Questions and Answers
for Competitive Agreement Initiative

Listing Status of Drugs Products for the Competitive Agreement

1. Will any drugs (molecules) be de-listed as a result of the Competitive Agreement Initiative?

No molecule (i.e., enalapril, ranitidine, metformin, and gabapentin) would be de-listed from the Formulary. Rather, certain generic version of the above-named drug products could have their listing status changed to "not a benefit" status. The brand name drug and up to two generic versions of the drug could be listed as a benefit on the Formulary.

2. What does "not a benefit" mean?

"Not a benefit" means that the product would not be reimbursed as a benefit under the ODB Program and would be designated as "Not a Benefit" on the Formulary. The product would maintain its interchangeability status.

3. Would "not a benefit" be automatic once winners are chosen?

Yes, manufacturers that are unsuccessful would have their drug product's listing status changed to "not a benefit" if the Executive Officer determines it is in the public interest to do so. This would occur on the effective date of the contract for each drug product.

4. If a brand did not win the competition, would patients continue to be allowed to pay the difference between the brand list price and the generic products reimbursed under the Competitive Agreement initiative?

Yes, as per the normal claim submission process, patients would continue to be allowed to pay the difference between the brand list price and the generic products reimbursed under this initiative.

5. How would this initiative affect listings on the Formulary?

If one brand manufacturer *and* one generic manufacturer were selected:

(a) The drug benefit price (DBP) published in the Formulary for the brand product would be reduced to the same level as the generic DBP, i.e. no more than 50% of the original brand price. In other words, both the generic manufacturer and brand manufacturer who are successful in the application

process would have the same DBP published in the Formulary – up to 50% of the original brand price.

(b) All unsuccessful manufacturers or manufacturers that elected not to participate would have the status of their drug product(s) changed to “not a benefit”, but would continue to be listed in the Formulary to maintain interchangeability. However, the product would not be an eligible benefit under the Ontario Drug Benefit (ODB) program.

If two generic manufacturers were selected:

(a) Both generic manufacturers would continue to be listed in the Formulary at the current DBP.

(b) All unsuccessful manufacturers or manufacturers that elected not to participate would have the listing status of their drug product(s) changed to “not a benefit”, and would continue to be listed in the Formulary to maintain interchangeability. However, the product would not be an eligible benefit under the Ontario Drug Benefit (ODB) program.

(c) Despite the above, the brand manufacturer that was unsuccessful would continue to be listed in the Formulary to support the “no substitution” provision in the legislation.

6. In the event of a brand manufacturer being selected as one of the winners, why does their price need to be reduced to 50% of the original price on the Formulary?

When both generic and brand name products are available, the ODB program pays for the lowest cost drug product listed on the Formulary. Brand manufacturers must reduce the price to match the generic price to allow pharmacists to select and dispense the lowest cost product since the legislative scheme specifies that only the lower cost product is eligible for reimbursement.

Below is the relevant section:

s. 6(1)(2) of the ODBA *– Amount Executive Officer to pay*

The amount the executive officer shall pay under subsection 5 (1) in respect of a listed drug product is the amount calculated by adding the amounts determined under paragraphs 1, 2 and 3 and subtracting from that total the maximum co-payment that may be charged in respect of the supplying of a listed drug product for an eligible person, as provided for in the regulations:

1. *The dispensing fee determined under subsection (2).*
2. ***The DBP for the drug product, but, if there are other listed drug products that are interchangeable with the drug product, the DBP***

shall be deemed to be the lowest of the DBPs for the drug product and the listed drug products that are interchangeable with it.

3. *The prescribed mark-up on that price.*

Manufacturers to Submit Volume Discount

7. Why arrange a volume discount process instead of reducing the DBP on the Formulary?

Products on the Formulary are reimbursed based on the lowest DBP for a drug product as defined in the regulations. In addition, there is a mandatory substitution requirement for generic products listed in the Formulary. Because two manufacturers would be selected for each proposed product using a volume discount process, both would have the lowest price, and thus both would be eligible to be dispensed by the pharmacist. In addition, the Ministry considered the impact on pharmacy's mark-up if the DBP was reduced.

8. How would the volume discount work? How would it be evaluated in the application process?

Manufacturers would be asked to submit a volume discount rate at which they would reimburse the Ministry. The actual volume discount would be calculated based on the quarterly sales for each individual drug product specified in the agreement. Manufacturers may submit different volume discount rates for different market shares. That is, manufacturers may provide a higher volume discount rate for achieving a higher market share.

