

Pharmaceuticals Policy Options Report: Options to Enhance the Affordability of Prescription Drugs in Bermuda

Report to the Bermuda Health Council

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PHARMACEUTICALS POLICY OPTIONS REPORT

Submitted to:
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24 November 2010

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EXECUTIVE SUMMARY

The Bermuda Health Council (BHeC) contracted with the Institute of Health Economics (IHE) to produce this *Pharmaceuticals Policy Options Report*. This report draws on documentation and information provided by BHeC, pharmaceutical policy literature and international reports, and interviews conducted with stakeholders by the investigating team.

Report policy options are:

- Bermuda may develop a national formulary listing only those medicines to be covered by the current Prescription Drug Benefit and by any future expansion of the health insurance benefit.
- The list of designated countries for drug importation could be reviewed, updated and clarified to ensure the drugs that are sourced meet good manufacturing practices.
- Bermuda could consider establishing a service to bulk-purchase drugs for all of Bermuda (both hospital and community sectors) with provisions for transparency of importation costs, duties and drug acquisition costs and regulation of mark-ups and/or profitability.
- Bermuda could update and expand the Bermuda Pharmaceutical Association Code of Professional Conduct and Ethics to more clearly establish public expectations and professional obligations for pharmacist services and pharmacy operations.
- A process may be established for regularly negotiating a ceiling on prescription drug markups and professional dispensing fees, including payment for higher value-added pharmacist services.
- Reasonable standards for the number of days' supply of medicines (e.g. 90 or 100 days) could be established for chronic medications once the patient is on a stable dosage regimen.
- Bermuda may review proposed amendments to the *Pharmacy and Poisons Act* to ensure pharmaceuticals policy options that are directly related to the regulation of pharmacist practice and pharmacy operations, as well as other policy options selected for implementation, are allowed or authorized under the Act.
- The draft *Pharmacy and Poisons Act* could be reviewed and considered for amendment to ensure the new pharmacy legislation enables:
 - Licensing of all importers of prescription drugs with mandatory reporting of drug purchases including date, drug name, identification number(s), quantity, costs, mark-ups/pricing, origin, and source.
 - Easier movement of prescription drugs to non-prescription status with requirements for regular updates of drug schedules.
 - Removal of requirement for physicians to sign prescription requesting generic drugs.
 - Authorization for pharmacists to generic substitute based on professional discretion and patient interests.
 - Enhanced pharmacist professional services (e.g. limited prescribing authority; medication management).

- Specific requirements for pharmacy records and submission of data for a prescription drug information system.
- Bermuda could develop programs to promote the safe, effective use of prescription drugs, including increased awareness of Bermuda residents regarding prescription costs, the need for more personal responsibility for health (e.g. medication compliance, healthy lifestyles), and the value of pharmacist services.
- In collaboration with health professionals, Bermuda may adopt accepted prescribing guidelines, at minimum, for the most common disease categories. Due to limited resources, it should not look to develop its own guidelines, rather, to promote the awareness and adherence to well-established sources.
- Bermuda could develop a health professional education campaign that promotes safe, effective, and cost-effective prescribing including the existence of, and adherence to, prescribing guidelines.
- Bermuda may establish a prescription drug information system that mandates the collection and operation of a central repository of data for all prescriptions dispensed in Bermuda.
- We identify two policy options regarding changes to the financing of prescription drugs: a comprehensive option (universal coverage of a comprehensive list of medicines) and an incremental option (universal coverage for drugs essential in managing chronic diseases of central importance).

Pharmaceutical policy challenges are complex and require a systems approach. A high performing pharmaceutical sector requires the coordination of multiple policy instruments to address the interdependence of various facets of the system. Three inter-related objectives that support overarching health goals include promoting the accessibility, affordability and appropriateness of medicines. In this document we have outlined pharmaceuticals policy options that address this "triple-A" framework — ones that are based on international experience, yet suitable for the Bermuda context.

These policy options need to be considered within the context of broader health and pharmaceutical strategies, and further research and consultation will be required to ensure the health needs of Bermuda residents continue to be met through prescription drugs that are available, cost-effective, and used in a manner that provide optimal patient health outcomes.

1 Introduction

The Bermuda Health Council (BHeC) contracted with the Institute of Health Economics (IHE) to produce this *Pharmaceuticals Policy Options Report* to outline potential policy options available to the Government of Bermuda to enhance the affordability of prescription drugs. This report draws on documentation and information provided by BHeC, pharmaceutical policy literature and international reports, and interviews conducted with stakeholders by the investigation team.

While the pharmaceutical market consists of medicines used in hospitals, non-prescription (over-the-counter) medicines, and prescriptions dispensed in community pharmacies, this reports focuses primarily on the latter, which represent the majority of pharmaceutical expenditures.

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1.1 Bermuda context

Unique geographic, demographic and economic factors create certain challenges to providing for the health needs of Bermuda's population. Being an island nation with a relatively small but diverse population of local and expatriate residents poses logistical challenges in health policy, health human resource supply, and health regulation. The aging of Bermuda's population and the increase in rates of obesity and overweight (currently estimated at 64%) puts growing strain on health system demands. The unique nature of Bermuda's economy, its sensitivity to global economic trends, and its tax system also create challenges for sustainable and equitable health care financing.

Total health expenditures in Bermuda for 2009 are estimated to be US\$ 557.7 million, and prescription drug expenditures for 2009 are estimated to be US\$ 37.4 million, equivalent to 6.7% of total health spending. Bermuda's prescription drug expenditure as a proportion of overall health spending is low compared to most countries, and below all OECD countries. Using 2008 data, selected other countries' percentage of pharmaceutical spending in relation to total health spending was: Canada (17.2%), France (16.4%), Germany (15.1%), Aus (14.3% in 2007), US (11.9%), UK (11.8%), and NZ (9.4%).

¹ Department of Health. (2007). Health Survey of Adults and Children in Bermuda 2006. Government of Bermuda.

² National Health Accounts Report 2010, for fiscal year 2008-2009 ending March 31, 2009.

³ OECD Health Data 2010 (stat extracts: accessed at Nov 10, 2010).

http://www.oecd.org/document/16/0,3343,en 2649 34631 2085200 1 1 1 1,00.html

Bermuda's system of social insurance for hospital care has created a basis for a health insurance system that offers more extensive health coverage, including financing for the purchase of prescription drugs. Below is a list of OECD countries and per capita spending on prescription (outpatient) drugs in 2007 (US \$). Bermuda ranks fifth below both Canada and the US.

