

Two months after the European Medicines Agency (EMA) ruling on the safety of the Astra-Zeneca Covid-19 (Vaxzevria®) vaccine, ASPHER provides an update.

25 May 2021

On 15 March 2021, the EMA ruled on the use of the COVID-19 Vaccine Astra-Zeneca, suspension injectable, since renamed Vaxzevria®, and its adverse effects. The EMA¹, like the World Health Organisation² and the Medicines and Healthcare Regulatory Authority (MRHA) in the United Kingdom³, considered that the thromboembolic events and coagulation disorders^a - now grouped under the term *Vaccine-induced immune thrombotic thrombocytopenia (VITT)*^b - identified through pharmacovigilance systems, did not call into question the overall benefit-risk balance of this vaccine for a country's population. The EMA, therefore, recommended an update of the Summary of Product Characteristics (SPC) and package insert for this drug. The 19 March, the Association of Schools of Public Health in the European Region (ASPHER) welcomed European Medicines Agency judgement on the safety of AstraZeneca Covid-19 vaccine.⁴

Thus, two months later, while the indication for the vaccine has not been changed - the therapeutic indication mentioned by the European SPC for Vaxzevria remains "*active immunisation to prevent COVID-19 caused by SARSCoV-2, in individuals 18 years of age and older*". However, precautions have been added in the updated SPC published on 28/04/2021⁵. The section 4.4 "*Special warnings and precautions for use*" includes additional information on the risk of *Thrombosis with thrombocytopenia syndrome and coagulation disorders*^c and on the *Risk of bleeding with intramuscular administration*. Similarly, the package leaflet includes new information on *Blood disorders* in the *Warnings and Precautions* section. Similar additions were made to the SPC and package insert in the UK version.⁶

There is continuing debate⁷ about the age groups for which the vaccine should or should not be used. In the UK, for example, vaccination continued for all adults over 30, but on 7 May, the Joint Committee on Vaccination and Immunisation (JCVI) recommended also avoiding its use between the ages of 30 and 40⁸. In France, it has been reserved since 19 March for adults over 55^{9,10}, in Germany for those over 60¹¹, while the Danish authorities decided not to use it at all for their vaccination campaign from

^a very rare cases of unusual blood clots associated with low platelet counts and sometimes bleeding, mainly in young people

^b corresponds to the thrombosis associated with thrombocytopenia (TTS) syndrome, also known as atypical thrombosis

^c "*Thrombosis with thrombocytopenia syndrome and coagulation disorders*" in the last version of the SPC on 20 May 2021, (see ref 5)

11 March^{12,d}. Thus, the variations in scientific and public health advice given by the various expert health authorities and the policy decisions by national governments has not made the risk-benefit situation clear enough to our citizens across Europe. This situation forms part of ASPHER's wider concerns about lack of transparency and agreements on evidence by public health policy makers, and the subsequent impacts on effective pandemic management and international equity of impact.

Such divergences have contributed to uncertainties and anxieties, and have fuelled reduced vaccine acceptability, and reinforced the hesitancy towards towards the AstraZeneca vaccine.¹³ Without calling into question the validity of SARS-CoV-2 vaccination programmes, including with Vaxzevria, the question of an individual level clinical evaluation of the use of this vaccine is now also asked^{14,e}, by considering one's personal health situation, and not only a collective one in relation to receiving the Astra-Zeneca vaccine (age, sex, presence of co-morbidities).

