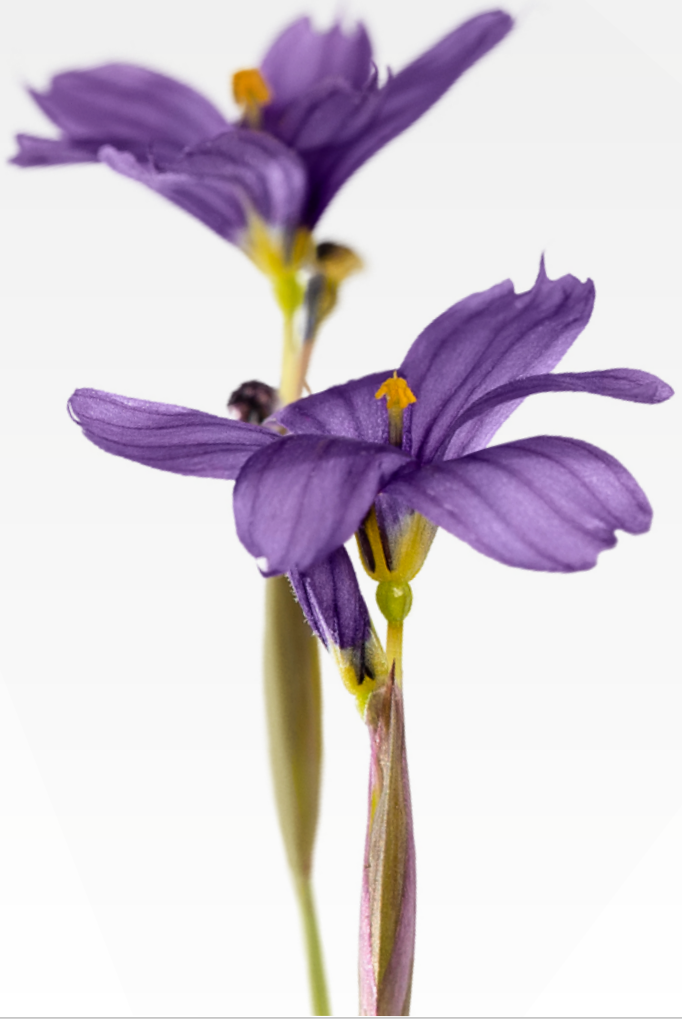


November 2021

Drug Submission Requirements

TELUS Health

Table of contents

Section 1

General

Section 1 - General

Please submit all information electronically to TELUS Health at drug.submissions@telus.com, including:

a) Cover letter
b) Review type requested (e.g. new drug)
c) Documentation requirements for the review type in a compressed file folder – see corresponding sections below

If the drug submission is too large to be sent by email, please email drug.submissions@telus.com for instructions on access to the Gateway file transfer site.

For select drug submissions, TELUS Health may call upon experts in drug reviews within the health industry to provide additional input. TELUS Health will request and facilitate sharing of drug submission materials between the pharmaceutical manufacturer and the reviewer.

Statement of confidentiality: All parties involved in TELUS Health drug reviews are required to maintain confidentiality. Contracted external review committees are held under non-disclosure agreements.

Paper drug submissions will not be accepted.
Only electronic submissions by email or Gateway file transfer will be accepted.
Incomplete submissions will delay your review and may not be reviewed for consideration on the TELUS Health-managed formularies.