Per Capita Pharmaceutical Spending (2007) - US\$ per capita

Country	US\$ per capita
United States	752
Belgium	697
Canada	625
France	607
Bermuda	577
Germany	560
Norway	547
Switzerland	516
Japan	480
Luxembourg	467
Austria	463
Finland	453
Iceland	443
Sweden	436
Australia	424
Spain	423
Denmark	362
Slovak Republic	301
Slovenia	292
New Zealand	245
Korea	225
Czech Republic	185

In discussions with stakeholders, we gained valuable insights into key aspects of the Bermuda pharmaceutical sector, including the identification of multiple factors affecting expenditures on prescription drugs. These include:

lack of transparency into drug costs, mark-ups, and prescription pricing

⁴ Bermuda Health Council (2010). *Enhancing the Regulatory Framework for Health Insurers* (Public consultation paper) July 2001.

⁵ OECD – 2007. The 2007 prescription drug expenditure in Bermuda was \$36.9 million (Bermuda Health Accounts Report). The estimated population for Bermuda at mid-year 2007 was 64,009. Bermuda Government Department of Statistics: Mid-Year Population Projections July 1 2000 to July 1 2030. Bermuda. March 31, 2006.

- market power of importers/wholesalers and the fragmentation of purchasing power
- large number of countries from which drugs are imported, leading to issues with labelling, drug quality, and prices
- uncertainty about costs savings attributed to the use of generic drugs
- unregulated professional dispensing fees
- poorly understood value of pharmacist services
- need for updated pharmacist/pharmacy legislation
- drug schedules that are not current
- part time pharmacy inspector with heavy demands (and lack of succession plan)
- lack of detailed utilization and expenditure data (including standardized nomenclature for drugs)
- unmonitored patterns of medicine access, use and outcomes
- desire of many Bermuda residents to have the best health care, regardless of price
- insurer concerns about their ability to design and manage flexible and cost-effective drug plans
- relatively low levels of Bermudians trained as health professionals that return to Bermuda to work
- aging population and the need to provide health services for increasing numbers of retirees
- prevalence of smoking, obesity and chronic diseases such as diabetes
- need for educational campaigns to improve compliance, reduce waste, and increase awareness about cost-effective treatments
- need for improved use of technology such as on-line, real-time prescription claims adjudication.

Some stakeholders commented that the system is not perfect but works well, and they wouldn't want to see radical changes or greatly reduced flexibility in how the various components of the sector work. Some expressed mixed feelings about the introduction of a formulary, and others supported it.

1.2 GLOBAL TRENDS

For the past 20 years, there has been a nearly continuous and rapid rise in the availability, use and cost of prescription drugs (in Bermuda and around the world). Because of this, pharmaceutical policy issues that historically may have appeared to be minor are now sufficiently important in scale, scope or health-system impact that they should be addressed.

For example, prescription drugs are now commonly indicated for chronic conditions routinely seen in primary care (e.g., diabetes, hypertension, asthma). Ensuring that the population has access to these treatments is a primary policy goal in support of health status equity and to reduce future demands on the health care system. To achieve desired health outcomes – and minimize undesired effects – requires quality use of medicines: that the right patients get the right drugs, in the right doses, and that they use them in the right way, for the right duration, with appropriate monitoring and follow-up. To sustain access to quality care requires that the treatments selected be as affordable as possible for individuals and for the population as a whole.

Policy opportunities are being created in the pharmaceutical sector by the expiry of patents on the 'blockbuster' drugs of the past 20 years. It is estimated that medicines with global sales of over USD\$140-billion will come off patent in the next 5 years. This presents a chance to secure significant savings from the use of generic drugs, provided that generic prices are competitive and that generics are prescribed and dispensed whenever appropriate.

Just as rising generic availability poses opportunities, trends toward specialized medicine and the targeting of drug development are placing increasing pressures on patients and payers. For example, with approximately 30% of drugs in development today being for cancer treatments, and the cost of recently-marketed cancer drugs often exceeding USD\$100,000 insurers in the US are increasingly capping health benefits for cancer care.⁷ The challenges of financing new high-cost drugs in an equitable, sustainable, and evidence-based manner are especially great for countries with relatively small populations.

1.3 Costs-drivers and cost-control

Drawing on international experience with cost-drivers and cost-control mechanisms can help to inform policymaking in Bermuda, particularly since Bermuda does not currently have adequate information systems to measure trends in the domestic market.

Cost-drivers for pharmaceuticals can be grouped into four categories: aging, the need for therapy, the growth rate of use for given needs, and the cost of drugs chosen. Each of these has implications for policy and practice.

International experience suggests that population aging has an important albeit gradual impact on prescription drug expenditure at a population level.⁸ Aging is, however, an important determinant of prescription drug needs and out-of-pocket costs for individuals. Aging can pose a barrier to accessing necessary care if coupled with changes in employment status and related access to private insurance — as was historically the case with drug coverage in the US. Health status also plays an important role in predicting drug costs. Although it is not possible for pharmaceutical policy to directly alter population health (e.g. obesity rates), it is nonetheless important for policy-makers to be aware of, and plan for, expected needs for medical treatments and the implications of inadequate access. In some drug classes, evidence suggests that to provide access to treatments generates more savings in health system costs than the drugs themselves.⁹

⁶ IMS Health (2010) "IMS Forecasts Global Pharmaceutical Market Growth of 5-8% Annually through 2014; Maintains Expectations of 4-6% Growth in 2010" (NORWALK, CT, April 20, 2010) http://www.imshealth.com/

⁷ Reed Abelson (2010) "Insurers Test New Cancer Pay Systems" New York Times.

⁸ Morgan SG. Booming prescription drug expenditure: a population-based analysis of age dynamics. <u>Med. Care</u> 2005; 43(10): 996-1008.

⁹ Choudhry et al (2007) "Should Patients Receive Secondary Prevention Medications For Free After a Myocardial Infarction? An Economic Analysis" Health Affairs.

