# *STATE DEVELOPMENT, NATURAL RESOURCES AND AGRICULTURAL INDUSTRY DEVELOPMENT COMMITTEE*

**Members present:**

Mr CG Whiting MP (Chair)
Mr BA Mickelberg MP
Ms JC Pugh MP
Mr PT Weir MP

**Staff present:**

Ms S Galbraith (Committee Secretary)
Ms S Cawcutt (Committee Secretary)
Ms C Furlong (Assistant Committee Secretary)

## PUBLIC BRIEFING—INQUIRY INTO THE MEDICINES AND POISONS BILL 2019 AND THE THERAPEUTIC GOODS BILL 2019

### TRANSCRIPT OF PROCEEDINGS

**MONDAY, 27 MAY 2019**

**Brisbane**

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**The subcommittee met at 1.59 pm.**

**CHAIR:** Good afternoon. I would like to begin by acknowledging the traditional owners of the land on which we gather today. I declare open this public briefing for the committee's consideration of the Medicines and Poisons Bill 2019 and the Therapeutic Goods Bill 2019. Thank you for your attendance here today. My name is Chris Whiting. I am the member for Bancroft and chair of the committee. We have a subcommittee for the purpose of this briefing. With me here today are: Mr Pat Weir, deputy chair and member for Condamine; Mr Brent Mickelberg, member for Buderim; and Ms Jess Pugh, member for Mount Ommaney.

The committee's proceedings are proceedings of the Queensland parliament and are subject to the standing rules and orders of the parliament. I remind members of the committee of the instructions under schedule 3 and schedule 8 of the standing orders that Public Service employees may be called upon to provide factual and technical background to government legislation and administration; however, a committee shall not ask an officer or a department to give opinions on matters of policy. The proceedings are being recorded by Hansard and the witnesses will be provided with a copy of the transcript. To assist with clarity, can you please identify yourself when you first speak and speak clearly and at a reasonable pace.

All those present today should note that it is possible you might be filmed or photographed during the proceedings by media, and images may also appear on the parliament's website or social media pages. The media rules endorsed by the committee are available from committee staff if required. I ask everyone present to turn mobiles phones off or to silent mode. I also ask that if witnesses take a question on notice today they provide the information to the committee by 10 am on Monday, 3 June 2019. I now welcome officers from the Department of Health.

### GIBSON, Ms Eve, Acting Manager, Legislative Policy Unit, Strategy Policy and Planning Division, Department of Health

### HARMER, Mr David, Senior Director, Strategic Policy and Legislation Branch, Strategy Policy and Planning Division, Department of Health

### YOUNG, Dr Jeannette, Chief Health Officer and Deputy Director-General, Department of Health

**CHAIR:** I now invite you to make an opening statement, after which committee members may have some questions for you.

**Dr Young:** Thank you for the opportunity to brief the committee today about the Medicines and Poisons Bill 2019 and the Therapeutic Goods Bill 2019. The Medicines and Poisons Bill will introduce a new legislative framework for the regulation of medicines and poisons in Queensland. This bill will, among other things, replace the Health Act 1937, which is one of the oldest pieces of legislation in Queensland. The bill is supported by the draft Medicines and Poisons (Medicines) Regulation 2019 and the draft Medicines and Poisons (Pest Management, Poisons and Other Regulated Substances) Regulation 2019, which the minister tabled in parliament when the bill was introduced. The Therapeutic Goods Bill adopts the Commonwealth Therapeutic Goods Act 1989 as a law of Queensland. The bill is supported by the draft Therapeutic Goods Regulation 2019, which the minister also tabled in parliament when the bill was introduced.

The Medicines and Poisons Bill significantly reforms and modernises the regulatory framework for medicines and poisons in Queensland. The Therapeutic Goods Bill supports this new framework by improving the regulation of medicine safety and quality assurance, and also enhances national uniformity. These reforms are being progressed in separate bills to improve clarity and ease of access for stakeholders. However, it is appropriate that the two bills be considered by the committee together as they comprise a package of reforms that deal comprehensively with the regulation of medicines, poisons and therapeutic goods.

Subject to the passage of these bills and the making of supporting regulations, the new framework is expected to commence in 2020. This will allow time for education and implementation activities to be undertaken and industry to familiarise themselves with the new framework and prepare for changes. I propose to provide a short summary of each bill for the committee. First, I will speak about the Medicines and Poisons Bill and then the Therapeutic Goods Bill.

The Medicines and Poisons Bill will repeal the existing legislation that regulates medicines, poisons and pest management in Queensland and establish a new framework comprising the bill and two supporting regulations. One regulation will focus on medicines, while the other will predominantly focus on poisons and pest management. The regulations have been drafted separately, as they generally apply to different industries and stakeholder groups.

The purposes of the new framework are: to ensure medicines and poisons are made, sold, used and disposed of in an appropriate, effective and safe way; to ensure health risks arising from the use of the substances are appropriately managed; and to ensure persons who are authorised to carry out activities using the substances have the necessary competencies to do so safely. Broadly, these purposes are achieved by: identifying the substances and activities to be regulated; restricting access to medicines and poisons to those who have a need to use the substance for a therapeutic, industrial or other purpose; ensuring these people have the necessary competencies to carry out activities safely and requiring them to be accountable for the use of the substances; and ensuring the safety of the use of medicines and poisons by appropriately regulating their manufacture, supply to the consumer and final disposal where a substance has become waste.

