Ontario Public Drug Programs
Competitive Agreements

Briefing for Stakeholders
July 4, 2008

Ontario

AGENDA

- Background and context for Competitive Agreements
- Overview of proposed Competitive Agreements framework
- Discussion

- Presenters
  - Helen Stevenson, Assistant Deputy Minister and Executive Officer, OPDP
  - Brent Fraser, Director, OPDP
  - Angie Wong, Senior Manager, OPDP
  - Louis Dimitracopoulos, Manager, Supply & Financial Services Branch

COMPETITIVE AGREEMENTS: ORIGINS & HIGHLIGHTS

Origins

- Achieving better value and best use of resources for drug spend was part of the Government's Plan to Reform Drug System, announced in April 2006
- Price of generic drugs is regulated at no more than 50% of brand price
- Our research, confirmed by publicly available studies, suggests that we pay more for some generic drugs than other countries
  - Looked at prices in several jurisdictions, including the United States, Germany, England and New Zealand
  - Research revealed that some products were significantly less expensive in those jurisdictions
- Research indicates that 50% of brand price is not always a good indicator of the costs of production, and thus too high a price for some generic drugs
- Competitive agreements framework, designed to achieve savings on some of these drugs, has been developed over past 6 months

COMPETITIVE AGREEMENTS: ORIGINS & HIGHLIGHTS

Highlights

- Competitive agreements will be issued for small number of drugs
- First wave of 4 drugs will be issued July 25th, 2008. Additional waves will follow, and process will be reviewed after each wave
- Eligible drugs are off-patent, where multiple generic alternatives exist, with significant volume for the ODB population
- Competitions will not be winner take all – two contracts (winners) will be awarded
- Applicants will submit proposals as per the Government's standard procurement process
- Winners will be evaluated based on both volume discounts offered and their ability to provide security of supply, among other things
- Contract lengths are proposed to be 2 years, with a 1 year renewal option
- Actual price in Formulary will be published at regulated 50% price (lower prices will be achieved through volume discounts rebated to the Ministry)
- Savings will be reinvested in the Ontario Public Drug Program
- Process will be clear and transparent

COMPETITIVE AGREEMENTS PROPOSED TIMELINE

Communication with stakeholders

Monday, June 23	Letter to pharmaceutical manufacturers announcing July 4th briefing
Friday, July 4	Briefing/consultation with pharmaceutical manufacturers
Monday, July 7	Briefing/consultation with pharmacies and distributors
Monday, July 7	Letter to manufacturers of four selected molecules
Tuesday, July 15	Follow-up consultation