The extent to which patients receive prescriptions for their medical needs is a significant determinant of prescription drug spending as well as patient health outcomes. Achieving the desired effects of medicines depends on ensuring they are prescribed and used appropriately. Medication management for the purpose of encouraging appropriate use is increasingly seen as necessary for cost control and obtaining value for money spent on pharmaceuticals. On this basis, many countries have invested in prescription information systems, medication management policies, quality use of medicines campaigns, and other demand-side initiatives. 10

The literature on drug cost-drivers has consistently found that factors influencing the cost per day of treatment received have a direct effect on expenditure levels and trends. These factors include the selection of options from within treatment categories, the rate of generic drug use, and the prices paid for medicines and pharmacist services. Policy makers can use evidence-based coverage processes to inform decisions to pay for certain treatments and thereby steer prescribers and patients to more effective (and cost-effective) therapeutic choices. Formularies can also be used as powerful tools in negotiations over the prices of patented and non-patented products. Other tools to control the cost of medicines include price regulation, profit controls, global budgets, reference pricing, tiered formularies, and generic substitution by pharmacists. 11

1.4 Policy options and rationale

Given Bermuda's small population, lack of local pharmaceutical manufacturing presence, relative isolation, and reliance on international supply of medicines, some of the policies used abroad may not readily apply in the local context (e.g. domestic product regulation or health technology assessment). Other policies – such as a national formulary – can be adapted for the Bermuda context. From a policy perspective, one is trying to mimic an environment akin to that of a larger country with a predominant payer such as the government. Finally, Bermuda's unique circumstances lend it to some policy solutions that could truly be unique, made-in-Bermuda policies (e.g. a publicly- mandated wholesaler for pharmaceuticals).

In the sections that follow, we provide policy options for consideration. The policy options contained in this report are ones that address problems identified through the consultation process and align with the goals of the BHeC Strategic Plan for 2009-2012. They concern several specific policy areas including drug coverage; drug importation and distribution; retail pharmacy; quality use of medicines; data systems; and, prescription drug financing.

¹⁰ See, e.g., Australia's National Prescribing Service (NPS) http://www.nps.org.au/ or British Columbia's PharmaNet-eRx system http://www.health.gov.bc.ca/pharmacare/pharmanet/netindex.html

11 Tele, Paula; Groot, William. Cost Containment Measures for Pharmaceuticals Expenditure in the EU Countries: A Comparative

Analysis. The Open Health Services and Policy Journal, 2009, 2, 71-83.

2 Drug coverage

Policy on drug coverage (e.g., formulary listing decisions) and related decision-making processes are closely related to policy on drug financing. Formulary-based policies that create a common list of drugs available to the population help promote equity in access to medicines. Formularies have become the backbone of many expenditure management policies, being used to identify drugs that are available, to secure price discounts for drugs purchased, and to even specify conditions by which a physician may prescribe certain drugs for certain patients. In economic terms, formularies concentrate buying power by steering purchases toward particular products – generally because drugs on the formulary are often available at a lower cost to the patient and the drug plan. Potential inclusion on the formulary is a powerful incentive for manufacturers to lower their price in order to be included. 12 Mechanisms to do this include rebates, discounts, bundling of products, tendering or sole-supply, and listing agreements that manage expenditure risk through caps on spending or utilization management.

2.1 A NATIONAL FORMULARY

Policy instrument: Bermuda could develop a national formulary listing only those medicines to be covered by the current Prescription Drug Benefit and by any future expansion of the health insurance benefit.

Rationale: Aligns with Strategic Goals of Equity and Efficacy and Bermuda Health Council Act 2004 Section 5(a), (h).

In a system that does not offer public drug benefits or some form of universal coverage for pharmaceuticals, formularies are of limited policy value. However, because of the Prescription Drug Benefit for seniors and the future potential for a universal drug benefit through the health insurance system, a national formulary would have important benefits for Bermuda. Advantages would include the development of a more focused list of drugs that are imported from approved countries; more certainty over the international supply of drugs based on availability and volume; the opportunity to educate patients and prescribers about evidence-based selection of drugs that are listed on the formulary; and, the ability to monitor utilization and expenses of a fewer number of drugs.

BGA¹³ carries over 3,000 prescription drug products and the Bermuda Hospital Board (BHB) carries over 1,000 prescription drug products. Individual pharmacies may choose to import drugs if they are more readily available or less expensive than through BGA. As a result, drug purchasing power in Bermuda, which is already low due to a small population base, is extremely fragmented. Additionally, physicians and pharmacists come from many different countries and have familiarity with a wide range of

¹² Given the small size of Bermuda's pharmaceutical market, manufacturers may not be as readily convinced to lower drug prices as one would see in larger markets.

13 BGA is the island's only wholesaler and they have an approximate market share of 70%. They also import other health and

non-health items. They carry about 4,500 SKU's.

pharmaceuticals, some of which may be either hard to source, or are very expensive compared to other medications that would be as safe or effective.

Given the extensive experience of BHB in drug procurement and the dispensing of retail prescriptions by the out-patient dispensary, the hospital formulary should be aligned with the national formulary as closely as possible to increase purchasing power and decrease waste. It also allows for better medication reconciliation as patients move from hospital back into the community.

A domestic formulary committee would consider drug listing decisions based on appraisals of therapeutic value for money completed in other jurisdictions¹⁴ with an emphasis on price, availability, cost-effectiveness, prescribing guidelines, and other relevant selection criteria. The formulary would include the most commonly prescribed drugs¹⁵ but would be extensive enough to cover a wide range of therapies. Private prescription insurance plans may choose to fund drugs not on the government formulary, but they would do so at some financial risk. The minimum requirement would be that everyone must fund what is on the formulary.

3 PHARMACEUTICAL IMPORTATION AND DISTRIBUTION

3.1 Designated countries for drug importation

Policy instrument: The list of designated countries for drug importation may be reviewed, updated and clarified to ensure the drugs that are sourced meet good manufacturing practices.

Rationale: Aligns with Strategic Goal of Quality and Bermuda Health Council Act 2004 Section 5(k). 16

Some stakeholders expressed concerns about the quality of pharmaceuticals imported from abroad, noting that importers were not licensed in advance, and that drugs were being purchased from some countries not on the list of approved countries of origin for pharmaceuticals. Fear of low quality drugs, including those with non-English labels, or counterfeits, were expressed. Pharmaceuticals are currently being imported from as many as 32 countries and while this does increase the potential supply of medications, it may also lead to higher costs. As a result, the list of designated countries for drug importation should be reviewed and updated to ensure confidence in the system.

¹⁵ The list does not have to be limited to the most common 100 or 200 drugs – it could be very extensive, covering a wide range of pharmaceutical products. Over time, as the formulary committee gains experience and expertise, the drug list could be refined.