This document outlines the submission requirements by review type, as follows:

1. New drug products & new indication
2. Biosimilar products
3. Expanded Indication
4. Line extension
5. Generic products

Section 2

New drug & new indication

Section 2 - New drug & new indication

Submission components should be provided as separate files with clearly identifiable file names. Components should include at minimum:

1. **Executive summary**

2. **Health Canada notice of compliance**

3. **Product monograph (English and French)**

4. **Product summary (TELUS Health Excel template)**
   a) Brand & generic names
   b) Manufacturer name
   c) DIN
   d) Route
   e) Indication(s)/listing request
   f) Unit drug cost (Ontario, before markup)
   g) Rx/OTC
   h) NOC date
   i) Market launch date
   j) Annual cost estimate per patient
   k) Brand/generic
   l) Administration setting

5. **Pricing**
   a) Price sheet – official pricing for Canada (unit price and package price)
      - If providing package pricing, include definition of pack description i.e. # tablets/pack or actuations/device
   b) Product listing agreements – PMPRB referenced countries, **if applicable**
   c) PMPRB reference pricing for PMPRB referenced countries, **if available**

6. **Fact sheet (TELUS Health Word template)**
   a) Therapeutic classification (e.g., atorvastatin, HMG-CoA reductase inhibitor)
   b) AHFS classification
   c) Drug schedule (Federal and NAPRA)
   d) Specialist/general practitioner prescribing
   e) Distribution channels (direct/wholesale/specialty pharmacy)
   f) Disease prevalence/incidence
   g) Recommended and maximum dosages, duration of therapy
   h) Monitoring requirements (if any)
   i) Adverse reactions (>1%)
   j) Cost of therapy comparison table
      - All relevant alternatives
      - Unit drug cost (Ontario)
      - Cost per year (Ontario)
   k) Patent expiry date(s)

l) Clinical trial summary
   - NCT number
   - Inclusion/exclusion criteria
   - Interventions
   - Number of trial participants
   - Outcome measures/main findings

m) Public HTA submission status
   - CADTH
   - INESSS

n) Contact Information
   - General
   - Medical information

7. Patient support program information (TELUS Health Excel template)

a) Drug name
b) Patient support program name
c) Third party administrator
d) Description of program
e) Primary contact name
f) Contact email
g) Phone number
h) Fax number
i) Address

8. Clinical summary

a) Relevant clinical studies
   - Supporting evidence for labelled indications
   - Evidence from secondary sources

b) Comparative studies
   - Clinical comparative studies (benefit, safety)
   - Network meta-analyses

c) Place in therapy
   - Prevalence & incidence in Canada
   - Special population(s) for which the submitted drug is effective
   - Clinical advantages

9. Budget impact analysis

As per the Patented Medicine Prices Review Board (PMPRB) guidelines and the TELUS Health BIA guidance document:

- Executive summary
- Written report
- Modifiable MS Excel model
- Perspective: private payer
- Eligible population (relevant to the private payer)
- Drug cost
- Duration of therapy
- Estimated market share
- All relevant comparators
- 3-5 year time horizon
- Present incremental budget impact as cost per 100,000 private lives OR cost per private plan member

10. Pharmacoeconomic analysis

In line with the CADTH 2017 Economic Guidelines

a) Executive summary
b) Detailed report
c) Modifiable MS Excel model
d) Perspective: **Private payer perspective (societal/public perspective is not appropriate but preferred to no model and can be assessed on case-by-case basis)**
e) If possible, include productivity costs in the analysis relevant to the private payer (e.g., absenteeism, presenteeism); disability costs, allied healthcare provider costs (e.g., chiropractic, physiotherapy, massage), assistive devices, rehabilitation and out of hospital costs not covered by public healthcare system. For estimating the productivity loss resulting from patients prematurely leaving the workforce, the friction cost approach is recommended in a private payer perspective – the human capital approach can be presented as ancillary information.
f) Comparators: Standard of care relevant alternatives for the disease treated and at usual comparable therapeutic dose
g) Time horizon: over reasonable course of the disease treated
h) Disease prevalence/incidence: Canada
i) Include all relevant clinical outcomes and assessment of all relevant costs.
j) Provide incremental cost-effectiveness ratio (ICER) as cost per quality-adjusted life year (QALY) (i.e., cost-utility analysis (CUA))**
k) Probabilistic sensitivity analysis

