Ninth Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction

1 November 2022

English only

Geneva, 28 November to 16 December 2022
Item 10(b) of the provisional agenda
Review of the operation of the Convention as provided for in its Article XII
Articles I-XV

Advances in Science and Technology: Impact on Response to the COVID-19 Pandemic and Relevance to Article VII of the Biological and Toxin Weapons Convention

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I. Summary

1. This working paper considers recent developments in science and technology relevant to Article VII of the BTWC, with particular examples emerging from the global response to the COVID-19 pandemic. Advances in surveillance, detection and diagnostics, and in vaccines and therapeutics have also been considered under the standing agenda item on science and technology in BTWC meetings; these may contribute to global efforts to respond to infectious disease outbreaks whether of natural, accidental or deliberate origin. Information sharing will be a key factor for future progress. The BTWC process for review of scientific and technological advances needs the flexibility to address emerging issues relevant to particular provisions; this should be addressed by the Ninth Review Conference in deciding the structure and role of the future programme.

II. Introduction

2. This working paper considers recent developments in science and technology (S&T) and related areas relevant to Article VII of the BTWC, using particular examples emerging from the global response to the COVID-19 pandemic. Advances in S&T have also been considered under the standing agenda item on science and technology in the BTWC Meetings of Experts, MX2; these S&T developments will contribute to global efforts to respond to infectious disease outbreaks whether of natural, accidental or deliberate origin. Information sharing on this topic will be a key factor for future progress in the operationalisation of Article VII. The BTWC process for review of scientific and technological advances also needs the flexibility to address emerging issues relevant to particular provisions of the Convention; this should be addressed by the Ninth Review Conference in deciding the structure and role of the future Intersessional Programme.

3. The spread of SARS-CoV-2 has resulted in an infectious disease outbreak on a scale not experienced in living memory, and it is not yet over. As we experienced with the Ebola Virus Disease outbreak of 2014, there are many lessons to be identified from biological events such as disease outbreaks. Lessons are still being identified and some may not yet be recognised. Looking back at key lessons that were identified following the Ebola outbreak of 2014, many are still relevant to the challenges we are facing with the current SARS-CoV-2

global health emergency, such as; the requirement to strengthen national capacities for response and preparedness; Ensuring the WHO has an appropriate and implementable mandate for responding to and investigating outbreaks; strengthening infectious disease surveillance, monitoring and early warning systems; improving information sharing; and investing in new research and development. There are several factors that the UK considers to be particularly important when responding to large-scale infectious disease outbreaks. Here, in no particular order, are some examples:

A. Disease Surveillance and Monitoring

4. The requirement for effective disease surveillance and monitoring has been of critical importance throughout the COVID-19 pandemic. The UK Health and Security Agency (UKHSA) carry out detailed variant surveillance analyses, which contribute to the variant risk assessments and designation of new variants of concern (VOC) and variants under investigation (VUI). Many factors of viral evolution are monitored to determine new variants and subsequently assess their impact on diagnostic and therapeutic targets and biological risk management measures. Data covering a wide range of biological properties are assessed including but not limited to; changes in transmissibility, severity or immune evasion, growth rate and transmissibility which could lead to a displacement of the current dominant variant. As of the 17 September 2022 0.6% variants were the Omicron variant BA.2 (VOC-22JAN-01), 2.1% Omicron BA.4 (VOC-22APR-03), 87.8% Omicron BA.5 (VOC-22APR-04), 4.5% Omicron BA.2.75 (V-22JUL-01), 4.5% Omicron BA.4.6 (V-22SEP-01) and 0.5% were classified as other[1].