Market share is divided into four tiers for the purposes of the application: the tiers are:

- less than 10%,
- 10-40%,
- 40-70% and
- greater than 70%.

The tiers are set by the Ministry and will be included in the Call for Application. Manufacturers would be required to provide a volume discount rate for each market share tier. Each market share tier would be weighted differently. Manufacturers would be expected to provide a volume discount rate for each form and dose of the drug product in each market share tier.

Applications would be assessed based on the total effective volume discount rate.

More detailed information will be found in the Call for Applications. Please note that an example of the calculation of the rate is also included at the end of this document.

9. Do the applicants set the Volume Discount market share tiers?

No. Tiers are set by the Ministry at <10%, 10-40%, 40-70% and >70%. Applicants would provide a volume discount for each of these pre-set tiers.

10. Would selected manufacturers be forced to accept the same volume discount rates?

No. Each successful manufacturer would provide volume discounts to the Government of Ontario based on their proposed rate for each drug product. The volume discount rates as noted in the agreement between the ministry and the manufacturer would be treated as confidential, and would not be disclosed to the other successful manufacturer.

11. How would manufacturers pay volume discounts?

The volume discounts would be calculated on a quarterly basis for each fiscal year as follows:

- April to June is Q1,
- July to September is Q2,
- October to December is Q3, and
- January to March is Q4.

Market share totals would be reset each quarter.

12. How is the volume discount calculated?

Winners would pay an amount based on the volume discount in each tier, for the volume applicable to that tier. For example, a manufacturer offers a 20% volume discount in the <10% market share tier, and a 40% volume discount in the 10-40% tier. If they achieved 35% market share, they would pay a volume discount of 20% on the first 10% of their volume, and a 40% volume discount on the remaining 25% of their volume.

13. Would the total expenditure by the ODB Program for each drug product be posted?

Yes. The Call for Applications would include the total ODB volume and cost for each strength and form of each drug product for fiscal year 2007/08.

14. Can winners disclose their volume discount rate to partners in the supply chain, such as pharmacies?

No. Volume discount rates are confidential, and should not be disclosed to anyone.

Certain Terms and Conditions

15. Would the contract effective date be the same for both winners?

Yes, the effective date would be the same for both winners for each drug product. Contracts for different drug products may have different effective dates, but for each drug product, both winners would have the same effective date.

16. What happens if the selected manufacturer experiences a stock-out?

There would be several provisions in the contract that would set out the requirements for guarantees of supply. Per the conditions for listing and continued listing, successful manufacturers must be able to supply the entire market if required, and would be liable for any measures the government has to take to obtain supply in the event of a stock-out.

If winner A were to stock-out, winner B would be expected to supply the short-fall. If winner B cannot meet this new demand, winner A would be liable for reimbursing the OPDP for costs associated with sourcing stock for the market.

If neither manufacturer is able to supply the drug product, the Executive Officer will need to consider other options that will be at the expense of the current winners, as per the terms of the contract.

17. Would manufacturers have time to wind down their safety stock at the end of contracts?

Yes. New contracts would be awarded several months prior to the expiration of current contracts. If current manufacturers are not selected again, they would have an opportunity to wind down their safety stock while the new winners build their safety stock in order to maintain sufficient stock security for the ODB market.

18. Will there be a period of time for manufacturers and pharmacies to sell their inventory before contracts begin? This is commonly referred to as a "wash-out" period.

The contracts would go in to effect between October 1st, 2008 and January 1st, 2009. It is intended that manufacturers and pharmacies would be informed of the

winners of each contract by mid-September. Manufacturers and pharmacies were made aware of the specific drug products for this Call for Applications the week of July 7, 2008. The Ministry believes that there is sufficient notice for manufacturers and pharmacies to accurately plan their inventory and production schedules.

Application Process

19. Would the Evaluation Committee members be posted?

The members of the Evaluation Committee would be posted when the results of the Competitive Agreement have been announced.

20. Would the Applicant's conference be open to all manufacturers?

Yes, all manufacturers may attend.

21. Why award two manufacturers instead of one?

The Ministry wants to ensure there is adequate supply of the drug products for the entire ODB market, and thus wants to ensure two sources for each drug product.