** TELUS Health submission requirements are for a CUA model, however, it is recognized that a CMA model would be appropriate under certain circumstances. TELUS Health will review each of these submissions on a case by case basis and reserves the right to HOLD a review if the conditions for a CMA model submission are not felt to be met or provide the appropriate level of information for decision making. As stated in the CADTH guidelines, "the preferred approach for the pharmacoeconomic analysis is a cost-utility analysis. In some specific situations, a cost-minimization analysis (CMA) could be submitted, but the sponsor is asked to review these criteria and ensure they meet all three in order to avoid delays in the review. Only one type of economic evaluation can be included in each submission (e.g.,submitting both a cost-minimization analysis and cost-utility analysis for the same population within the same submission will not be accepted).

A sponsor may choose to submit a cost-minimization analysis where it considers that all three of the following conditions are met:

1. The drug represents an additional drug in a therapeutic class in which there is already [many] reimbursed drug[s] for the same indication:
2. The drug under review demonstrates similar clinical effects (i.e., have at least equivalent effectiveness and/or efficacy and be equivalently or less harmful) compared to the most appropriate comparator(s), based on:
   - One or more clinical studies that directly compared the drug under review to relevant comparator(s)
   - One or more indirect comparisons that allow for the comparison of the drug under review to relevant comparator(s)
3. The drug under review is anticipated to result in equivalent or lesser costs to the health system.

As comparative efficacy and safety will be assessed within the review, the appropriateness of a cost-minimization analysis cannot be confirmed by CADTH during the screening phase of the process."

11. References

a) Pivotal clinical trial publications (if not published please provide written summary of the outcome data)
b) Indirect comparison reports or network meta-analysis reports performed by manufacturer to inform the economic models
c) Articles referenced in the PE and BIA models

Section 3

Biosimilar

Section 3 - Biosimilar

Submission components should be provided as separate files with clearly identifiable file names. Components should include at minimum:

1. **Executive summary**

2. **Health Canada notice of compliance**

3. **Product monograph (English and French)**

4. **Product summary (TELUS Health Excel template)**
   a) Brand & generic names
   b) Manufacturer name
   c) DIN
   d) Route
   e) Indication(s)
   f) Unit drug cost (Ontario, before markup)
   g) Rx/OTC
   h) NOC date
   i) Market launch date
   j) Annual cost estimate per patient
   k) Brand/generic
   l) Administration setting

5. **Pricing**
   a) Price sheet – official pricing for Canada (unit price and package price)
      - If providing package pricing, include definition of pack description i.e. # tablets/pack or actuations/device
   b) Product listing agreements – PMPRB referenced countries, **if applicable**.
   c) PMPRB reference pricing for PMPRB referenced countries, **if available**.

6. **Fact sheet (TELUS Health Word template)**
   a) Therapeutic classification (e.g., atorvastatin, HMG-CoA reductase inhibitor)
   b) AHFS classification
   c) Drug schedule (Federal and NAPRA)
   d) Specialist/general practitioner prescribing
   e) Distribution channels (direct/wholesale/specialty pharmacy)
   f) Disease prevalence/incidence
   g) Recommended and maximum dosages, duration of therapy
   h) Monitoring requirements (if any)
   i) Adverse reactions (>1%)
   j) Cost of therapy comparison table
      - All relevant alternatives
      - Unit drug cost (Ontario)
      - Cost per year (Ontario)
   k) Patent expiry date(s)

l) Clinical trial summary
   - NCT number
   - Inclusion/exclusion criteria
   - Interventions
   - Number of trial participants
   - Outcome measures/main findings

m) Public HTA Submission Status
   - CADTH
   - INESSS

n) Contact information
   - General
   - Medical information

7. Patient support program information (TELUS Health Excel template)

a) Drug name
b) Patient support program name
c) Third party administrator
d) Description of program
e) Primary contact name
f) Contact email
g) Phone number
h) Fax number
i) Address

