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Challenges to pharmaceutical policymaking: lessons from Australia's National Medicines Policy

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ABSTRACT

Objective: National medicines policies (NMPs) provide a means for governments to achieve their objectives in relation to pharmaceuticals and other medicines. This research aimed to identify challenges to implementing the objectives of the Australian NMP from the perspective of key stakeholders.

Methods: In 2012 and 2013, we conducted 30 semi-structured interviews with stakeholders involved in the discovery, clinical testing, regulation and funding of medicines in Australia. We asked participants to describe their careers and to give their opinions on specific issues surrounding drug development, clinical research, regulation and subsidisation in Australia. Data were analysed using Morse's outline of the cognitive basis of qualitative research and Charmaz's outline of data analysis in grounded theory. The initial phase of "open coding", revealed findings that could be mapped to three of the four objectives of the NMP. We then conducted "focused coding" for themes relevant to these objectives.

Results: Participants identified many issues relevant to the ongoing evolution of the NMP, relating primarily to ongoing tensions between the commercial objective of ensuring a viable medicines industry, and the non-commercial objectives of ensuring that medicines are safe, effective and affordable. There were also a number of other challenges identified to the achievement of both the commercial and non-commercial objectives of the NMP. These included limits to government funding, globalisation, consumer advocacy, changing scientific paradigms and new information technologies.

Conclusions: There are many issues that need to be addressed if policymakers are to achieve the best outcomes from the NMP. Tensions between the commercial and non-commercial objectives of the NMP suggest the need to ensure that one stakeholder group's imperatives do not stifle those of other groups. At the same time, there are a number of emerging issues that are likely to concern all stakeholders equally, and these are both challenges and opportunities for new kinds of collaboration.

KEY QUESTIONS

1. What is known about the topic?

We know that stakeholders have a number of concerns about medicines policy, but little is known about the specific challenges to implementing medicines policy from the perspective of those involved.

2. What does this paper add?

We demonstrate that stakeholders have many concerns that could impact upon the implementation of medicines policies. These relate primarily to ongoing tensions between the objective of ensuring a viable medicines industry, and the objectives of ensuring that medicines are safe, effective and affordable. There are also a number of issues that potentially pose a challenge to achieving both commercial and non-commercial objectives of the NMP. These include limits to government funding, globalisation, consumer advocacy, changing scientific paradigms and new information technologies.

3. What are the implications for practitioners?

Policymakers need to systematically address the barriers to the ongoing implementation of the NMP. Policymakers should also ensure that one imperative (such as the commercial imperative) does not stifle other objectives. Other emerging issues are likely to concern all stakeholders, and these provide opportunities for new kinds of collaboration among stakeholders.

INTRODUCTION

National medicines policies are expressions of governments' medium and long-term goals in relation to the development, testing, regulation, subsidisation and quality use of medicines.^{1,2} Australia was one of the first industrialised nations to formulate a national medicines policy in the mid-1990s. In 2000, the Commonwealth Government of Australia gazetted its "National Medicines Policy" (NMP), aimed at "meet(ing) medication and related service needs, so that both optimal health outcomes and economic objectives are achieved."³ The NMP does not provide specific technical direction, but rather offers 'frameworks for action' that balance divergent interests among stakeholders, most notably those between governments and manufacturers.^{4,5}

Australia's NMP has four central objectives: 1) medicines should meet appropriate standards of quality, safety and efficacy (mostly the responsibility of the Therapeutic Goods Administration-TGA); 2) timely access to the medicines that Australians need, at a cost that individuals and the community can afford (mostly through the Pharmaceutical Benefits Scheme); 3) quality use of medicines (through, for example, the National Prescribing Service) and 4) maintaining a responsible and viable medicines industry.³ The NMP specifies how each of these objectives should be achieved, and which stakeholder groups have primary responsibility for ensuring success.

