

Bringing New Drugs to Market **(Teacher's Guide)**

Activity Name

Bringing New Drugs to Market

Broad Area of Learning

- Health and well-being
- Personal and career planning

Targeted Competency

Competency 1: Seeks answers or solutions to scientific or technological problems

Components of the Targeted Competency

- Defines a problem
- Develops a plan of action

Curricular Concepts

- Tissues, organs, and systems (anatomy and physiology)
- Develop an experimental protocol

Grade Level

- Secondary 3 (Grade 9)

Instructional Strategies

- Role play
- Thinking about the roles of pharmaceutical drugs
- Developing a mock drug approval
- Orally communicate experimental results

Required Materials

- Student document “Bringing a drug to market”
- Projector/Smartboard and Prezzi presentation (https://prezi.com/xz8badkh_5tw/steps-to-commercializing-a-new-drug/)
- Computer or other electronic device (to conduct research)

Approximate Duration

- 400 minutes

Activity Context and Rationale

For a drug to go on sale in a pharmacy, it has to pass through a series of important tests. Indeed, the approval of a new drug is a rather lengthy process – the drug must demonstrate its effectiveness, while showing no serious side effects in humans. Prospective drug molecules must first be tested in petri dishes in the laboratory, and then on small animals, before they can be administered to patients in a clinical trial.

The purpose of this activity is to demonstrate the rigor and importance of the pre-clinical trial stage of the drug approval process. By simulating the development of a new molecule and a protocol to verify its effectiveness, the student will have to critically and analytically think about the types of experiments needed. Through a final oral presentation, this activity will also enable the entire class to learn or review several systems of the human body in depth.

This is a fictitious activity aimed at better understanding the approval process for drugs in Canada. Thus, the different drugs proposed by the students and their mode of action can be totally fictitious. Nevertheless, this activity offers a stimulating and concrete exercise for students to demonstrate creativity, analytic thinking, and effective communication skills.

Sequence of Activities

1- Introduction (15-20 minutes)

The teacher can question the students to determine their prior knowledge of the pharmaceutical field. Suggested questions include:

- 1- Why do you think some new drugs are approved, while others are not?*
- 2- What characteristics do the medications we buy have in common?*
- 3- How can we be assured that a drug will work as advertised?*
- 4- Why must we test on laboratory animals, such as mice, before administering a drug to humans?*

Next, the teacher presents the following slide show illustrating the steps of the drug approval process in Canada: https://prezi.com/xz8badkh_5tw/steps-to-commercializing-a-new-drug/ .

2- Student Preparation (75-90 minutes)

In groups of two or more, students complete the two sections of the student document. To begin, they must first consider the effect that their drug will have on the body. Students may refer to their notes or other educational materials to help them decide on a mode of action. During this time, the teacher circulates around the room and asks guiding questions to help students progress through the lesson.

3- Presentation Development (150 minutes)

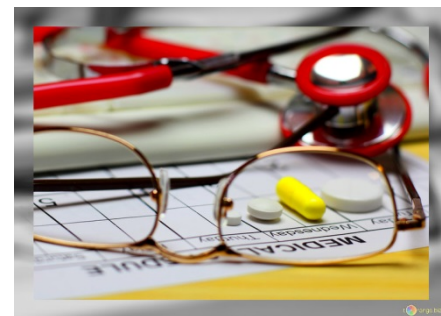
Students develop their Prezzi presentations, incorporating visual elements such as pictures, graphs, and statistics. They may refer to the rubric (see accompanying document) while making their presentations in order to know how they will be evaluated. Students will need access to a computer or other device in order to design a presentation using the freely available Prezzi software: <https://prezi.com/>

4- Presentations to the Class (150 minutes)

Students take turns presenting their projects according to the criteria described in the rubric.

Bringing a Drug to Market

As your teacher has described, medications sold in pharmacies must pass a series of important tests. Drug approval is a rather lengthy process that verifies the effectiveness and safety of a drug, while detecting any potential side effects. In this activity, you will have the opportunity to design a pharmaceutical drug with a specific effect in the human body and develop a hypothesis to explain its mode of action. Then, you will need to develop an experiment to test your hypothesis and the efficacy of your molecule in a mock pre-clinical trial. You will then present your findings to the rest of the class using a presentation method of your choice (Prezzi, PowerPoint, or other).



Activity 1: Choice of a drug and its role in the body

Like all pharmaceuticals, your molecule must have one or more effects that will positively influence your health. For example, painkillers such as analgesics (Advil™, Aspirin™) work by diminishing the sensation of pain and blocking the chemical signal of pain to the brain, while anticoagulants prevent clotting in blood vessels. In short, for a drug to work it must have a precise action on one or more systems of the body (blood system, nervous system, musculoskeletal system, respiratory system, etc.)

