How do we know the COVID-19 vaccine is safe? Who reviews it? You s...

has already begun.

The pandemic has sparked many questions about how vaccines are made and evaluated. We took some of the questions we've received from readers, added a few of our own, and put them to one of the top experts at Health Canada.

Dr. Supriya Sharma trained as a pediatrician, but has also done research on blood diseases, worked for a year in Australia and completed a master's in public health at Harvard University in international health and health policy.

Almost 20 years ago, she signed up for a two-month stint at Health Canada — and never left. She's now the senior medical adviser for the team that oversees the approvals of pharmaceuticals, medical devices and, yes, vaccines.

Her answers to our questions have been lightly edited for clarity.

## How does a COVID-19 vaccine get approved to be used in Canada?

Usually with a vaccine, the company provides all the data from all of the studies that have been done, including the laboratory studies, the animal studies, all the clinical trials, to the test in humans, and all the information around the manufacturing.

Once that's completed, that is provided to Health Canada.

For COVID-19, we realized that you needed to have a more flexible process; something that's more agile. So we put in what was called an interim order. That interim order gives us some flexibility in how we do the review.

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So the COVID-19 vaccines that we currently have under review — we have three under review — are coming through this new pathway.

Now, it's important to note that it is what we call an expedited pathway, which is intended to make the overall review process faster, but it's still maintaining the same standards for the reviews of the vaccine. So, safety; efficacy, meaning how well the vaccine works; and quality in terms of manufacturing of the vaccine.

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