Impact of COVID-19 on the global supply chain of antiretroviral drugs: a rapid survey of Indian manufacturers

Bharat Bhushan Rewari, Nabeel Mangadan-Konath, Mukta Sharma
Department of Communicable Diseases, World Health Organization Regional Office for South-East Asia, New Delhi, India
Correspondence to: Dr Bharat Bhushan Rewari (rewarib@who.int)

Abstract
Most people living with HIV in low- and middle-income countries are treated with generic antiretroviral (ARV) drugs produced by manufacturers in India – the “pharmacy of the developing world”. India’s nationwide lockdown in March 2020 in response to the coronavirus disease 2019 (COVID-19) pandemic therefore prompted concerns about disruption to this essential supply. A preliminary assessment of ARV drug manufacturers in India in March 2020 indicated a range of concerns. This prompted a rapid questionnaire-based survey in May 2020 of eight manufacturers that account for most of India’s ARV drug exports. The greatest challenges reported were in international shipping, including delays, increased lead times and rising costs. Contrary to expectations, lack of access to the active pharmaceutical ingredients (APIs) required for ARV drug manufacture was not a major hindrance, as manufacturers reported that their reliance on China for API supplies had reduced in recent years. However, their reliance on overseas markets for the raw materials required for local API synthesis was a major challenge. The findings from this survey have implications for addressing some of the immediate and medium-term concerns about the production and supply of generic ARV drugs. Long-term orders to support multi-month dispensing and buffer stocks need to be in place, together with computerized inventory management systems with real-time information from the lowest-level dispensation unit. Manufacturers and industry associations should have regular, formal interaction with the key ministries of the Government of India regarding these issues. Measures to improve the resilience of the generic ARV drug supply system are essential to minimize ongoing supply shocks resulting from the COVID-19 pandemic and to prepare for future emergencies.

Keywords: antiretroviral drugs, COVID-19, HIV, India, manufacturers, shortages, supply chain

Background
The beginning of 2020 marked the start of the “Decade of Action” to accelerate efforts towards achieving the 2030 Sustainable Development Goals (SDGs). These include the SDG 3.3 target of ending the AIDS epidemic and other diseases as a public health threat. The successes achieved so far in terms of reducing new HIV infections and AIDS-related mortality are attributable to both preventive measures and a significant scale-up of antiretroviral therapy (ART). By 2019, estimated ART coverage among people living with HIV in the World Health Organization (WHO) South-East Asia Region had reached 60%, although this was still far from the 90–90–90 target by 2020. Therefore, it is important to ensure continued and sustained scale-up of ART. This will help to achieve the target in two ways. First, the direct therapeutic benefit of ART to people who are receiving treatment reduces the number of AIDS-related deaths worldwide. Second, ART has the potential ancillary benefit of reducing new HIV infections, since ART reduces viral load in people receiving it, which significantly reduces the risk of transmission to someone else.

As with other low- and middle-income countries, most ART dispensation in countries of the region occurs through the public sector. Scale-up of ART in many countries has been possible owing to a seamless supply of low-cost and high-quality antiretroviral (ARV) drugs, especially from generic manufacturers based in India. This started as early as 2001, when an Indian generic manufacturer was able to supply a triple combination of ARV drugs for less than US$ 1 per person per day. The trend has continued since then, and India has been referred to as the “pharmacy of the developing world”; the majority of people with HIV in low- and middle-income countries are treated with generic ARV drugs produced by Indian manufacturers.

