The Stakeholders Forum on Codeine Care and Medicines with a potential for overuse, misuse and abuse

28 February 2020

INDUSTRY PROPOSAL FOR THE CONTROL OF SUPPLY OF CODEINE-CONTAINING MEDICINES SOLD AS PHARMACIST INITIATED THERAPY (PIT)

Executive summary:
The signatories to this collaborative industry proposal believe that the proposed, revised Codeine Care Initiative (CCI) detailed below, will allow for the effective management of codeine-containing preparations. The proposal includes all supply chain stakeholders from manufacturer right up to patient point-of-sale. The secured data collected through this initiative from all stakeholders would, for the first time, provide regulators and authorities with relevant information on where potential risks lie within the supply chain of codeine-containing medicines (or any other substance with a potential for overuse, misuse or abuse).

Background:
Currently, several countries supply codeine-containing medicines as Pharmacist Initiated Therapy (PIT) including the United States of America, United Kingdom, Canada, Germany and South Africa. Although there are limited statistics available[1], it is common knowledge that these products are at times overused and misused by certain patients (<2%)[2] who acquire the medicine through deception and/or pharmacy-hopping. However, overuse and misuse often occur through no intentional fault of the patient or pharmacist due to the lack of access to a full patient medication history. Research shows that pharmacy users used between 2 and 17 different pharmacies per year to obtain prescription medications[3].

A collaboration of pharmacists across sectors, including corporate and independent community pharmacies, institutional, manufacturing, wholesale and distribution pharmacies, plus other stakeholders such as dispensing software companies and professional associations met to discuss the codeine dilemma. This Forum of stakeholders who are committed to quality pharmaceutical care for the public share the concern about the continued overuse, misuse and abuse of codeine-containing medicines, including unintended overdosing by duplication of different types of codeine-containing medication. This is largely due to the relative ease with which these medicines can be bought from different pharmacies, despite the Regulations which ensure their supply by a pharmacist and the use of a Schedule 2 register, as there is currently no single integrated dispensing system or record mechanism that can calculate national consumption of medication for any given patient regardless of the pharmacy(ies) purchased from.

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[1] South Africa Demographic and Health Survey 2016 Pages 313 – 316
https://www.samrc.ac.za/reports/SADHS2016

[2] South Africa Demographic and Health Survey 2016 - statistical tables on pg. 327 and pg. 328,
https://www.samrc.ac.za/reports/SADHS2016

[3] Multiple pharmacy use and types of pharmacies used to obtain prescriptions.
https://www.ncbi.nlm.nih.gov/pubmed/24091483

There are a wide range of codeine-containing products for different ailments varying from treatments for colds and flu, sinusitis, coughs, sports injuries, headaches, toothache and other painful conditions. A patient may require a cold and flu preparation, plus a cough syrup and then add pain medication without realising that they have in fact tripled the recommended dosage of codeine. As already mentioned, patients access pharmaceutical care at multiple pharmacies and a key failing in the current healthcare system is the lack of a national sector-wide database, which would inform pharmacists at the point of dispensing, of the potential overuse, misuse, abuse or duplication of a product recently dispensed to or currently used by a patient. Without sight of a complete history of dispensed codeine-containing products irrespective of place of purchase, it is impossible for the pharmacist to pick up these duplications which can lead to overuse, overdosing and may also result in addiction and subsequent abuse.

As a forum of concerned pharmacists, we propose a mechanism we believe will mitigate the overuse, misuse and abuse of medicine or scheduled substances such as codeine-containing medicines sold as pharmacist-initiated therapy (PIT) only in pharmacies across South Africa and importantly, protect patients from harm by accidental duplication of medication. This mechanism involves the establishment of a central database to facilitate appropriate action by persons selling medicines or scheduled substances with an overuse, misuse or abuse potential and protect patients from harmful duplication of therapy.

We welcome the investigations and commitment by both the South African Health Products Regulatory Authority (SAHPRA) and South African Pharmacy Council (SAPC) on the feasibility of introducing a mechanism to better protect the public of South Africa. We welcome the invitation from SAHPRA to submit proposals for the amendment and strengthening of the intervention and to make legally enforceable proposals regarding alternatives to re-scheduling codeine to prescription only. At a meeting of SAPC members on 13 February 2020 the following statement was released by Council: “Council supports initiatives to control the overuse, misuse and abuse of medicines and pending the findings of the SAHPRA investigation will follow its normal processes to address this matter.”

