2) The Pharmacist will ensure the use of the Codeine Care Program in the pharmacy and that all staff empowered by legislation to dispense various schedules of codeine products are familiar with all aspects of the program.	100%	None.	N/A	Medicines Control Council Schedule 2 and the Codeine Care Project Protocols	In the test customer's record sheet for each pharmacy.
Criterion 3) The Pharmacist shall ensure that the patient / consumer is provided with the full Patient Information Leaflet (PIL) of the particular codeine containing product and all other necessary information and warnings required by the Consumer Protection Act, in their language of choice.	100%	None.	N/A	Medicines Control Council Schedule 2 and the Codeine Care Project Protocols	In the test customer's record sheet for each pharmacy.
Criterion 4) The Pharmacist will ensure that in working with and on the Codeine Care Program, s/he and his/her staff limit their counseling of patients to that within the scope of practice of a pharmacist,	100%	None.	N/A	Medicines Control Council Schedule 2 and the Codeine Care Project Protocols	In the test customer's record sheet for each pharmacy.

and that s/he will not attempt to provide services that fall within the scope of experienced and trained substance abuse counselors and professionals, and that referral contacts of reputable facilities and professionals are provided to patients or clients for all matters that fall outside of the basic counseling associated with the safe use of medicine.					
Criterion 5) The Pharmacist shall ensure that the patient (purchaser) of codeine are informed about the program using the information provided by CPS, and that prior to recording, the patient consents to his/her details to be included into the program and that such consent is confirmed by means of a signature in the pharmacy's schedule 2-book or any other register or form designated by the pharmacist for this purpose.	100%	None.	N/A	Medicines Control Council Schedule 2 and the Codeine Care Project Protocols	In the test customer's record sheet for each pharmacy.
Criterion 6) The pharmacist undertakes to accurately record all data on the program, including the patient's consent, or to indicate if a person did not provide consent (in which case no personal details are recorded at all). If the pharmacist falsely records-consent or - any other information, such false recording will not only constitute a violation of the applicable ethical- and legal provisions, it will also constitute fraud, and CPS, when this comes to its attention, may report such recording to any appropriate authority it deems fit.	100%	None.	N/A	Medicines Control Council Schedule 2 and the Codeine Care Project Protocols	In the test customer's record sheet for each pharmacy.
Criterion 7)	100%	None.	N/A	Medicines Control	In the test customer's

Based on the information provided by the program, the pharmacist will exercise his/her judgement in taking appropriate steps in dispensing, or prior to dispensing a codeine-product to the patient, such as counselling the patient or referring the patient to an appropriate service provider. The pharmacist may also choose to make a note on the particular patient and any circumstances that may warrant use in excess of the maximum indicated.				Council Schedule 2 and the Codeine Care Project Protocols	record sheet for each pharmacy.

Data Collection Sheet

Standard A: All customers requesting non-prescription medicinal products containing codeine will be consulted, advised and supplied the product according the Medicines Control Council Schedule 2 and the Codeine Care Project Protocols

Test Shopper Scenario

Legitimate use

Inappropriate use

Requesting codeine products by name

Suspected misuse for intoxication purposes

Suspected misuse for therapeutic purposes

Suspected misuse for opiate withdrawals

Suspected pharmacy hopping

Lack of patient awareness of other forms of pain management

Lack of patient awareness of codeine related harm

Criteria					**Comments** (these are for the data collector to add notes on each criterion if they think clarification is required)