The principal concept of the bill is that any activity performed with a substance must be done in an authorised way. Doing something in the authorised way means that the person must be authorised to carry out that activity and they must comply with the requirements of the regulation that are prescribed. It is the bill that sets out the overall framework for regulating medicines and poisons, while the technical detail is included in the regulations. For example, the bill defines key concepts used in the framework and sets out circumstances in which medicines and poisons are authorised to be used. The bill establishes classes of licences and approvals, known as 'substance authorities', which entitle persons to use medicines and poisons, and provides application and assessment processes for these authorities. I will now outline some of the other key features of the bill in more detail.

The bill regulates all substances listed as medicines and poisons in the Commonwealth Standard for the Uniform Scheduling of Medicines and Poisons, also known as the poisons standard. The poisons standard classifies substances into 'schedules' of substances from 'schedule 2' to 'schedule 10' based on risk and the level of regulatory control required. For example, committee members may have heard substances referred to as 'S4', which are prescription-only medicines like an antibiotic or prescription animal remedies; or 'S8s', which are 'controlled medicines' such as strong pain relievers. The bill adopts the classification into schedules in accordance with the Commonwealth poisons standard, which promotes national consistency for stakeholders and industry.

The bill also regulates pesticides and fumigants registered or permitted for use by the Australian Pesticides and Veterinary Medicines Authority. Under the framework established by the bill, a person may undertake a regulated activity with a 'regulated substance' if they hold an authority under the bill, such as a manufacturing licence, wholesale licence, retail licence, pest management licence, prescribing approval or a general approval. The bill authorises a regulation to prescribe classes of general approvals.

The draft medicines regulation and draft poisons regulation provide for particular classes of persons to be authorised to carry out activities with regulated substances because of their profession or occupation or because of the position they hold. These people are referred to as 'approved persons' and are not required to apply for a licence or general approval under the bill to carry out specific activities. Approved persons include pharmacists and nurses using medicines in their work; and veterinary surgeons and persons carrying out a pest control activity using a pesticide to treat livestock at a place where livestock is being processed for a commercial purpose, for example, applying tick treatment to cattle at a commercial dip. The bill also provides that a primary producer, or an agent of a primary producer, can carry out a pest control activity or fumigation activity on land owned or occupied by the primary producer without requiring a licence, for example, when the primary producer sprays fruit using a pesticide to protect the fruit from insects.

The bill includes heads of power to enable the medicines regulation to prescribe how each occupation, profession or position may use medicines. This is reflected in the separate schedules to the medicines regulation. For example, the draft medicines regulation specifies: the particular medicines for which an approved person will be authorised to have access; the activities that may be

carried out, such as possessing, administering, supplying or prescribing medicines; and any conditions governing the activities to be carried out with a particular medicine. For example, the person may be required to hold particular qualifications, comply with recognised industry or government standards or be under direct supervision to carry out an activity.

The medicines regulation also outlines requirements about how to supply, store and dispose of regulated substances and how to keep associated records. For example, certain substances may need to be stored in a way that prevents public access or require childproof packaging. The poisons regulation includes provisions about standard controls for the management of poisons risks. It covers matters such as labelling, containers, storage and disposal. The regulation also deals specifically with agricultural and industrial poisons that are highly dangerous and require additional controls. The poisons regulation provides general controls relating to access and use of scheduled poisons; prescribes who is an approved person and what are exempt activities; and specifies requirements for manufacturers, suppliers and persons carrying out pest management activities.

As outlined in the explanatory notes for the bill, the reach of this regulatory framework is significant. It impacts on manufacturers and wholesalers of regulated substances; licensed retailers of medicines and poisons; trained health professionals with authority to deal with medicines; pest management technicians and primary producers carrying out pest management activities; and landholders authorised to use regulated poisons. While the bill retains many features of the existing framework, the new framework has been modernised and streamlined. Many of the changes are to reduce regulatory costs or burdens and future-proof the legislation so it is more flexible and can better meet the needs of industry, while still appropriately managing public health and safety risks.

The bill simplifies and streamlines the process for obtaining a substance authority in a number of ways. For example, manufacturers with multiple sites will be able to obtain a single licence for all sites, and there will be automatic recognition of Commonwealth manufacturing licences in Queensland. The current legislation includes some very prescriptive rules about storing regulated substances. The bill replaces those prescriptive rules with a new requirement for certain entities who deal with regulated substances to have a substance management plan. Substance management plans will be required for manufacturers and wholesalers; and entities such as hospitals, pharmacies, schools and childcare facilities, detention centres, and ambulance stations. A substance management plan is a co-regulatory tool to assist authority holders to consider and manage known and foreseeable risks associated with dealing with regulated substances, and to document this for their employees and agents.