5. The UK has also developed and used a digital contact tracing app for disease control. Its development and use during the pandemic meant that its epidemiological impacts could be investigated in a real life scenario. Using modelling and statistical comparisons of data from when the app launched on 24 September 2020 to the end of December 2020, it was estimated, using statistical comparison, that using the app averted around 594,000 positive COVID-19 cases. Analysis of infection rates in contacts identified by the app supported the theory that a contact tracing app can be a beneficial tool in controlling disease spread. App uptake is an important aspect to consider and has the potential to be hugely influential on effectiveness. It was estimated that 28% of the total population, 16.5 million out of an eligible 34.3 million people in England, used the app regularly. Furthermore, it was estimated that for every 1% increase in app users the reduction of cases was between 0.8% (from modelling) and 2.3% (from statistical comparison)[2].

6. For an app such as this to work effectively, the population is required to use and follow it appropriately. A study looking at the adherence to the test and trace app between March 2020 and January 2021 identified that only 51.5% of people were able to identify the key COVID-19 symptoms as outlined by the app, which ultimately limited its effectiveness. The study showed that although there was intent to follow the behaviours required by the test and trace app, such as self-isolating and sharing details of close contacts, actual adherence to them was low. A key lesson identified from the test and trace app is that there needs to be better understanding of why certain people cannot or do not follow guidance, and this could require financial reimbursement and or practical support to encourage adherence to the guidelines in any future use of such a technology[3]. Further study of the types of support offered to enable adherence to guidance as well as factors influencing observed differences in behaviour, such as age and gender could provide useful insights into future emergency responses.

7. Population monitoring, including increased or mass population testing and widespread genotyping could also be valuable tools in the response to a disease outbreak.

[1] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1109820/Technical-Briefing-46.pdf

[2] C. Wymant *et al*. The epidemiological impact of the NHS COVID-19 app. *Nature*, 2021, 594(7863), 408-412.

[3] L. E. Smith *et al*. Adherence to the test, trace, and isolate system in the UK: results from 37 nationally representative surveys. *BMJ*, 2021, 372608

Further development of robust infrastructure and cost-effective, high-throughput methods of sensitive yet specific testing with minimally invasive sampling will be required to successfully implement this approach on a large scale. The effectiveness any testing regime will still be dependent on strong adherence to self-isolation guidelines following receipt of a positive result.

8. Strengthening global surveillance of variants (as well as continued surveillance in the UK) will be important in understanding the risk from new waves of disease emerging. Current genomic surveillance strategies are highly variable between countries and in many cases, genomic data is not shared on public databases[4]. Strengthened and better-aligned surveillance would be mutually beneficial in detecting and understanding emerging variants and their spread.

B. Testing and Diagnostics

9. In response to the COVID-19 pandemic, the UK's COVID-19 testing capacity has vastly expanded through establishment of test facilities within the NHS, academia, universities, lighthouse testing facilities, the military and other private and non-profit community sectors[5]. Although mostly now shut down due to the cessation of free mass testing in the UK, the COVID-19 testing capability included the largest network of diagnostic testing facilities in British history. Part of this capability was the establishment of several Lighthouse laboratories which were high throughput facilities dedicated to COVID-19 testing for NHS Test and Trace. The Lighthouse laboratories were set up by experienced scientific executives and technical leaders with decades of experience. Each Lighthouse laboratory was reviewed by experts and supported by an external expert clinical virology advisor who provided technical critique and support to the laboratory team on behalf of NHS Test and Trace[6].

10. In June 2021, the UK's first testing mega lab – the Rosalind Franklin Laboratory in Royal Leamington Spa – began processing tests on behalf of NHS Test and Trace. As part of the UK's NHS Test and Trace network, the laboratory is the biggest of its kind in the UK and uses cutting-edge technology to process up to 300,000 tests per day. It has also adopted pioneering new genotype assay testing, to identify quickly variants of concern and new mutations. The Rosalind Franklin Laboratory is owned and operated by the Department of Health and Social Care (DHSC) and enabled the UK to scale up the use of rapid, asymptomatic testing during peak infection levels, as well as continued testing of individuals using laboratory-based methods. The aims of scaled up testing included diagnosing people with symptoms, testing close contacts of those who have tested positive, helping detect VOCs, understanding how the virus was spreading and confirming rapid test results. During universal free testing in the UK, COVID-19 swab samples from testing sites such as COVID-19 drive-through and walk-through testing centres, and the NHS front line were sent to laboratories for analysis.