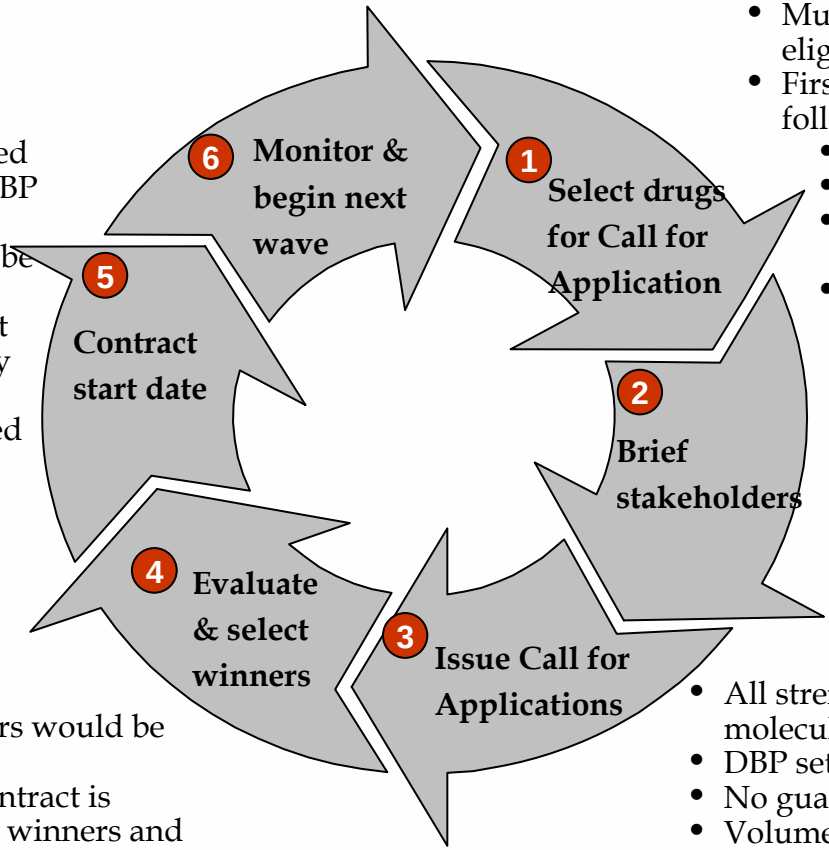
Call for Applications

Friday, July 25	Release Call for Applications
Thursday, August 1	Applicants Conference
Friday, August 22	Deadline for Applications
Friday, September 12	Successful Applicants decided

Contract with winners

September 12-30	Finalize contract and final notifications to all applicants
October 1 – January 1	Contract start date
December 31, 2010	Contract end-date, up for one year renewal

OVERVIEW OF COMPETITIVE AGREEMENT APPROACH



- Multi-screen approach identifies eligible drugs
- First wave of four (4) drugs met following criteria:
  - High volume
  - Multiple suppliers
  - High public share of volume
  - Lower prices in other jurisdictions

- Proposed process discussed in detail
- Feedback requested

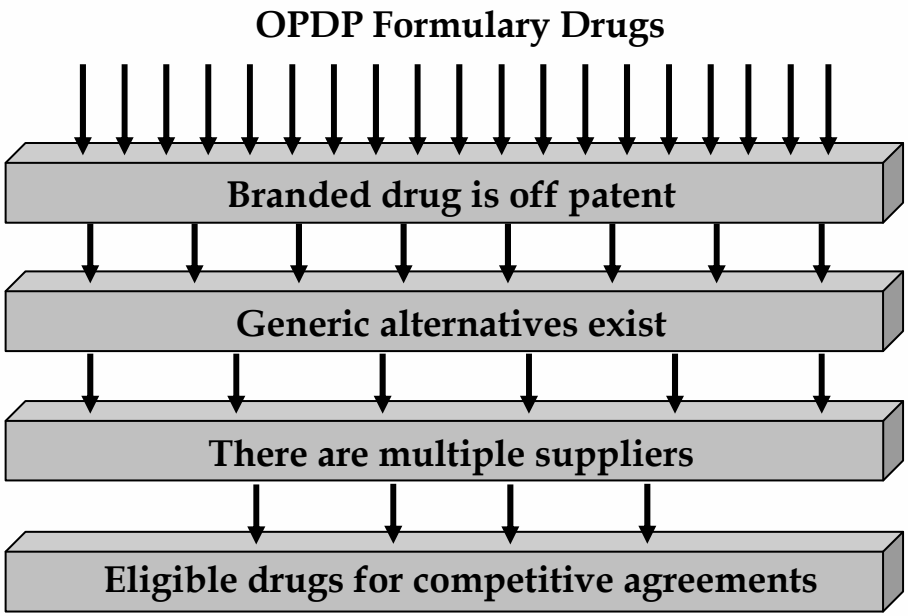
- All strengths and forms of a molecule issued together
- DBP set at current generic price
- No guaranteed volumes; free market
- Volume discounts through an "effective discount rate" for different levels of market share achieved

- Two winners would be selected
- A 2-year contract is awarded to winners and renewable for up to 1 additional year

- Winning applicants listed at the current generic DBP
- Non-competing and losing applicants could be removed as a benefit* from the Formulary, but retain interchangeability
- Winners pay volume discounts to OPDP based on the discount they offered and the market share they achieve (reconciled quarterly)

* If two generics win, the branded supplier will remain listed at a higher price for no substitution requirements