8. Clinical summary

a) Relevant clinical studies
   - Supporting evidence for labelled indications
   - Supporting evidence for off label indications
   - Evidence from secondary sources

b) Comparative studies
   - Clinical comparative studies (benefit, safety)

c) Place in therapy
   - Prevalence & incidence in Canada
   - Special population(s) for which the submitted drug is effective
   - Clinical advantages

9. References

a) Pivotal clinical trial publications (if not published, please provide written summary of the outcome data)

Section 4

Expanded indication

Section 4 - Expanded indication

Applies to the scenario of expansion of an existing indication (e.g. addition of pediatric population to existing indication).

Submission components should be provided as separate files with clearly identifiable file names. Components should include at minimum:

1. **Executive summary**

2. **Health Canada notice of compliance**

3. **Product monograph (English and French)**

4. **Fact sheet (TELUS Health Word template)**
   a) Therapeutic classification (e.g., atorvastatin, HMG-CoA reductase inhibitor)
   b) AHFS classification
   c) Drug schedule (Federal and NAPRA)
   d) Specialist/general practitioner prescribing
   e) Distribution channels (direct/wholesale/specialty pharmacy)
   f) Disease prevalence/incidence
   g) Recommended and maximum dosages, duration of therapy
   h) Monitoring requirements (if any)
   i) Adverse reactions (>1%)
   j) Cost of therapy comparison table
      - All relevant alternatives
      - Unit drug cost (Ontario)
      - Cost per year (Ontario)
   k) Patent expiry date(s)
   l) Clinical trial summary
      - NCT number
      - Inclusion/exclusion criteria
      - Interventions
      - Number of trial participants
      - Outcome measures/main findings
   m) Public HTA submission status
      - CADTH
      - INESSS
   n) Contact information
      - General
      - Medical information

5. **Clinical summary**
   a) Relevant clinical studies
      - Supporting evidence for labelled indications
      - Supporting evidence for off label indications
      - Evidence from secondary sources

   b) Comparative studies
      - Clinical comparative studies (benefit, safety)
      - Cost-effective alternatives

   c) Place in therapy
      - Prevalence & incidence in Canada
      - Special population(s) for which the submitted drug is effective
      - Clinical advantages

6. **Pricing**
   a) Price sheet – official pricing for Canada (unit price and package price)
      - If providing package pricing, include definition of pack description i.e. # tablets/pack or actuations/device

   b) Product Listing Agreements – PMPRB referenced countries, **if applicable**.
   c) PMPRB reference pricing for PMPRB referenced countries, **if available**.

7. **Budget impact analysis**

   As per the Patented Medicine Prices Review Board (PMPRB) guidelines and the TELUS Health BIA Guidance Document:
   a) Executive summary
   b) Written report
   c) Modifiable MS Excel model
   d) Perspective: Third party payer/private payer
   e) Eligible population
   f) Drug cost
   g) Duration of therapy
   h) Estimated market share
   i) All relevant comparators
   j) 3-5 year time horizon
   k) Present incremental budget impact as cost per 100,000 private lives

8. **References**
   a) Pivotal clinical trial publications (if not published, please provide written summary of the outcome data)
   b) Indirect comparison reports or network meta-analysis reports performed by manufacturer to inform the economic models

Section 5

Line extension

Section 5 - Line extension

Applies to the following scenarios for an existing brand:

1. **New strength**
2. **New formulation**

Submission components should be provided as separate files with clearly identifiable file names. Components should include at minimum:

1. **Executive summary**

2. **Health Canada notice of compliance**

3. **Product monograph (English and French)**

4. **Pricing**
   a) Price sheet – official pricing for Canada (unit price and package price)
      - If providing package pricing, include definition of pack description i.e. # tablets/pack or actuations/device
      - Include pricing of original strength/formulation

   b) Product Listing Agreements – PMPRB referenced countries, **if applicable**.
   c) PMPRB reference pricing for PMPRB referenced countries, **if available**.

