Executive Summary

Pharmacists are seen as the custodians of medicine and not merely traders in potentially harmful goods. The nature of the profession however suggests that there is always risk involved in the treatment of patients or consumers with medication; and it is the pharmacist’s responsibility to see that he/she applies his/her thorough knowledge to weigh up the risk/benefit ratio of each individual treatment regimen for each patient or consumer and advise the patient/consumer accordingly.

In particular regard to over-the-counter (OTC) medication, the onus rests almost entirely on the shoulders of the pharmacist to ensure that the patient/consumer is given the correct advice and is recommended the most suitable medication for the particular ailment from which he/she suffers.

When a pharmacist dispenses potentially addictive or harmful medication such as products containing codeine, the responsibility he/she carries increases dramatically. The keeping of a Schedule 2 record or register is compulsory for all pharmacists in South Africa. It however is limited in the extent to which it curbs the potential abuse and misuse of certain drugs and as such it is suggested that it is a somewhat futile exercise. The information recorded is only useful for repeat sales of a product in that particular pharmacy. Other pharmacies throughout South Africa do not benefit in any manner or form from the information, nor do the authorities ever use the information collected. The entire process is circumvented by individuals addicted to these products or substances supplying false information to the pharmacist and by ‘pharmacy-hopping’ where they obtain their ‘stash’ of medication from different pharmacies with the pharmacist been none the wiser to a previous or future purchase elsewhere. Even in the event of a pharmacist establishing the addiction dependence of an individual, little can be done in the form of intervention other than the refusal of a sale. Unfortunately the individual subsequently merely obtains the product to satisfy their need from another pharmacy or from a variety of pharmacies.

It has been observed that the up-scheduling of medication does little to stop the abuse of drugs from occurring as is evident from the up-scheduling of d-nor-pseudo-ephedrine in an attempt to prevent
the manufacturing of ‘tik’ (crystal methamphetamine) and the abuse of the drug itself. This up-scheduling has had a huge financial impact on pharmacies and more importantly it has taken away the effective treatment of obesity (of which South Africa is admittedly burdened) by responsible self-medication; whilst done little or nothing to prevent the manufacture of ‘tik’ and abuse thereof.

The up-scheduling of codeine containing products 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. It is suggested that this step could take place solely because of the perceived dependence producing potential of the drug. If this was to occur, millions of people in South Africa would be deprived of a useful self-medication option to treat minor ailments due to the social problems of a minority group. These individuals would be forced to seek help from their doctor and as such would firstly further burden an already over-burdened healthcare system and in addition would need to pay the doctor’s consultation fee in order to obtain a prescription for an OTC codeine containing product.

The South African Community Pharmacist Sector (CPS) of the Pharmaceutical Society of South Africa (PSSA) will illustrate the effective control that pharmacists themselves can implement in order to eliminate or at least dramatically decrease the abuse and misuse of codeine. It should be noted that additional substances with similar abusive potential can be controlled in the same fashion. As such the Codeine Care Project is born.

**Introduction – Codeine Care Project**

The project undertaken to ensure control of, in this case codeine containing products, will expand the use of the PharmaTAG™ compliance and counterfeit detection system. This system was presented to CPS EXCO earlier this year and was accepted and signed off.

The Codeine Care Project allows pharmacists and dispensing doctors to utilize 2D barcodes on packs in order to conduct patient usage checks via an ordinary mobile phone, scanning kiosk, or through a web page on their existing dispensing system. All three ‘vehicles’ (mobile phone, kiosk and computer) can be used interchangeably or just one or two of the three can be utilized. It is entirely up to the pharmacist or pharmacy concerned.

The Codeine Care Project is envisioned to be a ‘shared’ project between various role-players namely pharmacies (independents and corporates), the pharmaceutical manufacturing industry, the police’s narcotics department, state and private run social welfare organizations, and the regulators. The Project will provide information to the Department of Health, the Medicine Control Council, the South African Pharmacy Council and any other stakeholder deemed appropriate by the regulators to manage decision making with regard to the dispensing and sale of codeine containing products and the abuse pattern and potential thereof. It is to be noted that the compliance to regulations such as The Protection of Personal information Bill (POPI) is to be ensured.

By way of background, CPS consulted with the Australian Pharmacy Guild during a Pharminterkom meeting in Brisbane, Australia during August of 2010 for the rights and use of their software to run their ‘Project Stop’, to be utilized in South Africa. The investigation resulted in the conclusion that it would not be affordable for CPS to roll out this project in South Africa. Alternatives were investigated and work was done to come up with a similar model for South Africa which is cost effective and as far as possible self-sustaining in that it would not increase cost for the pharmacist and more importantly
for the patient/consumer. The model was devised and has evolved through collaborative work between CPS, TrustaTAG Systems (an information technology company active in the healthcare industry) and various software companies active in the South African pharmacy arena. In addition, consultation with the manufacturers manufacturing and selling codeine containing substances was performed.

