

PROTOCOL FOR CODEINE CARE PROGRAM

1. Background to the Registry

According to the International Narcotics Control Board 2010 Report of the Availability of Internationally Controlled Drugs, South Africa is ranked as the number one country in Africa and number 49 in the world (of 193 member states) in terms of average consumption of defined daily doses of narcotic drugs. South Africa is one of a handful of countries which allows codeine containing substance to be purchased as an OTC drug.

South Africa is signatory to three major conventions:

1. 1961 UN Single Convention on Narcotic Drugs;
2. 1971 Convention on Psychotropic Substances; and
3. 1988 UN Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances.

South Africa is in addition signatory to the African Union and Southern African Development Community Drug Control Protocol. In the records a resolution was adopted by the UN conference for the adoption of a Convention on Psychotropic Substances under Article 9 and reads:

1. The parties shall require that substances in Schedule 2, 3, and 4 be supplied or dispensed for use by individuals pursuant to medical prescription only, except when individuals may lawfully obtain, use, dispense or administer such substances in the duly authorized exercise of therapeutic or scientific functions;
2. The parties shall take measures to ensure that prescriptions for substances in Schedule 2, 3 and 4 are issued in accordance with sound medical practices and subject to such regulation, particularly as to the number of times they may be refilled and the duration of their validity, as will protect the public health and welfare.
3. Notwithstanding paragraph 1, a party may, if in its opinion local circumstances so require and under such conditions, including record-keeping, as it may prescribe, authorize licensed pharmacists or other licensed retail distributors designated by the authorities responsible for public health in its country or part thereof to supply, at their discretion and without prescription, for use for medical purposes by individuals in exceptional cases, small quantities, within limits to be defined by the parties, of substances in Schedule 3 and 4.

Article 20 reads:

1. The parties shall take all practicable measures for the prevention of abuse of psychotropic substances and for the early identification, treatment, education, after-care, rehabilitation and social reintegration of the persons involved, and shall co-ordinate their efforts to these ends.
2. The parties shall assist persons whose work so requires to gain an understanding of the problems of abuse of psychotropic substances and its prevention, and shall also promote such understanding among the general public if there is a risk that abuse of such substances will become widespread.

The INCB report of 2010 includes:

Paragraph 58: 'In several countries, the diversion and abuse of narcotic drugs involve preparations for which certain control measures, such as the requirement for prescription, are not mandatory under the 1961 Convention. Such preparations include, for example, cough syrups containing codeine, dihydrocodeine, ethylmorphine and pholcodine. The Board again calls on all Governments to be on the alert for problems involving the abuse of pharmaceutical preparations not requiring prescriptions, and to adopt, if necessary, measures to effectively prevent the diversion into illicit traffic and abuse of such preparations.'

The above suggests that South Africa in alignment with international standards, must as speedily as possible adopt further control mechanisms or measures to mitigate the misuse and abuse of the various preparations such as those to which are referred in the above paragraph. The first step in this regard is the control of the use of codeine. This step is especially relevant to a country in which codeine containing products are available OTC.

2. Objective of the Registry

- 2.1. The Codeine Care Program constitutes a patient Registry of medicines containing codeine dispensed over a 6 month period.
- 2.2. The overarching objective of the Registry is of a public health nature, namely to ensure the appropriate and safe use of medicine, in particular codeine.
- 2.3. The Registry aims to –
 - 2.3.1. Empower pharmacists to fulfill their legal and ethical duties in ensuring the interest of patients in the use of codeine, by providing critical information to the pharmacist to enable him/her to appropriately advise the patient on the use, or potential abuse of codeine, and where to obtain help;
 - 2.3.2. Give effect of the legal record-keeping requirements set by the 10 April 2003 General Regulations (GNR.510) to- and the Medicines and Related Substances Act No 101 of 1965 ("Medicines Act");
 - 2.3.3. Empower pharmacists to evaluate whether possession and use of codeine is lawful;
 - 2.3.4. Enable the provision of de-identified aggregated information to regulators on codeine sales and repeat-sales to the public, with a view of informing future regulations and/or other appropriate interventions that might be required.