 $^{^{14}}$ HTA organizations include NICE in the UK, CADTH in Canada, and the Australian PBAC.

¹⁶ The authority to designate countries for drug importation is found in the *Pharmacy and Poisons Act 1979*.

The *Pharmacy and Poisons Act* allows the Minister of Health to establish the list of approved countries. The process for reviewing and updating the list of countries must be done in consultation with key stakeholders including importers, wholesalers, pharmacy purchasers, BHB, and drug manufacturers.

3.2 A PUBLICLY-MANDATED WHOLESALER FOR PHARMACEUTICALS

Policy instrument: Bermuda may consider establishing a service to bulk-purchase drugs (e.g. both prescription and non-prescription) for all of Bermuda (both hospital and community sectors) with provisions for transparency of importation costs, duties and drug acquisition costs and regulation of mark-ups and/or profitability.

Rationale: Aligns with Strategic Goals of Efficacy and Accountability and *Bermuda Health Council Act* 2004 Section 5(a), (h).

Several of the stakeholders interviewed were concerned about the importation and distribution of pharmaceuticals in Bermuda being concentrated through a single entity. The concerns expressed were primarily in regards to the lack of transparency into true costs of the drugs including the costs of distribution (e.g. packing and shipping, duties) and mark-ups. BHB chooses to import its own drugs directly to avoid some of the challenges regarding costs and supply. Drugstores often import drugs directly on their own for similar purposes. This leads to a more fragmented and expensive distribution system, with little opportunity to control what drugs are imported and why.

A publicly-mandated drug wholesaler contracted to purchase and distribute pharmaceuticals for all drugstores, hospitals and medical facilities in Bermuda would enable the Bermuda government to ensure true costs of drugs are reported, monitored and controlled such that Bermuda residents benefit from increased certainty around drug costs and supply. It should help to lower drug costs due to increased efficiencies and regulated mark-ups/or profits. It will also make it easier to implement and manage a national formulary system, and to ensure physicians are selecting drugs for which the best evidence of safety, effectiveness, and cost-effectiveness exists. Over time, this will help further reduce prescription expenditures.

The wholesaler service should be established through an open and fair tendering process, where interested businesses (independent or consortia) would be invited to submit proposals that meet explicit selection criteria. Such processes would not preclude the current wholesaler from winning the contract or from continuing to import other health and non-health related items as it currently does. The process would provide for a single entity to import and distribute the majority (or all) of pharmaceuticals in Bermuda, but with the necessary transparency and controls in place to ensure Bermuda residents of good value for money, while at the same time not restricting the ability of the private sector to operate profitable businesses.

4 PHARMACY RETAIL

4.1 Professional standards and the Registrar

Policy instrument: Bermuda may update and expand the Bermuda Pharmaceutical Association *Code of Professional Conduct and Ethics* to more clearly establish public expectations and professional obligations for pharmacist services and pharmacy operations.

Rationale: Aligns with Strategic Goals of Quality and Accountability and Bermuda Health Council Act 2004 Part III, Section 14(1-3) and Section 5(c), (d).

The need for appropriately resourced and funded oversight of the practice of pharmacists and the operation of pharmacies, particularly at a time when a thorough review and updating of the *Pharmacy and Poisons Act* is in progress, would necessitate the establishment of a full-time position of Registrar (or Senior Pharmacy Officer that reports to the Chief Medical Officer in the role of Pharmacy Registrar) and the creation of a full-time pharmacy professional practice consultant to replace the current part-time pharmacy inspector.

The office of the Senior Pharmacy Officer/Registrar would be accountable for all current activities of the office of the Pharmacy Registrar, with new responsibilities that could include:

- Oversight of the newly established formulary committee
- Regulatory supervision and enforcement including taking a lead role in modernizing and updating the *Pharmacy and Poisons Act*; the *Code of Professional Conduct and Ethics*; Drug Schedules; and, the list of designated countries for drug importation
- Oversight of drug importation including the publicly-mandated wholesaler for pharmaceuticals
- Reviews of drug pricing; and, analyses of patterns of drug utilization and expenditure
- Participation in treatment guidelines review and adoption, including ongoing Continuing
 Professional Education of pharmacists

The new pharmacy professional practice consultant would report to the Senior Pharmacy Officer/Registrar, and would focus on supporting pharmacists in practice change management, enabling them to add more value to the health system through improved patient outcomes and utilization of more cost-effective medications. In the next section we outline several pharmacist services that are more patient-focused and that will require a considerable expenditure of time and effort to implement effectively.

4.2 PHARMACY PROFESSIONAL FEES AND MARK-UPS

Policy instrument: A process may be established for regularly negotiating a ceiling on prescription drug mark-ups and professional dispensing fees, including payment for higher value-added pharmacist services.

Rationale: Aligns with Strategic Goals of Efficacy; Corporate Strategic Objective 3.3 to develop clear and transparent processes to establish fees for regulated services; and, *Bermuda Health Council Act 2004* Part III, Section 15(1)(b) and Section 5(h).

Prescription mark-ups and professional dispensing fees are established annually by pharmacy owners. As payers of prescription drugs, the Bermuda government and private insurance companies are in the untenable position of being price-takers, with little or no transparency around retail prescription pricing. Price ceilings or maximum prescription mark-ups and dispensing fees should be negotiated between the Bermuda government and an appropriate representative body for pharmacists and pharmacies¹⁷ to ensure these components of retail prescription prices are transparent and well-managed. The negotiated fees would be established as the "usual and customary" fees, meaning that both public and private insurers would benefit from greater price certainty, with more managed expenditures on professional pharmacist services.

Consideration should be given for using the current level of compensation as the starting point for negotiations. Although an international comparison of mark-ups and professional fees is outside the scope of this document, the current \$30.50 fee is considerably higher than in Canada or the US, ¹⁸ albeit with a much higher cost of living and doing business in Bermuda.