**Role Players**

In order to understand how the system works it is important to understand the products provided by the various companies which form the backbone of the Codeine Care Project.

**PharmaTAG™**

PharmaTAG™ is a product of TrustaTAG Systems and forms a patented system that provides unique 2D TAGs printed on packs which enable consumers to use their own mobile phones to simply scan a TAG on a product, carton or strip pack and then receive detailed, enhanced, legally compliant, pre-approved information on the specific product in question i.e. in this case the Patient Information Leaflet (PIL).

**What is 2D Barcode?**

- A 2D barcode is a mechanism or vehicle by which, through the scanning of a TAG using a mobile phone with a very basic camera (a basic feature phone or smart phone can be used), unlimited information (in this instance the PIL and codeine warnings) can immediately be made available to the user’s phone in the language of their choice (the language offering is limited to the language offering provided by the pharmaceutical company in question).
- Note that nine out of 10 phones sold in South Africa are capable of scanning a TrustaTAG™.
- Once the 2D barcode is attached to a product, the barcode never changes, whilst the PIL and accompanied legally compliant information can be instantly updated as required.
- The 2D barcode is printed on the printed packaging components of the product in the same manner as that of the traditional 1D barcode that all products today display.
- It is to be noted that a 1D barcode however requires expensive readers to read the data attached to them, whilst, as discussed, the 2D barcode only requires a basic mobile phone.
- Whilst printing instruction is very simple, TrustaTAG Systems does provide a comprehensive printing guide to all clients.

Manufacturers of codeine containing products in South Africa have agreed to fund the initial customization of the existing systems as part of their social responsibility program. The on-going maintenance of the system will be self-funding through various sponsorship activations. Payment for the kiosk scanner build will be sought from other manufacturers of codeine. This too will be a one-off expense.

**Dispensing Vendors**

Dispensing vendors are those companies who currently supply and manage the dispensing software systems within pharmacies. There are a small handful of such vendors in South Africa who service the pharmacy industry. These vendors have been approached and integration of the Codeine Care system
has been discussed and common ground found. TrustaTAG Systems will provide the interface to these vendors in order for them to integrate into their existing system so as to ensure a smooth, easy and cost effective surfacing of the technology on an existing computer as an additional tab so to speak. The cost of this integration which is minimal, it is envisioned, will be borne by the vendors in exchange for use of the TAGs in pharmacies so as to ensure the pharmacist has the PIL information at hand at the point of dispensing. These dispensing vendors will print the TAG on a label affixed to a dispensed pack.

Aim of the Project

The objective is to instil a culture of responsible use of medication amongst the public and medicine providers (pharmacists, doctors, clinics, nurses, etc.). Potential abusers should be identified, screened, consulted and referred for treatment. Intervention by the SAP might be necessary where a crime is suspected and by social welfare organisations for the treatment and rehabilitation of abusers of such drugs. CPS will work to engage with these stakeholders to ensure buy-in.

Problem Statement

The problem that is currently faced is the lack of support and intervention in the discovery of a drug abuser addicted to codeine, amongst other drugs. The discovery of such a person relies almost entirely on serendipity as there is no effective communication structure between the authorities and suppliers in the diagnosis and treatment of such persons. The Codeine Care Project will establish the buy-in of pharmacists (across the spectrum) and patients/consumers alike in the implementation thereof and the successful identification and rehabilitation of abusers whilst keeping patient information confidential at all times. Again, it is to be reiterated that adherence to all laws in this regard be ensured and undertaken.

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.

It is to be further noted that whilst the same TAG is used to access both the PIL and the validation and tracking tool, only the pharmacists/pharmacist assistant will have access to both offerings. The consumer/patient will not have access to the validation and tracking tool.

Materials and Methods

The model developed is based on the premise that a South African ID number will be made available at the point of dispensing.
Existing claims processing patient history will be used to deliver a Codeine Registry product that is closely aligned with the pharmacy’s daily workflow process – all within the confines of that which is permitted by law.
CPS will create a management company which will incorporate but not be limited to the following:
   a. Creation of a Code of Conduct in collaboration with the regulator to be signed by all related parties.

   b. A mechanism will be created that will provide amongst others a confidentiality arrangement between pharmacist and patient/consumer with informed consent used for referral and treatment in order to ensure compliance to POPI. The patient/consumer will be alerted to their rights in terms of collection of personal data and can opt-in or opt-out with the knowledge that to opt-in allows purchase of codeine containing products but to opt-out prohibits purchase whether prescribed or not.

c. Assisting providers, where required in the management of these products.

d. Working with the Department of Health on a national and local level/SAPS/social workers where patients/consumers are identified as abusers. This will be done in a highly confidential manner and to which the Code of Conduct should be strictly adhered.
e. Provide pharmacists the opportunity to purchase scanning kiosks, where required.