11. Real-time PCR, from an extracted throat and nasal swab, is the gold standard used by the majority of diagnostic laboratories for COVID-19. The development of Endpoint PCR (ePCR) in the Milton Keynes Lighthouse Lab, a technology adopted from industry, is one option being utilised to scale and speed up PCR testing, as a single ePCR line has the potential to run over 15,000 samples concurrently, and a testing capacity of over 150,000 samples daily. ePCR is used alongside real time PCR in the Milton Keynes Lighthouse Lab to increase their testing capacity with minimal facility and operational adaptations, whilst the Rosalind Franklin Laboratory now utilises ePCR predominantly. It has been suggested that the scalability and performance of ePCR may have the potential to allow for routine whole-

[4] Z. Chen *et al.* Global landscape of SARS-CoV-2 genomic surveillance and data sharing. *Nature Genetics*, 2022, 54, 499–507

[5] https://www.gov.uk/government/news/two-new-megalabs-to-open-in-2021-to-transform-the-uks-diagnostic-facilities

[6] http://allcatsrgrey.org.uk/wp/download/infection_control/NHS-Test-and-Trace_-how-we-test-your-samples-gov.uk.pdf

population diagnostic monitoring during a pandemic using few centralised testing labs[7]. Maintaining investment and development of the UK's testing and diagnostic capability will future proof the UKs capabilities for future response to large-scale infectious disease outbreaks[5]. The Rosalind Franklin Laboratory, in a post COVID-19 era, aims to create and upskill scientists with a programme of training and, with close links to universities, to inspire a new generation to choose a career in S&T[8].

12. In addition to PCR based testing, the lateral flow test is a widespread, readily accessible and user-friendly testing option based on antibody technology.Most rapid point of care (POC) diagnostic tests do not meet the quality standards required to replace centralised laboratory-based tests[9]. However, lateral flow tests are a popular POC diagnostic that have been widely used in combination with PCR based techniques to confirm SARS-CoV-2 infection[10] and have played an important role in controlling the COVID-19 pandemic in many countries as well as resource-limited settings throughout the global response to COVID-19. The widespread public acceptance and overall success of lateral flow tests for mass POC diagnostics has accelerated research into similar technologies for a range of other infectious and non-infectious ailments, such as cancer, organ function monitoring, sepsis and concussion.

C. Genetic Sequencing

13. Whole genome sequencing (WGS) and the genotyping of variants can aid tracking of disease transmission and lineages during an outbreak, especially when combined with geographical data[11]. Throughput, resolution, scalability, flexibility and affordability have continued to improve for high throughput sequencing technologies. As such, whole genome sequencing has played a pivotal role in the global response to the COVID-19 pandemic.

14. Since the first genome sequence of a new coronavirus associated with human respiratory disease was published by Chinese scientists in early 2020, genetic sequencing of COVID-19 and subsequent variants has become commonplace in many countries[12]. The benefits of sequence monitoring were highlighted in the UK when the B.1.1.7 lineage was identified due to sequencing surveillance being conducted in London, where an increase of B.1.1.7 cases coincided with an increase in S gene target failures[13]. Other benefits include; using sequence data to shape emergency and longer term responses to infectious disease outbreaks, enabling preparation or predictive measures for future events, enabling earlier identification of the causative agent during outbreaks through routine sequence monitoring , enabling tracking of transmission of known lineages and identification of emerging variants or variants with enhanced biological properties[11,13,14]. However, cost is still a significant limiting factor and generally only a small proportion of confirmed positive samples are sequenced and assigned a lineage, this potentially means other circulating or new lineages may be missed[14].