Criterion 1) All sales of Schedule 2 codeine containing medicines are required to be recorded in a schedule 2 register.	Y	N	DK	NA	
Criterion 2) The Pharmacist will ensure the use of the Codeine Care Program in the pharmacy and that all staff empowered by legislation to dispense various schedules of codeine products are familiar with all aspects of the program.	Y	N	DK	NA	
Criterion 3) The Pharmacist shall ensure that the patient / consumer is provided with the full Patient Information Leaflet (PIL) of the particular codeine containing product and all other necessary information and warnings required by the Consumer Protection Act, in their language of choice.	Y	N	DK	NA	
Criterion 4) The Pharmacist will ensure that in working with and on the Codeine Care Program, s/he and his/her staff limit their counselling of patients to that within the scope of practice of a pharmacist, and that s/he will not attempt to provide services that fall within the scope of experienced and trained substance abuse counsellors and professionals, and that referral contacts of reputable facilities and professionals are provided to patients or clients for all matters that fall outside of the basic counselling associated with the safe use of medicine.	Y	N	DK	NA	

Criterion 5) The Pharmacist shall ensure that the patient (purchaser) of codeine are informed about the program using the information provided by CPS, and that prior to recording, the patient consents to his/her details to be included into the program and that such consent is confirmed by means of a signature in the pharmacy's schedule 2-book or any other register or form designated by the pharmacist for this purpose.	Y	N	DK	NA	
Criterion 6) The pharmacist undertakes to accurately record all data on the program, including the patient's consent, or to indicate if a person did not provide consent (in which case no personal details are recorded at all). If the pharmacist falsely records- consent or - any other information, such false recording will not only constitute a violation of the applicable ethical- and legal provisions, it will also constitute fraud, and CPS, when this comes to its attention, may report such recording to any appropriate authority it deems fit.	Y	N	DK	NA	
Criterion 7) Based on the information provided by the program, the pharmacist will exercise his/her judgement in taking appropriate steps in dispensing, or prior to dispensing a codeine-product to the patient, such as counselling the patient or referring the patient to an appropriate service provider. The pharmacist may also choose to make a note on the particular patient and any circumstances that may warrant use in excess of the maximum indicated.	Y	N	DK	NA	

Part B: A process audit of increase in knowledge around the safe supply of codeine according to the Medicines Control Council Schedule 2 and the Codeine Care Project Protocols after training.

Standard B: Staff will score 70% of above following training in how to supply non-prescription medicinal products containing codeine according the Medicines Control Council Schedule 2 and the Codeine Care Project Protocols					
Criteria	**Target**	**Allowable exceptions**	**Definitions**	**Evidence base ***	**Location**
Criterion 1) All sales of Schedule 2 codeine containing medicines are required to be recorded in a schedule 2 register.	100%	None.	N/A	Medicines Control Council Schedule 2 and the Codeine Care Project Protocols	End of test sheets at time One and Two
Criterion 2) The Pharmacist will ensure the use of the Codeine Care Program in the pharmacy and that all staff empowered by legislation to dispense various schedules of codeine products are familiar with all aspects of the program.	100%	None.	N/A	Medicines Control Council Schedule 2 and the Codeine Care Project Protocols	End of test sheets at time One and Two
Criterion 3) The Pharmacist shall ensure that the patient / consumer is provided with the full Patient Information Leaflet (PIL) of the particular codeine containing product and all other necessary information and warnings required by the Consumer Protection Act, in their language of choice.	100%	None.	N/A	Medicines Control Council Schedule 2 and the Codeine Care Project Protocols	End of test sheets at time One and Two
Criterion 4) The Pharmacist will ensure that in working with and on the Codeine Care Program, s/he and his/her staff limit their counselling of patients to that within the scope of practice of a pharmacist, and that s/he will not attempt to provide services that fall within the scope of experienced and	100%	None.	N/A	Medicines Control Council Schedule 2 and the Codeine Care Project Protocols	End of test sheets at time One and Two

