

Does the Up-Scheduling of Codeine Containing Products Align with The Role of the Pharmacist? – A South African Context

1. Is Rescheduling the Solution?

The misuse and abuse of codeine medication has been a rising problem in South Africa. Circumstances would call for more stringent regulations to control the medication abuse. Other countries such as Australia have been faced with the same problem and opted for the up-scheduling of codeine medications. Australia implemented an initial up-scheduling of low strength (less than 15mg) codeine-containing medications in May of 2010 from a schedule 2 to a schedule 3 medicine, thus preventing the sale of such medications without pharmacist consultation however, cold and flu medication containing codeine remained available to patients without pharmacist consultation (Cairns et al., 2016; Cairns et al., 2019). The legislation was reviewed, as the up-scheduling of low-strength codeine-containing products did not prove to curb codeine misuse (Cairns et al., 2016), as reports still displayed a great deal of codeine-related deaths (Roxburgh et al., 2015). This resulted in a further up-scheduling of all codeine-containing medications to a schedule 4 medicine (prescription only) that was implemented in February 2018 (Cairns et al., 2019).

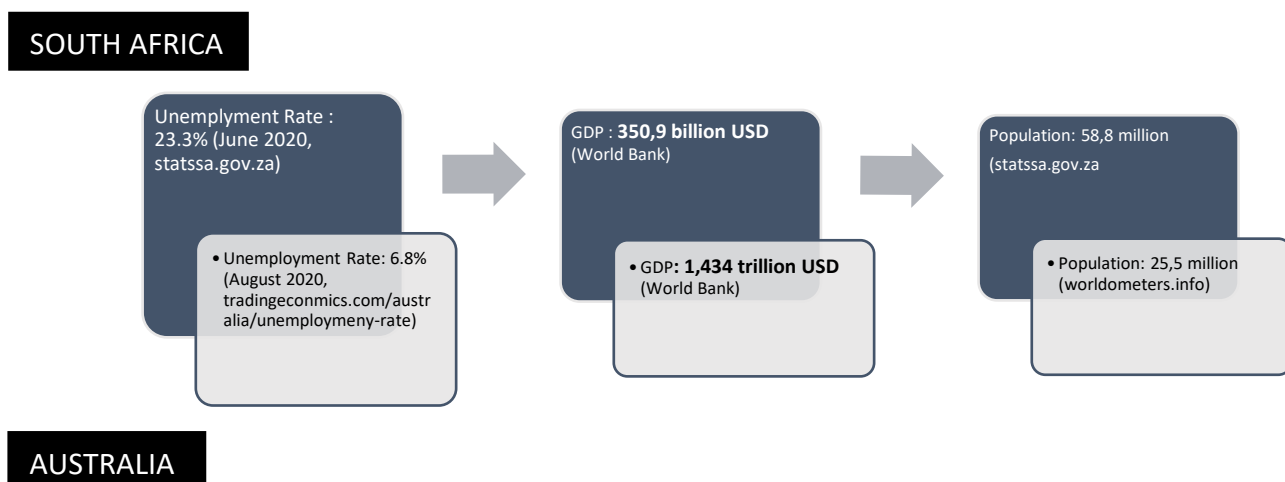


Figure 1: showing salient economic, employment and population differences between South Africa and Australia

Countries including Australia, New Zealand and the United Kingdom have opted to reform regulations and re-schedule OTC codeine containing products to prescription only medicines. However, the same concept cannot be implemented in South Africa to match the affect due to the difference in the economic state of the country. Patients within these countries have the opportunity to access codeine containing products through a more efficient health care system than what exists in South Africa.

As is seen in figure 1, South Africa is a poorer country with a higher population and unemployment rate. The GDP difference in itself shows the vast differences between a first world country and a third world one. South Africa relies on a two-tiered health care system, with approximately 80% of South Africans accessing health care through the overburdened and under-resourced public health care system. The primary health care model in South Africa is unique, with retail pharmacies complimenting the primary health care clinics by providing access to affordable medication and care for minor conditions. It is evident that the primary health care model in countries that have up-scheduled codeine containing products to a prescription only medicine does not compare with South Africa and thus up-scheduling of codeine is not a contextually relevant solution.

Furthermore, rescheduling of medicine sends a strong message of distrust to the pharmacy profession. Pharmacists should be entrusted to educate patients about misuse as the custodians of medicine and trusted by patients.

It should also be noted that rescheduling of OTC codeine products is not a holistic solution, as it does not provide a solution to treating the substance abuse disorder that underpins the abuse of codeine containing products. Proposed solutions to codeine abuse should provide pharmacists and healthcare providers with the tool to identify cases of misuse/abuse, allowing the necessary interventions to be undertaken for the benefit of the patient by the pharmacist.

