

Survey: Impact of COVID-19 Pandemic on Rare Disease Patients in Canada

Question		gsk
1.	At this time, to the best of your knowledge, what is the most likely impact of COVID-19 on (adequate) supply of your company's drugs to Canadian patients? If the answer varies by drug, please provide either specific drug information or respond in general across all drugs.	GSK is seeing a significant increase in demand for several medicines. GSK is addressing the increase in demand through the application of an allocation policy. This approach allows for fair and equitable distribution of GSK medicines and vaccines to all our customers. This is an evolving situation which we will keep under review.
2.	If interruption or shortage in drug supply were anticipated or took place, where could Canadian patients find information about the situation and any plans for addressing or mitigating the impact? Is there a website, information line, or contact person?	GSK is addressing the increase in demand through the application of an allocation policy. This approach allows for fair and equitable distribution of GSK medicines and vaccines to all our customers. This is an evolving situation which we will keep under review. All manufacturers are obligated to post drug shortages on www.drugshortagescanada.ca
3.	This question addresses any clinical trials that your company has at this time that includes Canadian sites or Canadian patients in other countries. At this time, to the best of your knowledge, have you experienced or do you anticipate any interruptions, delays, or modifications in the conduct of these trials due to COVID-19? Please describe any modifications or other adjustments.	GlaxoSmithKline (GSK) is continually evaluating and responding to the rapidly evolving situation in relation to COVID-19 and the impact this is having on the planning and conduct of clinical trials. Our priority is the safety and well-being of those who support and participate in our trials. As such, we are implementing proactive measures to protect the safety of study participants, staff at our clinical trial sites and our employees while ensuring regulatory compliance and the scientific integrity of our clinical trials.
4.	To the best of your knowledge, are there any clinical trials that will not take place or will be delayed as a result of COVID-19? Please describe.	At this time, GSK remains supportive of enrolling new patients into ongoing clinical studies, provided that the investigator sites are confident they will be able to conduct the protocol specified safety and efficacy monitoring required for the study. However, we are recommending that investigators ensure the appropriate monitoring and follow-up of currently enrolled subjects before considering recruitment of new patients. There may be exceptional cases that require GSK to pause individual trial enrollment. Such decisions will be taken on a case by case basis considering the therapeutic area and the patient population involved in the clinical study

5.	Where can patients find information about any increased risk of getting COVID-19 or increased impact of COVID-19 due to any medications provided by your company?	 COVID-19 is an emerging and rapidly evolving situation and because consumer safety is our number one priority, we are closely monitoring statements from the public health authorities and medical experts. All medicines, including the GSK products, are strictly regulated to ensure its use complies with local healthcare authority requirements. Ensuring the quality, safety and reliable supply of our products remains our goal to meet the needs of consumers and customers. Each individual's treatment plan being different, GSK recommends that people speak directly with their doctor or healthcare provider if they have questions about the potential impact COVID-19 may have for them.
6.	To the best of your knowledge, are there any changes in patient support programs that are anticipated or planned, related to issues due to COVID-19? Please describe.	 GSK has automatically extended all bridging for up to three months for any patient that may have lost coverage, had coverage interruption or requires renewal. GSK has delayed its pediatric Nucala PSP launch which was due to launch on March 30 GSK has started offering HCP options for either home or remote training/ visits – if product is injectable or infuseable in a clinic setting and if the safety profile of the drug allows for home administration
7.	How can patients or patient organizations find updated information about your company's policies, plans, or actions related to COVID-19? How will you communicate with patients or patient groups?	GSK Canada has a COVID-19 section on its website at https://ca.gsk.com/en-ca/media/press-releases/ Patient groups can contact Hélène Pineau who is Lead, Patient Affairs at GSK Canada Helene.X.Pineau@gsk.com
8.	Is there any other information that you wish to communicate share at this time?	