3. Legislative frameworks applicable to the Registry

- 3.1. Medicines Act provides legal mandate to record certain particulars

The Medicines Act contains the following provisions that mandate the collection of certain information at pharmacy level:

Section 22A:

(5) Any Schedule 2, Schedule 3, Schedule 4, Schedule 5 or Schedule 6 substance shall not be sold by any person other than—

(a) a pharmacist, pharmacist intern or a pharmacist's assistant acting under the personal supervision of a pharmacist, who may sell only Schedule 2 substances without a prescription;

*(6) Any sale under subsection (5) shall only take place on condition that—
(a) all the prescribed particulars of every sale shall be recorded in the prescribed manner in a prescription book or other permanent record required to be kept in the prescribed manner...*

Schedule 2 contains the following substances:

Codeine (methyilmorphine),

(a) oral solid preparations, in combination with one or more therapeutically active substances, and containing 20 milligrams or less of codeine (calculated as base) per dosage unit; or

(b) liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, and containing 20 milligrams or less of codeine (calculated as base) per 5 millilitre dosage unit. (S6)

Regulation 11 describes as is stipulated in section 22A(6), the manner in which information are to be kept:

(1) A prescription book or other permanent record in respect of Schedule 2, 3, 4, 5 and 6 medicines or substances shall be kept on all premises where prescribed medicines are dispensed or sold and shall contain the following details—

(a) the name of the medicine or scheduled substance;

(b) the date on which the prescription was dispensed;

(c) the dosage form and quantity of the medicine or scheduled substance;

(d) the name and address of the patient ... ;

(e) where applicable the name of the medical practitioner, dentist, veterinarian or any other authorised person who issued the prescription; and

(f) prescription reference number.

The Medicines Act and the General Regulations of 2003 therefore authorize the keeping of information by a pharmacist. No explicit provision exist in the Medicines Act for the sharing of information, however the purpose of the Medicines Act is to ensure that medicines supply is lawful and that there are records available to ensure the lawfulness of possession and use and sharing should be permissible if within these parameters.

The only ground for refusal to dispense would be violations of the Medicines Act and regulations. A pharmacist would, however, pursuant to his or her ethical responsibilities, use the information s/he can access to counsel the patient, refer the patient and/or provide the patient with an alternative medicine as is provided for in the 2008 Code of Conduct for Pharmacists, issued in terms of the Pharmacy Act.

3.2. Drugs and Drug Trafficking Act, Act 140 of 1992

The Drugs and Drug Trafficking Act (“Drugs Act”) works with the Medicines Act (section 2) and its section 4(b) prohibits possession of dangerous dependence producing substances unless a person -

(i) he is a patient who has acquired or bought any such substance—

(aa) from a medical practitioner, dentist or practitioner acting in his professional capacity and in accordance with the requirements of the Medicines Act or any regulation made thereunder; or

(bb) from a pharmacist in terms of an oral instruction or a prescription in writing of such

*medical practitioner, dentist or practitioner,
and uses that substance for medicinal purposes under the care or treatment of the said
medical practitioner, dentist or practitioner;*

*(ii) he has acquired or bought any such substance for medicinal purposes—
(aa) from a medical practitioner, veterinarian, dentist or practitioner acting in his
professional capacity and in accordance with the requirements of the Medicines Act or any
regulation made thereunder;*

*(bb) from a pharmacist in terms of an oral instruction or a prescription in writing of such
medical practitioner, veterinarian, dentist or practitioner; or*

...

*with the intent to administer that substance to a patient or animal under the care or
treatment of the said medical practitioner, veterinarian, dentist or practitioner*

The Schedule to the Drugs Act contains a list of “Dangerous Dependence-Producing Substances”, which included “Codeine (methylmorphine), except preparations and mixtures containing not more than 20 milligrams of codeine per recommended or prescribed dose”.

The Registry therefore fulfills the purpose of establishing compliance with section 4 and the Medicines Act in that it might pick up unlawful possession (i.e. greater quantities or with greater frequency than prescribed or permissible) and use (i.e. use that is not medicinal) that would otherwise have been undetected. It also allows practitioners to exercise the “care” referred to in section 4.

Similar provisions exist in relation to drug dealing (section 5) and therefore a registry would be capable of detecting persons potentially acquiring codeine for purposes of drug dealing in contravention of section 5.

Section 9 authorises disclosure to a police officer or the prosecuting authority “notwithstanding anything to the contrary contained in any law which prohibits him or her from disclosing any information relating to the affairs or business of any other person; or from permitting any person to have access to any registers, records or other documents” of “such information as he or she may consider necessary for the prevention or combating, whether in the Republic or elsewhere, of a drug offence”. A drug offence includes a contravention of section 4(b), as outlined above. However, reporting to the police remains contentious, and it may be advisable to reporting is undertaken not by the specific pharmacist, but by one of the structures of the registry. Reporting may also result in persons not providing their details or refusing to consent to inclusion of details in the registry.