15. Genotyping is a related and well-established technology that can provide complementary high throughput data to whole genome sequencing but in a lower cost and more time-efficient manner. This uses a small panel of single nucleotide polymorphisms (SNPs) to assign lineage to a higher proportion of COVID-19 positive samples. Genotyping

[7] J. Roix *et al*. Evaluation of endpoint PCR (EPCR) as a central laboratory based diagnostic test technology for SARS-CoV-2. DHSC. 2021.

[8] https://www.gov.uk/government/news/rosalind-franklin-laboratory-processes-one-millionth-pcr-test

[9] V. Sunkara, *et al*. Lab-on-a-Disc for Point-of-Care Infection Diagnostics. *Acc.Chem. res*., 2021, 54

[10] Zhou, Y, *et al*. Point-of-care COVID-19 diagnostics powered by lateral flow assay., *Trends in Analytical Chemistry*, 2021, 116452.

[11] E.L. Stevens *et al*. The Public Health Impact of a Publically Available, Environmental Database of Microbial Genomes. *Frontiers in Microbiology*, 2017, 8, 808

[12] Wu *et al*. A new coronavirus associated with human respiratory disease in China. *Nature*, 2020, 579,265-269

[13] Volz *et al*. Assessing transmissibility of SARS-CoV-2 lineage B.1.1.7 in England. *Nature*, 2021, 593, 266-269

[14] H. Harper *et al*. Detecting SARS-CoV-2 variants with SNP genotyping. *PLOS ONE*, 2021, 16(2), e0243185

has been widely used in the UK and although it does not produce full sequence information it can, in the majority of cases, accurately assign a variant to a positive sample, which is sufficient to identify or rule out transmission routes in monitoring viral spread. Using genotyping technology for real-time monitoring of COVID-19 variants can, in turn, facilitate emergency responses and provide information for epidemiological studies and predictive modelling for future infectious disease events.

16. The main drawback of genotyping and a key reason why it would not be sufficient to replace the requirement for whole genome sequence surveillance is that it relies upon an up-to-date reference library of full genome sequences to screen against and enable the design of SNP panels[11,14]. UK trials began with genotyping target panels in March 2021, and since then genotyping has been used to identify the variants Alpha, Beta, Delta, Gamma and Omicron[15]. Genotyping results were most notably used for rapid identification of the Delta and Omicron variants, with this becoming the predominant method of variant identification during the infection peak from November 2021 to March 2022[16].

D. Data Analysis – big data, machine learning, AI, cloud computing, information sharing

17. The COVID-19 pandemic provided an environment for rapid advances in data analysis, big data and machine learning. This has not only been used in AI-enabled drug discovery, rapid variant lineage tracing and modelling of infection spread, but has also provided the opportunity for AI to be incorporated into rapid decision-making technologies. Such technologies were in demand to facilitate the national and global response to the spread of COVID-19[17]. The pandemic encouraged the development of more intelligent, highly responsive, and efficient detection and diagnostic methods, including identification of patients most at risk of developing complications such as pneumonia[18], and providing decision-making tools for disease management[19]. Algorithms have also been developed for the automatic and accurate classification of COVID-19[20].

18. The ever increasing digitalisation of health information, provides greater amounts of higher quality data, resulting in a lower requirement for input into disease surveillance. Despite challenges in collating large datasets from various sources across the globe, comprehensive data sharing mechanisms were formed in a short timeframe to accommodate the huge amount of resource and data coming from the pandemic.

