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## Regulatory flexibilities and access to COVID-19 vaccines during the pandemic in Bhutan

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## ABSTRACT

Summary Coronavirus disease 2019 (COVID-19) is rapidly evolving with millions of cases and death reported globally. The first-ever case of COVID-19 in Bhutan was confirmed on 5 March 2020 in a 76-year-old American tourist. The national regulatory authorities have implemented varying degrees of regulatory flexibilities to prevent unnecessary death by ensuring timely access to medical products and technologies during the pandemic. The Drug Regulatory Authority of Bhutan, as a national medicines regulatory agency responsible for ensuring the quality of medical products has implemented several regulatory mechanisms to ensure access to medical products including COVID-19 vaccines during the pandemic. In this commentary, we discuss the regulatory flexibilities that ensured access to medical products and COVID-19 vaccines during the pandemic.

## 1. Introduction

Coronavirus disease 2019 (COVID-19) is rapidly evolving and as of 8 May 2022, over 521 million confirmed cases and more than six million deaths have been reported globally.<sup>1</sup> The first-ever case of COVID-19 in Bhutan was confirmed on 5 March 2020 in a 76-year-old American tourist.<sup>2</sup> Since then, Bhutan reported 59,552 confirmed cases and 21 deaths so far.<sup>3</sup> COVID-19 pandemic has induced severe disruptions to the healthcare system<sup>4</sup> including the national medicines regulatory systems. The national regulatory authorities have implemented varying degrees of regulatory flexibilities to prevent unnecessary death by ensuring timely access to medical products and technologies during the pandemic.<sup>5</sup>

Since the beginning of the COVID-19 pandemic in Bhutan, His Majesty, the King commanded the government to do everything possible to keep every Bhutanese safe from COVID-19.<sup>6</sup> In response, the government has developed and implemented several COVID-19 support programs for people affected by the pandemic. The Drug Regulatory Authority of Bhutan (DRA) as a national responsible agency for ensuring the quality of medical products,<sup>7</sup> has implemented several regulatory mechanisms to provide access to medical products including the COVID-19 vaccines during the pandemic.

In Bhutan, basic healthcare services are provided free of cost by the State. However, Bhutan is largely dependent on imported medical products. The Medicines Act of the Kingdom of Bhutan defines vaccines and biological as medical products,<sup>8</sup> and all medical products imported and distributed for use in the country must be registered with the DRA.<sup>9</sup> This means every

single medical product needs to be technically reviewed and approved and this process usually takes a minimum of two months. However, providing access to and facilitating prompt delivery of medical products, especially COVID-19 vaccines during the pandemic is critical. In this commentary, we discuss the key regulatory mechanisms employed by the DRA to provide access to medical products with a focus on COVID-19 vaccines during the pandemic.

## 2. Regulatory flexibilities during the pandemic

Critical shortages of oxygen were reported in many countries including neighbouring India<sup>10</sup> and this disrupted oxygen supplies to Bhutan. Responding to the increased demand for oxygen supplies, the DRA expedited the licensing of new oxygen manufacturing facilities, and the key personnel working in these facilities were exempted from the competency assessment by the DRA. An interim guideline<sup>11</sup> adopted for the regulation of surgical face masks and surgical respirators allowed community pharmacies to import and sell surgical face masks and surgical respirators. Imported face masks were approved based on a documentary review.

Bhutan experienced four national COVID-19 lockdowns ranging from 21 to 42 days.<sup>12</sup> The DRA appointed service delivery focal persons who worked during the lockdowns to deliver essential regulatory services such as import authorizations, vaccine lot release, and product registration. A team of officials travelled across 17 districts to monitor adverse events following immunizations in 220 and 214 vaccination sites during the first and

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second vaccination campaigns, respectively. Community pharmacies were permitted to operate in respective zones during the lockdowns to facilitate home delivery of basic essential medicines in coordination with the Ministry of Health. The product samples required to be submitted for the registration of medical products were exempted to ease the regulatory burden.

### 3. Emergency use authorization for COVID-19 vaccines

An emergency use authorization (EUA) is a regulatory mechanism adopted by national regulatory authorities to approve the use of unapproved medical products (or unapproved uses of approved medical products) to manage declared public health emergencies for which there are no adequate, approved, and available alternatives.<sup>13</sup> In Bhutan, EUA for COVID-19 vaccines and COVID-19 antigen self-test kits were granted by the DRA. Acknowledging the unprecedented speed at which the COVID-19 vaccines were being developed and the complexity involved in performing a complete, independent assessment of the safety, efficacy and quality of such vaccines, a recognition and reliance mechanism was adopted to leverage the assessment conducted by stringent national regulatory authorities or Pharmaceutical Inspection Committee/Schemes member countries. The guideline for EUA was formulated to ensure rapid access to COVID-19 vaccines.

Approval processes for EUA were significantly expedited by reducing turnaround time from 60 days to 7 days by a dedicated team of regulatory officials who reviewed the applications for EUA vis-à-vis the national regulatory requirements. The first EUA for the COVID-19 vaccine was granted on 17 March 2021. Since then, EUA was granted for all six COVID-19 vaccines and 4 antigen self-test kits used in the country. Similarly, lot release certificates for COVID-19 vaccines were issued on the date of arrival of the consignment to complement the government's effort for the rapid delivery of COVID-19 vaccines.

### 4. Conclusion

The Medicines Act<sup>8</sup> does not provide an exemption for vaccine lot release during public health emergencies. This could potentially compromise the vaccine cold chain in resource-limited settings where vaccines are required to be quickly distributed to health centres owing to the scarcity of cold chain facilities. Therefore, future amendments of the legislation may include exemption of vaccines lot release during public health emergencies like the COVID-19 pandemic. Reliance mechanisms can be cost-effective for a resource-constrained country like Bhutan but excessive adoption of reliance and recognition mechanisms without adequate systems in place to oversee the products could create a potential regulatory loophole through which substandard medical products may enter the supply chain. There is a need for training of regulatory officials on good reliance practices to manage risk ensuing from reliance mechanisms.

Going forward in the post-pandemic era, regularizing EUA to routine marketing approvals needs to be carefully monitored and implemented. Continuing with regulatory processes adopted during the pandemic could disrupt the whole regulatory system, creating an avenue for substandard products to enter the market. There must be a clear timeline for how long the regulatory exemptions introduced during the pandemic will continue. The reactive regulatory approach adopted and implemented during the pandemic may have to continue or be replaced post-pandemic. Hence, proper evaluation and risk-benefit rationality must guide such decision makings.

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Both authors made equal contributions in writing this commentary.

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### Consent for publication

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### Declaration of Competing Interest

The authors declare that they have no competing interests.

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