It is a common theme in most countries that pharmacists are under-utilized as health professionals. Given their extensive clinical expertise and training in drug therapy, and their high accessibility in the community, pharmacists are well-positioned to add more value to the health system. A proportion of dollars saved through the implementation of policy initiatives that reduce expenditures on medications should be re-invested in these pharmacist services.¹⁹

Compensation systems must create incentives for pharmacists and pharmacy owners to transition from only drug product-focused (dispensing) services to more patient—focused (patient care) services that are valued by the community. Funds should be allocated to specific services in a strategic, incremental fashion such as giving pharmacists the authority/incentive to:

Dispensing fees in Canada and the US range from as little as US\$ 1.99 to as high as US\$ 30, with average fees being on the order of US\$ 10. See, e.g., http://telushealth.com/ealert/en/docs/avgdispfee_jan-june2009.pdf

¹⁷ Either the Bermuda Pharmacy Owners Association and/or the Bermuda Pharmaceutical Association should be considered, and the interests of both pharmacy owners and pharmacists should be represented.

¹⁹ Some of these services may require changes to legislation and regulations governing pharmacist scope of practice. These are mentioned in section 5.4

- 1. Adapt a new prescription the pharmacist assesses and adjusts specific details such as dosing intervals or format, when necessary to meet patient needs.
- 2. Therapeutic substitute the pharmacist assesses a new prescription and changes the prescribed drug to another drug of equal or lesser cost in the same therapeutic category that better meets the patient's health needs.
- 3. Renew a prescription the pharmacist assesses patient needs to ensure continuity of care when appropriate.
- 4. Conduct a medication review in a one-on-one appointment with a patient taking 3 or more medications the pharmacist provides information and answers questions to improve patient understanding about what medications they are taking, why, and how to take them and prepares a current medication list.
- 5. Conduct a standard medication management service in a one-on-one appointment with a patient taking 3 or more medications the pharmacist identifies and resolves actual or potential drug therapy problems to optimize drug therapy outcomes.

4.3 LENGTH OF PRESCRIPTIONS DISPENSED

Policy instrument: Reasonable standards for the number of days' supply of medicines (e.g. 90 or 100 days) could be established for chronic medications once the patient is on a stable dosage regimen.

Rationale: Aligns with Strategic Goal of Efficacy and Bermuda Health Council Act 2004 Section 5(h).

The Bermuda government should implement a "90" or "100" days' supply policy for beneficiaries of public prescription drug plans. Private health insurers may also implement a similar policy to save on overall prescription drug expenditures.

For higher quantities of drugs, there does not appear to be a consistent approach to the application of professional fees. In some cases, drugstores are adding a second fee or a discretionary higher fee on prescriptions for larger quantities. For example, a \$50 fee may be charged for a 2 or 3 month supply of a drug, or multiple fees may be charged if the patient requests multiples of individual dosage forms, such as several inhalers at one time.

Generally, it represents good clinical practice for patients to visit their doctor regularly, and to have prescriptions filled at frequent intervals (e.g. for shorter-term acute therapy) or for medications that require a high degree of monitoring. However, once a patient is stabilized on a maintenance dosage regimen for most chronic medications, it is prudent to dispense the prescription for a three month supply (rather than for three, one month supplies), with a single mark-up and professional fee, leading to lower overall costs due to fewer physician visits and a reduced number of professional dispensing fees.

The patient must be stabilized on a dosage regimen, or it may lead to higher overall costs due to increased wastage of prescription drugs that are either ineffective or not tolerated by that patient. Provisions will continue to be necessary for larger quantities of prescription medications to enable lengthy "vacation" or "travel" supplies (e.g. up to six months).

The categories of medications for chronic therapy must be chosen wisely to ensure patient health outcomes and overall medication costs are not compromised.²⁰ The process to establish such a list should be consultative and collaborative in nature, drawing on the expertise and input of health professionals such as physicians and pharmacists, to ensure the needs and best interests of Bermuda residents are met through this policy.

4.4 PHARMACY AND POISONS ACT AMENDMENTS

Policy instrument: Bermuda may review proposed amendments to the *Pharmacy and Poisons Act* to ensure pharmaceuticals policy options that are directly related to the regulation of pharmacist practice and pharmacy operations, as well as other policy options selected for implementation, are allowed or authorized under the Act.

Rationale: Aligns with Strategic Goal of Quality, Equity and Efficacy and Bermuda Health Council Act 2004 and Section 5(k).

The Bermuda government has already prepared a draft Bill entitled *Pharmacy and Poisons Amendment Act 2010*, signalling its clear intent to update pharmacy legislation in Bermuda. In discussions with stakeholders, most were unaware of the progress being made in this area and many expressed concern that it be done in a transparent and thorough manner.

The draft Bill should be reviewed and considered for amendment to ensure the new pharmacy legislation enables:

4.4.1 LICENSING OF ALL IMPORTERS OF PRESCRIPTION DRUGS WITH MANDATORY REPORTING OF DRUG PURCHASES INCLUDING DATE, DRUG NAME, IDENTIFICATION NUMBER(S), QUANTITY, COSTS, MARK-UPS/PRICING, ORIGIN, AND SOURCE

Presently an import license is only required for each shipment of pharmaceuticals containing controlled substances such as narcotics. Expanding requirements to include all prescription drugs, and making this an annual requirement enables the collection of more detailed and timely information regarding pharmaceuticals being brought into Bermuda. If a publicly-mandated importer/wholesaler of prescription drugs is contemplated, the legislation should reflect this.

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²⁰ Typical categories of maintenance drugs include, but are not limited to, cardiovascular drugs (e.g. antihypertensives), thyroid supplements, anti-arthritics, oral hypoglycemics, and lipid lowering agents.

4.4.2 EASIER MOVEMENT OF PRESCRIPTION DRUGS TO NON-PRESCRIPTION STATUS WITH REQUIREMENTS FOR REGULAR UPDATES OF DRUG SCHEDULES

Several stakeholders expressed concern that drug schedules had not been updated in some time, leading to confusion about which products require a prescription vs. pharmacist-only or drugstore-only sales. Medicines with a long history of safe use may move to non-prescription status in some countries, making them readily available for purchase by the general population at reduced costs to the health system by eliminating the need for a prescription by a physician. The Act should be amended to enable and ensure timely movement of drugs from Schedule 3 to Schedule 4²¹ and this could be facilitated through the office of the new Senior Pharmacy Officer/Registrar in collaboration with key stakeholders and the Pharmacy Council.