5. **Fact sheet (TELUS Health Word template)**
   a. Therapeutic classification (e.g., atorvastatin, HMG-CoA reductase inhibitor)
   b. AHFS classification
   c. Drug schedule (Federal and NAPRA)
   d. Specialist/general practitioner prescribing
   e. Distribution channels (direct/wholesale/specialty pharmacy)
   f. Disease prevalence/incidence
   g. Recommended and maximum dosages, duration of therapy
   h. Monitoring requirements (if any)
   i. Adverse reactions (>1%)
   j. Cost of therapy comparison table
      - All relevant alternatives
      - Unit drug cost (Ontario)
      - Cost per year (Ontario)

   k. Patent expiry date(s)
   l. Clinical trial summary
      - NCT number
      - Inclusion/exclusion criteria
      - Interventions
      - Number of trial participants
      - Outcome measures/main findings

   m. Public HTA submission status
      - CADTH
      - INESSS

   n. Contact information
      - General
      - Medical information

Section 6

Generics

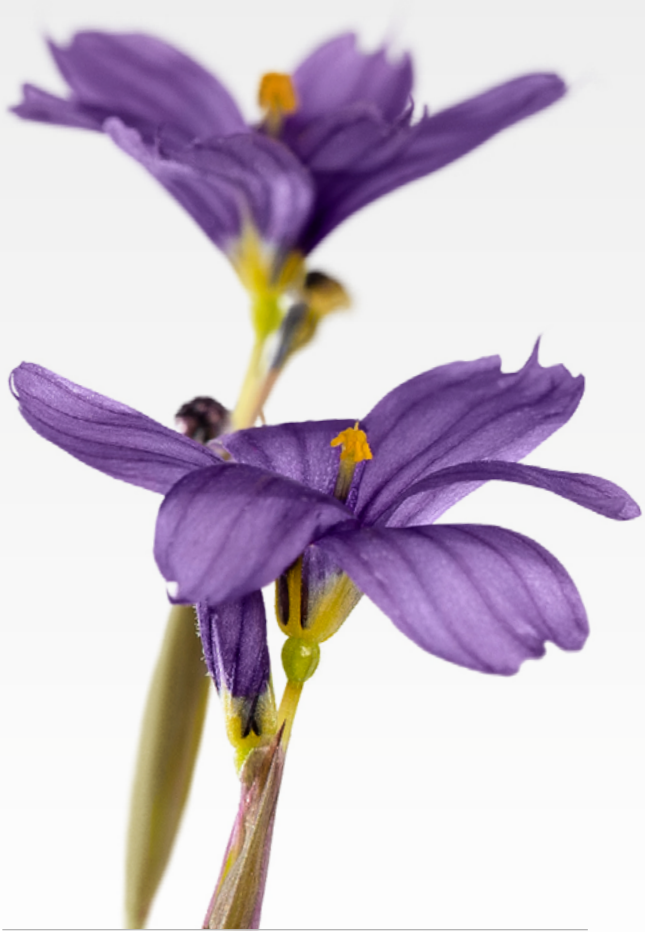
Section 6 - Generics

1. Pricing

a) Price sheet – official pricing for Canada (unit price and package price)
- If providing package pricing, include definition of pack description i.e. # tablets/pack or actuations/device

2. Fact sheet (TELUS Health Word template available)

a) Brand name
b) Generic name
c) Therapeutic classification (e.g., atorvastatin, HMG-CoA reductase inhibitor)
d) AHFS classification
e) Drug schedule (Federal and NAPRA)
f) Distribution channels (direct/wholesale/specialty pharmacy)
g) Noc date
h) Launch date
i) Indication(s)
j) Product information
k) Pricing
l) Contact information
- General
- Medical information



Our EDR solution helps **drive collaboration** among all stakeholders to **improve client experiences.**

Learn how

TELUS Health

THS3847-11-2021