Risks felt by part of any population must be balanced by objective pharmacovigilance and epidemiological data. The situation has changed little over the last two months. Since the March alert, some further rare new cases of atypical thrombosis (TTS) have been reported, with a total of 142 cases in EEA on EudraVigilance database (the EU drug safety database)¹⁵ since the start of its administration in February, compared to the 52 million doses of Vaxzevria administered in Europe (EU, EEA)¹⁶. Available data indicate an attributable rate of post-Vaxzevria Thrombotic Thrombocytopenic Syndromes (TTS) in Europe of perhaps around 1 case per 100 000 injections^{17,18,19}. Moreover, as specified by CINES D.B. and all, *"This should be considered in the context of the incidence of cerebral venous sinus thrombosis in the general population (estimated at 0.22 to 1.57 cases per 100,000 per year)."*²⁰ The EMA, in its latest assessment report of 23 April 2021, confirms that while *"Vaxzevria has been associated with an increased risk of TTS which, if any of these adverse events were to occur, could be fatal^f, the frequency of these events has been characterised as very rare based on current reporting rates. No risk factors for TTS have been identified at this time."*^{21,22}

This issue of TTS type adverse reactions to the Astra-Zeneca vaccine also concerns the new COVID-19 Vaccine Janssen, suspension for injection authorised since 21 April by the EMA. As this vaccine is based on the comparable approach and technology as the Astra-Zeneca vaccine, it is not surprising to find some similar reports of adverse effects^{23,24}. This finding raises a question of whether there is a clear causal relationship established between these types of adenovirus vaccines and the thromboses identified. Good public health practice is to investigate and assess causality objectively and according to agreed criteria derived from the historical Bradford-Hill tenets²⁵.

^d Also Greece: 30 years, Sweden and Finland: 65 years.

^e HAS: "The undeniable usefulness of AstraZeneca's vaccine in the fight against the Covid-19 epidemic must be weighed against each individual situation, taking into account the benefits of being vaccinated and the risks of adverse effects, which are very rare but serious." (see ref. 14)

^f Very rare cases, but with a high mortality rate of about 40% among reported cases (see ref 19).

It should also be noted that evaluation of vaccines should continue systematically as they are rolled out widely^{26.g}. Thus, when it was first put on the market, Vaxzevria was not recommended by EMA for people over 55 years of age due to a lack of initial information on the older age groups^{27.h}. Since then, with the accumulation of data in the last few months, in particular due to its wide use in the United Kingdom and on the basis of a clinical study conducted in Scotland, it has proved to be effective, with fewer safety concerns, for elderly people, in particular over 65 years of age. This is now adopted by health agencies and institutions in their vaccination guidelines^{28,29,30}, while possibly recommending certain precautions.^{31,32}

Nevertheless, faced with such uncertainties, countries such as Denmark and Norway³³ have decided to stop using this vaccine. They consider that the benefit/risk balance of the vaccine may be questioned. Thus, the Norwegian Institute of Public Health's explains that *"since few people die from COVID-19 in Norway, the risk of dying after being vaccinated with AstraZeneca's vaccine would be higher than the risk of dying from the disease, especially for younger people."*ⁱ

Ultimately, a public health strategy for choosing and prioritising vaccines must take into account many factors: therapeutic efficacy on the virus and its variants, the types of adverse effects and their incidence rate, the number of people to be vaccinated, the priority target populations, the evolution of evidence as vaccination campaigns progress, the storage and availability of vaccines at the various vaccination facilities, the methods of transport and logistics constraints, their nominal costs and their cost price, the availability and layout of healthcare structures, the resources in health professionals, and the level of control of the epidemic itself. The policy examples of Denmark and Norway of no longer using adenovirus based vector vaccines should not be generalised to all countries and circumstances, given many European populations have been more severely affected by the pandemic.