- Warnings in relation to codeine are those stipulated by the regulator.

- Pharmaceutical companies will be advised by CPS as to the urgency of putting TAGs onto products and providing the PIL information behind the TAG. TAGs will be provided by TrustaTAG Systems as will access to the ‘codeine template’ behind the TAGs.

- It is noted that the ITG is seeking to engage MCC on a blanket approval for 2D barcodes on packs.

Proposal

Pharmacy Application

How does it work?

- For all codeine containing products, TrustaTAG Systems will link a rules-based validation/checking and tracking tool module to the product TAG of which only pre-approved healthcare professionals have access.

- A pharmacist/pharmacist assistant simply downloads the TAG reader onto their phone, if their phone is not pre-loaded with the TAG reader, and simply scans the product in question. The pharmacist can alternatively use his/her scanner kiosk or computer to follow the same process.

- The registration process is facilitated by the scanning of a registration TAG (provided by TrustaTAG Systems).

- The registration landing page will allow for a once off registration process by the pharmacist/pharmacist assistant.

- This registration process will be secured in a manner that will not allow a patient/consumer to masquerade as a pharmacist/pharmacist assistant by validating credentials submitted with the appropriate authorities.

- The system is able to recognise a mobile phone device ID or a scanning kiosk ID and the next time this device (mobile phone/kiosk) is used to scan a codeine containing product, it will automatically display the validation/checking and tracking offering.

- It is to be noted that every single mobile phone on the planet has a different device ID and TrustaTAG Systems recognises and stores the scan. The same applies to the scanning kiosk.

- The system, through the scan, will immediately pick up and display the name of the product e.g. Syndol 10s, Sinumax Co 20s, Lenapain 20s, etc. and calculate the amount of codeine in each product and display accordingly.
In the case of the dispensing computer, a drop-down facility is featured with all codeine containing products. This allows for pharmacies who do not wish to use a scanner or mobile phone but would instead prefer to continue to use their existing dispensing computer to access the system. This also allows for the validation/tracking of those products which do not display a 2D barcode. The 2D barcode is pack is however encouraged as without this element the system is less robust.

In addition, the system will display a text box into which the pharmacist/pharmacist assistant must provide the patient/consumer’s RSA ID number followed by a simple click to submit. In the case of corporate pharmacies with loyalty cards, a loyalty card can be used as they already have ID numbers captured. The card number will be linked to an ID number and as such will update the central database.

The system will revert with the consumption history of Syndol, Sinumax Co, Lenapain or other codeine containing products purchased over a prescribed period of time by that individual and will capture the new purchase should the purchase proceed.

It is not necessary for a consumer to actually show their RSA ID or drivers licence but rather to simply provide their RSA ID number or in the case of the corporate pharmacies, a loyalty card. The system has rules built into it which will mitigate a consumer providing false ID numbers. In addition, allowances have been made for foreign nationals who won’t have a RSA ID number. Guidance in this regard will be sought from the South African Pharmacy Council and Medicines Control Council as to whether an actual ID, passport or drivers licence must be provided. It is however suggested that the requirement of providing an ID number or passport number in the case of foreign nationals is built into the regulations to ensure compliance.

The necessary Consumer Protection Act requirements in terms of permission gained and terms and conditions supplied in terms of keeping patient/consumer and healthcare professional data will be adhered.

Security of the 2D Barcode

The 2D barcode system is hosted in a secure cloud platform, providing on-demand compute, storage, networking and content delivery capabilities to host, scale and manage web applications on the internet through multiple data centres. These data centres ensure 99.9% uptime for all services.

In addition to being hosted in an extremely secure data centre, the system provides several different levels of security, ensuring that only expressly authorised personnel (with final sign off from the Responsible Pharmacist) can modify the company’s PIL data.

The system also provides for multiple levels of approval before publishing of the PIL, and extremely detailed tracking of each and every event, ensuring that a detailed audit of approvals and changes is available to companies securely and in real-time.
• A security white paper is available on request.

**Security of the Data Base**

• The data base is also hosted in a secure cloud platform, providing on-demand compute, storage, networking and content delivery capabilities to host, scale and manage web applications on the internet through multiple data centres. These data centres ensure 99.9% uptime for all services.