Developing a substance management plan should not be burdensome for those places that must make a plan. Entities generally already have documented quality or risk management policies and procedures relating to regulated substances in place. For example, existing occupational health and safety management plans and accreditation documentation are likely to deal with risks associated with the use of medicines and poisons. Organisations and entities can use these existing policies and procedures as the basis for developing a substance management plan. In addition, to assist entities to meet these requirements, Queensland Health will develop a communication and awareness strategy and will develop templates and example substance management plans for different types of industries and stakeholders, which they will be able to tailor to their own circumstances.

The bill includes a number of tools to ensure that Queensland Health is better able to monitor and respond to health risks. I am going to briefly outline some of these. The chief executive may make an emergency order to take immediate action to manage risk or significant harm or illness in an emergency situation. You will find several examples outlined in the explanatory notes where these powers may be used. The types of situations include an outbreak of an infectious disease, a natural disaster or severe weather event, or to support a biosecurity emergency order.

The bill includes a new power for the chief executive to make an emerging risk declaration if there is a reasonable belief that an unscheduled substance or device poses a risk of injury or illness—for example, where a domestic cleaning product such as washing powder was contaminated with substances that are known to cause health risks. These powers will enable the chief executive to prevent substances entering the market until their safety has been assessed. This ensures swift action can be taken until a final decision has been made at the national level about new or emerging substances that may pose a risk to health.

The bill includes a power for the chief executive to make a recall order if there is a risk of harm to persons or animals because of labelling, packaging, efficacy or other safety issues from a regulated substance—for example, where the label on a product containing hydrofluoric acid incorrectly states the acid concentration, which contains a higher concentration likely to cause immediate injury to a person. Depending on the circumstances, manufacturers, wholesalers and retailers may be required

to stop the manufacture or supply, recall the substances from end users, destroy the substances, relabel or repackage the product, publish warnings about the product, or take other measures to protect the public from harm.

The minister, chief executive or Chief Health Officer may also make a public warning under the bill. A public statement may be issued where it is in the public interest to warn or inform the community about a person who has contravened the Medicines and Poisons Act or committed any unlawful practices or offences against other relevant legislation.

The bill also requires Queensland Health to keep public registers. These registers will provide transparency and public assurance by allowing Queenslanders to confirm if a person holds the appropriate authority before engaging them. For example, consumers will be able to check whether a pest management technician holds a current licence.

The bill also establishes a head of power for Queensland Health to implement a real-time prescription monitoring system to manage the use of dependence-forming medicines. This will be known as the monitored medicines database. Monitored medicines are listed in the draft medicines regulation. Misuse of pharmaceutical opioids is an increasing concern for our community. Unlike illicit opioid drugs, access to pharmaceutical opioids is enabled by the writing of a prescription. In Australia, there is considerable evidence of the widespread misuse of prescription opioids. Levels of prescription opioid overdose, including accidental overdose, are at record levels in Australia and internationally.

In Queensland we are seeing an increase in cases of prescription opioid related overdoses and deaths, an increase in people on treatment programs, increased referrals to alcohol and drug treatment services, and more evidence of these drugs entering into illicit markets. The Health Ombudsman's 2016 report *Undoing the knots constraining medicine regulation in Queensland* recommended that controlled drug prescription history for a patient should be available in real time to the prescriber at the time of prescribing and to the dispenser at point of dispensing. This would better inform treatment providers and further decrease the public health risk for patients.

The Implementation of real-time prescription monitoring is also a recommendation of the Commonwealth government's National Drug Strategy 2017-2026, supported by the Queensland government. All S8 medicines and some high-risk S4 medicines will be monitored under the monitored medicine database. These include benzodiazepines such as Valium and codeine, which are used to treat pain, and medication used for the short-term treatment of sleeping problems, such as Stilnox.

To aid in clinical decision-making, all medical practitioners—indeed, all prescribers and pharmacists—will be required to check the database before they prescribe or dispense such dependence-forming medicines. The database will show if the person has previously been supplied or prescribed the medicine.

The bill further streamlines the process for prescribing medicinal cannabis in Queensland by enabling non-specialist medical practitioners to prescribe without the need for approval from Queensland Health. Specialist medical practitioners can already prescribe. So this removes the final duplication with the Commonwealth approval process. From 1 July this year, provisions in the Health and Other Legislation Amendment Act 2019 will commence that enables the specialist medical practitioners to prescribe medicinal cannabis to any patient they believe will benefit from the treatment without approval from Queensland Health, just as they would for any other controlled or restricted medicine. The Commonwealth government will maintain strict controls on the use of these substances through their regulatory scheme.

I will now turn to the Therapeutic Goods Bill 2019. Queensland shares responsibility for the regulation of medicines, poisons and therapeutic goods with the Commonwealth government. The Commonwealth Therapeutic Goods Act 1989 places standardised controls on the manufacture, import, export, supply and advertising of medicines for human use in Australia. The assessment and monitoring controls applied by the Commonwealth act ensure that all therapeutic goods available in Australia are safe and fit for their intended purpose.