The proposal:

A collaboration of key industry stakeholders including manufacturers, wholesaler/distributors, institutional and community pharmacists, professional associations and dispensing software companies have met to produce the following proposal.

1. Institute a monitoring, reporting and education system around the supply of codeine-containing medicines from manufacturer through wholesale/distributor to pharmacy at-point of supply to the patient as Schedule 2 medicines. This monitoring system will include a mechanism which flags potential misuse, over-supply and unintended overdose. Sanctions, including capping of supply quantities, cessation of supply and reporting across the industry will also apply.
2. Manufacturers will continue to manage and discard substandard products not fit for market through Good Manufacturing Processes (cGMP).
3. The current codeine care project which integrates across all major dispensing systems will be upgraded to include data input along the entire supply chain with reporting at each level. These reports will include sales from;
    - manufacturer to wholesale/distributor,

- wholesale/distributor to healthcare professionals in community/institutional pharmacy including dispensing doctors, and
- community/institutional pharmacy to de-identified patient

and will be submitted to SAHPRA and SAPC on request. These reports can be customized to the needs of SAHPRA/SAPC.

In the event where diversions are identified in the system, the respective stakeholders will monitor and take reasonable precautions to discourage, and necessary steps to mitigate, risk. Where risks are suspected, the Pharmaceutical Crime Task Group[4] will be notified to intervene as they are adequately posed to address matters such as diversion from regulated channels.

4. Patient information will only be available at the point of dispensing by a pharmacist. Patients' information is "de-identified" in all other reports.
5. We recommend SAHPRA to include a boxed warning to be printed on the packaging of all codeine-containing medicine for example.

> **"Exceeding the prescribed dose, together with prolonged and continuous use of this medication, may lead to dependency and addiction."**

Common warning pictograms could be included on cartons of all codeine-containing products in order to ensure comprehensive education of the public inclusive of people who are illiterate.

6. SAPC to publish and enforce a minimum standard for the supply of medicines with a potential for misuse, overuse and abuse (see Annexure A) to tighten up supply by a pharmacist only through an electronic tool.
7. In addition, SAPC must include compliance questions in the current inspection questionnaire to allow monitoring of order quantities and dispensing records around these identified medicines. Non-adherence to monitoring of the supply of codeine-containing medicines must result in disciplinary action by SAPC.
8. Create a support and referral framework to assist members of the public who may require assistance to reduce or stop using these medicines including where to find addiction support and relevant helplines.
9. Education, training and continuing professional development (CPD) for healthcare professionals to help identify and manage members of the public who are struggling with addiction. The nine Schools of Pharmacy will be requested to ensure including these training in their undergraduate academic programs.
10. Public awareness programs, specifically designed to cater for different demographic groups (such as the youth) will be designed around responsible use of codeine containing products.
11. Other licensed sellers of medicine and schedule substances such as dispensing doctors and nurses, must also be enforced to report order and dispensing data to this mechanism.

SAHPRA CONCERNS:

The Stakeholders Forum noted several concerns expressed by SAHPRA in the invitation regarding the previously proposed Codeine-Care Initiative (CCI) as a tool to identify and curb the illicit abuse of codeine-containing products. Since the initial launch of the initiative, a lot has changed in the legislative healthcare environment which we would like to bring to your attention.

[4] The Pharmaceutical Crime Task Group is a group formed to mitigate crime in the pharmaceutical space. This group's membership extends to the South African Police Service (SAPS), the Hawks, Port Health, SAHPRA, SAPC, Companies and Intellectual Property Commission (CIPC), among others.

<u>SAHPRA concern</u>: The requirement for purchasers to submit information not required in terms of the existing law.

We believe that the law does make provision for the submission and publication of information as is contained in the following pieces of legislation *(our emphasis in bold for your convenience)*:

Medicines and Related Substances Act, 101 of 1964:

22B. Publication of information relating to medicines, Scheduled substances, medical devices or IVDs.

(1) Notwithstanding the provisions of section 34 the Authority may, if it deems it expedient and in the public interest, disclose information in respect of the prescribing, dispensing, administration and use of a medicine, Scheduled substance, medical device or IVD.
[Subs. (1) substituted by s. 15 (b) of Act No. 14 of 2015.]

(2) The Director General may publish the information referred to in section (1) or release it to the public in a manner which he or she thinks fit."
[S. 22B inserted by s. 10 of Act No. 94 of 1991, substituted by s. 23 of Act No. 72 of 2008 and amended by s. 15 (a) of Act No. 14 of 2015.]