The NMP recognises that all four of its objectives are interdependent and must be pursued in an integrated way. The NMP also emphasises the importance of "partnerships", and of ensuring that all stakeholders are accounted for in pursuit of the objectives of the NMP so that the interests of one stakeholder group does not come to dominate medicines policymaking. The NMP doesn't aim to finally resolve the inherent tensions among stakeholder objectives but rather to provide each stakeholder group with a 'reference point for lobbying'⁶ and a means to manage tensions and avoid any one objective being pursued to the exclusion or detriment of the others.⁷

Since the inception of the NMP, it has formed the conceptual basis for a number of substantial developments in policy and regulation aimed at improving the registration, post-market surveillance, promotion, prescribing and use of medicines, as well as promoting system sustainability. Numerous working groups and forums, comprising government, manufacturer, medical, pharmacy and consumer representatives, have been formed to tackle these policy issues.^{5,7-10}

While Australia's NMP has come to be regarded as an exemplary model of coordinating stakeholders towards shared objectives,⁷ policymaking processes have frequently involved contest, negotiation and compromise among the NMP's 'partners'. Reforms in drug pricing and listing, for example, have directly pitted the government's necessary focus on cost-containment against industry's imperative of getting the highest price it can for its products. These reforms include the F1/F2 formulary split that distinguishes between newer patented medicines and older generics, and the accelerated price

disclosure requirements that allow the Government to save money from the discounting arrangements between pharmacists and wholesalers for generic medicines.^{11, 12}

Given how contested medicines policymaking can be, it is essential to know what might be the barriers to the implementation and evolution of these policies from the perspective of the stakeholders involved. We are not aware of any work that has focused explicitly on this question in Australia, with the exception of one qualitative study that we conducted, in which we explored the engagement of the Australian pharmaceutical industry with the concept of quality use of medicines (QUM).^{13 p314} This research demonstrated that, while employees of pharmaceutical companies claimed that they were committed to QUM and had a good understanding of the concept, QUM did not seem to have brought about structural changes to industry. Nor was QUM positioned as the central goal or framework in designing a company's operational strategies. Moreover, participants expressed a significant degree of ambivalence towards governments and medical organisations. These findings were interpreted to mean that uptake of QUM by the pharmaceutical industry is far from perfect and that its implementation is "infused with issues of power and vulnerability; trust and mistrust; altruism, self-interest and coercion."^{13 p319}

While there is still much work to be done in relation to QUM, of the four NMP objectives, it is the most developed and has had the greatest resources devoted to it. There is a "National Strategy for Quality Use of Medicines"¹⁴ and the National Prescribing Service has been heavily invested since its inception in the late 1990's in a "partnership approach", involving "health professionals, consumers, the Government and the pharmaceutical industry coming together to solve problems" relating to quality use of medicines.^{15 p31} Far less systematic attention has been paid to the three other objectives of the NMP.

In 2012 and 2013, we conducted research aimed at exploring drug development, clinical research and the regulation and funding of medicines from the perspective of all key stakeholders. In this article, we present the results of this study that pertain to the implementation of the National Medicines Policy.

METHODS

We chose a qualitative approach to eliciting stakeholders' perspectives because we wanted to explore issues in depth, and allow our participants to spontaneously raise issues that they thought were important—both so that no major themes would be missed, and so that the issues of greatest salience to stakeholders could be identified. We conducted 30 face-to-face interviews in late 2012 and early 2013. This is a typical number of interviews for an in-depth qualitative study, which aims for depth, variation and thematic saturation rather than generalisability.¹⁶

Sampling was purposive. To ensure that our research encompassed all phases of drug development, we conducted interviews with stakeholders involved in basic science research, clinical research, medicines regulation and funding, as well as with consumer representatives. We sought the views of those working in the pharmaceutical industry and in universities, research institutes and government regulatory and funding agencies. Industry participants came from a variety of professional backgrounds, particularly academic research, clinical medicine, and pharmacy. They held a variety of positions in the pharmaceutical industry as medical directors, clinical research managers, regulatory affairs managers and pricing and reimbursement managers.