19. The WHO hosts the COVID-19 Knowledge Hub, curated by the Global Outbreak Alert and Response Network (GOARN) partners. This aims to act as a focal point for wide-ranging, reliable resources and uses multidisciplinary evidence to inform evidence-based decision-making[21]. The Allen Institute for AI's COVID-19 Open Research Dataset (Cord-19)[22] and EU Commission's COVID-19 Data Portal[23] are other examples of collaborative

[15] Public Health England. SARS-CoV-2 variant data update, England Version 25 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1063301/routine-variant-data-update-25-data-england-25-march-2022.pdf

[16] Public Health England. SARS-CoV-2 variant data update, England Version 25 SARS-CoV-2 variants of concern and variants under investigation in England - Technical briefing 21. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1063301/routine-variant-data-update-25-data-england-25-march-2022.pdf

[17] R. Vaishya *et al.* Artificial Intelligence (AI) applications for COVID-19 pandemic. *Diabetes and Metabolic Syndrome: Clinical Research and Reviews*, 2020, 14(4) 337-339

[18] M. Quiroz-Juárez. Identification of high-risk COVID-19 patients using machine learning. PLos One, 2021, 16(9), e0257234

[19] I. Dayan *et al*. Federated learning for predicting clinical outcomes in patients with COVID-19. *Nature Medicine*, 2021, 27(10), 1735-1743.

[20] N. Baghdadi *et al.* An automated diagnosis and classification of COVID-19 from chest CT images using a transfer learning-based convolutional neural network. Computers in Biology and Medicine, 2022, 144, 105383

[21] https://extranet.who.int/goarn/COVID19Hub

[22] https://www.kaggle.com/datasets/allen-institute-for-ai/CORD-19-research-challenge

[23] https://www.covid19dataportal.org/

platforms designed to act as a hub for reliable research. These resource collections make the use of AI and machine learning more feasible, in part through advances in natural language processing, which can be used to assess the sheer volume of information being produced from the pandemic in a fraction of the time it would take medical professionals.

E. Vaccines and Therapeutics

20. The COVID-19 pandemic has driven scientists, regulators and policy makers to take an approach to vaccine development like no other. This will no doubt provide key lessons for accelerated vaccine development and production in response to future biological threats.

21. Emerging viruses such as SARS-CoV-2, avian influenza and Ebola in recent years have driven the research community to focus on emerging zoonotic viruses and associated vaccine development[24]. The speed with which multiple SARS-CoV-2 vaccines were developed, tested and authorised for use in the UK was influenced by the depth of existing research into Coronaviruses and new generation vaccines; increased funding; and an adapted UK vaccine approval process[25]. Lessons identified in previous outbreaks which were declared a Public Health Emergency of International Concern have been learnt and new approaches have been developed; in particular, the new regulatory pathway enabling the rapid approval for emergency use of vaccines to treat COVID-19. For example, in 2020 changes were made to The Human Medicine Regulations Act (MHRA) 2012 - the UKs core legislation regulating medical products - to allow temporary authorisation of an unlicensed product, subject to safety, quality and efficacy as defined by the UK's Medicines and Healthcare products Regulatory Agency (MHRA)[26]. These changes allowed for a regulatory process known as a 'rolling review'. A 'rolling review' can be used to complete the assessment of a promising medicine or vaccine during a public health emergency in the shortest time possible. This process was ultimately used for a number of COVID-19 vaccines. Data on the safety, quality and efficacy of the first of these vaccines, the Pfizer mRNA vaccine, were submitted to the MHRA between 1st October and 2nd December. The MHRA expert scientists and clinicians reviewed data from the laboratory pre-clinical studies, clinical trials, manufacturing and quality controls, product sampling and testing of the final vaccine and also considered the conditions for its safe supply and distribution. This process lead to the first COVID-19 vaccine for the UK, developed by Pfizer/BioNTech, being granted temporary authorisation from MHRA on 2nd December 2020 for use in the UK[27]. Under temporary authorisation, the product is not considered to be fully licenced for marketing, but allows for supply of an unlicensed pharmaceutical product in response to specific public health threats. The temporary authorisation period lasts a fixed year, within which terms and obligations are defined, such as the requirement of further studies and further data submitted. The decision to temporarily authorise can be renewed annually until these defined obligations are met after which temporary authorisation can be converted to standard marketing authorisation[26].