General Regulations:

40. Vigilance

(1) A person who has applied for registration of a medicine in terms of section 15 of the Act, a holder of a certificate of registration in respect of a medicine or Scheduled substance, or a holder of a license in terms of section 22C(1)(b) **must inform the Authority**, in the manner and within the time frame as determined by the Authority, of any –
   (a) new or existing quality, **safety** or effectiveness concerns related to any medicine or scheduled substance, including but not limited to adverse drug reactions; and
   (b) risk management activities associated with paragraph (a).

(2) A person who has applied for registration of a medicine in terms of section 15 of the Act, a holder of a certificate of registration in respect of a medicine or Scheduled substance, or a holder of a licence in terms of section 22C(1)(b) must maintain or have access to records of the reports and case reports referred to in subregulation (1) above.

(3) A health care provider, veterinarian or any other person should inform the Authority, in the manner as determined by the Authority, of any –
   (a) suspected adverse drug reactions; or
   (b) **new or existing safety, quality or effectiveness concerns**, occurring as a result of the use of any medicine or scheduled substance.

(4) Any person referred to in subregulation (1) must-
   (a) **whenever requested by the Authority, conduct a concise critical analysis** of the safety, quality or effectiveness of the medicine or Scheduled substance submit the results thereof to the Authority within a specified time frame;
   (b) in the case where, after receipt of the results referred to in paragraph (a), the Authority determines that the medicine or Scheduled substance may not be safe to use, submit to the Authority, if required to do so –
      (i) case reports of all adverse events or suspected or actual adverse drug reactions in respect of the medicine or Scheduled substance;
      (ii) where applicable **the usage figures** of the medicines or Scheduled substance, as well as periodic safety update reports and performance studies; and
      (iii) **any other data as requested by the Authority**; and
   (c) keep and maintain or have access to records of the adverse event data in respect of their medicines or Scheduled substances.

(5) Subregulations (1), (2) and (3) also apply in the case of all categories of unregistered medicines sold or used which are not subject to registration or in terms of sections 14(3), 14(4), 15C, 21 and 36 of the Act.

National Health Act, 2003 section 15(1)

A health worker or any healthcare provider that has access to the health records of a user may disclose such personal information to any other person, healthcare 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.

35. Prescription book or permanent record

(1) A prescription book or other permanent record in respect of Schedules 1, 2, 3, 4, 5 and 6 substances shall be kept in **hard copy or electronically** on all premises where such substances or medicines are sold or dispensed.

(2) In the case of Schedule 1 medicines and substances sold by any person other than a manufacturer or wholesaler, a prescription book or other permanent record contemplated in subregulation (1) shall contain the following particulars:
   (a) The name of the person to whom it was sold;
   (b) the name and quantity of the substance or medicine; and
   (c) the name of the pharmacist, pharmacist intern or pharmacist's assistant who sold it.

(3) In the case of Schedule 2, 3, 4 and 5 medicines and substances sold by any person other than a manufacturer or wholesaler, the prescription book or other permanent record contemplated in subregulation (1) shall contain the following particulars:
   (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, **identification number** and address of-
      (i) the patient;
      (ii) in the case of a prescription for a neonate, the name, identification number and address a parent or guardian; or
      (iii) in the case of a prescription issued by a veterinarian, the person to whom the medicine or scheduled substance was sold;
   (e) where applicable, the name of the medical practitioner, dentist, veterinarian or any other authorised person who issued the prescription; and prescription reference number, which is the reference number or unique identifier assigned at the point of dispensing.

(4) The manufacturer or wholesaler shall keep an accessible permanent record of sales of Schedule 2, 3, 4, 5 and 6 medicines and substances in the form of invoices that shall reflect the-
   (a) date and transaction of the sale;
   (b) name of the medicine;
   (c) name and address of the purchaser;
   (d) quantities sold;
   (e) batch number; and
   (f) price at which the medicine was sold.

(5) A prescription book or other permanent record contemplated in this regulation shall be kept for a period of at least five years after the date of the last entry made therein.

Conclusion: With reference to the National Health Act, we believe that such sharing (as part of the definition of "processing" of personal information) is "necessary" for the "legitimate purpose" of a

pharmacist's duties towards a patient, and definitely falls within the "ordinary course and scope" of such duties, as set out in the Code of Conduct.
With the publication of the General Regulations in 2017, the provision of the patient's identification number on prescriptions, either from an authorized prescriber or through pharmacist-initiated therapy, became a legal requirement.