Moreover, to all these technical criteria or conditions must be added elements related to the population's perception and acceptability of the proposed products, and the degree of health literacy of the population. The strategy for using vaccines must be adapted to local conditions and circumstances³⁴. ASPHER, however, reinforces its strategic position that wide population coverage is fundamental to achieving goals of vaccine-derived herd immunity. Furthermore ASPHER advocates high and equitable vaccine uptake within each country as a step towards achieving country-level elimination of transmission of

^g EMA, *Vaxzevria SCP, Authorisation details/ Conditional approval: "This medicine received a conditional marketing authorisation. This was granted in the interest of public health because the medicine addresses an unmet medical need and the benefit of immediate availability outweighs the risk from less comprehensive data than normally required"* (see ref. 24)

^h EPAR (European public assessment report), *"Most of the participants in these studies were between 18 and 55 years old. There were not enough results in older participants (over 55 years old) to provide a figure for how well the vaccine will work in this group. However, protection is expected, given that an immune response is seen in this age group and based on experience with other vaccines; as there is reliable information on safety in this population, EMA's scientific experts considered that the vaccine can be used in older adults. More information is expected from ongoing studies, which include a higher proportion of elderly participants."*

ⁱ *Ibid. Geir Bukholm. Director of Infection Prevention and Control. Division for Infection Control and Environmental Health (NIPH): "Since there are few people who die from COVID-19 in Norway, the risk of dying after vaccination with the AstraZeneca vaccine would be higher than the risk of dying from the disease, particularly for younger people." In NIPH recommendation (see ref 32)*

SARS-CoV-2 virus variants. Europe-wide collaboration on developing and sharing of good public health practice has not been evident.

ASPHER supports global public health governance and in particular that each European country should have an independent advisory committee for immunisation policies. These recommended National Immunization Technical Advisory Groups (NITAG to S) should have public health and vaccine expertise along with other sciences and disciplines and lay representation to formulate proposals to governments according to acceptable public health standards.

ASPHER remains concerned about the erosion of public health capacity and professional influence on policies in some European Countries and will seek to assess the effectiveness of country level public health advisory machinery and processes.

ASPHER advises of the risk of damage to the image of the health authorities if, conversely, the choice of a country's age groups for the use of Astra-Zeneca's vaccine were made largely on the basis of economic criteria and the desire to sell off or acquire vaccine stocks, and not solely on sound public health criteria. In this regard, ASPHER recognises that science and communication are pivotal in public health and calls for effective health communication strategies between the government, the media, scientists, health authorities, and the public³⁵. Communication strategies shall highlight the rationale behind decision making and shall be adapted to the constantly changing notions that emerge during health emergencies³⁶. Such an approach would potentially affect hesitancy levels and ultimately vaccine acceptance³⁷. ASPHER, as Europe's representative organisation for Schools of Public Health, identifies the need to effectively train public health professionals in strategies of health communication³⁸.

The role of adenovirus-based vector vaccines could be reconsidered in the light of these elements, compared to the more expensive alternatives available, including current mRNA vaccines (BioNtech/Pfizer and Moderna). Adenovirus vaccines have so far provided logistical convenience, organisational flexibility and an attractive price.^j The mRNA vaccines offer better efficacy also on variants, but require heavy logistics, specific organisation and a cost approximately 5 times higher^k.

ASPHER advocates that an international position on strategies for the possible use of adenovirus-based vector vaccines be considered and published under the auspices of the WHO, and regularly reviewed in the light of advances in knowledge about the uptake, effectiveness and safety of these vaccines, while considering SARS-Cov2 virus epidemiology on transmission and emergence of variants.

ASPHER recommends, in line with the WHO Director-General's call to *"sharing vaccine doses, to protect the most at-risk, not just the most-rich"*³⁹, in particular in the framework of the COVAX initiative, while providing a similar level of information for all countries and ensuring the high quality

^j Adenovirus vaccines: storage conditions at +2 to +8 °C, vaccination in private practice possible, price between 3 and 4 € per dose

^k mRNA vaccines: storage conditions at -80°C, new storage possibility -25 and -15°C for 2 weeks, then thawing, vaccination in vaccinodrome or hospital, price around €15 per dose

of pharmacovigilance and post-marketing surveillance of effectiveness and safety. If it turns out that some countries have unused stocks of Astra-Zeneca and Jansen vaccines due to their local situation analysis, use of this supply should be given transparent and objective consideration by COVAX with international public health experts. Principles of weighing efficacy, safety, fairness and building country resilience should be included.