Interviewees were identified first through organizational websites and the professional contacts of the research team and then via snowball sampling from the initial group. 33 people were approached in total and 3 declined to be interviewed (one industry employee, one academic basic scientist and one regulator). All participants signed consent forms and agreed to speak from their own (rather than their organisation's) perspective.

Semi-structured interviews lasting one to two hours were conducted by one of the research team. Participants were first asked to describe, in their own words, their career trajectories and experiences. They were asked how they came to work in their current positions, how they learned to fulfil their current roles and responsibilities, and about the influence of any role models. They were asked to describe people they admired and people of whom they disapproved and to discuss those aspects of their work they found most and least rewarding. They were then asked for their opinions on specific issues surrounding drug development, clinical research, regulation and drug subsidisation in Australia, such as the globalization of clinical research, the current regulatory and economic environment, and relationships between industry and academia.

Interviews were recorded and transcribed verbatim. For data analysis, we drew both on Morse's outline of the cognitive basis of qualitative research¹⁷ and on Charmaz's outline of data analysis in grounded theory.¹⁶ This procedure involved initial coding for themes, and synthesizing themes into analytic categories. Coding was conducted independently by three researchers, and agreement was reached on the major themes and analytic categories. Thematic saturation—i.e. the point at which no new themes were emerging—was reached after approximately fifteen interviews.

We emphasise that, because we wanted to allow issues to arise spontaneously, interviews were loosely structured and did not focus explicitly on issues to do with the NMP. The initial phase of “open coding” revealed findings that could be mapped to three objectives of the NMP: 1) medicines should meet appropriate standards of quality, safety and efficacy; 2) timely access to the medicines that Australians need, at a cost that individuals and the community can afford; and 3) maintaining a responsible and viable medicines industry. We then conducted “focused coding” in order to extract further themes relevant to these three NMP objectives. At this point it became clear that the issues we had identified could be divided into two broad analytic categories: 1) issues reflecting tensions between the commercial and non-commercial objectives of the NMP, and 2) issues potentially impacting upon all objectives of the NMP.

Because interviews were semi-structured and numbers representing each sub-group were small, we did not attempt to draw fine distinctions among subgroups. We therefore note in our results where obvious differences in opinion were evident between stakeholder groups (e.g. between industry and non-industry participants) but we do not focus on these distinctions or make any claims about their generalisability.

The study was approved by the university's research ethics committee.

RESULTS

Two key analytic categories arose from the data. The first was that there remains a significant amount of perceived tension between the objective of ensuring a viable medicines industry and the objectives of ensuring that medicines are safe, effective, accessible and affordable—i.e. between the commercial and non-commercial goals of the NMP. The second was that there is a set of emergent challenges to drug development that are of significance to the achievement of both commercial and non-commercial objectives of the NMP.

Ongoing tensions between objectives of the NMP

The most obvious tension to arise from our data was that between the objective of ensuring a viable medicines industry and the objectives focused on safe, effective, accessible and affordable medicines.

There was a view among some participants that relationships between industry and other stakeholders are improving, and some industry participants were of the view that even the most commercially-oriented industry activities are supportive of the “public health” objectives of the NMP such as promoting the *development of high quality, safe and effective medicines*.

P10 (Industry clinical and regulatory affairs manager): It was just too difficult a drug to leave on the market as a [disease] drug, when GPs would be managing it ... and the company chose to pull it off the market pretty soon after its launch, and I think that was a good call.

Most participants (from both inside and outside industry), however, were less sure about the compatibility of the objective of supporting the pharmaceutical industry and the other objectives of the NMP. This, in turn, was seen by participants to stem mostly from lack of commitment on the part of industry employees to the goals of public health.

Promoting commerce vs. developing high quality, safe and effective medicines

With respect to the objective of developing *high quality, safe and effective medicines*, several (non-industry) participants argued that, while industry was generally compliant with registration requirements, it was not sufficiently committed to post-registration “pharmacovigilance” and post-marketing research.

P22 (Academic researcher/clinical pharmacologist): it’s almost like you’ve got to drag them kicking and screaming ... you’ve actually got to track them down and see if [a promised surveillance activity] occurred.