SAHPRA concern: The reliance on identity documents, which some legitimate purchasers may not have at hand or be in possession of.

With the publication of the General Regulations in 2017, it became compulsory to indicate the patient's identification number on prescriptions and in the prescription book:

General Regulation:
33. Particulars which must appear on prescription for medicine
(3) A prescription shall at least state the following:
(a) The name, qualification, registration number with the relevant statutory health council and address of the prescriber;
(b) the name**, identification number** and address of-
(i) the patient;

35. Prescription book or permanent record
(3) **In the case of Schedule 2, 3, 4 and 5 medicines and substances sold** by any person other than a manufacturer or wholesaler, the prescription book or other permanent record contemplated in subregulation (1) shall contain the following particulars:
(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**, identification number** and address of-
(i) the patient;

According to the General Regulations[5] to the Medicines and Related Substances Act, identification number is defined as the number drawn from a birth certificate, passport, valid driver's license, South African identification document or any other relevant document issued by the Department of Home Affairs.

Conclusion: Identification can be confirmed in multiple ways and should be provided at the time of dispensing, similar to procedures in banks, airports and at facilities such as police stations, courts, etc. In the interest of patient and medication safety, the patient's identity must always be confirmed.

SAHPRA concern: Potential breaches of the Protection of Personal Information Act (4 of 2013).

Protection of patient's information and maintaining confidentiality is already enforced by SAPC:

Good Pharmacy Practice (GPP) Rules:
2.7.3.6 Confidentiality
No information may be divulged about the affairs of any person obtained in the course of dispensing a prescription except to a person authorised to have access to such information and acting within his/her lawful jurisdiction. More information regarding this minimum standard can be found in the Code of Conduct as published by Council in rules.

[5] National Department of Health. 2017. General Regulations. GN 859 of 25 August 2017. Pretoria: Government Printers.

2.8 Minimum standards for patient information and advice

Patient information is of vital importance in the correct use of medicines. Lack of information and misunderstanding contribute to the failure of the therapy, thus wasting resources and adding to the costs of care.

2.8.1 Purpose

Patient information must respect patient autonomy, improve health and enhance the outcome of medical treatment by:

(a) empowering consumers to make informed decisions about their medical treatments and take responsibility for their own health care;

(b) improving communication between patients and health care providers; and

(c) aiding and encouraging effective use of medicines.

2.8.2 General considerations

(a) Pharmacists and other persons registered with Council must (within their scope of practice) give advice and information to patients on how to use medicines safely and effectively to maximise therapeutic outcomes.

(b) **Pharmacists must have access to as much information as they require within their ethical and professional judgement to meet the individual needs of patients**. Such information should include the patient's medical/clinical records.

2.9 Minimum standards for record keeping procedures

Patient medication records must be kept in the pharmacy, except in institutional pharmacies where the pharmacist has access to the necessary information in the patient's medical/clinical records.

2.9.1 Patient medication records

(d) Patient medication records must:

(i) be readily retrievable by manual or electronic means;

(ii) **enable the pharmacist to identify medicine dispensed previously and known disease conditions;**

Code of Conduct: Pharmacists

1.1 WELLBEING OF THE PATIENT

Principle: A pharmacist's prime concern in the performance of his/her professional duties must be for the wellbeing of both the patient and other members of the public.

1.3 CONFIDENTIALITY

Principle: A pharmacist must respect the confidentiality of information acquired in the course of professional practice relating to a patient and may not disclose such information except under certain prescribed circumstances.

In adhering to this principle the following should be taken into consideration:

1.3.1 A pharmacist must restrict access to information relating to a patient to those who, in his/her professional judgment, need that information in the interests of the patient or in the public interest.

1.3.2 A pharmacist must ensure that anyone who has access to information relating to a patient:

(a) is aware of the need to respect its confidential nature; (b) does not disclose such information without the written consent of the patient.

1.3.3 If a pharmacist judges it necessary to disclose information relating to a patient, the content should be limited to the specific matter involved. The following are guidelines regarding circumstances when information might need to be disclosed:

(a) Where the information is to be shared with others who participate in, or assume responsibility for, the care or treatment of the patient, and would be unable to provide that care or treatment without that information (the need-to-know concept).
(b) Where disclosure of the information is to a person or body that is empowered by statute to require such a disclosure; for example in connection with a scheduled medicine or a notifiable disease.