In the face of a potential adverse event, the breadth and depth of safety assessments conducted at multiple levels by a range of independent organisations increases confidence in the rigour with which potential risks or side effects are investigated and managed.

To this end, all stakeholders, including industry itself, regulatory bodies, the medical community, academia and research, and the general public have a role to play in monitoring the safety of the vaccines for COVID-19.

From an epidemiological and public health-based methodological point of view, the operational definition of the adverse event must be clear and the frequency of its occurrence must be examined. Here it has to be compared whether the number of observed cases overall and per age and sex group (or per study group according to their variables of interest) is higher than the expected number of cases (the frequency with which the health problem has been occurring, prior to the vaccination period or independently of the vaccination period).

In addition, systematic steps should be applied to assess the association between the vaccination process and the event. Establishing a causality argument is an important research activity with important scientific, clinical and social implications. Among these methodological tools Sir Austin Bradford Hill proposed criteria for establishing such an argument. These criteria include strength of association, consistency, specificity, temporal sequence, biological gradient, biological rationale, coherence, experimental evidence, and established analogy.

We call on all international public health agencies to adopt a rigorous approach to determining risk. We further call on them to be transparent in the communication of the standard of evidence and the standard of risk on which they are basing their decisions. We believe there needs to be an international consensus on decisions of risk of this importance and we call on international agencies led by WHO to make this happen.

For more information, please contact :

John Middleton john.middleton@aspher.org or Robert Otok robert.otok@aspher.org

Prepared on behalf of The ASPHER COVID-19 Taskforce Vaccination Group by
J.Philippe Naboulet, Laurent Chambaud, John Reid, Jose M Martin-Moreno, Giulia Sesa, John D Middleton*

* corresponding author

The ASPHER COVID-19 Taskforce Vaccination Group:

Brian Li Han Wong, Ines Siepmann, J Philippe Naboulet, Carlo Signorelli, Manfred S Green, Judit Simon, John Reid, Jose M Martin-Moreno, Nadav Davidovitch, Laurent Chambaud, Lore Leighton, Kasia Czabanowska, Giulia Sesa, Mohamud Sheek-Hussein, Ranjeet Dhonkal, Robert Otok, John D Middleton

