

**FORM 51-102F3**  
**Material Change Report**

**1. Name and Address of Company:**

Pediapharm Inc. (the “Issuer”)  
225 - 1 Place du Commerce  
Verdun, QC H3E 1A2

**2. Date of Material Change(s):**

October 31, 2017

**3. News Release:**

A news release was disseminated November 1, 2017 through the facilities of Marketwire.

**4. Summary of Material Change(s):**

The Issuer announces Health Canada’s notice of compliance (approval) for Cuvposa™ (Glycopyrrolate oral solution 1 mg/ 5 mL) which is indicated to reduce chronic severe drooling in patients aged 3-18 years with neurologic conditions associated with problem drooling (e.g. cerebral palsy (CP)).

**5. Full Description of Material Change**

**5.1 Full Description of Material Change:**

Pediapharm Inc. (the “Company”) is very pleased to announce Health Canada’s notice of compliance (approval) for Cuvposa™ (Glycopyrrolate oral solution 1 mg/ 5 mL) which is indicated to reduce chronic severe drooling in patients aged 3-18 years with neurologic conditions associated with problem drooling (e.g. cerebral palsy (CP)).

Chronic drooling, or excessive production of saliva (sialorrhea), is a common condition found in children with CP but it may also be diagnosed in patients with other neurological disorders (i.e. severe developmental delay, autism spectrum disorders, sensory impairments, traumatic brain injuries as well as neurogenetic and metabolic disorders.)

It is estimated that the cerebral palsy prevalence ranges from 110-150 out of 100 000 person in the population<sup>1</sup> while prevalence of chronic drooling in children with CP vary from 37.4% to 58%<sup>2</sup>. It has been estimated that 25% to 35% of children with cerebral palsy drool to varying degrees, and 10% of these children have chronic severe drooling<sup>3</sup>. The Company estimates that the total market potential for Cuvposa is approximately 5,000 patients in Canada.

According to Dr. Pierre Marois, Pediatric Physiatrist at Montreal’s Ste-Justine Hospital “Often underestimated, sialorrhea implies clinical and social consequences, and has several impacts related to the overall health of children with CP, regarding dysphagia and respiratory health, their socio-emotional development, and emotional and work overload for families and caregivers”. Furthermore, Dr. Marois added that “due to the limited treatment options available, sialorrhea is an all-too-often poorly managed condition in pediatric patients suffering from neurologic disorders such as cerebral palsy. Cuvposa is an important advancement in the treatment of chronic severe drooling in children with neurologic disorders.”

“The approval of Cuvposa in Canada is another example of how we are guided by our mission to improve the health and well-being of Canadian children” stated Richard Labelle, Pediapharm’s Vice-President of Sales and Marketing. “Cuvposa represents a unique opportunity to introduce innovation for children with CP, many of whom are facing the burden of chronic severe drooling on a daily basis.”

“Cuvposa, our third product approved by Health Canada in the last 15 months, has an estimated annual peak sale of \$4-5 million and will be a significant contributor in our goal to achieve \$30-35 million of annual revenue within the next 5-7 years” stated Sylvain Chretien, President and CEO of Pediapharm. “We strongly believe in the value we have created with our strong product pipeline and our goal is to continue to add strategic products to our portfolio.”

Pediapharm’s partner, Merz, acquired the product in 2012. Although Cuvposa had already been made available in the United States, Merz successfully increased awareness of the possibility of treating chronic drooling to the benefit of the underserved patient population.

“At Merz, we continue to look for ways to bring our products to patients who need them,” said Bob Bennett, President and General Manager of Merz Pharma Canada. “Our partnership with Pediapharm, Canada’s leading pediatric pharmaceutical company, signifies our commitment and we are thrilled that they will be commercializing Cuvposa for appropriate patients in Canada.”

#### **About Cuvposa™**

Cuvposa (glycopyrrolate) is indicated to reduce chronic severe drooling in patients aged 3 –18 years with neurologic conditions associated with problem drooling (e.g., cerebral palsy).

Cuvposa is available as a 1 mg/ 5 ml cherry flavored oral solution.

Glycopyrrolate is a competitive inhibitor of acetylcholine muscarinic receptors that are located on certain peripheral tissues, including salivary glands. Glycopyrrolate indirectly reduces the rate of salivation by preventing the stimulation of these receptors.

Results of a randomized, double-blind, placebo-controlled Phase 3 study of 38 patients showed that 75% of children and adolescents treated with Cuvposa experienced an improvement in symptoms of chronic severe drooling at week 8, versus 11% who received placebo. Dry mouth, vomiting, constipation, flushing and nasal congestion were the most commonly reported adverse reactions.

#### **About Merz Pharma.**

Merz North America is a specialty healthcare company dedicated to the development and marketing of innovative quality products for physicians and patients across the United States and Canada. Merz products are distributed through two divisions, Aesthetics and Neurosciences, and are developed with the goal of improving patients’ health and quality of life by delivering therapies that bring about real progress. Merz North America is a privately-held company based in Raleigh, North Carolina. To learn more about Merz North America, please visit [www.merzusa.com](http://www.merzusa.com). For more information about Merz Pharma Canada, Ltd. or their products, please visit [www.merzcanada.com](http://www.merzcanada.com).

#### **REFERENCES**

1. Mapping Connections: An understanding of neurological conditions in Canada <http://www.phac-aspc.gc.ca/publicat/cd-mc/mc-ec/section-3-eng.php>
2. Walshe M. & al., Interventions for drooling in children with cerebral palsy (review), The Cochrane Library 2012, Issue 11
3. Drooling in children, Paediatric Child Health Vol 4 No 6 September 1999

**5.2 Disclosure for Restructuring Transaction:**

Not Applicable

**6. Reliance on Subsection 7.1(2) or (3) of National Instrument 51-102 *Continuous Disclosure Obligations*:**

Not Applicable

**7. Omitted Information:**

Not Applicable

**8. Executive Officer Knowledgeable of Material Change:**

Roland Boivin  
Chief Financial Officer  
Telephone: (514) 762-2626 ext. 202

**9. Date of Report:**

November 2, 2017