22. The first COVID-19 vaccine was a new generation mRNA vaccine. Whilst being the first mRNA vaccine to gain approval, it was backed by years of mRNA vaccine research, which sped up development. Existing coronavirus research into SARS and MERS included vaccine development and the identification of the spike protein as an effective vaccine antigen and how to stabilise it[28]. The second COVID-19 vaccine to be approved in the UK, the Oxford-AstraZeneca viral vector vaccine, similarly benefited from prior research, including the identification of the modified adenovirus viral vector[25]. Both mRNA vaccines

[24] D. Van Riel and E. De Wit. Next-generation vaccine platforms for COVID-19. *Nature Materials*, 2020, 19(8), 810-812.

[25] P. Ball. The lightning-fast quest for COVID vaccines — and what it means for other diseases. *Nature*, 2020, 589, 16-18

[26] Brodies LLP The mechanics of medicines regulation - shining a spotlight on the MHRA vaccine approval decision 2020 https://brodies.com/insights/healthcare-and-life-sciences/the-mechanics-of-medicines-regulation-shining-a-spotlight-on-the mhra-vaccine-approval-decision/

[27] https://www.gov.uk/government/news/uk-medicines-regulator-gives-approval-for-first-uk-covid-19-vaccine

[28] R. N. Kirchdoerfer. Stabilized coronavirus spikes are resistant to conformational changes induced by receptor recognition or proteolysis, *Scientific reports*, 2018, 8, 15701

and viral vector vaccines show considerable promise for rapid development of future vaccines in response to emerging pathogens, due to their platform design. This platform is modular in approach and simplifies the design and manufacture of vaccines by utilising a common platform, or backbone, into which relevant genetic material from a novel pathogen can be inserted as soon as genetic sequences and suitable antigenic motifs are established. The platform can therefore be adapted to any suitable pathogen in a vastly reduced timescale. Having a common manufacturing process for new vaccines from a given platform also increases the rate at which large scale production can be achieved, by utilising established capabilities with little more than optimisation required[29].

23. Older vaccine types, such as inactivated or live attenuated vaccines, require the growth of large quantities of the virus, making development and manufacture more costly and time consuming. Additionally, in the case of SARS-Cov-2 and other high consequence pathogens, development and production would need to be conducted within high containment, further increasing cost and time requirements. By comparison, next generation vaccines (e.g. mRNA and viral vector) can begin development using just the viral genetic sequence, once known, in the absence of the physical virus. The timing and safety benefits, as well as adaptability, of these new vaccine technologies over their older counterparts have the potential to change the way in which rapid global responses are handled in the face of new emerging biological threats that would otherwise require acquisition and manipulation of the pathogen 24[24].

24. Despite the positive potential of new platform vaccines, not only for the COVID-19 pandemic but also for protecting against future emerging viruses, there are still some barriers that need to be overcome for effective distribution and delivery. One considerable challenge with these vaccines is their storage and distribution requirements. Unlike many traditional vaccine products, viral vector vaccines and mRNA vaccines require strict temperature control during storage and transportation. Vaccines currently in use in the UK for COVID-19 are highly effective in protecting against severe disease and death. However, none of the vaccines produce sterilising immunity, where infection is completely prevented. Therefore, a range of data from real world studies are regularly reviewed to estimate the effectiveness of vaccines against COVID-19 infection, symptomatic disease, severe disease and transmission. For the vaccines considered so far, primarily Cominarty (Pfizer-BioNTech) and Vaxzevria (Oxford-AstraZeneca), the effectiveness against severe outcomes appears similar for the alpha and delta variants, although effectiveness against delta is probably reduced to some extent. A preliminary assessment of omicron variant sub-lineages did not find evidence of a difference in vaccine effectiveness against symptomatic disease for BA.2 compared to BA.1[30]. However, a number of studies have shown that immunity afforded by vaccination is not long lasting, and effectiveness against symptomatic disease reaches <20% after 20-25 weeks, even following a booster dose[31].