The Commonwealth Therapeutic Goods Act applies to all Queensland corporations and to Queensland entities of any structure, including partnerships, trusts or sole traders, that trade interstate or overseas. Due to constitutional limitations, the Commonwealth act does not apply to manufacturers who are not corporations and who are not engaged in trade outside Queensland. To ensure that all entities manufacturing medicines are subject to the same strict requirements and controls, the bill adopts the Commonwealth Therapeutic Goods Act 1989 as a law of Queensland. This extends the requirements under the Commonwealth act to all Queensland based manufacturers who are not already regulated under this act.

The bill supports a COAG commitment to adopt a nationally consistent approach to the management of medicines, poisons and therapeutic goods, bringing Queensland into line with other jurisdictions. The bill provides a transitional period of two years from commencement to comply with the Commonwealth act. During the transitional period, a person is not liable to be prosecuted for not complying with the Queensland Therapeutic Goods Act.

As I am sure the committee appreciates, this bill is extraordinarily complex and technical and the result of a very long period of development. The bill will significantly modernise and streamline the regulation of medicines and poisons in Queensland. If passed, it will be supported by an education and awareness campaign for stakeholders, which will be important in ensuring industry and stakeholders understand their obligations and the benefits it offers for the health and safety of Queenslanders. My two colleagues and I are very happy to take any questions.

**CHAIR:** Thank you, Dr Young. We appreciate the enormity of the work that has been done by the department to come to this stage. We thank you for that. You touched on the Therapeutic Goods Bill and the long time frames and the enormous amount of intergovernmental energy that has gone into producing this bill. Could you outline the COAG process that led us to this point?

**Dr Young:** Yes. COAG in 2006 first discussed that they wanted to see harmonisation across the country. At this stage, all states except Western Australia and Queensland have gone ahead and adopted the national framework for their state.

**CHAIR:** You have probably about 14 years of annual meetings and discussion among people in the departments about what is needed to be done in getting Queensland to this position; is that correct?

**Dr Young:** We have had a lot of discussions over the years, yes.

**CHAIR:** Has it been a similar process for the Medicines and Poisons Bill as well? It may not have been such a large intergovernmental exercise.

**Dr Young:** No, we do work at a national level. The discussions and the decisions about the scheduling of different drugs from schedule 2 to schedule 10 is done at the national level that involves the states as part of that process. All of the recommendations go through to the Commonwealth and they then make those decisions, but we have been involved in those decisions. The intent is that, given that health occurs across borders and health workers move across borders, we try to harmonise where possible.

**CHAIR:** In general terms, if we are getting harmonisation across all the jurisdictions, I would say that these bills represent a great leap forward in ensuring better health outcomes for Queenslanders. Can I make such a general statement?

**Dr Young:** I would agree with that, yes.

**Mr WEIR:** Obviously, because of my background, I am interested in the agricultural side of the bill. I am curious about the training or the issuing of licences if you are a primary producer who needs to spray weeds. From Roundup through to Paraquat, there are a lot of differences. Is there going to be a licence required for different levels? How is that going to work?

**Dr Young:** It depends. It is quite complicated. The bill controls the manufacture, wholesale and retail supply of all the schedule 7 substances, which are the more dangerous poisons, including pesticides and fumigants. But if you want to control pest plants, the use of that chemical does not require a licence. That is covered under the Agricultural Chemicals Distribution Control Act 1966. Our legislation applies only to pest animals.

**Mr WEIR:** It is not restricted to 1080 baits and that type of thing?

**Dr Young:** We have increased the allowable concentration of fluoroacetic acid in baits from 0.03 per cent to 0.05 per cent. That actually means that there can be a broader range of baiting products without an approval. That was done on a health risk assessment that there is no increased risk to public health. That has been loosened a little bit, if that is helpful.

**Mr WEIR:** If I have a property and I have an employee whom I have asked to lay baits—whether that be for dingoes or wild pigs—that employee does not have to do training, get certificates or get a licence of some sort, or does the landowner have to?

**Dr Young:** Primary producers undertaking pest management activities on their own properties will not require a pest management licence. There is no change there. That also applies to their agents or employees. I understand that there is an issue if there are neighbours involved. Neighbours providing in-kind services in relation to pesticides used on a primary producer's property are considered an agent of the property owner and, therefore, also do not require a pest management licence. Does that answer your question?

**Mr WEIR:** Contractors?

**Dr Young:** Agents or employees do not.

**Mr WEIR:** Agents. Do contractors come under 'agents'?

**Dr Young:** If you have a fee-for-service person, they'll require a pest management licence—unless they are an approved person under the poisons regulation. Does that make sense? Fencing contractors and commercial cattle-dip operators, for instance, do not require a pest management licence but will need to be competent so that they can be regarded as approved persons.

**Mr WEIR:** I might get a contractor in to spray weeds. Let us say he is using Paraquat. You have to keep those poisons in a safe environment. When I get a contractor in, or even if I am doing it myself, I take those poisons out of that safe environment. I put them on a truck, a water truck. I take them down the paddock. They could be near a road. They have gone from that safe environment onto a truck. Am I liable if somebody comes along and pinches one out of there?