The Drugs Act also contains a number of presumptions in relation to possession being unlawful until otherwise proven, and the registry could be a valuable tool, should it be so authorized, to rebut such presumption.

3.3. National Health Act, Act 61 of 2003

The National Health Act contains provisions on record-keeping and disclosure. Section 14 states that “all information concerning a user, including information relating to his or her health status, treatment or stay in a health establishment, is confidential.”

However, disclosure may take place under the following circumstances:

(2) Subject to section 15, no person may disclose any information contemplated in subsection (1) unless—
(a) the user consents to that disclosure in writing;
(b) a court order or any law requires that disclosure; or
(c) non-disclosure of the information represents a serious threat to public health.

The Registry complies with both sections 14(2)(a) and (b) in that the Medicines Act and regulations require the recording of certain information and, for the sharing of such information in a national database, the patients would have to consent to such sharing and inclusion in national database.

Section 15 creates a third option to authorize the sharing of information amongst pharmacies and pharmacists, and also potentially with law-enforcement bodies, viz:

15. Access to health records. (1) A health worker or any health care provider that has access to the health records of a user may disclose such personal information to any other person, health care provider or health establishment as is necessary for any legitimate purpose within the ordinary course and scope of his or her duties where such access or disclosure is in the interests of the user.

(2) For the purpose of this section, “personal information” means personal information as defined in section 1 of the Promotion of Access to Information Act, 2000 (Act No. 2 of 2000).

There can be little dispute that such disclosures (i.e. sharing across pharmacies) are in the interest of patients who may be vulnerable to addiction to codeine.

Section 90(1) of the National Health Act empowers the promulgation of regulations relating to –

(g) returns, registers, reports, records, documents and forms to be completed and kept by the national department, provincial departments, district health councils, health care providers, private health establishments and public health establishments.

The Codeine Care Program will strive to ensure recognition of the registry through regulations under section 90(1)(g) of the National Health Act.

3.4. The Protection of Personal Information Bill, Bill No 9B of 2009 (“POPI Bill”)

The POPI Bill is a constitutional piece of legislation, deriving its authority from section 14 of the Constitution of the Republic of South Africa. Once signed into law (it was passed by Parliament in September 2013 – then becoming the POPI Act), it could potentially override the provisions listed above (clause 3(2)(a) of the Bill). The Codeine Care Project therefore aims to also ensure compliance with the provisions in POPI.

The criteria set by POPI are:

- Persons should know that personal information about him/her is being collected.
- Persons should know what the purposes of such information-collection and use are (refer the objectives set out above in par 2).
- Personal information can only be processed lawfully and in a reasonable manner.
- Persons are entitled to know that their data is secure from outside access or unauthorised access (e.g. in the pharmacy).
- Information collected must be adequate, relevant and not excessive (refer par 4.1 below)

- only information that is reasonably required to ensure the safe use and assessment of lawfulness of possession are required).
- Processing complies with an obligation imposed by law, i.e. the Medicines Act, Pharmacy Act and National Health Act.
- Persons are entitled to know for how long data will be retained and when it will be destroyed, or, if archived, by when and for how long (refer par 4.5 below).
- Further processing must be explicitly authorized and are done without the publication of any identifiable information. The Codeine Care Program will further process the data on the registry in order to ensure that further regulatory and other action may be taken in the interest of the safe use of codeine in South Africa in future.
- Reasonable steps must be taken to ensure that the data is complete, accurate, not misleading and updated where necessary.
- Persons are entitled to know who are collection and processing the information.
- Persons are entitled to request and see what information is being held on them by the Codeine Care project.