4.4.3 REMOVAL OF REQUIREMENT FOR PHYSICIANS TO SIGN PRESCRIPTION REQUESTING GENERIC DRUGS

The Second Schedule of the *Pharmacy and Poisons Act* requires the prescribing physician to sign in one of two places to indicate either "dispense as written" or "alternate equivalent substance may be supplied". Physicians may inadvertently (or by habit) sign either the right side or the left side of the prescription order, without considering the consequences of ordering the more expensive brand name product, when an interchangeable generic product may be available at a lower price. By changing the format of the standard prescription form, it enables pharmacists to more readily dispense the generic equivalent of the medication, where appropriate, thereby leading to lower overall drug costs. It also facilitates any drug benefit policies that require mandatory generic substitution by eliminating unnecessary controls over prescribing.

Pharmacists would be compelled, through provisions in the updated *Code of Professional Conduct and Ethics*, to provide the patient with optimal drug therapy, based on their professional judgement. This means letting the patient know if a lower cost (e.g. generic) interchangeable medication is available, and in consultation with the patient, dispensing the lower priced medication, unless there is a compelling reason not to (e.g. the patient insists on the brand drug; the generic medication is not available; or if the physician requests, in writing on the face of the prescription, the specific brand or manufacturer of the medication to be dispensed).

4.4.4 AUTHORIZATION FOR PHARMACISTS TO GENERIC SUBSTITUTE BASED ON PROFESSIONAL DISCRETION AND PATIENT INTERESTS

This is a necessary extension of the above policy instrument that would allow pharmacists to use their professional judgement to dispense the lower priced (generic) medication to the patient as long as it is deemed to be interchangeable, unless the patient (or prescriber) specifically requests the higher priced brand name drug. Note: the drug benefit plan may be designed to only pay up to the price of the generic

²¹ One stakeholder suggested the movement of ibuprofen would be one such example of a drug that should achieve non-prescription status and would save considerable money in the health system.

medication, in which case patients would have to pay the difference in price if they specifically request the brand product.

4.4.5 ENHANCED PHARMACIST PROFESSIONAL SERVICES (E.G. LIMITED PRESCRIBING AUTHORITY; MEDICATION MANAGEMENT)

Please refer to section 4.2 for a description of suggested enhanced pharmacist services. To benefit from these enhanced services, legislation must first enable them, and secondly, patients or payers must be willing to fund the services.

4.4.6 Specific requirements for pharmacy records and submission of data for a prescription drug information system

Section (46) of the Act should be amended to require dispensing records be kept in a computerized system (in addition to original hard copies of prescriptions being kept on file as is currently the requirement), specifying the mandatory data elements. In addition, the Act²² should be amended to enable the creation of a prescription drug information system that would be maintained by the Bermuda government, or its designate, complete with a list of mandatory data elements to be captured by the system. For more details, please see policy instrument 6.1.

4.4.7 Specific requirements for continuing professional education (cpe) for pharmacists to maintain annual licensure to practice

A wider scope of practice would also necessitate more robust requirements for ongoing professional education of pharmacists to ensure they develop and demonstrate the specific knowledge and competencies required to practice according to the enhanced pharmacist professional services referred to in sections 4.2 and 4.4.5.

5 QUALITY USE OF MEDICINES

5.1 Public Education Campaigns

Policy instrument: Bermuda could develop programs to promote the safe, effective use of prescription drugs, including increased awareness of Bermuda residents regarding prescription costs, the need for more personal responsibility for health (e.g. medication compliance, healthy lifestyles), and the value of pharmacist services.

²² There may be other statutes in Bermuda that will require an amendment to enable the prescription drug information system, but they have not been reviewed as part of this project.

Rationale: Aligns with Strategic Goals of Quality, Efficacy and Accountability and *Bermuda Health Council Act 2004* Section 5(i).

During the interviews it was made clear that Bermuda residents value their lifestyle highly, possibly even over their own health, until such time as they enter the health system as a patient. Obesity has been identified as a major health problem in Bermuda, particularly as the population ages and the risk of type 2 diabetes increases. Much of this is lifestyle related, and continued reinforcement of the health benefits of healthier living will support the goals of reducing overall health care and prescription expenditures.

Stakeholders suggested Bermuda residents, as patients, expect the best treatments including access to the most expensive prescription drugs. Patients often request brand name drugs as they have a perceived higher value and quality, and at times they request expensive medications be imported from abroad despite their high cost. At the same time, medication compliance is a problem where patients may not get prescriptions filled, or if they do, they don't take them as prescribed. This results in less optimal health outcomes, increased physician visits, unnecessary hospitalizations, and reduced value for money on prescription drugs.

An awareness campaign that identifies areas of high expenditures will help ensure Bermuda residents are mindful of decisions they make regarding prescription drugs, including the cost savings associated with the use of less expensive alternatives, such as generics.

In many jurisdictions, including Bermuda, pharmacists are not utilized to their full potential as primary care providers. Often they are the first health professional people turn to, and they are certainly the most accessible. However, people do not have a clear expectation of the services their pharmacists can provide, and they do not demand this higher level of service. Pharmacists are also not specifically compensated for higher levels of care (e.g. chronic disease management). The result is that many drug therapy problems continue to occur that erode the health status of the population of Bermuda.

A multi-faceted public education campaign will help to ensure all Bermuda residents do their part, and would be a necessary component of any sustained effort to make prescription drugs more affordable.

5.2 Prescribing guidelines for common disease categories

Policy instrument: In collaboration with health professionals, Bermuda may adopt accepted prescribing guidelines, at minimum, for the most common disease categories. Due to limited resources, it should not look to develop its own guidelines, rather, to promote the awareness and adherence to well-established sources.

Rationale: Aligns with Strategic Goals of Quality and Accountability and Bermuda Health Council Act 2004 Section 5(j).

In many countries, national guidelines are developed or adopted to guide prescribing decisions. The National Institute for Health and Clinical Excellence (NICE) in the UK provides guidance to health professionals in the prevention and treatment of disease using new and existing medical treatments and procedures including advice on specific diseases and conditions. It also makes recommendations on how to improve health and prevent illness and disease. Published clinical guidelines are available for most common medical conditions, alphabetically by title.

The Health Council of Canada²³ is an excellent resource for sources of drug information for prescribers, including the international network known as the Cochrane Collaboration, an independent not-for-profit organization that supports well-informed decisions about health care through the publication of reviews supported by the best available information.

To augment any guidelines that are already in place, key stakeholders in Bermuda should plan and implement a process to review and assess the suitability of one or more international sources of prescribing guidelines, and formally adopt (or adapt) these guidelines for use in Bermuda. As prescribing guidelines are evidence-based, it would be advantageous to align these guidelines with drugs listed on the national formulary. Use of prescribing guidelines will help to ensure Bermuda physicians prescribe the most effective and cost-effective medicines, helping to keep prescription drugs more affordable while gaining the best value possible in terms of health outcomes.