**Ms Gibson:** In terms of the primary producers themselves and any employees, as Dr Young said, they are not required to have a pest management licence under the scheme. If you are talking about a contractor who might be on a more fee-for-service type arrangement rather than their own employee, I guess that is the distinction. Those people, as Dr Young said, would require a licence unless our regulation specifies that they are an approved person. That provides them with an as-of-right authority to undertake their work. As Dr Young said, that might be somebody putting in fence posts or doing commercial cattle dipping. Those people will not need to seek a licence; they will just have an as-of-right authority. Otherwise, some fee-for-service providers—contractors like you are talking about—would require a licence.

The other distinction I want to make was Dr Young mentioned that the concentration of the fluoroacetic acid is being increased in the new scheme from 0.03 to 0.05 as the allowable concentration that primary producers are able to use without a licence, and then above that there is an existing requirement for primary producers to have an approval from the department for more high-risk poisons. Above that allowable level of 0.05 per cent they would require that sort of approval from us.

**CHAIR:** That is a current requirement?

**Ms Gibson:** Yes. The allowable concentration is changing slightly to reduce that bureaucracy around what needs to be approved, but the existing requirement to have an approval for high-risk poisons is an existing one.

**Mr WEIR:** Storage is existing as well?

**Ms Gibson:** Yes.

**Mr WEIR:** There are no amendments to storage in the legislation?

**Ms Gibson:** I am not aware that there are any changes. We would have to double-check that and get back to you within the hour, if that is okay.

**Mr WEIR:** That would be a concern out there for sure. If you could check that, I would appreciate it.

**CHAIR:** If we can get an answer on any potential changes to storage requirements by the end of the hearing, that would be fine. If not, we can make that a question on notice.

**Ms PUGH:** I note that the Office of the Health Ombudsman 2016 report *Undoing the knots of constraining medicine regulation in Queensland* talks about the importance of having real-time monitoring for certain medications. You have touched on that, Dr Young. Can I ask you to expand on the importance of real-time monitoring and any potential community benefit that we will see from having real-time information versus the two-week delay that we currently have for those medicines?

**Dr Young:** The difficulty at the moment is that pharmacies are required to report to the department every seven days but, of course, then that is in retrospect by the time it gets to the department, which results in the 14 days. During that 14-day period there is the opportunity for individual patients to seek large amounts of different drugs from different doctors who would not know that they have already sought the medications from somewhere else. If they go to different pharmacies, pharmacies would not know that the person has already obtained various scripts. We have unfortunately had a number of deaths that have gone to the coroner and we have seen exactly that happen.

It is really important that the person prescribing the drug—the doctor—knows what other drugs that person has already been prescribed because, of course, people can go to any doctor they choose. They do not need to go to a consistent doctor. Similarly, there is a back-up then because not only can the doctor look at what has been previously prescribed when they are writing out a script but also when the patient goes to a pharmacy to get that script filled the pharmacist can check what has been supplied. There is that double-check which will make it a far safer process.

There are, of course, some exemptions here. We expect that anyone prescribing those various drugs that will be determined in the regulation does go online and check the database, but there are some circumstances where that would not be appropriate—if someone has had a major injury and they need some immediate pain relief, for instance, in the emergency department. There are cases, of course, where it is not appropriate that they check that database, but certainly before writing scripts for amounts for a person to go and get dispensed we would expect them to check that database.

The other reason we think it is really important is that at the moment doctors and pharmacists are able to ring a hotline that can access the data that the department has—given that it is two weeks out of date, it is still very useful information—but that takes time and that is not really what we should be aiming for in a modern health service. We think it is much better that people can go online and look at the information and make their own decisions, rather than have to pick up a phone and talk to people and get that information.

**Ms PUGH:** You will have that real-time information and, as you pointed out, that means at that time the doctor will have the information and so will the pharmacist. From a clinical perspective, can you outline any potential opportunities that will create for intervention with those addictive but legal substances that have contributed to a number of deaths over the last few years?

**Dr Young:** That is a very sensible point that you have made. When you know that someone is seeking additional medications that they are probably addicted to if they are getting large amounts, you can then put in place strategies to work with that person. That happens at the moment. It is just that we have that gap where we have seen deaths result because people have been given large doses that they could then overdose on.

**Mr MICKELBERG:** You mentioned earlier that most primary producers and their agents would not require a pest management licence, but I think you said they would need to be assessed as competent. How is it proposed you would assess that competence?

**Dr Young:** That is for those people who come onto the property who are contractors who are approved. That came out of that statement. It is not farmers or their direct employees; it is other people who have a right to access those products and use them and they do not have to seek a licence.

**Mr MICKELBERG:** It might be an individual—for example, a council contractor who does wild dog control who is authorised? Is that the sort of example we are talking about?

**Ms Gibson:** I think we are talking about people like fruit pickers who might be seasonal workers who come onto a property and might be needing to apply different chemicals. It is for that role. The competencies for those sorts of people will be spelled out in a departmental standard that will be produced during implementation and that would set out the specific competencies required to be held by those sorts of workers.