1.3.8 None of the above precludes the collation of data from patient records, on condition that it is presented anonymously, for the purpose of research or as information to an interested commercial source however strict confidentiality should be maintained with respect to all details relating to both the patient and the prescriber. This would include confidentiality not only of names and addresses, but also telephone numbers and postal codes.

Conclusion: Apart from abovementioned maintenance of patient confidentiality at the point of dispensing, all patient information will be de-identified once captured and submitted to the database. The warning message that the dispensing pharmacist will receive will only indicate that codeine-containing medicines were purchased recently and that a risk may exist, however it will not give details as to where medicine was purchased.

SAHPRA concern: The inability to include licensed sellers other than community pharmacies that are connected electronically.

Inclusion of the entire supply chain will give SAHPRA records of codeine-containing products sold to all healthcare professionals including dispensing doctors, nurses and pharmacists. The revised Codeine Care Initiative will also further control all records of supply from pharmacies. It is our suggestion that the South African Medical Association (SAMA) and/or the Health Professions Council of South Africa (HPCSA) and/or South African Nursing Council (SANC) should consider a system for medical practitioners and dispensing nurses. Further, the current proposed monitoring system can accommodate upload of data from other healthcare professionals involved in the sale of codeine products.

SAHPRA concern: The ability of the Initiative to address diversion from regulated channels.

Sales/supply data along the entire supply chain from quantities manufactured by industry, distributed to and from wholesalers, order quantities from community and institutional pharmacies and dispensing data will all be available from the Initiative and potential diversions between supply and receipt will be reported to allow action from regulated authorities.

Conclusion:

From the abovementioned industry-wide proposal and supporting legislations, we believe South African citizens will best benefit from the proposed revised initiative where pharmacists will be able to have access to patients' purchasing history across the pharmaceutical environment which will enable the pharmacist to intervene effectively and professionally. It is our collective statement that up-scheduling will not deliver the same outcome. In order to facilitate understanding of the content of our submission, the Stakeholders Forum request for oral representation and presentation to the review committee.

List of Stakeholders who participated in drafting this submission *(in alphabetical order)*:

Forum Member Name	Sector/Designation
Adcock Ingram	Manufacturer

Allegra	Dispensing Software Company
Aspen	Manufacturer
BCX	Information and communications Technology Company
Cipla Medpro	Manufacturer
Clicks	Corporate Community Pharmacies
ComputAssist	Dispensing Software Company
Dis-Chem	Corporate Community Pharmacies
Diverse IT	Pharmaceutical Software Solutions
DSV	Logistics and Transport Company
EasyRx	Dispensing Software Company
Huge Networks	Telecommunications Service Provider
ICPA	Independent Community Pharmacy Association NPC
Johnson & Johnson Consumer	Manufacturer
Life Health Care	Private Institutional Pharmacies
Mediclinic	Private Institutional Pharmacies
Medirite	Corporate Community Pharmacies
Netcare	Private Institutional Pharmacies
PLASA	Pharmaceutical Logistics Association of South Africa
PSSA	Pharmaceutical Society of South Africa
Pick n Pay Pharmacies	Corporate Community Pharmacies
Reckitt Benckiser	Manufacturer
SCA	Self-care Association of South Africa
SAACP	South African Association of Community Pharmacists
University of the Witwatersrand	Higher Education Institution

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Annexure A

Suggested Minimum Standard to be published by SAPC as part of GPP[6].

Minimum Standard on the supply of medicines with a potential for overuse, misuse or abuse

(a) A pharmacist must comply with the rules relating to confidentiality of information obtained in the course of dispensing or the supply of medicines (refer Rule 2.7.3.6 of the GPP);

(b) Every pharmacy must have a policy in place regarding how to effectively deal with the overuse, misuse and/or abuse of medicines with abuse potential including referral to addiction support services;

(c) A pharmacist must actively participate in any lawful arrangements made for warning patients, the profession and other healthcare professionals of the overuse, misuse and/or abuse of medicines with abuse potential, which could include but are not limited to:

   i. partaking in and supporting the collection of data relating to the supply (including dispensing) of medicine with abuse potential in (from) his/her pharmacy;

   ii. reporting to the patient's medical practitioner, as well as a competent authority, such as the SAHPRA, the overuse, misuse and/or abuse of medicines with abuse potential, in accordance with guidelines published by Council in this regard, which could include a list of such medicines / substances.

   (refer adverse drug reaction reporting – rule 2.7.3.10)

[6] GPP - Rules relating to good pharmacy practice