References

- 1 EMA Statement, Available from: <https://www.ema.europa.eu/en/news/covid-19-vaccine-astrazeneca-benefits-still-outweigh-risks-despite-possible-link-rare-blood-clots>
- 2 WHO statement, Available from: [https://www.who.int/news/item/19-03-2021-statement-of-the-who-global-advisory-committee-on-vaccine-safety-\(gacvs\)-covid-19-subcommittee-on-safety-signals-related-to-the-astrazeneca-covid-19-vaccine](https://www.who.int/news/item/19-03-2021-statement-of-the-who-global-advisory-committee-on-vaccine-safety-(gacvs)-covid-19-subcommittee-on-safety-signals-related-to-the-astrazeneca-covid-19-vaccine)
- 3 UK MHRA statement, Available from: <https://www.gov.uk/government/news/uk-regulator-confirms-that-people-should-continue-to-receive-the-covid-19-vaccine-astrazeneca>
- 4 ASPHER, ASPHER welcomes European Medicines Agency ruling on safety of Astra-Zeneca Covid-19 vaccine, 19 March 2021, Available from: <https://www.aspher.org/covid-19-task-force.html>
- 5 Vaxzevria, suspension for injection, SPC (summary of product characteristics) and leaflet, updated 28/04/2021, Available from: https://www.ema.europa.eu/en/documents/product-information/vaxzevria-previously-covid-19-vaccine-astrazeneca-epar-product-information_en.pdf
- 6 COVID-19 Vaccine AstraZeneca solution for injection registered in the UK, SPC (summary of product characteristics) and leaflet, updated 15/04/2021, Available from: <https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca/information-for-healthcare-professionals-on-covid-19-vaccine-astrazeneca>
- 7 Pugh J, Savulescu J, *Not recommending AstraZeneca vaccine for the elderly risks the lives of the most vulnerable*, 05/02/2021, Available from: <https://theconversation.com/not-recommending-astrazeneca-vaccine-for-the-elderly-risks-the-lives-of-the-most-vulnerable-154605>
- 8 JCVI, JCVI advises on COVID-19 vaccine for people aged under 40, Press release 07/05/2021, Available from: <https://www.gov.uk/government/news/jcvi-advises-on-covid-19-vaccine-for-people-aged-under-40>
- 9 Ministère de la santé (France), *La stratégie vaccinale et la liste des publics prioritaires*, 01/12/2020, Available from: <https://solidarites-sante.gouv.fr/grands-dossiers/vaccin-covid-19/publics-prioritaires-vaccin-covid-19>
- 10 HAS, *Avis n° 2021.0018/AC/SEESP du 19 mars 2021 du collège de la Haute Autorité de santé sur la place du vaccin AstraZeneca dans la stratégie vaccinale suite à l'avis de l'agence européenne des médicaments concernant des événements indésirables survenus dans plusieurs pays européens chez des personnes vaccinées*, Available from: https://www.has-sante.fr/jcms/p_3244283/fr/avis-n-2021-0018/ac/seesp-du-19-mars-2021-du-college-de-la-haute-autorite-de-sante-sur-la-place-du-vaccin-astrazeneca-dans-la-strategie-vaccinale-suite-a-l-avis-de-l-agence-europeenne-des-medicaments-concernant-des-evenements-indesirables-survenus-dans-plusieurs-pays-europeens-chez-des-personnes-vaccinees
- 11 Robert Koch-Institut, *Beschluss der STIKO zur 4. Aktualisierung der COVID-19-Impfempfehlung und die dazugehörige wissenschaftliche Begründung*, 01/04/2021, Available from: https://www.rki.de/DE/Content/Kommissionen/STIKO/Empfehlungen/Vierte_Empfehlung_01042021_Download.pdf?__blob=publicationFile
- 12 DHA, *Denmark continues its vaccine rollout without the COVID-19 vaccine from AstraZeneca*, 18/04/2021, Available from: <https://www.sst.dk/en/English/news/2021/Denmark-continues-its-vaccine-rollout-without-the-COVID-19-vaccine-from-AstraZeneca>
- 13 Petersen MB, Jørgensen FJ, Bor A, Lindholt MF, *"Did the suspension of the AstraZeneca-vaccine decrease vaccine acceptance?"* March 18, 2021, PsyArXiv, Available from: doi <https://doi.org/10.31234/osf.io/uh4y6>
- 14 HAS, *Vaccines against Covid-19: the HAS maintains the age limit of 55 years for Vaxzevria®*, Press release, 12/05/2021, Available from: https://www.has-sante.fr/jcms/p_3266654/fr/vaccins-contre-la-covid-19-la-has-maintient-la-limite-d-age-de-55-ans-pour-vaxzevria