Promoting commerce vs. ensuring access to affordable medicines

With respect to *ensuring access to affordable medicines*, a number of participants expressed concern about the price that the pharmaceutical industry demands for its medicines. Frustration was also expressed about the perceived unwillingness of the industry to see itself as part of a broader social and economic system of health care, which has no option but to consider opportunity costs.

P16 (Government payer): I get ... frustrated with industry, who says you’re not doing this, and you’re not doing that, and we say well guys what do you want us to do? Do you want us to close hospitals so we can pay for you?

Importantly, even some industry participants acknowledged that industry is not always fully committed to, or able to commit fully to, making their medicines affordable.

P12 (Industry medical director): The most frustrating thing for me personally is I think industry is becoming far too fixated on making money, and losing sight of what we are really here to do [which] is to provide innovative, high-quality, affordable medicines.

P14 (Industry pricing/reimbursement manager): We’re focusing on a narrow, narrow population; to generate the return on a narrow population you have to multiply the price, it’s a hard reality. And the same hard reality is that individuals can’t afford that.

Challenges to promoting a viable medicines industry

While participants focused mostly on the ways in which the pharmaceutical industry might thwart other (non-commercial) objectives of the NMP, there was also some talk about how these other aspects of the NMP might thwart the objective of promoting a viable medicines industry. Concern was expressed, for example, by both industry and non-industry participants about the TGA and the PBAC demanding ever-more data from those conducting trials, thus placing undue pressure on pharmaceutical companies conducting trials.

P20 (Academic clinical researcher): The whole system of governance ... It’s now being taken over by people clearly with OCD, who’ve got no insight at all. It’s just preposterous. And it’s killing the whole game.

Concern was also expressed by both industry and non-industry participants about pricing reforms that might make companies less willing to invest in clinical research in Australia because they are unlikely to get a return on investment.

P14 (Industry pricing and reimbursement manager): We must justify a commercial return commensurate with the rest of our industry, with our past performance, and with other industries as well. And that will determine where we channel our research, and that’s where the payer question comes into it, which is if the commercial return on the investment is not within what our expectations with our risk of return ratio would be, then we would have to channel it elsewhere.

Other tensions

In addition to tensions between commerce and public health, concern was also expressed about the tendency of the TGA to have a restrictive view about which clinical benefits are worthwhile, thus inappropriately preventing some useful medicines from entering or staying on the market. In this way, the objective of promoting the development of high quality, safe and effective medicines was seen to be in tension with the objective of ensuring access to medicines.

P25 [Academic clinical researcher]: [The regulators] seem to tend to focus on some aspect that they think is important, and be fairly closed minded about other potential benefits. So for instance when the newer insulins came in they seemed to be only willing to recognise the benefit of reducing blood sugar levels, in other words HbA1c, and to not be willing to recognise the benefit of reducing risk of hypoglycaemia, which as far as diabetic patients and physicians are concerns is extremely important.

Emergent challenges of relevance to both commercial and non-commercial objectives of the NMP

All participants, no matter what their role, spoke at length about a number of broader social, political, economic and scientific forces, including increasing limitations of government funding for biomedical research and development, globalisation, consumer advocacy, changing scientific paradigms, and new information technologies. These were seen to have the potential to slow down—if not derail—achievement of both commercial and non-commercial objectives of the NMP.

Lack of government funding for drug development and policymaking

All participants complained about what they perceived to be inadequate government support for the objectives of the NMP (as well as for their own activities).

- *Challenges to developing high quality, safe and effective medicines*

With respect to *promoting the development of high quality, safe and effective medicines*, concern was expressed about the reliance of the TGA on commercial funding. While some participants (both within and outside industry) saw it as an advantage for the TGA to be funded by industry and thus independent of government and not reliant on public service funding, others (primarily from outside industry) were concerned about the effects of industry funding on the TGA's independence and ability to carry out their tasks thoroughly.