22. What happens if there are fewer than two applications?

In the event that the Ministry receives only one application for a drug product, the Executive Officer may consider entering into a supply agreement with that particular applicant. In the event that no applications were received for a drug product, the Executive Officer will review potential options and make a decision based on what is in the best interest of the public.

23. If both winners are generic manufacturers, will the brand volume be included in market share calculations?

Yes. The market share of the winning manufacturers will be considered to be their volumes divided by the entire ODB Program demand, which includes brand volume.

24. Would the unsuccessful manufacturers be able to receive feedback on why they were not selected?

Yes, manufacturers that were not selected may request a debriefing.

25. How would the Ministry notify the winning supplier and communicate the outcome of the process?

The results would be communicated as follows:

1. Winners would be notified
2. Applicants who did not win would be notified
3. Current manufacturers of the product who did not participate would be notified
4. A notice would be issued to pharmacy via the Bulletin Board System (BBS) and posted on the Ministry website.

General

26. How would the savings achieved from the Competitive Agreements be used?

Savings would be re-invested in the Ontario Public Drug Programs.

27. Which jurisdictions did the Ministry review in developing the Competitive Agreement initiative?

The Ministry reviewed and examined the models from a number of jurisdictions, including British Columbia and Saskatchewan, the United States, England, Germany and New Zealand.

28. What were the defining criteria for the four selected drug products in wave one?

In choosing the four drug products, the following factors were considered:

1. Availability of brand and generic equivalents
2. Multiple suppliers
3. High volume of utilization
4. Significant share of total Ontario utilization by the public sector
5. Significantly lower prices in other jurisdictions

29. Which drug products would be applicable for wave one of the Competitive Agreements?

The molecules would be as follows:

1. Enalapril Maleate 2.5mg TAB, 5mg TAB, 10mg TAB and 20mg TAB
2. Metformin 500mg TAB

3. Gabapentin 100mg CAP, 300mg CAP, 400mg CAP

4. Ranitadine 150mg TAB, 300mg TAB

30. Will Gabapentin suspension or Ranitadine injection or oral solution be applicable for wave one of the Competitive Agreement Initiative?

No. Only the tabs and capsules would be applicable. There would be no change to the listing status for Gabapentin suspension, Ranitadine injection or Ranitadine oral solution.

31. What was the total utilization for these molecules by the OPDP in fiscal 2007 (April 2007 – March 2008)?

1. Enalapril Maleate

2.5mg TAB	2,107,580	$1,334,353	4.6%
5mg TAB	8,936,139	$6,679,648	22.8%
10mg TAB	13,683,789	$12,264,383	41.9%
20mg TAB	8,341,267	$8,987,621	30.7%
Total		$29,266,005	100%

2. Metformin hydrochloride

500mg TAB	234,006,048	$22,673,024	100%

3. Gabapentin

100mg CAP	3,049,692	$612,910	8.9%
300mg CAP	9,165,706	$4,459,930	64.6%
400mg CAP	3,134,437	$1,830,392	26.5%
Total		$6,903,232	100%

4. Ranitidine hydrochloride

150mg TAB	47,983,457	$19,439,210	91.0%
300mg TAB	2,453,104	$1,914,568	9.0%
Total		$21,353,778	100%

32. What does the term "off-patent" mean in the Competitive Agreement information material?

For the purposes of the Competitive Agreement process, "off-patent" refers to products that are currently listed on the ODB Formulary and which there are multiple manufacturers that would be able to supply the product.

33. What does it mean to be "in good standing" with the Ministry?

Examples of issues that would cause a supplier to not be "in good standing" are supply issues such as significant stock-outs, payment issues, or non-compliance with the regulations.

34. Would professional allowances to pharmacy be affected by this process?

Pharmacies and manufacturers have communicated to the Ministry that professional allowances are provided on a "bundle" of products, and rarely on individual products. Maximum professional allowances are capped at 20% of the total ODB sales for each manufacturer.

35. What happens if pharmacies dispense the product of a manufacturer that is no longer a benefit, and then claims to have sold the product of a winning manufacturer for reimbursement from the ODB Program?