Up-scheduling, although effective in certain countries, will not be ideal or feasible for developing countries due to the socio-economic challenges that exist in those countries. The difficulty with this for such countries is that up-scheduling applies not only to analgesics but

to cough and cold medications as well which are highly effective for symptomatic relief of self-limiting viral illnesses (Van Hout and Norman, 2014). Up-scheduling of codeine medications would burden healthcare system's which are already overburdened (Van Hout, 2016), as there will be insufficient doctors for every patient requiring medication for common self-limiting conditions such as a migraine or cough (for example, Greece has 610 Doctors per 100,000 population and South Africa only 40.7 per 100,000 population).

When flu medicines are not available OTC it creates barriers for low income patients to access primary care for minor ailments and results in the overburdening of clinicians and patients along with additional costs to taxpayers (Le Roux, 2013). Up-scheduling could unintentionally run the risk of patients treating their pain and other self-limiting illnesses with inappropriate alternative medication. The increased fluctuation of patients needing to visit doctors for prescriptions for minor ailments could cause a rise in inappropriate prescribing (Van Hout and Norman, 2016). Many low income patients could be displaced to using stronger opioids as a result of an up-scheduling. For example, visiting a doctor may result in them been prescribed something stronger or a higher dose which is a concern. In addition, is a person has a substance abuse disorder they could potentially be introduced to more potent psychoactive substances and their prognosis can be worsened.

2. Will Up-Scheduling OTC Codeine Products Decrease the Abuse and Misuse?

With the proposed up-scheduling of codeine containing products, demand prescribing by patients will become a common practice, and the concept of pharmacy shopping will be shifted to doctor shopping. "Doctor Shopping" is possible with manual prescribing practices and involves a patient consulting with multiple doctors in order to seek many prescriptions of the same drug. Manual prescriptions in itself are easily taken advantage of in cases of prescription drug abuse. Patients are able to alter prescriptions by forging a physician's handwriting in order to adjust dosages or adding of drugs to existing prescription, or by embezzling a doctor's prescription-pad and forging prescriptions in their entirety. While legislation prescribes that pharmacists are responsible for averting such fraud by determining the authenticity of prescriptions during the dispensing cycle, the automated electronic recording of supply and sales will provide an on-demand tracking/tracing function and reduce

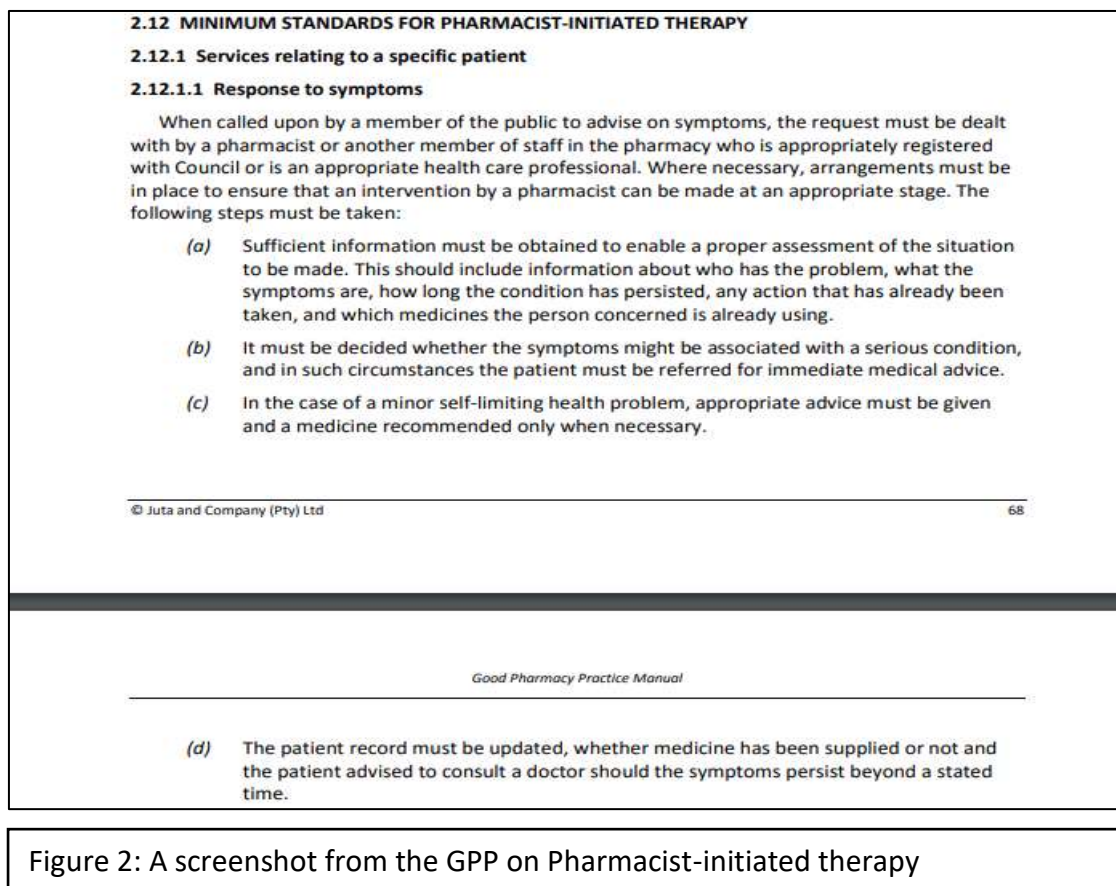
time-consuming manual processes that places a demand on pharmacists to verify prescriptions with doctors. If a pharmacist has access to a data monitoring system, such as the Codeine Care Initiative, pharmacists are able to tap into patient history and identify cases of misuse and abuse, thus providing pharmacists with the opportunity to act as the Custodians of medicine and intervene in cases on drug misuse and abuse.