Your first task is to choose what effect your drug will have on the human body. The following questions will help you identify important information that should be included in your presentation. Be creative in the effect of your molecule! Some examples of drug effects include:

- *A drug that increases muscle strength*
- *A drug that improves concentration for long periods of time*
- *A drug that improves vision in the dark*

To help you make a choice, research some of the different human body systems and choose an attribute or function that you would like to improve or eliminate, or a disease affecting one of these systems that could be treated with a drug.

Body system choices: *digestive, blood, nervous, muscular, skeletal, lymphatic/immune, urinary, respiratory, one of the five senses, etc.*

1- What is the function of your medication? *Students must specify how their drug will impact the targeted body system or disease (increase muscular strength, decreased sense of fear, overcome the cause or a symptom of a disease, etc.)*

4- Choose two measurable attributes in both the test and control groups of mice, and explain the method you will use to obtain a measurement of this attribute (e.g. search for hidden food in a maze; withdraw a blood sample for analysis; etc.). Then, describe how your measurements will be analyzed between the two groups (e.g. compare times taken to retrieve hidden food; blood glucose levels following meals; etc.), and how the test could show evidence of a therapeutic effect.



Attribute 1	Method	Analysis & Interpretation
	<p>Type of experiment chosen to measure the first attribute (e.g. a timed mouse maze with food at one end)</p>	<p>Description of the predicted results and how they will be analyzed and interpreted (e.g. times will be averaged for each group and then compared, predict that mice taking the drug will find the food faster due to a keener sense of smell, etc.)</p>

Attribute 2	Method	Analysis & Interpretation

Activity 3: Presentation of your drug and protocol



You must now present a proposal for a pre-clinical trial for your drug. Use the guidelines below to help develop your presentation. Each slide should have images, graphics, or photos to illustrate the information that you have found.

Slide 1: The health issue or human ability to be addressed

What ability, disease, or health issue does your drug target? What made you decide to pursue it? What benefits will the person taking the medication have?

Slide 2: System to be treated

How does the organ or system on which your drug acts function naturally?

Slide 3: Drug's desired effect on the targeted system

On which function of the targeted system does your drug act? What is its mechanism of action? How will interactions on the molecular level lead to observable effects? Be specific in your explanations.

Slide 4: Pre-clinical experiments

What experiments will you use on your two groups of mice (test & control) to demonstrate the efficacy of your drug? What tools or objects will you use in order to carry out this strategy? Explain the details of your experiments and provide a rationale for choosing these particular experiments.

Slide 5: First attribute to analyze

What attribute will you analyze in this experiment? Why do you think this test is important in order to demonstrate the efficacy of your molecule? How will you measure or quantify the data that you get? How will you interpret the results of this experiment?

Slide 6: Second attribute to analyze

What attribute will you analyze in this experiment? Why do you think this test is important in order to demonstrate the efficacy of your molecule? How will you measure or quantify the data that you get? How will you interpret the results of this experiment?

Slide 7: Feasibility and societal impact

In your opinion, why should the drug that you have proposed be approved? What are the possible positive effects that your drug could have on health for both individuals and society at large? What are some of the possible negative effects?

Rubric: Bringing a Drug to Market

Names: _____

Evaluation Criteria	A	B	C	D	E
Quality of research in the student document /15	<i>All questions in the student document are adequately answered.</i>	<i>The majority of the questions in the student document are adequately answered.</i>	<i>Most of the questions in the student document are adequately answered</i>	<i>Few of the questions in the student document are adequately answered</i>	<i>None of the questions in the student document are adequately answered</i>
Quality of information in the oral presentation /15	<i>All required elements are presented clearly and in detail (role of the drug, mode of action, types of experiments)</i>	<i>Required elements are addressed in adequate detail (role of the drug, mode of action, types of experiments)</i>	<i>The majority of the required elements are addressed in some detail (role of the drug, mode of action, types of experiments)</i>	<i>The majority of the required elements are addressed in little detail (role of the drug, mode of action, types of experiments)</i>	<i>Few to none of the required elements are addressed in any detail (role of the drug, mode of action, types of experiments)</i>
Quality of information presented visually /20	<i>Visual elements support all aspects of the oral presentation with precision and detail</i>	<i>The majority of the presentation is supported with precise and detailed visuals</i>	<i>The majority of the presentation is supported by visuals with some precision and detail</i>	<i>Most of the presentation is supported, with little precision or detail in the visuals</i>	<i>Little to no precision or detail is apparent in the visual elements</i>
Overall presentation appearance and originality /10	<i>Presentation style is very relevant, original, and aesthetic</i>	<i>Presentation style is quite relevant, original, and aesthetic</i>	<i>Presentation style is relevant, original, and aesthetic</i>	<i>Presentation style shows little relevance, originality, or aesthetics</i>	<i>Presentation style shows no relevance, originality, or aesthetics</i>

Total : /60