5.3 Professional Education

Policy instrument: Bermuda could develop a health professional education campaign that promotes safe, effective, and cost-effective prescribing including the existence of, and adherence to, prescribing guidelines.

Rationale: Aligns with Strategic Goals of Quality and Accountability and Bermuda Health Council Act 2004 Section 5(j).

Physicians and other health professionals will need to be made aware of the above-mentioned guidelines and implications for their professional practice. Clear expectations should be established regarding adherence to guidelines and the need to be accountable for high quality, evidence-based prescribing.

²³ http://www.healthcouncilcanada.ca/en/index.php?option=com_content&task=view&id=195&Itemid=10

6 DATA SYSTEMS

6.1 A PRESCRIPTION DRUG INFORMATION SYSTEM FOR BERMUDA

Policy instrument: Bermuda may establish a prescription drug information system that mandates the collection and operation of a central repository of data for all prescriptions dispensed in Bermuda.

Rationale: Aligns with Strategic Goals of Quality and Accountability; Corporate Strategic Objective establishing basic infrastructure to enable monitoring of utilization and expenditure on prescription drugs; and, *Bermuda Health Council Act 2004* Part III Section 15(e).

The implementation of a prescription drug information system will require the Bermuda government to assess and amend various statutes such as the *Pharmacy and Poisons Act*, to enable the development and implementation of a prescription network and data base, with authorizations for health providers to disclose information to the system and similar authority for the system to collect and use the information. Health information privacy laws will need to be established to govern the appropriate collection, use, and disclosure of personal health information – one that balances the need to patient privacy with that of better managing the health system.

Bermuda will need to implement an electronic information exchange standard for prescription claims and data collected by the prescription information system with functional drug identification nomenclature to facilitate data collection, drug utilization review and flexible drug plan design. This builds on the current agreement of pharmacy owners to begin sending in the Drug Identification Number (DIN), Product License (PL) number, or the National Drug Code (NDC) number as data elements in the prescription claim, and would require the Health Insurance Department to review and update its Pharmacy Claim File Layout to ensure all required data elements are being identified and collected.

The goal would be to establish an island-wide pharmacy information network, connecting all pharmacies to insurers and government drug plans, as well as the central prescription drug repository. Initially data would be sent electronically through batch processes (e.g. on a daily basis), but the system would be designed to accommodate online, real-time data exchange. A natural progression of the system would be to link to physician office-based electronic medical record systems, allowing prescribers to check patients' medications prior to selecting prescription drug therapy. Ultimately, an electronic health record could be established to support all aspects of patient-centric health care services.

Considerations include running the system as a government "utility"; the need for multidisciplinary governance and oversight; and, special start-up and ongoing operational funding. It would also need to be part of a broader vision to manage the health system better and improve patient care through the use of enhanced information technologies such as electronic medical records and electronic health records.

7 Prescription drug financing

Policy regarding the financing of prescription drugs can affect a number of important outcomes in this sector of the health system. Financing is perhaps the most significant determinant of access to necessary medicines given that patient-borne costs are one of the most common barriers to using medicines prescribed; this is especially true for those with relatively low incomes and those with multiple chronic diseases. Financing also determines the distributional consequences of costs related to necessary medicines. This can be an important determinant of overall socioeconomic equity given the scale of health and pharmaceutical costs at the individual and societal level. Finally, the policies and laws related to prescription drug financing can affect the overall sustainability of the system. For example, rules enabling the purchasing power of a monopsony purchaser (or of a purchasers' consortium) can reduce prices of medicines.

The Bermuda Health Council has suggested that regulations for health insurance in Bermuda might be modified to turn the "Standard Hospital Benefit" into a "Standard Health Benefit" package that provides enhanced healthcare coverage beyond hospitalization for Bermuda residents. There is no explicit mention of prescription drug benefits, however, it would be logical for such an expanded benefit to include prescription drugs given it is already part of common practice and drugs are such a critical component of health care.

We identify two policy options regarding changes to the financing of prescription drugs: a comprehensive option and an incremental option. Each option has different implications for the extent of health insurance expansion required in Bermuda; however, the feasibility of these options will be dependent on the implementation of other policy instruments outlined in this document concerning drug coverage; distribution and pricing; retail pharmacy; and data systems.

7.1 Universal prescription drug coverage

Policy instrument: Universal coverage of a comprehensive list of medicines is the first option for expanding health insurance coverage to include prescription drugs. This would add medicines used in the community setting to the minimum health benefit required in the *Health Insurance Act*, and would bring government policy in line with what the private sector has already put into place.

Rationale: Aligns with Strategic Goals of Equity and Efficacy and *Bermuda Health Council Act 2004* Section 5(a).

²⁴ Goldman DP, Joyce GF, Zheng Y. *Prescription Drug Cost Sharing: Associations With Medication and Medical Utilization and Spending and Health*. <u>JAMA</u> 2007;298 (1):61-69; Adams AS, Soumerai SB, Ross-Degnan D. *The case for a medicare drug coverage benefit: a critical review of the empirical evidence*. <u>Annual Review of Public Health</u> 2001; 22:49-61.

Wagstaff A, van Doorslaer E, van der Burg H, Calonge S, Christiansen T, Citoni G, et al. *Equity in the finance of health care:* some further international comparisons. J. Health Econ. 1999; 18(3):263-90.

Experiences from countries with developed traditions of social health insurance – e.g., the Netherlands, France, Germany, Austria, and others – indicate that prescription drug benefits can viably be added to statutory health insurance. These international experiences also indicate that providing universal coverage for medicines requires policies designed to ensure that benefits are available to all, that funds are raised in an equitable manner, and that providing coverage is viable for participating insurers. This would help to protect insurers from undue risks by helping to average costs and protect year over year liabilities. It helps to provide the stability and value for money that payers, including insurers and government, are looking for in this sector.

Minimum formulary: To add pharmaceutical coverage to a standard health benefit requires explicit definition of which medicines must be insured for all eligible beneficiaries. Allowing insurers to compete in terms of which drugs are on their own formularies will engender a 'race to the bottom' by way of attempts at risk-selecting: e.g., to reduce costs and simultaneously attract only low risk clients, insurers will de-list drugs for costly-to-treat conditions (such as rheumatoid arthritis or affected psychosis). As described earlier in this document, international policy experience indicates that the most cost-effective way to set standards of pharmaceutical benefits is to adopt an evidence-based positive formulary. Insurers may compete by offering additional medicines not on this formulary; however, all would be required to provide coverage for all of the medicines on the formulary.