**Mr MICKELBERG:** Does the department have a view as to what that standard would look like? It is obviously not developed yet, but is it in the process of being developed?

**Ms Gibson:** We actually provided some of our draft standards to stakeholders as part of our external consultation process last year. I believe that one is still being developed, but it would set out specific nationally regarded competencies in that pest management fumigation space.

**Mr MICKELBERG:** Further to the substance management plan, you made a statement earlier and cited a heap of examples, one of which was childcare centres—just going back to the primary producers. Would a primary producer who, for example, deals in S6 or S7 pesticides be required to have a substance management plan?

**Ms Gibson:** Only if they were required to hold one under the conditions of an approval for use of high-risk poisons. It could be a condition of that approval, but I understand that that will not be made a condition of primary producers' approvals.

**Mr MICKELBERG:** When we talk about high risk—I think you are going to clarify that on the basis of the previous question—just for background and context, is S6 or S7, which is pretty regularly used by, for example, beef producers, considered high risk?

**Ms Gibson:** I do not believe so. I will check that with our poisons experts, but I think we are talking more about restricted S7s.

**CHAIR:** We have talked about the importance of education and information about these changes being disseminated. Amongst the stakeholders there would be a very established network and practices for disseminating that information. Clearly something of this magnitude needs communication across the broader population. What kind of things were you looking to feature in your plans? Are you looking to communicate those changes as broadly as possible to Queenslanders?

**Dr Young:** Yes, that is the plan, particularly those people who have roles in the act as prescribers or suppliers or they are approved persons. We would be working with all of them, and then the various entities that need to get licences. Some of that has changed fairly significantly, so we will be working with all of those because we have streamlined a lot of those processes.

There is not really a change for the general community. Once they are prescribed a drug, they will not see the difference. They will not see that their prescriber is checking a real-time monitoring database rather than making a phone call and those sorts of things. Consumers in general who do not have access to poisons now would not see any real change here. It would be mainly people who are prescribing or supplying who would see the changes.

**CHAIR:** Clearly the greatest impact on consumers will be the monitored medicines database. It obviously will grab the most attention. Maintenance of privacy will obviously be a very important part of this. Will that maintenance and protection of privacy be managed through clauses in the bill or in subsequent regulations?

**Dr Young:** The bill contains safeguards to ensure that personal information is protected. Prescribers and pharmacists will be bound by their professional obligations in relation to confidentiality of patient information—no different to how they are now. Apart from the automated upload of dispensing data by pharmacists, the monitored medicines database will be 'read only' for prescribers and pharmacists. It is intended that they will be unable to record or alter information in the database. The chief executive may impose a condition on a user for accessing or using information from the database and there will be offences included in the scheme to prevent misuse of the database. For example, the draft medicines regulation provides that an authorised user must take reasonable steps to ensure another person does not access the system—clause 115, 20 penalty units.

**CHAIR:** Obviously part of the clauses say that this can be done in regulations. It will be a combination of clauses and regulations that will handle those?

**Dr Young:** Yes.

**CHAIR:** Is there a connection or interface with the federal database My Health?

**Dr Young:** No, it does not interact with My Health because you can opt out of that. This is quite separate, but a lot of the information will be the same. If you do have a My Health Record then your scripts and what has been dispensed would be in there and they will also be in this database. There will be a sharing at the national level of scripts. The Commonwealth has been involved in this whole process. Indeed, they started a lot of that initial work in terms of finding a system because they actually want this across the whole country.

At this point in time, it has been slowly rolled out in a couple of states. There is a concern at the moment, given our close border with New South Wales. New South Wales at this time have not publicly announced whether or not they are going with real-time reporting. We will need to work closely with them on what happens going forward as to whether we can see scripts of people who reside particularly in northern New South Wales if they come across the border, because there is a lot of movement of people on the Gold Coast. There is some work there that we are doing but we are working quite closely at the national level. We expect that our real-time monitoring system will be in place towards the end of 2020.

**CHAIR:** Obviously, building a system that has a lot of integrity to it as well is going to be a primary part of constructing that database. Am I right on that?

**Dr Young:** Yes.

**Mr WEIR:** I notice there are amendments to the powers of inspectors and there is a lot of detail there. What are the major changes and why is there a need for the added powers for inspectors?

**Ms Gibson:** There are a lot of provisions in the bill and the explanatory notes about inspectors. Obviously, they are fairly standard provisions for any scheme that will involve enforcement and monitoring. It is not that necessarily all of the inspectors' powers are brand-new. We do have compliance and monitoring under the current scheme. Is that what you are asking about—inspectors under the scheme?

**Mr WEIR:** I was really asking whether there are new and extended powers in this bill, above and beyond what the inspectors have today.

**Ms Gibson:** Not that I am aware of. The inspectors' powers do not look exactly the same as under the current scheme, but it is largely to adopt a consistent compliance and monitoring scheme with what we have now.

**Mr WEIR:** It is the same powers. It addresses stopping or moving vehicles, powers after entering, and seizure and forfeiture. Are they all as they are under the current legislation?