In response to the coronavirus disease 2019 (COVID-19) pandemic, many countries in the WHO South-East Asia Region began implementing lockdowns and other measures in March 2020. India’s lockdown began at midnight on 24 March 2020, initially for a period of 3 weeks, followed by multiple
extensions. This prompted concerns about the procurement and supply chain management of ARV drugs and the ability of India’s generic ARV drug manufacturers to meet regional and global demand. While the COVID-19 pandemic might be expected to have adverse effects on provision of health care in all settings, its immediate capacity to disrupt services for HIV, tuberculosis and malaria in low- and middle-income countries with high burdens of these diseases was a particular concern. Modelling studies estimate that a 6-month interruption of supply of ARVs across the whole population of people living with HIV on treatment in sub-Saharan Africa would be expected to lead to an approximately twofold increase in HIV-related deaths and a similar increase in mother-to-child transmission over 1 year.10 A separate study estimates that in low- and middle-income settings with a high HIV burden, COVID-19 disruption to services could increase mortality by 10%, largely as a result of interruption of ART.11

This policy and practice paper reports findings arising from the activities of the WHO Regional Office for South-East Asia to minimize disruption in the supply of ARV drugs from Indian manufacturers. A preliminary assessment of ARV drug supply in countries of the region was done in March 2020, the results of which prompted a rapid questionnaire-based survey in May 2020 of the eight manufacturers that account for most of India’s ARV drug exports.

Approach

Preliminary assessment: March 2020

From the start of the COVID-19 pandemic, the WHO Regional Office for South-East Asia was liaising regularly with the national AIDS programme (NAP) managers of countries of the region, through the WHO country offices. Early support included technical guidance, advisory notes and related communications emphasizing the importance of continuity in ART. At the same time, the regional office actively promoted sharing of experiences and good practices among the countries in areas such as innovative service delivery options including community-led models, as well as early policies and experiences regarding measures such as multi-month dispensing of medicines.

A preliminary assessment of WHO country offices and NAPs to gauge countries’ ARV drug stock levels in March 2020 found that, although there were no acute shortages, there were concerns about the supply of certain medicines in the medium to long term. These concerns in March were set against a background of potential official restrictions on medicines. For example, there were concerns regarding an export policy amendment made in early March by the Government of India restricting export of certain essential drugs,12 although the restrictions imposed through this amendment were lifted in April.13 Similarly, another directive from the Government of India asked manufacturers to maintain adequate stocks of fixed-dose combination lopinavir–ritonavir, since this was one of the formulations being considered for inclusion in clinical trials on COVID-19 management.14

Early efforts to minimize COVID-19-related disruptions for Member States’ health-care systems by the WHO Regional Office for South-East Asia included facilitating shipping arrangements for current ARV drug orders. We informally contacted manufacturers in India during the last week of March 2020 to ascertain their ability to fulfill orders that were already in the pipeline for ARV drugs to countries of the region and whether or not any delays in lead times were anticipated. Most manufacturers indicated that, at that time, they had adequate stock of the active pharmaceutical ingredients (APIs) required for ARV drug manufacture. They did, however, indicate other challenges. These included reduced workforce in plants and for loading trucks; lack of ground transport to reach warehouses and beyond; shortage of packaging materials; and reduced movement of cargo flights.

Suppliers had found no flights or other means to transport these drugs, which were already manufactured and in the warehouses. Because of the lockdown, there were no forwarding agents to get clearances at international borders. It took significant time and interaction at multiple levels in WHO and other agencies to get supplies to countries. In the case of one of the countries sharing a border with India, delivery was rerouted by road through specially arranged goods carriers. For another country, supplies were transported by sea instead of air, to prevent impending stock-out situations. The issue of transport was more of a practical consideration than a policy issue, since the Government of India had by late March issued clarifications allowing transport of medicines, since they were defined as essential goods.15 We therefore shared relevant orders from the government with those manufacturers that had indicated that they were experiencing challenges, to facilitate ground transport; showing central government orders to local transport companies and authorities helped to ease the transport challenges.

From this initial work in March 2020, and in view of the evolving COVID-19 situation in the region, it was clear that evidence to inform longer-term mitigation efforts was needed. We therefore contacted ARV drug manufacturers in India to invite them to take part in a survey in May 2020. The objective was to identify the main challenges and constraints in ARV drug production and supply chain management in order to formulate recommendations and identify solutions.