P19 [Consumer]: Our post-medicine marketing and our post-device marketing results are not being fed into the system quickly enough for consumers to be protected quickly enough ... I think there's been some commitment to try and improve that, but I don't, it hasn't happened to my knowledge yet.

Both industry and non-industry participants also observed that government funding priorities and political manoeuvring could have a profound impact on the capacity of both academic and industry-supported researchers to conduct post-marketing research and surveillance.

P22 [Academic researcher/clinical pharmacologist]: There are a ton of people who are interested in adverse drug reactions, that would move into that area if money was put in that area, but there's just next to no money goes into that area ... It's a major source of morbidity and mortality in Australia ... and yet politicians come up with a kind of 'oh people need to be educated more about drugs' or some such thing, before they prescribe them. And you go 'oh good, all 10,000 of them?'

- *Challenges to ensuring access to affordable medicines*

With respect to *ensuring access to affordable medicines*, several industry participants—argued that the government does not commit enough money to the funding of medicines relative to other societal goods.

P9 (Health economist working in industry): I always like to go back to the banks – the Commonwealth Bank made \$10billion worth of profit last year. We spent \$8 billion on drugs for the whole country ... We forget to put stuff back into perspective.

A related concern—expressed by those inside and outside industry—was that equity of access to medicines—particularly medicines used to treat rare diseases or subsets of diseases—could be threatened by the PBAC’s mandate to ensure cost-effectiveness at a population level.

P22 [Academic clinical researcher/clinical pharmacologist]: so I chaired the (hospital medicines committee) and the most common bit of work we had was, ‘we’ve got a person with unusual disease for which there’s no good quality studies, we want to use this drug which seems logical...and we want to use something that has a mechanism of action that seems to make sense, can the drug committee pay for it, or will the hospital pay for it?’ And it was all because the pharmaceutical benefits scheme would not, because you know, unless there was this pharmaco-economic analysis, and of course that meant that funding was only provided for common diseases.

- *Challenges to promoting a viable medicines industry*

Lack of government investment in the pharmaceutical industry was seen to be a major threat to the objective of *facilitating a viable medicines industry* in Australia. Many participants believed that Australia does not invest in its pharmaceutical industry nearly as much as other countries do.

P6 (Industry pricing and reimbursement manager): The pharmaceutical industry in Australia doesn’t get the same government support as it does in Switzerland or the UK, because we haven’t really got much home-grown industry... So you will find in a lot of countries overseas that actually have R&D based pharmaceutical companies, they treat them better than they do in Australia in terms of government support.

Lack of government funding was also seen to be a threat to academic basic science and clinical research. A number of basic scientists felt that there were insufficient funding schemes to help them move the molecules they discover into the early stages of drug development, and to support investigator-driven clinical research. (This was coupled with what was perceived to be extreme risk aversion on the part of industry and reluctance on the part of industry—despite rhetoric to the contrary—to form genuine public-private partnerships).

P17 [Academic basic scientist]: a big issue for us was how does the NH&MRC fund that gap between this research discovery and where industry really comes in, development grants and things like that ...Everyone talks about the gap, because the gap is real, and the gap is a challenge.

Globalisation of drug development

Another issue raised by many participants—both inside and outside industry—was the trend of pharmaceutical companies towards conducting most, if not all, of their clinical trials in emerging economies/developing countries.

- *Challenges to developing high quality, safe and effective medicines*

Globalisation of clinical research was seen by both industry and non-industry participants to have both positive and negative effects on the capacity to *promote the development of high quality, safe and effective medicines*: On the one hand, the increasingly globalised nature of clinical research was seen to have stimulated efforts towards regulatory harmonisation, while on the other it was noted to have posed major challenges for regulators who needed to determine whether data derived from elsewhere is generalisable to the local population.

P22 [Academic researcher/clinical pharmacologist]: So the globalisation sort of thing whereby you decide to study diabetes and you look at India and you think there’s a few hundred million diabetics, that’s a good place to do a study, that’s where the ethics I think become a bit interesting. And also the science whereby you say well that is a population prone to diabetes, what does it mean for our non-Indian, non South Asian based ethnic groups?