3. Expanding The Role of the Pharmacist – The NHI Perspective

Recognition of pharmacists' value to patients and the health care system continues to grow in recent years. Pharmacists have the professional expertise to address key challenges facing the health care system, and thus, within the NHI context, the pharmacist is in an optimal position to be better integrated into the primary health care model. Such integration allows for the creation of efficient models of care focused on improved quality and health outcomes in addition to reduced costs. Many medications that are available OTC in a community/retail pharmacy are successfully used in the treatment of minor and acute conditions, an efficient and cost-saving option for many South Africans. The rescheduling of OTC codeine-containing products, not only hinders the accessibility of a much-needed therapeutic agent for analgesia, but also limits the role of the pharmacists – a stark contradiction to the goal of the NHI. Furthermore, access to affordable care for patients is the most important component that needs to be considered in any health reform legislation. Rescheduling of OTC codeine containing products will force many patients into a costly visit to a doctor, or seek suboptimal therapeutic alternatives from the pharmacy. Furthermore, the proposed solution of up scheduling OTC products does not align with the NHI's "one pharmacy approach" that speaks to electronic health record management by integrating electronic prescriptions as a tool to improve efficiency and standard of patient care in pharmacies. It is thus wise to consider the proposed technologies and tools in addressing codeine misuse, as the National Department of Health is promoting the uptake of these technologies in the health care industry. The NHI scheme may be delayed as a result of economic pressure and COVID-19.

Up-scheduling codeine medications also reduces the scope of practice for a pharmacist. The pharmacist plays an important role in preventing the misuse/abuse of medications as such misuse/abuse could be avoided/prevented by correct and proper counselling by pharmacists

upon sale (Hamer et al., 2014). Community pharmacists have further been found to identify patients misusing medications by observing suspicious behaviour (Hamer et al., 2014). The mentioned factors combined with extensive knowledge on medications and its toxicology, it is apparent that the pharmacist should be involved in the monitoring and advising of codeine medication use. As can be seen in the GPP section in figure 2, it is within a pharmacist's scope of practice to provide pharmacist-initiated therapy to individual patients based on the symptoms and health needs of the patient. An up-scheduling disregards the role of the pharmacist by removing the pharmacist's professional judgement and opinion as the custodians of medicine. The FIP has made the following policy statement: "Engage with pharmacists and their professional associations to maximise the potential contribution of pharmacists in the provision of harm reduction services through collaborative practice arrangements".



4. The financial implications of up-scheduling

The National Department of Health has been piloting and implementing numerous health system strengthening reforms aimed at improving medicine availability and access as per the NHI goals. Pharmacy professionals will be key resources as the custodians of medicines to enable the availability of essential medicines across the country. There is a great need for medicine availability, skilled medical human resources and quality care. A comprehensive approach should be taken in which the quality of the healthcare system is improved simultaneously with the rollout of the NHI, in order to benefit every South African. Up-scheduling codeine products would be detrimental to a responsible patient using the medication correctly because that patient would need to spend time and money consulting with a doctor to obtain medication which could be readily available for minor complaints and illnesses, that can be treated within the pharmacist's scope of practice.