Rapid questionnaire-based survey: May 2020

Eight leading manufacturers of ARV drugs based in India, which account for most ARV drug exports from the country, were invited on 19 May 2020 to respond to a semi-structured open-ended set of questions by email. The eight themes covered by these questions were largely determined by (i) what manufacturers themselves shared in March 2020; (ii) the authors’ initial experiences in March 2020 of facilitating delivery of essential commodities delayed by the COVID-19 situation, and (iii) media reports and research reports that were available on this topic, including the 12 March 2020 assessment by the Global Fund.16,17,18 The questions were intended to be as objective as possible but were also meant to encourage sharing of perspectives, concerns and possible solutions. To facilitate candid responses, we did not include questions on business-sensitive information, such as absolute volumes of production. The questions were as follows:

1. Do you have enough APIs and other active ingredients to manufacture ARV drugs at your usual capacity?
2. Have your supplies of key starting materials and other raw materials [for API synthesis] from China or other countries been impacted?
3. Are you facing shortage of workforce in your manufacturing plants?
4. Are there any issues in moving drugs from the plant to warehouses?
5. What are the challenges in shipping drugs to other countries?
6. Due to the lockdown, what percentage of your orders could not be met on time?
7. How soon do you think you will be able to normalize the supplies?
8. Can you please share your inputs or suggestions to ensure continued access to ARV drugs in the context of the evolving COVID-19 situation?

Considering that the information was required as quickly as possible to help countries to avert stock-out situations, we did not have enough time to undertake a pilot test of the questionnaire. Furthermore, we restricted the survey to manufacturers in India, since they have a predominant role in export of ARV drugs in the region and beyond. We sent the questionnaire to all Indian drug manufacturers known to us from which countries of the region had been procuring ARV drugs and for which contact details were readily available. Individual emails were sent on 19 May 2020 to the eight manufacturers identified, with the eight questions listed above. Three manufacturers responded within 24 hours while four more responded after a reminder, a week later. All eight companies contacted eventually responded, giving a response rate of 100%. They were assured that their responses would be analysed and reported only in aggregate, thereby ensuring confidentiality.

Descriptive responses from the manufacturers to the above questions were tabulated using Microsoft Excel. They were reviewed and coded to identify subthemes emerging from each question. We then summarized the responses to each of the questions. The aggregate relative importance of each of the areas covered in questions 1–7 was assigned a score of 0 to 5, with 0 reflecting the highest vulnerability and 5 reflecting the highest resilience, and plotted in a radar chart. It should be noted that this was not intended to reflect the business models or operational efficiency of the ARV drug manufacturers; it was merely an attempt to provide a graphical representation of the situation, similar to a scorecard. A word cloud depicting the relative frequency of key words that appeared in the responses was also created to help unpack the main themes.

**Key findings**

Fig. 1 shows the vulnerability–resilience scores as a radar chart, indicating that difficulties with international shipping were the challenge most often cited by the ARV drug manufacturers; these difficulties included increased costs in addition to factors causing delays and increasing lead times. The next biggest challenge was access to supplies of the key starting materials (KSMs) and other raw materials that are required for API synthesis. Overreliance of India’s manufacturers on China for APIs has given rise to concerns in the past, but respondents indicated that this had reduced in recent years. The more important consideration now was reliance on China and other overseas markets for supplies of KSMs and other raw materials required for manufacturing APIs. Notably, when the responses from all respondents are visualized in a machine-generated word cloud, “API” appears prominently (Fig. 2). This underscores the need to undertake more nuanced analyses of the determinants of the resilience of India’s ARV drug manufacturers, to mitigate future shocks.
Both international shipping and access to raw materials require urgent attention from policy-makers. Manufacturers and industry associations should have regular, formal interactions with the key ministries of the Government of India regarding these issues. Regular discussions with all stakeholders could identify ways of ensuring better preparedness to deal with such situations in the future.

The responses to questions 1–8 are summarized below.