Contribution schemes: Funds must be raised in order to cover the costs of medicines under an expanded health benefit. Patient contributions must be strictly regulated to avoid access barriers and the possibility insurers will select only low risk/high health clients. Premiums under a universal program should be community-rated (same premium for all individuals) and kept as low as possible so that all residents can afford to actively participate. It will therefore be necessary to collect additional revenues to cover the cost of medicines and to assist with risk-adjustment. A dedicated fund should be established for this purpose and contributions would ideally be progressive in nature (e.g. drawn from payroll taxes or other instruments that are more progressive than premiums).

Cost-sharing: Patient contributions under a universal program may involve co-payments; indeed, very few drug benefit programs worldwide provide coverage without patient charges of some type. ²⁶ However, it will be necessary to regulate the amount that may be charged for prescriptions filled. ²⁷ As discussed below, the regulated co-payments may be structured in a manner designed to steer patients toward lowest-cost alternatives. Appropriately constructed co-payments can achieve these outcomes without significant adverse events. Firms should be permitted to compete by reducing or even waiving co-payments (e.g. for certain groups of patients such as children, low income earners, seniors);

²⁷ See, e.g., Morgan SG, Hanley G, Greyson D. *Comparison of tiered formularies and reference pricing policies: a systematic review;* 2009.

²⁶ A deductible policy may be considered as an effective means of cost-sharing but is not recommended due to the blunt nature of this instrument – that is, is doesn't allow patient contributions to be steered toward the lowest priced or most cost-effective

however, none should be permitted to charge higher than the regulated rate because higher copayments can result in cream-skimming.

Guaranteed issue / risk adjustment: To ensure equity, access and viability for firms participating in the market, it is necessary to require that all firms provide the basic/mandated coverage at regulated premiums to any eligible client regardless of age, sex, race, or health status²⁸. Because needs for care will differ significantly across the population, it is essential that such differences be compensated for via a risk adjustment (or equalization) scheme. Failure to account for differential needs of insured clients will put insurers at unnecessary risk and thereby provide incentive for undesirable client selection policies by competing insurers. Risk equalizing payments would be provided from the dedicated fund established for this purpose. The method of calculating risk-related transfers depends on mechanisms used for cost control.

If pharmaceutical expenditure management was conducted by a central agency that maintained the national formulary – such as in New Zealand²⁹ - the risk equalization need only involve transfers based on actual costs per case covered. If expenditure management for pharmaceuticals is to be the responsibility of competing insurers, risk equalization payments must be computed based on best available risk adjustment methods. High quality risk adjustment is critical to reducing risk to insurers and incentives for risk-selection. While risk adjustment methods evolve, consideration should be given to risk equalization schemes that would use a mix of compensation based on standardized costs per age, sex, and health status adjusted case and historic drug expenditures. Such schemes offer a blend of maximum risk minimization (compensation based on historic costs) with incentives for cost management (case-mix based compensation).

Electronic claims adjudication: An enabling part of the policy infrastructure for effective drug benefits policy is data concerning the use and cost of medicines by all individuals in a population. As discussed in this document, information about medicines use and cost is necessary for tracking the population's access to and outcomes from health care; it is also necessary for financial matters related to tiered copayments, risk-adjustment, and price negotiation.

7.2 COVERAGE FOR CHRONIC DISEASE MANAGEMENT

Policy instrument: If expanding the standard hospital benefit to include prescription drugs is not currently viable in Bermuda, consideration may be given to offering universal coverage for drugs deemed essential to managing chronic diseases of central importance to Bermuda's population health.

²⁸ This is consistent with *Enhancing the Regulatory Framework for Health Insurers – Public Consultation Paper*. BHeC, July 2010.

Davis, P. "Tough but fair"? The active management of the New Zealand drug benefits scheme by an independent Crown agency. Aust. Health Rev. 2004; 28(2): 171-81.

Rationale: Aligns with Strategic Goals of Equity and Efficacy and *Bermuda Health Council Act 2004* Section 5(a).

Though most countries with developed health insurance systems also include relatively comprehensive prescription drug benefits, providing coverage for specific types of treatment is an option for countries wishing to take an incremental approach to drug coverage. This was proposed in 2002 for Canada by the (Romanow) Commission on the Future of Health Care in Canada; and a similar policy approach has been adopted by China.³⁰

A program of this nature could begin with universal public coverage of drugs to treat specific chronic diseases such as diabetes, hypertension, and/or asthma. It would use the purchasing power of a single buyer of medicines for the population to secure best available prices for a few, evidence-based treatments for such conditions. Such a policy could begin with highly selected medicines and expand gradually based on increased sophistication of those managing the purchasing processes for covered medicines and based on population demand for expanding such a program, for example, into other therapeutic areas.

8 Conclusion

Pharmaceuticals policy challenges in Bermuda, as in most countries, are complex and require a systems approach. A high performing pharmaceutical sector requires the coordination of multiple policy instruments to address the interdependence of various facets of the system. Three inter-related objectives that support overarching health goals include promoting the accessibility, affordability and appropriateness of medicines.³¹

In this document, we have outlined pharmaceuticals policy options that address this "triple-A" framework - ones that are based on international experience, yet suitable for the Bermuda context. These policy options need to be considered within the context of broader health and pharmaceutical strategies, and further research and consultation will be required to ensure the health needs of Bermuda residents continue to be met through prescription drugs that are available, cost-effective, and used in a manner that provide optimal patient health outcomes.

³⁰ Canada. *Building on Values: The Future of Health Care in Canada – Final Report*. Saskatoon: Commission on the Future of Health Care in Canada; 2002 November 28; and, Chen W, Tang S, Sun J, Ross-Degnan D, Wagner A. *Availability and use of essential medicines in China: manufacturing, supply, and prescribing in Shandong and Gansu provinces*. BMC Health Services Research 2010; 10(1):211.

³¹ Morgan S, Kennedy J, Boothe K et al. "Toward an Understanding of High Performance Pharmaceutical Policy Systems: A 'Triple-A' Framework and Example Analysis" The Open Health Services and Policy Journal 2009; 2 (1):1-9.

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