4. Registry Rules

4.1. Data fields contained in registry

The Registry only includes the following data fields:

- a) Identification or passport number of patient which is stored in a de- identified form and which would not be accessible to any pharmacist, the CPS or any third party – only the programmers would be able to access identify numbers. This personal number is only used to generate and call up the de-identified number of a particular patient that is included on the program:
- b) Pharmacist P number
- c) Name of product and pack size (the system by means of a Nappi code will identify how much codeine is in this product. Provision is made for a broken pack)
- d) History of codeine purchases over the last 6 months by grams of codeine and by product name
- e) The flag / alert for misuse is 4g of codeine per day
- f) Text box for pharmacist to be able to write notes e.g. why he chose to override the 4g per day

Once an identity number is entered, the following information already on the database and pertaining to a person would appear on the screen:

- The random number that is /was generated on the basis of the identity number provided
- The date of purchase
- The name of the products purchased over a six month period
- The ingredient – in this case codeine purchased over a six month period
- The amount of codeine in each pack purchased over a six month period

Should the pharmacist note that the purchases are frequent s/he will be in a position to make a judgment call on the dispensing or sale of the codeine containing product. Frequent episodes of purchase such as buying a bottle or box a day of a codeine containing product will not be flagged but the pharmacist will be able to note this occurrence and make a professional judgement call to this effect. Only when a maximum of 4gms in a month is reach does the system issue an alert.

The reason for keeping the information for a period of six months is that this period of time is sufficient to indicate any misuse or abuse of the products, i.e. according to the criteria listed in the POPI Act no more information than is reasonably required are stored.

4.2. Consent forms and agreements with participating pharmacies

Each participating responsible pharmacist and/or s/he and/or his authorized staff has to ensure that (a) the fact that the patient's details have to be entered into a register based on the requirements of the Medicines Act and regulations, is brought to the attention of the patient, and (b) the patient consents to entry of specified information (more than what Medicines Act and Regulations require) into a national database, on which the dispensing of codeine in the past 6 months to him/her would be visible to all participating pharmacies. The information pertaining to the Act is not kept in this national data base but in the pharmacy records as is required by the law.

The Codeine Care project will provide to participating pharmacies the requisite forms and notices [Annexures "A" and "B"]. Failure to obtain consent would mean that the collection of the information and the sharing thereof with other pharmacies would be unlawful and may be challenged.

4.3. Access to Registry, layers of access (visibility), access via PAIA

Every participating pharmacist has the right to enter data into the Registry, as per the data fields outlined above. The data as is required by regulation 11 is more invasive than that required by the Registry, which does not require any name or address and where the identity number is stored and used by the program, but not seen by any person or entity.

Participating pharmacies will only see the "history" section if a patient had already been entered into the database. A pharmacist can enter the ID numbers of his/her patients and obtain a report on purchases of codeine for the previous 6 months. The identity number is used to call up the patient's history and is not included on the information visible on the screen, nor on the report. The pharmacist will also be able to see if the patient has consented to participate or whether they are a new patient and require consent.

The Pharmaceutical Society of SA's Community Pharmacist Sector (CPS) has Drugwise as one of its services. As the custodian of this project, CPS will have access to the full database. The database de-identifies the individuals by allocating a random number to each patient so that no one besides the pharmacist can see a particular patient's history, in order to avoid non-compliance with POPI's provisions on further processing of information. The CPS's access and use of the database will be limited to aggregated data aimed at providing information to regulators to ensure greater safety in use and access of codeine by patients and others.

In instances where third parties request access to the database, or parts thereof, the provisions of PAIA will be strictly adhered to, which, in short means that third parties will not be able to access data of any person or persons.

4.4. Use of registry

The use of the Codeine Care Registry is limited to the objectives outlined above. The main purpose is to aid pharmacists in fulfilling their ethical duties to counsel and advise patients

on the safe use of medicine, and to ensure that they do not part-take in instances where patients obtain and possess codeine in contravention of the provisions of the Medicines Act.

The aim of the registry from a CPS perspective is to enable pharmacists to fulfill their legal and ethical duties, and to provide a platform for the sharing of information pursuant to the provisions of the National Health Act's section 15. Secondly, the CPS will use the information in a de-identified format for research purposes to lobby for legislative, regulatory and other changes, where needed.

4.5. Duration of data being kept

Although each data entry event will only be live for a period of 6 months, the database will be kept indefinitely, but then only to be used under circumstances envisaged by PAIA (persons requesting access) and for the CPS's research purposes outlined above.

4.6. Disclosures to third parties

As a matter of principle, the data in the Registry will never be disclosed to any third party, unless such third party is entitled to such information under circumstances clearly established as falling with the protective provisions of the PAIA. This will be in truly exceptional circumstances and will be handled on a case by case basis by CPS.

4.7. Correction of errors on Registry

In the instance of an ID number being incorrectly credited with a transaction, there is a mechanism for dispensing vendors and pharmacists to reverse a transaction, which can only be done by the program vendor (CPS's service provider) and on proper instruction and verification of the circumstances around the requested reversal. A record is kept of the reversal – i.e. what was reversed and by whom.

