Direction du médicament

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Director

South America mission
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Aim of the presentation

• To present INESSS’s mandates with regard to medication
• To explain the *Régime d’assurance médicaments* [drug insurance plan]
• To present the Direction du médicament
  – Assessment of medications for inclusion on the List of Medications
  – Optimal use of medication
  – Collective prescriptions across the province
• To discuss and answer queries
1. INESSS’s Mandates with regard to Medication
Organizational Changes

• Merging of two bodies into a single one last April 21
  – Highlights the importance of medication in the environment
  – Improves the integration of the different concerns throughout the medication cycle of life
  – Some 50 individuals supervised by 5 scientific co-ordinators
Cycle de vie du médicament

- Inscription
- Overview of medication use
- Systematic reviews
- Optimal use guides
- Clinical practice guidelines
- Collective or pre-printed prescriptions
- Impact assessments

- Annual scorecard
- Class review
- Obsolescence assessment
- Status re-assessment
- Real world evidence
- Soumissions
11 functions under the Act respecting INESSS, including:

- Assessing medications, technologies and interventions used in health care and personal social services.

- Developing recommendations and clinical practice guides aimed at optimal use.

(R.S.Q., chapter I-13.03)
More particularly, the Institute’s mission consists in:

1° assessing the clinical advantages and the costs of the technologies, medications and interventions used in health care and personal social services;

2° preparing recommendations and developing clinical practice guides to ensure optimal use of the technologies, medications and interventions used in health care and personal social services;
8° making recommendations to the Minister with a view to updating the list of medications referred to in section 60 of the Act respecting prescription drug insurance (chapter A-29.01);

9° making recommendations to the Minister for the purpose of updating the lists of medications provided for in section 116 of the Act respecting health services and social services (chapter S-4.2) and section 150 of the Act respecting health services and social services for Cree Native persons (chapter S-5);
Shared responsibilities
INESSS
Responsibilities in the area of prescription drug insurance

• The Minister is ultimately responsible for this matter, including:
  – Entering medications on the lists of medications for the RGAM [basic drug insurance plan] and for healthcare institutions after consulting with INESSS.

• The Ministry (MSSS)
  – Monitors and evaluates the basic drug insurance plan
  – Develops the directions and strategies surrounding the issue of medication
  – Acts as liaison between stakeholders in the public, parapublic and private sectors
INESSS
Responsibilities in the area of drug insurance

• **INESSS**
  – Assists the minister in updating the lists of medications
  – Promotes the optimal use of these medications
  – Makes recommendations to the Minister on any other question that the Minister refers to it and publishes them

• **RAMQ**
  – Administers the coverage of beneficiaries of the employment-assistance program, persons aged 65 years or older and persons not eligible for group insurance or an employee benefit plan
2. Régime général d’assurance médicaments
Régime général d’assurance médicaments (RGAM)

• A societal choice to ensure better access to medication

• The Régime général d’assurance médicaments (RGAM) was introduced in 1997 – already 19 years ago
Reasonable and equitable access to the medications required by people’s health conditions

Fair and equitable cost sharing

Integrated approach to medication coverage
• Universal: minimum basic coverage applies to all Quebecers regardless of income
• Mixed: population covered by the RAMQ or by a private insurer
• Contributory: funding includes the financial contribution of insured persons
Évolution des coûts bruts des ordonnances

 Millions $  

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• Reasons explaining these changes:
  – Increase in the average cost per prescription (arrival of new products and therapeutic transfer)
  – Increase in the number of insured persons using medication (older persons in particular)
  – Abolishment of the 15-year rule
  – Most of the blockbusters are generic now
  – Drop in the price of certain generic drugs
The main structural measures put in place following the revision of the RGAM in 2002:

- Creation of the Conseil du médicament (Institut national d’excellence en santé et en services sociaux since 19 January 2011)
- Introduction of new medication assessment criteria
- Global strategy aimed at monitoring the use of medication and promoting the optimal use of medication
3. INESSS and medication assessment: criteria, lists of medication, implications
• In exercising the functions described in paragraph 8 of section 5, the Institute must first assess the **therapeutic value** of a medication.

