

## Important Vocab for the Editorial

1. vaccine (noun) – a biological preparation that improves immunity to a particular disease.
2. vigilance (noun) – careful observation, surveillance.
3. pharmacovigilance (noun) – the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine related problem. All medicines and vaccines undergo rigorous testing for safety and efficacy through clinical trials before they are authorized for use. Courtesy: WHO
4. vital (adjective) – key, essential, important.
5. grapple with (verb) – tackle, confront, deal with, cope with.
6. Drug Controller General of India (DCGI) (noun) – Drugs Controller General of India (DCGI) is a department of the Central Drugs Standard Control Organization (CDSCO) of the Government of India responsible for approval of licences of specified categories of drugs such as vaccines, and etc. in India. Drugs Controller General of India, comes under the Ministry of Health & Family Welfare. DCGI also sets standards for the manufacturing, sales, import, and distribution of drugs in India.
7. candidate vaccine or vaccine candidate (noun) – a “potential” vaccine prepared in the research and development (R&D) centres and it can be used in human clinical trials.
8. Sputnik V (noun) – a COVID-19 vaccine candidate developed by the Gamaleya Research Institute of Epidemiology and Microbiology, Moscow and registered by the Russian Ministry of Health.
9. authorisation (noun) – approval, sanction, permission, consent, clearance.
10. vaccination (noun) – treatment with a vaccine to protect against a particular disease; immunization.
11. strategy (noun) – plan of action (in order to achieve a more expansive set of political, economic, health and security interests).
12. hinge on (verb) – depend on, be based, be dependent.
13. Oxford vaccine/Covishield (noun) – (ChAdOx1 nCoV-19) or (AZD1222) is a COVID-19 vaccine candidate developed by Oxford University and AstraZeneca, UK Ltd. (named Covishield in India). Serum Institute of India (SII), a biotechnology company has

partnered with global pharma giant AstraZeneca and Oxford University for this vaccine candidate 'Covidshield'.

14. Covaxin (noun) – India's first indigenous COVID-19 vaccine candidate (COVAXIN) developed by a Hyderabad-based company (Bharat Biotech) in collaboration with the ICMR (The Indian Council of Medical Research).
15. regulatory agency (noun) – an independent governmental body established by legislative act in order to set standards in a specific field of activity, or operations, in the private sector of the economy and then to enforce those standards.
16. human trial/clinical trial (noun) – a type of research that studies new tests and treatments and evaluates their effects on human health outcomes.
17. parallel (adjective) – equivalent, similar.
18. bridging trial (noun) – a supplemental study. (a bridging study on a medicine is an additional study executed in the new region to "build a bridge" with the foreign clinical data on safety, efficacy, and dose response).
19. trial (noun) – test, pilot study, experiment (phase 1, 2,3, and or human/clinical trial).
20. candidate vaccine BNT162b2 (noun) – mRNA-based vaccine candidate produced by Pfizer and BioNTech.
21. regulator (noun) – an association that supervises a particular business activity.
22. sticking point (noun) – obstacle, bone of contention; a problem or issue that makes you can't move beyond and it stops all progress and you are stuck.
23. untoward (adjective) – unexpected, unanticipated, inappropriate, inconvenient.
24. geography (noun) – (particularly in business) region.
25. necessitate (verb) – make necessary, require, call for.
26. in the first place (phrase) – at the beginning.
27. rush through (phrasal verb) – to deal with/act on something very quickly.
28. contribute to (verb) – make for, lead to, cause, give rise to, play a part in.
29. hesitancy (noun) – reluctance, unwillingness, disinclination.
30. vaccine hesitancy (noun) – a reluctance or refusal to be vaccinated or to have one's children vaccinated; reluctance or refusal to vaccinate despite the availability of vaccines.

31. **take one's cue from** (phrase) – follow the example of; follow the advice of.
32. **concede** (verb) – admit, acknowledge, accept, recognize.
33. **Atmanirbhar** (noun) – Hindi: “self-reliance” or “self-sufficiency”.
34. **vaccinate** (verb) – inoculate, administer, introduce (with a vaccine to provide immunity against a disease).
35. **translate into** (verb) – change, convert, alter.
36. **tie up** (phrasal verb) – to have a business deal/agreement/arrangement.
37. **bidder** (noun) – a person who makes an offer (formal one) for something.
38. **dose** (noun) – an amount/quantity of something.
39. **(large) fraction** (noun) – a (large) proportion/part/amount of something.
40. **pandemic** (noun) – the worldwide spread of a new disease; The illness spreads around the world and typically affects a large number of people across a wide area.
41. **ebb** (verb) – diminish, decrease, fade away, disappear.
42. **scale up** (phrasal verb) – increase, expand, augment; step up.
43. **uphill** (adjective) – arduous, difficult, hard/tough, taxing, demanding.
44. **paucity** (noun) – insufficiency, deficiency, shortage.
45. **ventilator** (noun) – a respirator, a device (used for a patient to breathe).
46. **black marketing** (noun) – the illegal trade of goods and services.
47. **proportion** (noun) – size/magnitude.
48. **inevitably** (adverb) – unavoidably, certainly, definitely.
49. **adverse** (adjective) – unfavourable, disadvantageous, bad.
50. **step up** (phrasal verb) – increase, intensify, strengthen, augment.
51. **ease up on** (phrasal verb) – do something in a less stringent way.
52. **facilitate** (verb) – make easy, make possible; assist, help/aid.

## Another beginning: On vaccine vigilance

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### Pharmacovigilance is vital as more vaccines become available and new side-effects seen

As India grapples with a vaccine shortage, the Drug Controller General of India has formally approved another vaccine candidate — Sputnik V —

under emergency use authorisation. Since January, India's vaccination strategy has hinged almost entirely on Covishield — the AstraZeneca vaccine — and to a very limited extent, Covaxin. Another significant move by the government is in allowing foreign-made vaccines approved by regulatory agencies in the U.S., the U.K., Europe, Japan or those that find mention in the World Health Organization's list of approved emergency use vaccines which can avoid conducting a local clinical trial but opt for a parallel bridging trial post-approval. Last year, Pfizer had approached Indian regulators for permission but a sticking point was over this question of the conduct of local trials. It is important to note that bridging trials are critical. A vaccine that is approved in a different country may have untoward effects in another population. Past learnings from the history of drug and vaccine effects across geographies were what necessitated such rules in the first place.

However, India is in a crisis. When it had the opportunity to conduct clinical trials in the right way, in the case of Covaxin and even Covishield, India rushed through its regulatory process. This contributed to the hesitancy surrounding these vaccines. It is still a mystery why India did not plan for enough stocks like the U.K. and the U.S. did. Now, it seems India is taking a cue from these countries by conceding that no country can be entirely 'atmanirbhar' in vaccinating its population. While there are several vaccine candidates at various stages of approval that India can choose from, it must not repeat the same mistake of assuming that choice translates into immediate availability. All of the Indian companies that have tied up with foreign vaccine companies are private players. That is, while they may promise vaccines in the millions, it will always be the case that priority will be accorded to the highest global bidders. India must compete to ensure that these doses are available to a large fraction of its adult population in quick time. The pandemic wave seems to have ebbed in the U.S., to some extent, because at least 30% of its adults have got one dose. For India, this job of scaling up was always going to be uphill. Scenes from last year — paucity of hospital beds, ventilators, black marketing of drugs — are now being replayed in worrying proportions. With more vaccines come inevitably more complications associated with adverse events and rare side-effects. This is where India's pharmacovigilance programme must step up. The easing up on conditions for facilitating more vaccines must be seen as a new beginning.