

detailed.

What would make the experts say, no, we're not approving this for Canadians?

Ultimately it comes down, and this seems very simple, but the benefits have to outweigh the risks.

You say, all right, so does it meet all the standards? Can it be manufactured at a high level of quality? If there are any risks associated with it, are there systems in place to be able to decrease those risks? Do they have a really good plan for monitoring the vaccine once it gets authorized?

When we look at that, then we have to decide, OK, does it meet the standards? And if yes, it's yes. And if it's no, then we say, no.

How do you know vaccines will be safe in the long term?

That's a good question. There are requirements in terms of following up for short- and medium-term side effects. For the Phase 3 clinical studies, it's a minimum of two months (that researchers will continue to follow volunteers).

But it's also important to remember that all of the studies continue to gather information, so as time goes on, we've got more and more data. By the time the vaccine goes through the review, goes through distribution and people start to receive it, all of that time we're receiving information.

So we have months of followup, sometimes longer, at the time of authorization. All the companies will be asked to continue to monitor their vaccines for another two years after that.

But it's true, we do need to still follow these vaccines long term, to see if there are any long-term risks that might come up. The clinical trials often involve tens of thousands of people, but these vaccines are going to go out and be given to millions of people.

So if there's something that's very, very rare, it might show up as we have more people vaccinated. So that's why it's really important that the monitoring continue, even after authorization.

What happens if some rare risk does emerge and something bad happens?