1. APIs and other active ingredients required to manufacture ARV drugs at usual capacity

APIs for the production of ARV drugs by Indian manufacturers are mainly sourced from India and China. Two out of the eight manufacturers that responded indicated that they had enough APIs and other ingredients to manufacture ARV drugs at normal capacity. However, one was a recent entrant into the ARV drug segment, and at the time it required APIs only to produce validation batches. Nevertheless, it expressed confidence that an API shortage was not anticipated and that emergency supplies could be started as early as August 2020.

Two other respondents stated that they usually maintained 3–4 months’ stock of APIs. However, because of COVID-19-related interruptions, an acute shortage was expected as early as June 2020, in the absence of specific measures to address the challenges. Such impending shortages were anticipated for only a few ARV products, for which in-house or in-country API production was not happening and the manufacturers were therefore dependent on supplies from other countries such as China. One manufacturer reported that a shortage of APIs and other active ingredients had already impacted its capacity by 20–30% of normal production capacity, while another manufacturer responded that the impact was only marginal. Two other manufacturers had full capacity to produce APIs themselves and hence did not find this aspect challenging. There were also indications that the costs of acquiring APIs were increasing, although these increases were marginal at the time of data collection. Respondents further added that it was hard to predict when API stock levels would return to normal.
2. KSMs and other raw materials for API synthesis
A significant proportion of KSMs used by Indian pharmaceutical companies are sourced from China, with a much smaller share coming from Indian and European sources. In line with the findings of the preliminary assessment, all eight respondents stated that they faced significant challenges in acquiring the KSMs and other raw materials required for manufacturing ARVs, especially those that would usually source from China. Two of them reported that they had been affected by this issue “hugely” and “heavily”. A couple of respondents explained that they had reduced their reliance on companies in China, or other foreign countries, for APIs but still depended on foreign sources for KSMs. Therefore, problems faced in obtaining KSMs and other raw materials from abroad had a significant impact on ARV drug production by manufacturers in India, according to respondents.

Business links for importing such raw materials were being re-established where they had been temporarily disrupted. However, challenges remained with regard to logistics and shipping, with issues such as delayed shipping, vessels being diverted to other ports and delayed customs clearance. With a reduced number of flights, sea routes were being attempted in some cases as an alternative option, but reduced staff at ports posed additional challenges. Moreover, manufacturers were trying to ensure multiple sources for these raw materials, to minimize the impact if one of them faced challenges. Two respondents mentioned an increase in freight costs as a further challenge faced in this regard, with one of them reporting a fourfold increase in logistics costs compared with the pre-COVID-19 period.

These challenges were particularly acute in the first quarter of 2020, and there were indications that supplies of KSMs and other raw materials had improved at the time of the survey in May 2020. Nevertheless, none of the respondents reported a full restoration to normalcy. One of the respondents even stated that it might not get back to normal before the end of the year, indicating a protracted impact.

3. Shortage of workforce in manufacturing plants
The impact on this front was not reported as severe by any of the respondents, with one of the manufacturers reporting no challenges faced at all. A reason cited for the reduced impact on this front was the government’s policy of exempting pharmaceutical manufacturing units from the lockdown. Yet respondents referred to governmental guidance on physical distancing in the workplace and some other challenges unique to local contexts that had prevented them from operating at 100% capacity.

Measures adopted by ARV drug manufacturers included reorganizing work shifts to meet physical distancing requirements; arranging special passes to enable free movement to and from units; facilitating pick-up and drop-off services for employees; and providing temporary accommodation for employees near manufacturing units. Accordingly, they were able to operate with a workforce of 50–80% of normal. Respondents stated that, as in the other domains, the challenges were greater during the first 4 weeks of lockdown in March to April 2020. The difficulties had eased significantly by the time of data collection in May.

4. Transport of drugs to warehouses and beyond
Six out of eight respondents indicated no challenges in transporting goods from manufacturing units to warehouses. In some instances, this was partly because warehouses were not far from manufacturing units. Others ensured that their transport mechanisms used governmental exemptions for pharmaceutical manufacturing as an essential service during the COVID-19 lockdown. Onward transport from warehouses to ports was, however, affected, especially where interstate transport was involved in reaching ports for shipment.