-
- 15 EMA, EMA/CHMP/214855/2021 Committee for Medicinal Products for Human Use (CHMP) Assessment report, 23/04/2021, Available from: https://www.ema.europa.eu/en/documents/referral/use-vaxzevria-prevent-covid-19-article-53-procedure-assessment-report_en.pdf
 - 16 ECDC, COVID-19 Vaccine Tracker, Available from: <https://qap.ecdc.europa.eu/public/extensions/COVID-19/vaccine-tracker.html#distribution-tab> (consulted on 22/05/2021)
 - 17 Paul Ehrlich Institute, COVID-19 Vaccine AstraZeneca – Safety Assessment Result: The Vaccine is Safe and Effective in the Fight against COVID-19, 08/04/2021, Available from: <https://www.pei.de/EN/newsroom/hp-news/2021/210319-covid-19-vaccine-astrazeneca-safety-assessment-result-vaccine-safe-and-effective.html>
 - 18 EMA, Vaxzevria, Available from: <https://www.ema.europa.eu/en/medicines/human/EPAR/vaxzevria-previously-covid-19-vaccine-astrazeneca#overview-section> (consulted on 20/05/2021)
 - 19 Cines BD, Bussel JB, SARS-CoV-2 Vaccine-Induced Immune Thrombotic Thrombocytopenia, N Engl J Med., April 16, 2021, DOI: 10.1056/NEJMe2106315, Available from: <https://www.nejm.org/doi/10.1056/NEJMe2106315>
 - 20 Op.Cit.
 - 21 EMA, EMA/CHMP/214855/2021, Committee for Medicinal Products for Human Use (CHMP) Assessment report, 23/04/2021, op. cit.
 - 22 EMA, EMA finds possible link to very rare cases of unusual blood clots with low blood platelets, 07/04/2021, Available from: <https://www.ema.europa.eu/en/news/astrazenecas-covid-19-vaccine-ema-finds-possible-link-very-rare-cases-unusual-blood-clots-low-blood>
 - 23 EMA, COVID-19 Vaccine Janssen: EMA finds possible link to very rare cases of unusual blood clots with low blood platelets, 20/04/2021, Available from: <https://www.ema.europa.eu/en/news/covid-19-vaccine-janssen-ema-finds-possible-link-very-rare-cases-unusual-blood-clots-low-blood>
 - 24 EMA, “Signal assessment report on Embolic and Thrombotic events (SMQ) with COVID-19 Vaccine Janssen (Ad26.COV2-S [recombinant])”, 06/05/2021, Available from: https://www.ema.europa.eu/en/documents/prac-recommendation/signal-assessment-report-embolic-thrombotic-events-smq-covid-19-vaccine-janssen-ad26cov2-s_en-0.pdf
 - 25 Fedak KM, Bernal A, Capshaw ZA, Gross S, Applying the Bradford Hill criteria in the 21st century: how data integration has changed causal inference in molecular epidemiology, Emerg Themes Epidemiol. 2015; 12: 14. Available from: doi: 10.1186/s12982-015-0037-4
 - 26 EMA, Vaxzevria (previously COVID-19 Vaccine AstraZeneca) COVID-19 Vaccine (ChAdOx1-S [recombinant]), Available from: <https://www.ema.europa.eu/en/medicines/human/EPAR/vaxzevria-previously-covid-19-vaccine-astrazeneca#product-information-section> (consulted on 20/05/2021)
 - 27 EMA, EPAR (European public assessment report), EMA/94907/202129 January 2021, Available from: https://www.ema.europa.eu/en/documents/assessment-report/vaxzevria-previously-covid-19-vaccine-astrazeneca-epar-public-assessment-report_en.pdf
 - 28 Public Health Agency of Sweden , Information on the use of the Astra Zeneca vaccine in the vaccination of people 65 and older, 13/05/2021, Available from: <https://www.folkhalsomyndigheten.se/the-public-health-agency-of-sweden/communicable-disease-control/covid-19/vaccination-against-covid-19/information-on-the-continued-use-of-the-astra-zeneca/>
 - 29 Health Council of the Netherlands, 09/04/2021, Doorgaan met AstraZeneca voor 60-plussers, andere vaccines voor 60-minners, Available from: <https://www.gezondheidsraad.nl/actueel/nieuws/2021/04/09/doorgaan-met-astrazeneca-voor-60-plussers>