- *Challenges to ensuring access to affordable medicines*

With respect to *ensuring access to affordable medicines*, concern was expressed by both industry and non-industry participants that if Australia lost its involvement in clinical research, then its clinicians would have less access to innovative medicines that can only be accessed through clinical trials.

P29 [Regulator]: I think it will be very important in the future, because I think we'll have a whole lot of specialists who have never had any experience of using new medicines as they come to market; we won't have clinical trials happening here, which means we won't have access to medicines.

- *Challenges to promoting a viable medicines industry*

Perhaps most obviously, both industry and non-industry participants argued that the globalisation of clinical research was a threat to the objective of *promoting a viable medicines industry* in Australia, because companies would no longer invest in Australian trials. Our participants' attributed this shift of trials out of Australia to the relative ease (and improving quality) of clinical research in emerging economies. They compared the system of research oversight in developing countries to that in Australia—arguing that the latter has become excessively bureaucratised, expensive and (relatively) slow.

P20 [Academic clinical researcher]: ...It's bad times. And anybody who claims differently needs to take a very good hard long look at what's happening with pharma, because every single pharma company that until four years ago had any major capital and resource investment in this country, to be the national or regional headquarters of a pretty substantial clinical research and development enterprise, have gone or are going.

Consumer advocacy

- *Challenges to developing high quality, safe and effective medicines*

Consumers were seen by both industry and non-industry participants to have a role in facilitating the *development of high quality, safe and effective medicines* by, for example, ensuring that labelling and product information were 'consumer-friendly', and by reporting adverse events. But consumers could also sometimes over-react to perceived safety concerns, or be too demanding of information, placing unnecessary pressure on the TGA.

P26 [Regulator]: The experience ... with the TGA, is that where if a doctor rang up and said 'I want to report something', you'd get it done in five minutes – the experience has been that you know, it can take 25 minutes or more to deal with a patient. ...and also they have expectations of information in return, and whereas you might say to a GP 'look there's been two cases worldwide and we don't think it's really very significant, we'll keep a watch on it' – you've got to spend a long time with a patient.

- *Challenges to ensuring access to affordable medicines*

Similarly, while consumer advocacy for *access to affordable medicines* was generally viewed positively, concerns were expressed, on the one hand, about the degree to which less powerful consumer groups were engaged in decisions about resource allocation, and on the other hand the perceived unwillingness of more vocal consumers (and their clinicians) to consider opportunity costs when advocating for access to particular medicines.

P16 (Government purchaser/payer): I get frustrated at times with some of the consumer demands, saying 'we want it' ... I remember a taxi driver saying to me once when I was in a taxi a few years ago, saying 'all the government can do is print more money'. And I said 'that says it all'.

Changing scientific paradigms

- *Challenges to developing high quality, safe and effective medicines*

New models of disease and treatment—particularly targeted therapies—were seen by all participants to have the potential to improve the effectiveness of medicines for specific sub-groups of patients. Many participants, however, (both inside and outside industry) noted that this paradigm (sometimes referred to as "personalised medicine") is yet to fulfil its potential. In particular, there was concern that these medicines the imperative to shift to a new paradigm might lead to the development of drugs that provide limited or very defined benefit and may not provide a significant advance over existing (older) medicines.

P10 [Industry clinical and regulatory affairs manager]: I think the era of personalised medicine is fantastic, but there needs to be an ongoing commitment to developing a drug throughout its life cycle ... by the end of the 20 year patent life, you've got companies going well will I invest that \$100 or \$200million to do this drug trial in this drug which has only got five years left. And so then what they are doing is they're trying to come up with a slow-release formulation, or a slightly different salt, or something that may have less immunogenicity, or something like that, and it seems to me that they are investing in a new therapy when there's still life left in the old one.