If this is not established to its satisfaction, the institute sends a notice to that effect to the Minister.
If the institute considers that the therapeutic value of a medication has been established, it sends its recommendation to the Minister after assessing

• (1) the reasonableness of the price;

• (2) the cost-effectiveness of the medication;

• (3) the impact that entering the medication on the list will have on the health of the general public and on the other components of the health and social services system; and

• (4) the advisability of entering the medication on the list, given the purpose of the basic prescription drug insurance plan.
• Assessment criteria set by the legislator

• All the partners concerned share a common understanding of the meaning and scope of each criterion

• Specific procedures for applying these criteria

• During review
• Assessment procedure

• Methods of application for the criteria

• List of documents to submit in applying to have a medication or product entered on the List
Assessing medications for Inclusion in the List - Timeline

Schedule and Volume of Applications

- Updates have taken place every 4 months since 2003 (February 1, June 1 and October 1) with amendments
- For multi-source drugs (generic equivalents): 9 updates per year
- Preparatory work takes 5 months
- Priority assessments are possible
- 400-500 applications per year (approx. 150 files covering novel drugs)
• List of medications covered by the RGAM
  • Regular Drug section and Exception Drug section
  • Registration of certain supplies
• List of medications for Institutions
  • Medications that can be or need to be administered in healthcare institutions
  • Serves as the basis for creating the local formulary
  • With or without criteria for use
In Short

• Assessment of medication for inclusion on the List
  – Based on the 5 criteria provided in the Act
  – Different possible recommendations (Notice of rejection, Notice of approval, etc.)
  – Publication on our website: recommendations made to the Minister and the Minister’s decision

• Québec has been a registered member of the pan-Canadian Pharmaceutical Alliance since September 2015... the minister can negotiate prices
4. INESSS and optimal use: functions, assessments and issues
Selected definition

Use that maximizes the benefits and minimizes the risks for the population’s health by taking into account the various possible options, costs and available resources, patient values and social values.
OPTIMAL USE- Selected Activities

- Notices and guides
- Overviews/Portraits of medication use
- Information, education and awareness for decision makers, practitioners and the public
- Management of a fund for the optimal use of medication
- Annual scorecard
OPTIMAL USE
GUIDES D’USAGE OPTIMAL EN ANTIBIOTHÉRAPIE
• Guides sur le traitement pharmacologique des ITSS
• Avis sur le remboursement des IPP (mars 2013 et juillet 2015)
• Guide d’usage optimal en autosurveillance glycémique
• Guide d’usage optimal sur le traitement pharmacologique de la maladie d’Alzheimer et de la démence mixte
• Outils d’aide à la pratique sur le repérage et le processus menant au diagnostic de la maladie d’Alzheimer et d’autres troubles neurocognitifs
• Guide d’usage optimal de la thérapie par pression négative pour le traitement des plaies complexes
• Les niveaux de soins: normes et standards de qualité incluant une proposition de formulaire normalisé
The MSSS put in place a major **clinical relevance project** linked to medication

- Launched in April 2015;
- INESSS plays a major scientific and clinical role in this project;
- Formation of a clinical governance committee including the Collège des médecins and the l’Ordre des pharmaciens du Québec
Clinical Relevance Project: INESSS’s role and responsibilities

- Propose to the governance committee an action plan and timetable for developing clinical recommendations for each of the drug classes in question.
- Submit to the MSSS a detailed budget plan required to carry out the clinical recommendations.
- Establish expert panels to carry out the clinical recommendations.
- Inform the governance committee of the progress of the work.
- Present to the governance committee clinical recommendations for each of the drug classes in question.
- Recommend to the governance committee evidence-based and adapted measures for implementing the clinical recommendations.
5. Provincial collective prescriptions
• According to section 39.3 of the Professional Code,

“[…] the word 'prescription' means a direction given to a professional by a physician, a dentist or another professional authorized by law, specifying the medications, treatments, examinations or other forms of care to be provided to a person or a group of persons, the circumstances in which they may be provided and the possible contraindications. A prescription may be individual or collective. ¹”

¹. Professional Code, CQLR, c. C- 26, s. 39.3.
• Agreement between the MSSS and INESSS
  – Hosting, updates, \textit{de novo} productions
  – Scientific watch
• Products
  – Collective prescriptions
  – Medical protocols (applicable standards)
• Objectives
  – Public access to health services
  – Improved co-operation through the use of health professionals’ competencies
  – Significant time savings for physicians
Collective Prescriptions

- 2016-2017
  - Updates for collective prescriptions
    - High blood pressure and anticoagulant therapy: June 2016
    - Dyslipidemia and diabetes: September 2016
  - De novo collective prescriptions
    - STDs and STIs and palliative care: December 2016
    - chronic obstructive pulmonary disease (COPD); and antidepressants: March 2017
Direction du médicament :
Aspirations

• To improve internal integration
• To optimize its contributions with its partners
• To better support institutions’ pharmacology committees
  – Assessments prior to the Notice of Compliance (NOC) in order to decrease the time between marketing and access
  – Improve the deliberative fact sheet to promote local decisions
    • Institutional formulary
    • Particular medical necessity
Direction du médicament:
Aspirations (cont’d)

• To improve our agility in responding to environmental changes
  • Mobility within and between divisions or departments
• To introduce the concept of innovation for medication
  • Development of evidence in real care contexts