One respondent that indicated that it had experienced early challenges relating to transport of goods to warehouses added that transport by lorry was returning to normal by the first half of May 2020. At the same time, another respondent, which had not faced any challenges so far, was not sure that this would continue. The respondent sounded a note of caution – “however, the situation is ever evolving” – indicating a lingering concern. Nevertheless, this question elicited the fewest indications of concern or challenges from the manufacturers.

5. International shipping disruption
All eight respondents reported disruption in international air traffic as a challenge that had impacted their operations. Sea shipping had been similarly affected, as had local transport by road to ports, and issues had been faced at ports. All this had led to increased lead times for most ARV products. In terms of air freight charges, respondents estimated a fourfold to tenfold increase in certain instances. Sea freight charges were also reported to be higher, to the tune of 1.3 to 1.5 times, than pre-COVID-19. Reduced flights were a challenge noted by all respondents. This was despite the fact that there had been no ban preventing movement of international cargo, and certainly not for essential goods. However, an overall reduction in flights meant less chance of gaining acceptance for a cargo booking request.

In the case of many destination countries to which shipping requires waivers and pre-clearance permissions, there were additional delays. Waivers and clearances were being received late because officials and systems in the destination countries were being directly or indirectly impacted by COVID-19. Additional challenges in this domain were reported in certain special instances. Respondents highlighted that, if the overall volume of a shipment was small, some cargo companies resisted the booking, which could be a major challenge for essential ARV drugs required in certain special cases, including for paediatric patients. Similarly, for destinations requiring multiple connecting flights, respondents indicated difficulties in securing confirmed end-to-end flight schedules. Six of the respondents also noted increased supply chain costs – local freight charges, air and sea fares, and demurrages due to delay – as another major challenge in addition to the overall delays in shipping.

6. Overall supply shock due to COVID-19
Two respondents estimated that 20–30% of their total orders could not be delivered on time because of the COVID-19 pandemic. A third manufacturer, without quantifying the effect in terms of percentage of total orders, shared that the delivery dates of “a few” of its orders had been shifted by 40–50 days. Delays were particularly likely in the case of orders with specific packaging requirements and/or products that were produced not regularly or routinely but on a made-to-order basis. Two of the respondents said that none of their promised delivery dates had been impacted. One of them attributed its
ability to meet delivery deadlines for ARV drugs to central and state governments' treatment of the pharmaceutical sector as an essential service.

Two other respondents reported overall challenges in this regard but did not assign any quantitative values to either percentage of overall orders affected or average number of days’ delay. One respondent indicated that the situation was fluctuating and dynamic, also mentioning that the rapid mitigation measures that were in place had helped to minimize any supply shock due to COVID-19. Two respondents elaborated on some of the measures that they had adopted in this regard, such as regular interaction with customers in order to prioritize orders; arranging alternative shipping arrangements whereby customers were able to get their orders picked up directly from warehouses; regular and close monitoring of the situation, including inventory management; and full utilization of governmental provisions with regard to the pharmaceutical sector as an essential service.

7. Forecast for a return to normalcy

The earliest forecast for normalcy to be restored was August 2020, as expressed by two respondents. Another respondent referred to its current backlog, quantified as 2 months, which it stated would need to be taken into account in considering when it would be able to restore normalcy. While maintaining an overall positive outlook, most respondents alluded to prolonged uncertainty.

One of the respondents attributed such prolonged uncertainty to the nature of the pandemic itself. The respondent observed that the COVID-19 pandemic could last much longer and did not foresee restoration of full production capacity until at least the end of the year. Nevertheless, most of the respondents were confident based on their experiences so far. They expressed hope that the improvements in the situation on the ground would be further enhanced in the coming weeks and months, including through proactive and innovative measures to overcome the specific challenges they were encountering. However, they indicated that much depended on external factors, hinting at a need for measures at policy level to improve the external operational environment.