- *Challenges to ensuring access to affordable medicines*

New models of disease and treatment—particularly targeted therapies—were seen by all participants to have the potential to *facilitate access to medicines* that would otherwise be deemed ineffective because subgroups who benefit would be obscured in large population studies. But it was also noted that an increased emphasis on targeted therapies could impede equitable and/or efficient *access to medicines* both for those who need them and for the population as a whole. First, it was noted that payers currently have difficulty assessing the evidence generated by smaller clinical trials, or more complex clinical trials with several study sub-groups. And this in turn might make them reluctant to fund some targeted therapies.

P16 [Regulator]: In some of the cases we don't have the right methodologies yet ... For example the PBAC has been trying to engender some debate on indirect comparisons and how do you do cross study comparisons, and try and minimise the uncertainty with respect to that. We've got the issue at the moment about with all trials with new cancer agents, ethics committees do not allow them to proceed unless they allow the people in the placebo arm or the control arm, to switch over to the active arm after a certain period of time. But we don't know how to manage that data, we don't know, and again I have a slide which says 'are we trying to tackle tomorrow's problems with yesterdays' science'.

A related concern (discussed above) was that equity of access to targeted therapies could be threatened by the PBAC's perceived mandate to ensure population-level cost-effectiveness. The concern here was that if expensive medicines for rare diseases, or rare subsets of diseases, were deemed to be too costly for the population as a whole, then patients with rare diseases would be unfairly disadvantaged.

On the other hand, it was noted that, when targeted therapies *are* funded, this funding (by definition) does not meet the needs of those from other patient subgroups. It also has costs for the population as a whole because these medicines (and their companion diagnostics) tend to be very expensive.

P5 [Industry clinical research]: They say it's quite easy, we'll just stratify and we'll develop it in just a sub group of people. But that's got all the implications then about, because you won't be able to identify that sub group necessarily in your clinical practice ... I mean they shouldn't be getting the therapy if it's not going to work in them, but you've spent all the money and you are subsidising therapies for only some patients, which I suppose you are helping them. But it's a complex societal issue.

P22 [Academic clinical researcher]: Do you know what the most expensive treatment in... or the most expensive item in the treatment of snake bite in Australia is? It's not anti-venom, it's the venom detection kit ...

- *Challenges to promoting a viable medicines industry*

The move towards more "targeted" therapies was also seen as a challenge to the objective of *promoting the viability of the medicines industry*, because of the increased complexity of developing these medicines. It was also noted that "data mining" has so far failed to live up to its promise as a new approach to drug discovery.

P29 (Policymaker): The development process for medicines now is so desktop related, there's all these people running programs and lots of matches to find chemicals that maybe will hit targets, but it doesn't seem to have made it any more efficient to actually finding new drugs.

New information technologies

- *Challenges to developing high quality, safe and effective medicines*

Finally, while new information technologies, databases and data linkage facilities were seen to be an important facilitator of pharmacovigilance and phase 4 studies (and, therefore, the *development of high quality, safe and effective medicines*), many of our participants expressed the view that their utility was limited by the unwillingness of government bodies to provide easier access to the necessary data.

P26 (Regulator): The obvious way to do it in Australia is to link the prescribing information and the Medicare information with state hospital records and death records, because you can track patients. And there's a great reluctance to give approvals for that. There have been a small number of examples, and I just hear conflicting stories about attitudes at high levels in the Dept. of Health as to whether they wish to entertain these or not.

- *Challenges to promoting a viable medicines industry*

New information technologies were also seen to facilitate the conduct of complex clinical trials—and therefore contribute to the objective of promoting a *viable medicines industry*.

P15 [Industry clinical research]: So these days our data capture systems are all electronic, so we can already sit in our office here, dial in and see the data coming in from the site. But now there's a potential that we could dial into the electronic medical record and compare the source data in the patient record with what's in our data capture system, which is something we have to do, to ensure the integrity of the data, ensure there is no fraud susceptibility to data to health authorities, because they're going to do that if they come out and do a spot audit. So that could have a huge productivity saving, so we don't have to physically fly to the site each time to do that, we can do that on an ongoing basis.