• Only those authorised by the South African Pharmacy Council will have access to the database and to the reports provided.

**Training of the General Public and the Healthcare Professional as on how to use the 2D Barcode**

• Pharmaceutical company representatives will train pharmacists and other appropriate healthcare professionals on how to download the Microsoft scanner and how to scan the 2D barcode. Additionally literature and website access to instructions will be provided. It is envisioned to also provide a DVD of the process.

• The 2D barcode is not new and there are in excess of six billion Microsoft TAGs in use on a daily basis around the globe.

• Pharmaceutical companies will seek to introduce the concept via the pharmacist to the consumer and via an educational campaign comprising various elements.

• 2D barcode scanning awareness is endemic with the younger generation.

• PSSA, CPS and Drugwise will have to embark on a campaign to educate the pharmacist regarding the checking and validation process, and the consumer regarding having to produce an ID number or loyalty card before purchase is permitted.

• It is recommended that this is done in collaboration with the pharmaceutical companies selling codeine containing substances and with SMASA, PIASA, PHARMISA, NAPM, etc. It is to be noted that SMASA has already agreed to partner CPS in this regard.

• In addition, it is planned to consult and advise Narcotics Anonymous, Central Drug Authority and United Nations Office on Drugs and Crime (UNODC) re the initiative.

**Cost to the Pharmacy**

• No direct cost is incurred by the pharmacist besides that of the cost of internet access.
• The Microsoft TAG reader is a free app.
• Many mobile phones come pre-loaded with the app.
• When the app is however not pre-loaded, the app must be downloaded. This once off download will result in a small data cost. The cost to download the app using the most expensive prepaid data = 10% of the cost of a single SMS.
• When the pharmacist scans a TAG, there is a very small data cost (similar to that of accessing the likes of Facebook). The cost to scan a single TrustaTAG™ = R0,01 (based on most expensive prepaid tariff).

It is to be noted that, should the pharmacist wish to purchase a kiosk scanner to place on his/her counter top, there will be a cost associated to this. These scanners will be provided to CPS at cost and they will in turn sell them onto pharmacies with a small mark-up which will enable CPS to cover costs. As noted the initial build will require funding for which industry will be approached.

Cost to the Consumer

• The Microsoft TAG reader is a free app.
• Many phones come pre-loaded with the app.
• When the app is however not pre-loaded the app must be downloaded. This once off download will result in a small data cost. The cost to download the app using the most expensive prepaid data = 10% of the cost of a single SMS.
• When the consumer scans a TAG, there is a very small data cost (similar to that of accessing the likes of Facebook). The cost to scan a single TrustaTAG™ = R0,01 (based on most expensive prepaid tariff).

Technical Implementation

1. TrustaTAG Systems will create a secure interface with which existing software vendors will integrate to include the Codeine Care functionality in their systems. This is similar to the existing eligibility functionality used in pharmacy. The advantages of this approach is that:
a. No vendors will be disadvantaged in any way from accessing the data.

b. Vendors can access Patient Information Leaflet data as well as 2D barcodes to print onto dispensing labels which further protects pharmacists from any legal compliance issues.

2. TrustaTAG Systems will further expand their existing Patient Information and Compliance modules to allow dispensing doctors and pharmacists to register certain mobile devices as devices for querying the Codeine Care System. The advantage of this approach is that:

   a. The database can be accessed only by authorized personnel in any location in South Africa, regardless of electrical power constraints imposed by other systems that require database interrogation through a personal computer.

3. TrustaTAG Systems will further expand their systems to include a low cost 2D barcode scanning kiosk as an option for pharmacists to place in their Schedule 2 and dispensing environments in order to speed up central database checks. These kiosks will be exclusively sold and maintained through CPS, with TrustaTAG Systems providing tier two support. This will require a 2D barcode to be on pack and as such manufacturers are requested to provide this vehicle.

4. The pharmacy will need to be able to populate the Codeine Care module with the following information irrespective of it being a Schedule 2 or dispensary purchase:

   a. Patient’s RSA ID number. Mask checking will ensure that the correct format of unique patient identifier is loaded. Where RSA ID is not available, accommodation can be made to enter a passport number.

   b. Patient’s surname – a combination of RSA ID and surname will be used to populate the patient history file and then match the eligibility to existing history.

   c. Patient’s first name.

   d. Service date for calculating intervals between purchases (this is generated automatically but can be overridden by the pharmacist if so required, with the override being stored in the audit log).

   e. Possibly a script number unique to each claim to assist in preventing duplicate submissions.

   f. The NAPPI code for the product. This is generated automatically by the system through use of the TrustaTAG Systems’ 2D barcode.

   g. The quantity of the product dispensed in order to track broken pack quantities calculating the amount of codeine in the product.
h. Days of therapy to be calculated on the system based on the quantity.

i. The exact nature and number of fields to be populated will be determined by a steering committee appointed by CPS.