**Mr Harmer:** As Dr Young said at the beginning, we are replacing one of the oldest acts in Queensland. In the process of drafting legislation consistent with current drafting standards, you see a raft of changes that look like significant reform when in reality it is just reflecting the previous regime and the newer language. There is probably no significant change in the framework here. What we have done is legislate to ensure there are appropriate and clear powers of inspection which can easily be enforced.

**Ms PUGH:** On page 8 of the explanatory notes for the Medicines and Poisons Bill you talk about Project STOP. It says that the Queensland Organised Crime Commission of Inquiry report said that the Queensland government should legislate to make Project STOP a database for the sales of pseudoephedrine. I recall for a number of years seeing signs in the pharmacy that let people know that their pseudoephedrine purchases were being monitored. What kind of impact have we seen that have on consumer choices in the purchase of pseudoephedrine products over the counter in pharmacies? Do you have that information?

**Dr Young:** No, I do not have that information. What I have is the other end, where we have used Project STOP to assist us to work out which pharmacies were inappropriately dispensing large amounts of pseudoephedrine. We have not seen the same degree of diversion of pseudoephedrine, possibly because it is easier for them to bring it in illegally than to go and purchase it from pharmacies and turn it into illicit substances. It was quite a big issue five or so years ago, but it has not been the same issue more recently. Project STOP possibly meant it was so hard for people to go and get large quantities that it was not worth their time to go to multiple pharmacies to buy it.

**Ms PUGH:** I recall also seeing those ads on television around what pseudoephedrine could be used for, which certainly made me pause about taking it when I did not necessarily need to. It was a highly effective campaign. I have another question about medicinal marijuana but I can wait.

**Mr MICKELBERG:** I have a question about medicinal cannabis as well. What schedule does medicinal cannabis sit in?

**Dr Young:** It depends. It can sit in schedule 4 or schedule 8.

**Mr MICKELBERG:** Is that to do with how it is manufactured and the level of THC?

**Dr Young:** Yes. THC.

**Mr MICKELBERG:** Some medicinal cannabis products will be subject to the real-time reporting requirements and some will not. Is that a fair summation?

**Dr Young:** Yes.

**Mr MICKELBERG:** I note that the explanatory notes say that manufacturers—and individuals as well, I think—who hold current licences will be able to have one licence for all sites but a fee would still apply for every site. What is the justification behind a fee applying for each site?

**Dr Young:** They currently apply for a separate licence for each site and there is a fee associated with each site. The regulatory burden and the administrative burden will be decreased—they will not have to go through the application process for each site—but they will still pay the same amount. It was about decreasing that administrative burden.

**Mr MICKELBERG:** Is it about compliance and assessment at each site and that is why there is a fee for each site?

**Dr Young:** Yes.

**Ms PUGH:** In terms of medicinal cannabis, how do you see these reforms impacting both the prescription and the potential use of medicinal cannabis going forward in Queensland?

**Dr Young:** This is now going to enable medicinal cannabis to be treated as any other therapeutic agent. It will go through the same processes, which are actually very rigorous. Schedule 8 processes for any schedule 8 are rigorous. It will make it, I believe, easier for prescribers because they do not need to know a different system; they just then use this system.

There is another issue, of course. Because they are in the main unapproved medicines—there are some that are on the Australian Register of Therapeutic Goods, so they are treated as normal therapeutics, but there are some that are not, the unapproved medicines—they still have a TGA process to go through. There is still that process but the state will not be duplicating it, so it will make it easier for doctors to prescribe the substances.

**Mr WEIR:** We talked earlier about the disposal. Are there any changes to the disposal methods or points? I am back on the agricultural side of it again.

**Ms Gibson:** No, and I have an answer around the storage. I understand that there are no changes in that space. For S7s, it is covered by OH&S legislation at the moment and that will continue. For restricted S7s, like your 1080 and your strychnine, it is the same conditions on the approvals that would apply now. In terms of what is considered a high-risk poison, I am told it is S8s and the prohibited substances, which is S9 and S10.

**Mr WEIR:** Are there any restrictions on the quantity of those S7s?

**Ms Gibson:** I would have to take that on notice and find out from the team.

**Mr Harmer:** I wonder if it is worth making a general comment about agriculture and primary production. In developing the provisions, the department consulted extensively and received feedback from AgForce which sought clarification around the impacts of various features of the bill. Dr Young has spoken to that already today.

For the most part, the impacts on the primary sector are that the framework remains largely unchanged. Probably the only significant point of difference is around the requirements on fee-for-service providers that my colleagues have spoken to today. I think the committee can be assured that there are no significant implications from this legislation for primary producers. It will remain largely as they experience it now.

**Mr MICKELBERG:** In relation to the Therapeutic Goods Bill, I note that the department said they are not aware of any current traders who will be affected by changes under the bill, but I notice there is a transitional period of two years which is on the basis of a precautionary principle. That just seems redundant if there are no traders identified. Could you expand on the rationale behind that decision?

**Dr Young:** In the department we are not aware of anyone who would be caught up by it, but we are not totally confident that there might not be some traders out there, so we will be undertaking a very thorough communication strategy to make sure that people are aware that this is now the case and that they are captured by this. That is why we want the two years, because it is a significant amount of work to go and get that authority. We just want to cover both bases.