4.8. Disclaimers

CPS cannot be held responsible for any errors that appear on the system, and each participating pharmacist and pharmacy is responsible to ensure that:

- a) The required information is made known to all patients / consumers;
- b) The required consents are indeed obtained, entered into a separate consent register and reflected accurately on the Codeine Care registry;
- c) No information is entered, apart from a tick that no consent was provided, should a patient / consumer refuse to consent. In such cases patients / consumers must still provide the details they are required to provide under section 22A and regulation 11 (this is not recorded on the Registry, but separately as is required by law) and a refusal to do so means that they are not entitled to the medicines being dispensed to them; or, if information is entered, a tick to indicate that written consent has been obtained by the dispenser.

CPS cannot guarantee and do not warrant that the data is representative of all patients who have received codeine products.

CPS, its service providers or contractors cannot be held responsible for any harm, loss, damage or any adverse effect that may result due to a pharmacist participating in the Codeine Care Program, or entering data into the Registry, or by using the software or any

materials or information that are published as part of, or are related to, the Codeine Care Program.

4.9. Ownership of the Registry (data within the Registry)

The data of each individual is the property of that individual.

De-identified aggregated data belongs to the CPS.

4.10. Ownership of the codes and program on which the Registry is based

The program on which the Codeine Care Registry is entered, and all source codes, etc. are owned by CPS's various service providers.

4.11. Revenue generated by the Registry (advertisements)

Although provision is made for advertisements to appear on the program from which the Registry is run (only on mobile phones and scanning devices), such advertisements should not be construed as an incentive to any pharmacist to dispense or prefer such product over any other product that s/he may deem clinically appropriate and in the patient's interest.

Advertising space is sold by TrustaTAG Systems and such opportunities are promoted by TrustaTAG Systems and all proceeds of such advertisements are for the account of TrustaTAG Systems so as to ensure that the system reaches a cost neutral situation for CPS. A negotiated percentage of advertising revenue will be shared with CPS. Subject to any changes in the Memorandum of Understanding between TrustaTAG and CPS, CPS have control of physical advertising space (on the physical kiosks).

4.12. Update and maintenance

The update and maintenance of the respective systems is the responsibility of TrustaTAG Systems and of the specific participating vendors and of eGateway (Attune). Participating pharmacists can inform the developers of bugs or glitches by contacting support@trustatag.com or if relating to their dispensing vendor system by contacting their dispensing vendor or as related to the data hosting by contacting eGateway.

Suggestions on the program software of the data fields, etc. can be made to the CPS at execdir@saacp.co.za

4.13. Registry structures

The Codeine Care program is driven by pharmacy professionals through the CPS. In order to ensure compliance with all relevant ethical principles, and to ensure that appropriate guidance are provided to participating pharmacists, the following structures are created as part of the Codeine Care project:

4.13.1. Oversight Committee

The Oversight Committee shall ensure that all technical, legal, practical, stakeholder and communication matters relating to the project are dealt with in a fair and reasonable manner. The Committee shall comprise of members of CPS, PSSA, and SMASA. The Committee shall meet once a quarter as a minimum and may make recommendations to the relevant parties in relation to contracts that may be required to be entered into and/or recommend that certain decisions should be made in order to enhance the program, respond to certain queries, etc. Consideration may be had for establishing a Joint Venture or a legal structure that encompass the aforementioned entities in order to create a juristic body, so it be deemed to be necessary.

4.13.2. Peer Review Committee

The Peer Review Committee will review the dispensing practices of participating pharmacists, and highlight cases where there appears to be misuse or inadequate control. This Committee will guide all participating pharmacist who so request, or those where there might be misuse or inadequate control. They may, from time to time, issue Guidance to participating pharmacists and may raise matters, without identifying individuals, with the MCC or Pharmacy Council in order to ensure the safe use of codeine.

The members of the Peer Review Committee will nominated by independent- and corporate pharmacy groups and individual participating pharmacies. Nominees must be persons of extreme good standing in pharmacy circles, known for their knowledge, independence and integrity, and should not be representing any interests when serving on the Peer Review Committee. A fair process of nomination will be used, and appointment will be made by a joint Committee of the CPS and PSSA will be followed.

The Peer Review Committee will set its own procedures and meet as and when required, but at least twice a year after receipt of a half-year and Final Annual Report on the Program.