5. Purchase history will be sent to TrustaTAG Systems for Drug Use Rules and Patient History Verification. At the outset, no checks will be rejected as this information is required in order to gather information to populate the patient history file.

6. A set of Risk Message Responses (RMRs) will be sent back to the pharmacy in order to warn the user of the eligibility results. These may include:

   a. Patient not previously registered – gather new data.

   b. Drug quantity error (identifies data entry errors in claiming).

   c. Refill too soon (patient has had too many codeine claims within a pre-defined period of time).

   d. Therapeutic duplication (where more than one codeine containing product is dispensed).

7. Real-time, monthly and quarterly sets of reports can be generated. Access to this data is strictly controlled and administered by CPS.

**Management Implementation**

1) CPS will create a Code of Conduct for the supply of codeine related products.

2) Providers will be required to agree to the following:

   a) Supply information to the national patient record for all codeine related sales.

   b) All sales to be done under the supervision of a qualified dispenser or pharmacist.

   c) Inform patient of national record and input all details needed from the patient.

   d) Counsel the patient on abuse if abuse is suspected.

   e) Notify CPS on detection of abuse.

   f) Assist the CPS with all information regarding the buying and selling of such products.

   g) Assist the social workings in helping codeine abusers.

3) Creation of National Helpdesk

   a) Make contact people available who can assist the consumer, provider, manufacturer and suppliers with queries.

   b) Liaise with social workers on abusers.
c) Creation of compliancy reporting per provider, made available to all relevant parties including MCC and Pharmacy Council.

Rollout

1. A national rollout of the Codeine Care Project will be initiated post the Pharmacy Council Conference in June (see Launch below). This rollout should include the implementation of the Code of Conduct. Pre the initial rollout a pharmacy software vendor rollout will occur which allows for installation and training of all parties.

2. Once the rollout is completed, the data flow back to CPS and other partners will be available real-time to all authorised parties.

3. Setup and maintenance of the CPS management company is to take place.

4. National Helpdesk for queries is to be set up.

5. IT infrastructure to be installed.

Results

1. Measurement of provider compliancy in:
   a. Supply of codeine related products.
   b. Adequate supply of required information.
   c. Abuse of codeine by patients.
   d. Over-riding of the system in unique cases.

2. Measurement of manufacturer and supplier compliancy in:
   a. Total market supply versus actual sales from providers.


Launch

The Codeine Care Project will be launched at the 1st National Pharmacy Conference which is being held at Sun City in June 2013. It is envisioned to designate a stand-alone stand to Codeine Care which will be manned by CPS and SMASA. SMASA’s PR agency has been briefed to present a proposal to SMASA which will in turn be shared with CPS. The cost of this will be borne by SMASA’s retainer fee paid to the PR agency. Adcock Ingram has agreed to cover any additional costs as they have the largest % of codeine containing products in South Africa.
Public Relations

As mentioned above, SMASA has made available their PR agency. In addition, marketing experts from the manufacturers involved have been made available to assist. SMASA will collate the press releases and the likes and, in collaboration with CPS, ensure roll-out. All work will be signed off by CPS. It is to be noted that due to Microsoft’s TAG technology being utilized in the Codeine Care Project, Microsoft have kindly agreed to participate in PR. The PR agency and SMASA will approach Microsoft to assist in marketing material for the launch.

Discussion and Conclusion

This project has enormous advantages for all involved, especially the patient/consumer whose interests will be served by protecting them from unknowingly getting involved in an addiction problem. The pharmacists will be empowered to fulfil their role of custodians of medicine with the help of modern technology. The pharmaceutical industry will benefit by knowing that their products are used for the therapeutic purpose for which they are indicated. The South African Pharmacy Council will benefit by knowing that the public is protected from exploitation (even if by default of ignorance from the provider).

In addition it is envisioned that this project will buy back much needed social capital for pharmacists. Further the project has already captured international interest. The International Pharmaceutical Federation (FIP) has expressed an interest in being kept informed of all progress. A slot to present at the 2014 FIP conference is being sought.

It is to be noted that buy-in and total co-operation has been obtained from the various corporate pharmacy groups.

It is to be further noted that this system can be rolled out to dispensing doctors and the State in time if deemed appropriate.