The AU Executive Council in February 2020 (EX.CL./Dec.1074(XXXVI)) described a strategic framework that guides drug policy development on the continent. Pillar 2 of the AUPA emphasizes: "Access to and availability of controlled substances facilitated for medicinal and scientific purposes while preventing their diversion". This implies that in some countries there are not enough analgesic products available because they cannot control abuse and there are better solutions than up scheduling.

5. Up-Scheduling: Not a Holistic Solution

The up-scheduling of codeine medications does not address the problem at hand, it merely shifts the supplier of the medication. A multidimensional intervention/strategy would need to be implemented in order to truly control the issue. The issue with an up-schedule is that the medicine is still being sold and abused. The further restriction could also result in the increased use of other opioids or drugs as low income patients struggle to treat their ailments. Misusers and abusers are also still able to access codeine medications as they are able to gain multiple prescriptions from multiple doctors as well as visit multiple pharmacies for the medication. A study by Mishriky et al. referred to this as simply moving from 'pharmacy hopping' to 'doctor shopping'. With all pharmacy software's not being linked and with no

alert in place to control amount of codeine dispensed to each patient, codeine abusers are able to cheat the system. Furthermore, an up-scheduling can be avoided by the introduction of a real-time monitoring system that can control the abuse whilst also encouraging different healthcare professionals to liaise together in combatting codeine misuse/abuse (McKenzie et al.,2020).

6. A Curriculum View: Developing Specializations and the Pharmacist's Scope of Practice

Pharmacists practice in a variety of health care settings. Although they are most often associated with dispensing medications in retail pharmacies, their role is evolving to include providing direct care to patients as members of integrated health care provider teams. The undergraduate curriculum at universities across the country have equipped pharmacists with the necessary skillset and knowledge base to attribute pharmacists as being the “drug expert”. Internationally, the evolving role has expanded into various specializations, such as clinical pharmacy, with South Africa following suit. However, several key challenges and barriers, prevent the full integration of pharmacists into health care delivery teams: restrictive laws and regulations governing the profession and lack of provider recognition in direct patient-care services, and limitations on pharmacists’ ability to access health information systems limit the ability of the pharmacist from practicing effectively and the full scope of practice. While the regulatory reform that is required to promote the evolving role of the pharmacist is yet to occur, the rescheduling of OTC codeine containing products appears to be completely contradictory to what is needed for the profession, and to the strategic goal of “universal health coverage”.

7. Expanding the Role of the Pharmacist. Drug addiction and rehab programs by Pharmacists: Creating new opportunities for the pharmacy profession

Pharmacists are an important but underutilized resource in the fight against prescription drug abuse, according to an expert Professor M. Norton in addiction pharmacy, Clinical Associate Professor of the University of Georgia College of Pharmacy is promoting the role of pharmacists in substance abuse treatment, by training pharmacists to recognize patients struggling with substance abuse and get them the help they need. He mentions that if we can

train pharmacists to identify such situations, we can increase the number of health care professionals available to the public to help get people into treatment. A prescription data monitoring system will provide pharmacists with the tools necessary to identify patients that need assistance, and as a result, pharmacists can have a big impact on the opioid dependence crisis. In the event of re-scheduling codeine containing products to prescription only products, it denies the pharmacist the opportunity to practice pharmaceutical care in the prevention of codeine use. Furthermore, it denies patient opportunity for behaviour change intervention by the pharmacist. Through early intervention, monitoring and screening patients can be referred to a multidisciplinary approach to treat the cause and effect.

8. Proposing A Technological Solution

Digitalization in the healthcare space has provided new opportunities for integration of patient medical histories through shared databases. Tools including e-prescribing, electronic health record management and health information exchange can be used to provide efficient a holistic approach of health care to a patient, while limiting inappropriate treatment. Furthermore, digitalization of patient records has been identified as a strategic goal by the National Department of Health, and thus supporting the Codeine Care Initiative aligns with The South African National Department of Health Strategic Plan (2015-2020) by facilitating improved decision making through health information exchange and electronic health record management systems.

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Professor Yahya E. Choonara | BPharm; MPharm; PhD; FAAS; MASSAf; MPS; TWAS (Pharm. Sci.)
Personal Professor of Pharmaceutics
Chair and Head | Pharmacy and Pharmacology
Principal Researcher and Co-Director | WADDP | <http://www.wits.ac.za/waddp>
University of the Witwatersrand | Faculty of Health Sciences
7 York Road, Parktown, 2193, Johannesburg, South Africa
W: <http://www.wits.ac.za/therapeuticsscience/pharmacy--pharmacology>