**Ms PUGH:** My question also touches on the Therapeutic Goods Bill. My question is a bit of a funny one and it is a bit of a girl question. The explanatory notes also touch on herbal medicines and vitamin supplements—things you might find in a natural health store, so moving away from what we come to understand as medicine. I am noticing as I get older and I start using more and more extreme beauty treatments that there are a lot of things you can buy that actually have warnings on them that you should not use them when you are pregnant or things like that. There are also some topical creams that carry warnings around not being used at particular times. Are we moving towards a point where we might have to start labelling creams and things that go on the skin because they are getting more and more effective at actually getting into the body? It is a bit of a funny issue, but I just bought an oil that says in giant letters 'Do not use while pregnant' because it has vitamin A in it, but there are a lot of vitamin A products on the market that I do not think carry that warning.

**Dr Young:** That is why we need to have that national process, and that is why we are a little bit concerned that there might be people in Queensland who are only producing substances within Queensland and not selling them across the border. That is why we want them to be caught up through the process. It is the role of the Therapeutic Goods Administration to go through all of those products, because most of them are produced in the country and move across borders.

**Ms PUGH:** So that will capture topical products?

**Dr Young:** When they think there is a risk, yes.

**Ms PUGH:** Fantastic.

**Mr MICKELBERG:** I have a follow-up question that has occurred to me since you answered my last question on the transitional period of two years in relation to the Therapeutic Goods Bill. Do the other states that have regulated in this space have a transitional period? The thrust of my question is whether this will enable a business or an operator from Queensland to sell into other states potentially and not be captured by legislation when the intent of that state is that it is illegal.

**Dr Young:** No. Until the transition period ends, they could only do it within Queensland because they are already captured by the Commonwealth bill.

**Mr MICKELBERG:** Okay. I have had experience with business operators who have expressed concerns in relation to the sale of gelatine or collagen products in Queensland and differing approaches across the states and, effectively, a differing compliance framework all over the place. This bill would seek to standardise that across all of Queensland for those types of businesses but also there is Commonwealth legislation; is that right?

**Ms Gibson:** If you are talking about businesses that might already be trading interstate, they will already be captured by the Commonwealth Therapeutic Goods Act. All the Queensland bill will be doing is closing a loophole for small businesses that are not already trading interstate, so it sounds like those sorts of businesses should already be complying with the Commonwealth act.

**Mr MICKELBERG:** Back to the Medicines and Poisons Bill, I notice within clause 90 there is a requirement for a pest management licensee to undergo a health check and there is also a reactive or an incident informed requirement where they might be made to do a health check if there is a reporting issue. Some of the examples within the explanatory notes make sense—for example, if they have mental health issues or various other conditions—but I noticed one of the examples is if they had a back injury. What is the justification behind that example? I understand that from an OH&S perspective, but that is not the department's role, I would contend.

**Dr Young:** I understand it is if they have to go into close spaces like roof cavity areas that they cannot get in and do the job appropriately.

**Mr MICKELBERG:** So it is if they cannot do the job properly. Okay; fair enough. Thank you.

**CHAIR:** I understand that the monitored medicines database is a national database.

**Dr Young:** No.

**CHAIR:** You have talked about interaction with other states. Is it a national database? If not, how does that interact with other states?

**Dr Young:** No, it is not a national database. Each state is rolling out their own version, but the Commonwealth is setting up a process that all scripts throughout the country come into one place and then each database accesses that, but they can only access their state's scripts. That is my concern with New South Wales. We need to all work together to work out how we manage people who move between states.

**CHAIR:** On the issue of testing or safeguarding the integrity of that, are there plans—I am not asking you to tell me what is being planned—or processes ready to be set in place about how we maintain the privacy and the integrity of this system to prevent hacking and the like?

**Dr Young:** Yes. All our IT systems of course need that in place to prevent people illegally looking at the information, but also there are audit processes in place if people go and access records that they should not be accessing.

**CHAIR:** As there are no further questions, we will close this session. There is one question on notice from the member for Buderim on the substance management plan in terms of checking the poisons schedule. It will be specified exactly what that question is. Did you want to come back to us?

**Mr MICKELBERG:** I think it was answered in the supplementary remarks.

**Ms Gibson:** You did have one other question, which I can respond to, about the quantity, and just noting David's statement that obviously there are no major changes in the primary production space. I have been advised that there are no restrictions on quantity for S7s. For restricted S7 approvals, the approval itself will specify the quantity of the 1080 or PAPP or strychnine and it will depend on the location and size of the property.

**CHAIR:** So your question has been answered in that case?

**Mr MICKELBERG:** Yes.

**CHAIR:** It seems we have no questions on notice, so that is fine. That concludes this briefing. On behalf of the committee, I thank all representatives who have participated in this hearing today. Thank you to our Hansard reporters and thank you to committee staff. A transcript of these proceedings will be available on the committee's parliamentary web page in due course. I declare this public briefing closed.

**The subcommittee adjourned at 3.04 pm.**