trained substance abuse counsellors and professionals, and that referral contacts of reputable facilities and professionals are provided to patients or clients for all matters that fall outside of the basic counselling associated with the safe use of medicine.					
Criterion 5) The Pharmacist shall ensure that the patient (purchaser) of codeine are informed about the program using the information provided by CPS, and that prior to recording, the patient consents to his/her details to be included into the program and that such consent is confirmed by means of a signature in the pharmacy's schedule 2-book or any other register or form designated by the pharmacist for this purpose.	100%	None.	N/A	Medicines Control Council Schedule 2 and the Codeine Care Project Protocols	End of test sheets at time One and Two
Criterion 6) The pharmacist undertakes to accurately record all data on the program, including the patient's consent, or to indicate if a person did not provide consent (in which case no personal details are recorded at all). If the pharmacist falsely records- consent or - any other information, such false recording will not only constitute a violation of the applicable ethical- and legal provisions, it will also constitute fraud, and CPS, when this comes to its attention, may report such recording to any appropriate authority it deems fit.	100%	None.	N/A	Medicines Control Council Schedule 2 and the Codeine Care Project Protocols	End of test sheets at time One and Two
Criterion 7) Based on the information provided by the program, the pharmacist will exercise his/her	100%	None.	N/A	Medicines Control Council Schedule 2 and the Codeine Care	End of test sheets at time One and Two

judgement in taking appropriate steps in dispensing, or prior to dispensing a codeine-product to the patient, such as counseling the patient or referring the patient to an appropriate service provider. The pharmacist may also choose to make a note on the particular patient and any circumstances that may warrant use in excess of the maximum indicated.				Project Protocols	

Data Collection Sheet

Standard B: Staff will score 70% of above following training in how to supply non-prescription medicinal products containing codeine according to the Medicines Control Council Schedule 2 and the Codeine Care Project Protocols.				
Criteria				**Comments** (these are for the data collector to add notes on each criterion if they think clarification is required)
Criterion 1) All sales of Schedule 2 codeine containing medicines are required to be recorded in a schedule 2 register.	Y	N	No answer	
Criterion 2) The Pharmacist will ensure the use of the Codeine Care Program in the pharmacy and that all staff empowered by legislation to dispense various schedules of codeine products are familiar with all aspects of the program.	Y	N	No answer	
Criterion 3) The Pharmacist shall ensure that the patient / consumer is provided with the full Patient Information Leaflet (PIL) of the particular codeine containing product and all other necessary information and warnings required by the Consumer Protection Act, in their language of choice.	Y	N	DK	

Criterion 4) The Pharmacist will ensure that in working with and on the Codeine Care Program, s/he and his/her staff limit their counselling of patients to that within the scope of practice of a pharmacist, and that s/he will not attempt to provide services that fall within the scope of experienced and trained substance abuse counsellors and professionals, and that referral contacts of reputable facilities and professionals are provided to patients or clients for all matters that fall outside of the basic counselling associated with the safe use of medicine.	Y	N	DK	
Criterion 5) The Pharmacist shall ensure that the patient (purchaser) of codeine are informed about the program using the information provided by CPS, and that prior to recording, the patient consents to his/her details to be included into the program and that such consent is confirmed by means of a signature in the pharmacy's schedule 2-book or any other register or form designated by the pharmacist for this purpose.	Y	N	DK	
Criterion 6) The pharmacist undertakes to accurately record all data on the program, including the patient's consent, or to indicate if a person did not provide consent (in which case no personal details are recorded at all). If the pharmacist falsely records- consent or - any other information, such false recording will not only constitute a violation of the applicable ethical- and legal provisions, it will also constitute fraud, and CPS, when this comes to its attention, may report such recording to any appropriate authority it deems fit.	Y	N	DK	

Criterion 7) Based on the information provided by the program, the pharmacist will exercise his/her judgement in taking appropriate steps in dispensing, or prior to dispensing a codeine-product to the patient, such as counseling the patient or referring the patient to an appropriate service provider. The pharmacist may also choose to make a note on the particular patient and any circumstances that may warrant use in excess of the maximum indicated.	Y	N	DK	

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Van Hout, MC. (2014) A Pharmacy Process Audit of compliance to the South African Medicines Control Council Schedule 2 standards for supply of non-prescription codeine containing products, compliance to the Codeine Care Protocols and audit of training of pharmacy staff in how to comply with these standards and protocols. CODEMISUSED Project European Commission 7th Framework Programme, EU. Brussels.