HOW DRUGS ARE SELECTED



Considerations for choosing drugs for Wave 1:

- High volume drug
- High public share of total volume
- Lower prices in other jurisdictions, suggesting potential for significant savings

PROPOSED CONSULTATION PROCESS

July 4 & 7: Initial briefing with stakeholders

- Describe proposed process
- Receive feedback on elements of the process

July 4 – 15: Feedback from stakeholders

- Stakeholders are invited to submit comments to competitiveagreements@ontario.ca
- Feedback will be amalgamated for future discussion

July 15: Follow-up discussion with stakeholders

- Tuesday, July 15th at 9am at [to be determined]
- Amalgamated feedback will be presented
- Discussion period for pertinent issues

After Wave 1 contracts are signed:

Debrief on process and solicit additional feedback

PROPOSED PROCESS FOR CALL FOR APPLICATIONS

Overriding Principles

- Brand and generic manufacturers will both be eligible to apply
- Security of supply will be a key consideration
- Savings will be achieved while not affecting the price on the ODB Formulary
- Process will be clear and transparent:
  - Criteria for evaluation in each category included in this document
  - Methodology for arriving at final score included in this document
  - Call for Application will include a contract template, allowing applicants to understand their obligations if they are successful
  - Evaluation committee will include a fairness commissioner to oversee the process
  - Feedback will be solicited after each wave to further improve the process

PROPOSED PROCESS FOR CALL FOR APPLICATIONS

Eligible Manufacturers

- Brand and generic manufacturers eligible to apply
- Manufacturers need to demonstrate how they will be able to produce all product required by the Ontario Public Drug Programs
- Manufacturers will be required to meet all regulatory requirements for listing

Ensuring Security of Supply

Supply and experience criteria:

- 50% of total score in evaluation will be based on supply and experience criteria
- Applicants who do not meet the required threshold will not be eligible to win

Supply requirements in contract:

- Winners will be required to keep three months' supply of molecules on hand as safety stock
- Winners will be required to notify Ministry in the event of an interruption in manufacturing causing the safety stock to be used
- In the event of a stock-out, winners will be required to compensate the Ministry for any costs incurred in obtaining replacement product

PROPOSED PROCESS FOR CALL FOR APPLICATIONS

Executive Officer Proviso

- Executive Officer (EO) under the Act may remove the designation of a drug product as a listed drug product on the Formulary if he or she considers it in the public interest to do so
- EO will consider the results of the competition to indicate whether the products on the Formulary are achieving the best value for money and are the best use of resources
- Call for Applications has been designed to determine in a clear and transparent fashion which manufacturers will provide the best value for money to assist the EO in making decisions in the public interest

PROPOSED PROCESS FOR CALL FOR APPLICATIONS

Volume Discount Offered

- Applicants required to offer volume discount for each form & strength of molecule
- Discounts offered on each form and strength weighted by the share each form & strength represents of total ODB spend on that molecule (detail & example follow)
- Applicants may offer different rates for different levels of market share achieved – offers will be divided into four market share tiers (detail & example follow)
- Offer for different strengths and tiers will be combined into a Total Volume Discount Offered
- Applicants will be ranked and scored based on the Total Volume Discount offered

Results of the Competition

- Supply and Experience score (50%) will be combined with the Total Volume Discount Offered (50%) to arrive at a total score for each applicant
- Two applicants with the highest scores win the competition and could be awarded contracts
- Both winners would compete for market share

PROPOSED PROCESS FOR CALL FOR APPLICATIONS

Implications for ODB Formulary

- Both winners would be listed or continue to be listed as benefits on the ODB Formulary
- Price for winners set at 50% of original brand manufacturer price (at time of generic submission)
- All unsuccessful manufacturers, or those who choose not to apply would no longer be listed as a benefit on the ODB Formulary ("Not a Benefit") based on the results of the Call for Applications
- If two generic manufacturers are successful, the original brand manufacturer would retain its "benefit" status at the current brand price to support the "no substitution" provision in the legislation
- If one generic manufacturer and the original brand manufacturer are successful, the published price of the brand product would be reduced to 50% of the original price, and be the same published price as the generic product
- Manufacturers will be notified immediately of any impending change to their listing status