This action would be considered professional misconduct and evidence to this effect would be submitted as a complaint to the Ontario College of Pharmacists. It would also be a breach of the regulation under the *Ontario Drug Benefit Act*. The Ministry has several methods of assessing whether claims appear to be inconsistent with manufacturer sales data. The Ministry would assign audit resources to monitor this activity. As is standard, in the event that there are concerns regarding the dispensing of these products, the Ministry would request copies of all invoices and purchase records to support the claims process. All invoices must be in a readily retrievable format and provided within the specified timeframe.

If the Ministry were to find a pharmacy that falsified reimbursement claims, it would exercise all options available under the law to remedy the situation and deal with all parties associated with this incident.

36. Can there be any guarantee of volumes in the Competitive Agreement?

No. The Ministry does not intend to direct pharmacies in their choice of the two suppliers.

37. How many products does the Ministry intend to launch for each wave?

The Ministry is launching four drug products (molecules) for the first wave. The number of drug products (molecules) for subsequent waves is to be determined.

Adjustments to Competitive Agreement Initiative based on feedback

The contract length is too long, and the renewal is too one-sided. More certainty as to the length of the contract would be preferred.

The one-year renewal has been eliminated. A two (2) year contract would be awarded and would begin between October 1st, 2008 and January 1st, 2009, and would end on December 31st, 2010.

Holding three months of supply for the entire ODB Program market is too much safety stock.

By the end of the third month after the start of the contract, each winner would be required to hold one month's supply of theODB Program's total requirement. Between both winners, two months supply of stock would be accessible by the market in the event of a stock-out. The new requirement is significantly less than the three months supply for the entire market originally proposed.

It would take a long period of time to build this inventory, thus it would be difficult to have this safety stock ready for the start of the contract.

At the start of the contract, each winner would be required to have a safety stock of two weeks supply of the entire market, ensuring there is one month's supply of the entire market's demand. Winners would be given three months after the start of the contract to build additionally required safety stock.

Winners would be required to supply regular inventory level reports to the Ministry.

Volume discounts should be based on a sliding scale, instead of using one volume discount rate and applying it to all volume.

Winners would pay volume discounts based on the volume discount in each tier, for the volume applicable to that tier. For example, a manufacturer offers a 20% volume discount in the <10% market share tier, and a 40% volume discount in the 10-40% tier. If they achieved 35% market share, they would pay a volume discount of 20% on the first 10% of their volume, and a 40% volume discount on the remaining 25% of their volume.

Sample calculation of Total Effective Volume Discount "rate"

Applicants fill out ONLY the *Discount Offered* line

Volume Discount Form

Molecule A 2.5 mg	DBP:	$0.3617			Weighted Discount Offered
Market Share Tier	> 10%	10% - 39.99%	40% - 70%	> 70%	
Tier Weight	10%	40%	40%	10%	
Discount Offered	*20%*	*30%*	*40%*	*45%*	34.50%
Effective Price	0.2894	0.2532	0.2170	0.1989	

Molecule A 5 mg	DBP:	$0.4279			Weighted Discount Offered
Market Share Tier	> 10%	10% - 39.99%	40% - 70%	> 70%	
Tier Weight	10%	40%	40%	10%	
Discount Offered	*15%*	*25%*	*30%*	*32%*	26.70%
Effective Price	0.3074	0.2713	0.2532	0.2460	

Molecule A 10 mg	DBP:	$0.5142			Weighted Discount Offered
Market Share Tier	> 10%	10% - 39.99%	40% - 70%	> 70%	
Tier Weight	10%	40%	40%	10%	
Discount Offered	*25%*	*30%*	*35%*	*40%*	32.50%
Effective Price	0.2713	0.2532	0.2351	0.2170	

Molecule A 20 mg	DBP:	$0.6204			Weighted Discount Offered
Market Share Tier	> 10%	10% - 39.99%	40% - 70%	> 70%	
Tier Weight	10%	40%	40%	10%	
Discount Offered	*30%*	*35%*	*40%*	*45%*	37.50%
Effective Price	0.2532	0.2351	0.2170	0.1989	

Drug Product	Total Drug Cost Apr 2007-Mar 2008	Percentage of total cost	Weighted Discount Offered	
2.5 mg	1000000	8.33%	34.50%	
5 mg	2000000	16.67%	26.70%	
10 mg	5000000	41.67%	32.50%	
20 mg	4000000	33.33%	37.50%	
Total Effective Volume Discount (Percentage of total cost x Weighted Discount offered)				33.37%