8. Recommendations and suggestions from the ARV drug manufacturers

Overall, respondents highlighted that they accorded high priority to supplying ARV drugs. They were resolved to adopt all possible measures to meet their commitments and ensure life-saving treatment for all people living with HIV globally. Their recommendations, listed below, are relevant to both the current COVID-19 pandemic and potential future emergencies. Some suggestions target manufacturers, while others are aimed at customers and policy-makers.

- Immediately increase stock levels of essential medicines in countries where potential disruption is expected. At the same time, discourage unreasonable stockpiling of medicines beyond a few months.
- Ensure longer-term contracts with lead times of more than 12 weeks. Issuance of orders in advance for 6–12 months could provide certainty to manufacturers and encourage them to stock up on the required raw materials and packaging materials.

Discussion

This analysis of the responses from the Indian ARV drug manufacturers has provided important insights into the challenges they face in ensuring uninterrupted and seamless supply to different countries of the region and beyond. Of the eight questions, five covered direct determinants of production and supply; two sought perception-based estimates of the current shock due to COVID-19 and prospects of re-establishing normalcy; and, finally, one was on manufacturers’ suggestions about how to mitigate current challenges and recommendations to minimize future shocks.

Since the start of the pandemic, the Global Fund has produced a regularly updated assessment of the impact of COVID-19 on health product supply chains. As of the 6 July 2020 update, reduced production of all pharmaceuticals in India was expected to continue throughout the lockdown period. As a result, delays of 1–2 months were expected over the next few months. With respect to freight and logistics, various contingencies have been noted, including rerouting of shipments; changing air freight to ocean freight or changing transit countries to utilize cargo-only aircraft; changing mode of
transport for final delivery; shipping to neighbouring countries; and exploring road transport and air charter options. The Global Fund notes that, in all these cases, cost impacts are highly likely. In May, the assessment concluded that 10% of orders faced delays of more than 30 days, including 15% of orders in transit; in July, these estimated delays had increased to 15% and 24%, respectively.16

The findings from this situation assessment have implications in terms of addressing some of the immediate concerns facing production and supply of ARV drugs in the region and globally. Some of these concerns directly affect supply, such as international shipping disruption, which emerged as a prominent concern among the ARV drug manufacturers. However, measures may also be required in relation to some not-so-direct aspects. For example, the pharmaceutical sector had the privilege of being an essential service during the COVID-19-related lockdown, but, since the packaging material sector did not receive the same treatment, some manufacturers faced issues with timely supply.

The situation assessment described in this paper was undertaken following challenges faced in relation to supplies of life-saving ARV drugs used by NAPs in the region. Therefore, our choice of the respondents invited to participate in this assessment, as well as the questions and the domains covered by those questions, was determined by immediate practical considerations. Consequently, this assessment has limitations compared with more formal research studies undertaken in this area.

These findings were also shared with the Strategic Information Unit and the AIDS Medicines and Diagnostic Services (AMDS) Unit at WHO headquarters. The AMDS Unit regularly interacts with all manufacturers to assess their capacity in relation to global demand consequent to changes in production and supply of ARV drugs in the region and globally. Some of these concerns directly affect supply, such as international shipping disruption, which emerged as a prominent concern among the ARV drug manufacturers. However, measures may also be required in relation to some not-so-direct aspects. For example, the pharmaceutical sector had the privilege of being an essential service during the COVID-19-related lockdown, but, since the packaging material sector did not receive the same treatment, some manufacturers faced issues with timely supply.

The situation assessment described in this paper was undertaken following challenges faced in relation to supplies of life-saving ARV drugs used by NAPs in the region. Therefore, our choice of the respondents invited to participate in this assessment, as well as the questions and the domains covered by those questions, was determined by immediate practical considerations. Consequently, this assessment has limitations compared with more formal research studies undertaken in this area.