PROPOSED PROCESS FOR CALL FOR APPLICATIONS

Other elements of proposed process

- Each molecule will be evaluated individually, thus no consideration will be given to "bundling" two molecules together
- Manufacturers must be able to provide all forms and strengths of each molecule

PROPOSED PROCESS FOR CALL FOR APPLICATIONS

Evaluation Committee

- Evaluation committee drawn from Ministry of Health and other ministries
- Committee will have five members, plus a fairness commissioner to review the process

Process for evaluating applications

1. Applications will be reviewed to determine if meet mandatory criteria
2. Applications meeting mandatory criteria will be summarized for review
3. Each Evaluation Committee member will score each application against supply and experience criteria
4. Evaluation Committee will meet to review ratings. Applicants not meeting supply and experience threshold will be eliminated
5. Supply and experience ratings (50%) will be combined with Volume Discount Rate offered (50%) to determine final score
6. Evaluation Committee will meet to review rankings and recommend winners
7. The Executive Officer would decide whether to enter into contracts with the proposed winners, and if so, the winners will be announced
8. Applicants who do not win and manufacturers who do not apply would be notified immediately

JOINT APPLICATIONS AND PROHIBITED COMMUNICATIONS

- Applicants may submit only one application per molecule
- Applicants may join together with other manufacturers in a joint application, but can only be part of one application per molecule
- Once the Call for Applications is released, all communications with the Government about the Call must be channeled through an Application Coordinator (named in the Call document). Communications with employees of the MOHLTC, MPPs etc. about the Call will be grounds for disqualification
- Prospective applicants must also not communicate with other prospective applicants about their applications (except to the extent of communicating to make a joint application). It is a federal offence to engage in bid-rigging or conspire to unduly restrain or injure competition

EVALUATION OF APPLICATIONS

Overview of process

Step 1: Mandatory Requirements

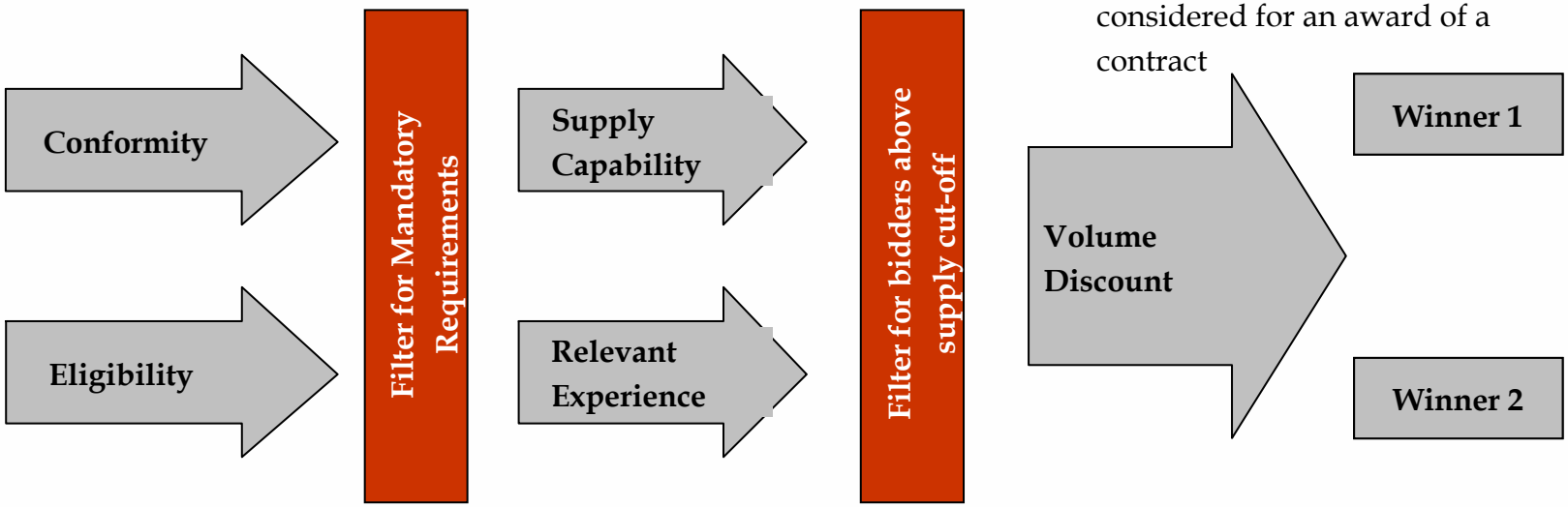
- Determine if applicants have met Mandatory Requirements for inclusion
- If any requirement is not met, exclude from further evaluation