-
- 30 AIFA, *Viral Vector COVID-19 Vaccines, Questions and answer*, Available from: <https://www.aifa.gov.it/en/domande-e-risposte-su-vaccini-vettore-virale> (consulted on 20/05/2021)
- 31 HAS, *Avis n° 2021.0008/AC/SEESP du 1er mars 2021 du collège de la Haute Autorité de santé sur l'efficacité du vaccin AstraZeneca chez les personnes âgées au vu des données préliminaires soumises au BMJ sur l'impact de la vaccination en Ecosse sur les hospitalisations*, 01/03/2021, Available from: https://www.mesvaccins.net/textes/20210301_AZ_HAS.pdf
- 32 HAS, *Avis n° 2021.0008/AC/SEESP du 1er mars 2021 du collège de la Haute Autorité de santé sur l'efficacité du vaccin AstraZeneca chez les personnes âgées au vu des données préliminaires soumises au BMJ sur l'impact de la vaccination en Ecosse sur les hospitalisations*, 02/03/2021, Available from: https://www.has-sante.fr/jcms/p_3240288/fr/avis-n-2021-0008/ac/seesp-du-1er-mars-2021-du-college-de-la-haute-autorite-de-sante-sur-l-efficacite-du-vaccin-astrazeneca-chez-les-personnes-agees-au-vu-des-donnees-preliminaires-soumises-au-bmj-sur-l-impact-de-la-vaccination-en-ecosse-sur-les-hospitalisations
- 33 NIPH, Norwegian Institute of Public Health's recommendation about AstraZeneca vaccine, 15/04/2021, Available from: <https://www.fhi.no/en/news/2021/astrazeneca-vaccine-removed-from-coronavirus-immunisation-programme-in-norw/>
- 34 NIPH, Norwegian-Danish study of rare side effects in connection with AstraZeneca vaccination published, 06/05/2021, Available from: <https://www.fhi.no/en/news/2021/norwegian-danish-study-of-rare-side-effects-in-connection-with-astrazeneca/>
- 35 Wang H, Cleary PD, Little J, Auffray C., *Communicating in a public health crisis.*, The Lancet Digital Health., 2020;2(10). Available from: [https://www.thelancet.com/journals/landig/article/PIIS2589-7500\(20\)30197-7/fulltext](https://www.thelancet.com/journals/landig/article/PIIS2589-7500(20)30197-7/fulltext)
- 36 Ibid.
- 37 European commission, *Expert Panel on effective ways of investing in Health (EXPH). Preliminary report on Vaccination Programmes and Health Systems in Europe. 2018*, 28/04/2021, Available from: <https://op.europa.eu/en/publication-detail/-/publication/Ofa5efff-b138-11eb-8307-01aa75ed71a1>
- ³⁸ Op. cit.
- 39 WHO, *Keynote address by the WHO Director-General at the COVID-19 press briefing*, 23/04/2021, Available from: <https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19-23-april-2021>

List all the ASPHER recommendations concerning vaccine above

Vaccines (<https://www.aspher.org/covid-19-task-force.html>)

ASPHER welcomes European Medicines Agency judgement on the safety of AstraZeneca Covid-19 vaccine. ([English](#)) ([French](#))

Vaccine Internationalism Statement: [Towards 'vaccine internationalism' an ASPHER statement on the need for an equitable and coordinated global vaccination approach to effectively combat COVID-19](#)

Vaccine Priority and Planning Statement: [ASPHER statement on the need for a coordinated, professional approach to policy and planning for COVID-19 vaccination roll-out](#)

ASPHER Statement on vaccination in Palestine: [The Right to COVID-19 Vaccination must be extended to Palestinians](#)

Vaccine nationalism will hinder our ability to effectively combat covid-19 (BMJ Opinion) January 2021: [We need an equitable and coordinated global approach to Covid-19 vaccination](#)

ASPHER COVID-19 Vaccine Statement (BMJ Opinion); November 2020: [Covid-19 vaccines- where are the data?](#)

ASPHER COVID-19 Vaccine Statement (BMJ Opinion); September 2020: [Vaccines for Covid-19: reasons for hope, but first for concern](#)