DISCUSSION

Summary

Our research makes clear that stakeholders see many challenges to implementing those aspects of the NMP focused on 1) medicines meeting appropriate standards of quality, safety and efficacy; 2) timely access to the medicines that Australians need, at a cost that individuals and the community can afford; and 3) maintaining a responsible and viable medicines industry.

These challenges fall into two groups: First, there are concerns about tensions between the objective of ensuring a viable medicines industry and the objectives of the NMP relating to *quality, safety and efficacy* of medicines, and *access to affordable medicines*. These concerns stem, from a sense that the pharmaceutical industry is insufficiently committed to public health. While some industry participants denied that such a tension exists, other industry participants, and all non-industry participants, saw significant divergence between the objectives of the pharmaceutical industry and those of other stakeholder groups. Second, our participants identified a number of challenges that impact upon both commercial and non-commercial objectives of the NMP, including those posed by limitations of government funding for biomedical research and development, globalisation, consumer advocacy, changing scientific paradigms, and new information technologies.

Practical implications

Our findings have a number of implications for those developing and implementing medicines policies in Australia. First, by identifying a set of perceived challenges to implementation of the NMP from the perspective of all key stakeholders, our findings could provide a useful organising framework for those with responsibility for developing and implementing national medicines policies.

Our findings might also be useful in guiding stakeholder collaboration. As mentioned previously, the NMP emphasises the importance of “partnerships”, and of ensuring that all stakeholders are accounted for in pursuit of the objectives of the NMP. While we did not formally evaluate this aspect of the NMP, and cannot say from this research how well stakeholders are working together, we did

identify a number of potential threats to stakeholder collaboration, stemming from the perception of ongoing tensions between the commercial goals of the pharmaceutical industry and the goals of other groups. In this regard it is noteworthy that the most significant reforms in Australian pharmaceutical policy to date have focused on the sustainability of the PBS, particularly changes to drug pricing arrangements. Reforms such as these have necessarily pitched government's cost-containment imperative against industry's profit imperative,^{5,7} and these unresolved tensions will need to be an explicit focus of ongoing policy development. We also identified a number of emerging issues that potentially impact upon both commercial and non-commercial objectives of the NMP. While these issues pose further challenges for policymakers, they also point to potential new opportunities for stakeholder groups to work together as "partners" to manage the external forces that affect them all. For example, all stakeholders could coordinate their approaches to managing the forces of globalisation. Scientists, regulators and clinicians could work together to ensure that targeted therapies are developed efficiently, regulated and funded appropriately, and prescribed rationally. And all stakeholders could work together to advocate for the government funding they need (rather than pitching their needs against one another's) within the constraints of current government budgets; to develop mechanisms for effective and non-reactionary consumer advocacy; and to make the best possible use of emerging information technologies.

Limitations and future directions

This was a small qualitative study, so further research is required to determine the generalisability of our findings. Further quantitative and qualitative research would also be needed to tease out differences among the subgroups we studied. It would be particularly interesting to identify areas of convergence and divergence between industry and non-industry groups and between consumers and those serving them. Because our method was inductive, we could not know in advance which themes would prove to be most significant and might need "unpacking." Additional studies could pursue more targeted questions. Finally, it is possible that many of the stakeholders we interviewed may have had concerns about quality use of medicines but, as mentioned previously, this was not the focus of our research and we did not attempt to draw out responses that might have related to QUM. It is worth noting, however, that some QUM-related concerns, such as medicines labelling and adverse event reporting, did arise in participants' discussions, which is not surprising given how closely QUM is related to the other objectives of the NMP¹⁴ Further research could focus on the QUM objective of the NMP.

CONCLUSION

Those who are involved in the development, testing, regulation and funding of medicines have a number of concerns that could potentially impact upon the ongoing evolution and implementation of the NMP. Policymakers need to be cognisant of these concerns if the NMP is to achieve its objectives. With respect to the over-arching principle of the NMP to promote partnerships and collaboration, policymakers need to be aware of ongoing tensions, while also recognising emerging areas of common concern. These shared concerns can be leveraged as new opportunities for stakeholders to unite in the pursuit of common goals.

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