Step 2: Supply Criteria

- Evaluate applicants on key supply criterion (other than price) using a scorecard
- If applicants achieve a score above a specific threshold, allow them to proceed to Step 3

Step 3: Price

- Evaluate eligible applicants based on their scores from the supply and experience section and their proposed volume discount rate
- The two applicants with the highest total scores would be considered for an award of a contract



MANDATORY REQUIREMENTS – APPLICANTS MUST MEET ALL REQUIREMENTS TO PASS TO NEXT STAGE

Category	Criteria	Possible score
Conformity	**Application:**	
	• Was submitted on-time	Yes/No
	• Is in correct format	Yes/No
	• Includes all required information	Yes/No
	• Does not include conditions/qualifications	Yes/No
	• Application is for all forms and strengths	Yes/No
	• Application is not bundled with another molecule	Yes/No
	• Applicant followed established process for obtaining further information	Yes/No
Eligibility	**Applicants:**	
	• Provides evidence of required Approvals or ability to gain Approvals within required timeframe*	Yes/No
	• Provides evidence of ability to reach required capacity by January 1, 2009	Yes/No
	• Is in good standing with OPDP	Yes/No

* Approvals include all regulatory requirements for sale in Canada (e.g., NOC) and ODB formulary listing for all forms and strengths of the molecule included in the Application

SUPPLY CAPABILITY AND RELEVANT EXPERIENCE CRITERIA – 50% OF FINAL SCORE

Category	Criteria
Supply Capability (40%)	• Approach to building required capacity • Previous supply performance to the ODB • Contingency plan for sourcing products in the event of a stock-out • Control over production of product • Reliance on sub-contractors for ancillary manufacturing (packaging, printing, etc.) • Experience and Capability of staff dedicated to managing contract • Control over critical raw materials • Quality of current distribution network in Ontario • Shipping time from manufacturing plant to Ontario distributors
Relevant Experience (10%)	• Management experience in Ontario market • Management experience in any jurisdiction • Years company has supplied the Ontario market • Years in business • Performance on similar contracts in other jurisdictions • Financial resources

Overall supply score = Capability Score + Relevant Experience Score (out of 50 total)
Applicants must achieve a score 35 or greater to pass to the evaluation of Volume Discount offered

VOLUME DISCOUNT RATE – 50% OF FINAL SCORE

Volume Discount Rate Offered

- Applicants submit a volume discount rate for each market share tier for each form & strength
- Higher market share tiers must have an equal or greater discount than lower tiers

Share	Weight of tier	Volume Discount Rate Offered
Tier 1 (e.g., < 10%)	10%	X%
Tier 2 (e.g., 10 – 40%)	40%	X%
Tier 3 (e.g., 40 – 70%)	40%	X%
Tier 4 (e.g., > 70%)	10%	X%

Calculation of Volume Discount Rate Score

- For each form and strength, a weighted volume discount rate will be calculated
- All forms and strengths will be combined into a total volume discount rate, which will be weighted according to the share of total spend on each form and strength
- Applicant with the highest total volume discount rate will receive 50 points