These findings were also shared with the Strategic Information Unit and the AIDS Medicines and Diagnostic Services (AMDS) Unit at WHO headquarters. The AMDS Unit regularly interacts with all manufacturers to assess their capacity in relation to global demand consequent to changes in guidelines on treatment and to notify them of future needs. The findings call for longer-term consideration of the issues raised, particularly since the COVID-19 situation is continuing to evolve in the region. Medium- to long-term measures to build resilience in the procurement and supply chain systems need to be in place.

Conclusion

The COVID-19 pandemic, especially the lockdowns and related developments, have impacted Indian ARV drug manufacturers to a significant extent. Mitigation efforts are continuing, and there was improvement in terms of the challenges faced as between March 2020 and May 2020. However, the situation is dynamic and requires policy-level and operational strategies to be developed for the medium to long term. This is important not only in the context of a potentially protracted COVID-19 episode in the region and globally but also to prevent future shocks.

This paper has set out a broad understanding of the key determinants of continued and seamless supply in the context of COVID-19. Based on inputs from eight leading ARV drug manufacturers in India, the paper summarizes some of the key challenges faced during lockdown in March to May 2020. Further, more in-depth analyses could be considered, leveraging the points made in this paper, some of which are hypothesis-generating ones. By producing this initial exploratory analysis, the authors hope to generate further deliberation and reflection among policy-makers and industry bodies.

Demand-side factors need to be considered too in mitigating the impact of COVID-19-related disruption to AIDS programmes. As soon as movement restrictions are relaxed, catch-up campaigns should be considered to improve coverage of testing, prevention and treatment interventions. Such catch-up campaigns must be informed by facility-level analysis of service coverage, incorporating considerations relating to equity and who may have been affected the most by COVID-19 disruptions. Proactive measures to improve service coverage, such as HIV testing and linking those who are positive to treatment, must be prioritized in the coming months.

Urgent measures need to be adopted to restore ARV drug manufacture and supply to normalcy and full capacity. Long-term orders to manufacturers, to ensure enough stocks for multi-month dispensation and buffer stocks, and computerized inventory management systems with real-time information from the lowest dispensation unit need to be in place. Furthermore, there must be adequate planning and reform measures to improve the resilience of supply chain systems. WHO has recently updated its guidance on maintaining essential HIV services during the COVID-19 pandemic. These longer-term measures are essential to minimize supply shocks in the event of disruption induced by a prolonged COVID-19 pandemic or future emergencies.

Acknowledgments: The authors express their sincere gratitude to the reviewers of this paper for their detailed comments and guidance. The insights provided by Dr Klara Tisocki, Regional Advisor for Essential Drugs and other Medicines, WHO Regional Office for South-East Asia, and the guidance of Dr Tjandra Yoga Aditama, Acting Director of the Communicable Diseases Department at the WHO Regional Office for South-East Asia, have been invaluable in shaping this work. The authors would also like to thank all the ARV drug manufacturers for their in-depth and timely sharing of the information that was required to undertake this assessment. Gratitude is also expressed to programme managers and staff of NAPs in the ministries of health of Member States, as well as to WHO country office focal points for their regular monitoring and timely reporting of ARV drug-related supply challenges faced in the context of COVID-19.

Source of support: None.

Conflict of interest: None declared. Furthermore, the authors declare that the responses received from the pharmaceutical companies for this assessment were provided purely on a voluntary basis and that the use of these responses in the analysis undertaken in this paper will not result in any endorsement of the pharmaceutical products produced by those companies or their preferential treatment.

Authorship: All authors contributed equally.

Rewari et al.: Impact of COVID-19 on supply of antiretroviral drugs from Indian manufacturers

References

12. Amendment in export policy on APIs and formulations made from these APIs. Notification in Gazette of India Extraordinary, Part II (Section 3). New Delhi: Directorate-General for Foreign Trade, Ministry of Commerce and Industry, Government of India; 3 March 2020.
13. Amendment in export policy on APIs and formulations made from these APIs. Notification in Gazette of India Extraordinary, Part II (Section 3). New Delhi: Directorate-General for Foreign Trade, Ministry of Commerce and Industry, Government of India; 6 April 2020.