VOLUME DISCOUNT RATE – 50% OF FINAL SCORE

Sample Calculation

OPDP Spend on Molecule

Form and Strength	OPDP spend on form and strengths	Share of total spend on each form and strength
Form and Strength A	$3,000,000	30%
Form and Strength B	$7,000,000	70%
Total OPDP spend on molecule	$10,000,000	100%

Calculation of Total Volume Discount Offered

Form and Strength	Share of total spend for molecule	Volume Discount Rate Offered
Form and Strength A	30%	35%
Form and Strength B	70%	38%

Total Volume Discount Rate Offered:
37.1%

IMPLEMENTATION OF COMPETITIVE AGREEMENTS

Awarding Contracts

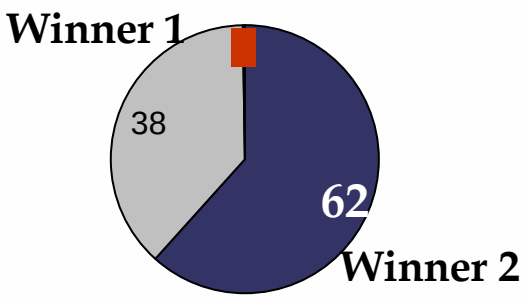
- Two winners would be awarded contracts in September if the EO determines it is in the public interest to list or continue to list their products.
- Template contracts will be provided with Call for Applications for review
- Submitting an application is a commitment to sign a contract if awarded
- Contract start date may begin as early as October 1, 2008 to January 1, 2009 based on the winners' capability of providing sufficient supply
- Contract start dates would be determined separately for each molecule
- Applicants who do not win, and manufacturers who do not apply, would be notified of timing of any Formulary changes
- Contract end date would be December 31, 2010
- Contract would have a renewable option for one year at the Ministry's discretion to December 31, 2011
- No guarantee of volumes or market share

Formulary Implications

- Any Formulary changes would be adjusted as at the contract start date

WINNING BIDDERS PAY OPDP REBATES EQUAL TO THEIR OFFERED DISCOUNT RATE BASED ON THEIR MARKET SHARE

Market Share Achieved



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Bid Information for one form and strength		
Market Share	**Volume Discount (%)**	
	Winner 1 (G2)	**Winner 2 (G3)**
Tier 1 (e.g., < 10%)	20%	30%
Tier 2 (e.g., 10 – 40%)	30%	35%
Tier 3 (e.g., 40 – 70%)	40%	40%
Tier 4 (e.g., > 70%)	50%	45%

Rebate = Volume Discount offered for market share tier

- Winner 1 = 30%
- Winner 2 = 40%

OPDP tracks market shares for winners, calculates rebates, and invoices suppliers on a quarterly basis

Invoices will include appropriate discount rates based on market shares for each form and strength

DISCUSSION

- Are there contract elements that may incent manufacturers to bid/bid more competitively? Would a different contract length for the winning bid be attractive to bidders?
- Are there any specific concerns with the timeline?
- Are there any immediate comments about the process?
- How much time is likely to be required to increase production capacity to be able to supply the entire market?
- Our goal is to start the contracts as soon as possible after choosing successful applicants. We propose to establish with successful applicants to start the contract between October 1, 2008 and January 1, 2009, depending on how quickly they can reach required capacity.
- To prevent stock-outs, we are proposing that successful applicants must hold a three-month supply of safety stock. In the event of a stock-out, if the other supplier cannot meet the shortage, successful applicants will be responsible for compensating the government for acquiring supply elsewhere

EXECUTIVE SUMMARY / HIGHLIGHTS

- Ontario Public Drug Programs is instituting a competitive application process to supply certain off-patent molecules that have been found to be significantly less expensive in other jurisdictions
- Call for Applications process will begin with the first wave of 4 molecules on July 25th, 2008
- Generic and brand manufacturers will both be eligible to apply
- Applicants will be evaluated on ability to ensure security supply, and the volume discount offered, among other things
- Two winners will be awarded contracts to begin in the last quarter of 2008, ending December 31st 2010. The Government will have the option to renew the contract for one additional year

PROPOSED CONSULTATION PROCESS

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