F. Therapeutics and Treatments

25. The unprecedented threat to health and healthcare systems posed by the COVID-19 pandemic prompted a multifaceted approach to rapid drug screening. One of the most feasible approaches to development of therapeutics in a compressed timescale is through repurposing drugs known to be effective in treatment of similar diseases. Not only can this approach identify potential therapeutic candidates quickly, it also has the advantage of the drugs having already been safety tested. Cost of development is also reduced, as initial screening can be carried out virtually through a range of computational methods. Virtual screening is very high throughput and narrows the options for further investigation[32].

[29] S. S. Rosa *et al.* mRNA vaccines manufacturing: Challenges and bottlenecks. *Vaccine*, 2021, 39(16), 2190–2200

[30] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1050999/Technical-Briefing-35-28January2022.pdf

[31] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1101870/vaccine-surveillance-report-week-35.pdf

[32] W. Jang. Drugs repurposed for COVID-19 by virtual screening of 6,218 drugs and cell-based assay

26. A number of large clinical trials have been carried out by the UK to identify effective therapeutic treatments for COVID-19. These include the Recovery Trial[33], which was one of the largest clinical trials in the world, and looked at a range of repurposed treatments for hospitalised patients. The Principle Trial[34] and Panoramic Trial[35] are both studying the efficacy of antiviral treatments for people at home, with the aim of preventing hospitalisation.

27. The Recovery Trial was instrumental in providing evidence-based advice for treatment of critically ill COVID-19 patients, using data from over 47,000 participants to give a definitive view on which drugs are effective and which are not. 36 The trial branched out to include hospitals from across six countries and in two years identified four highly effective treatments. Dexamethasone, a synthetic glucocorticoid with anti-inflammatory effects, was approved for use in COVID-19 patients in the UK in June 2020 as a result of the trial rapidly identifying its benefits. It is a cheap and commonly used therapeutic prescribed for a number of other inflammatory conditions. Tocilizumab, an immunosuppressive drug used to improve pain and swelling from various types of arthritis, was then approved in February 2021 and another arthritis treatment, Baricitinib, was also identified by the Recovery Trial as being effective in hospitalised COVID-19 patients, and was subsequently authorised for use. Ronapreve (previously known as REGEN-COV), a monoclonal antibody combination therapy, was the first antibody treatment identified for use in COVID-19 patients, with approval given for its use in patients who had not mounted their own immune response to the infection.

28. Aside from the Recovery Trial improving outcomes and saving countless lives, the trial also pioneered a streamlined approach to clinical trials and demonstrated how datasets from multiple sources can be successfully integrated.

29. In a similar way, the World Health Organization (WHO) is running an unprecedented global platform trial; the Solidarity Trial. This globally coordinated, randomised trial was initially set up to test four repurposed drugs and has more recently begun assessing three new drugs in the Solidarity PLUS trial. To ensure effective participation and valuable data collection in unprecedented times of hospital pressure the trial process has been hugely simplified with electronic participation assisted by a network of national coordinators37. This approach has paved the way for similar large and wide-ranging trials to be rapidly rolled out during future disease outbreaks.

III. Implications and Conclusions

30. Lessons identified from the global response to the COVID-19 pandemic will be relevant to the technological assistance that would likely be available if requested under Article VII as a result of a deliberate release of a biological agent. Advancements in S&T may also have key implications for progress on the global response to infectious disease outbreaks, whether natural, accidental or deliberate in origin. This could also allow analysis of additional requirements to enable a more effective response to future disease outbreaks or pandemics. States Parties should consider how these lessons could be applied to strengthen implementation of other aspects of the BTWC. This includes enhancing activities related to Article X cooperation on development and application of scientific discoveries for disease prevention and future pandemic preparedness. As well as considering research advances, it will be essential also to take account of regulatory and ethical issues. Advances in technologies for surveillance, detection and diagnosis may also provide useful tools to assist in any investigation carried out under the provisions in Article VI of the Convention, or launched by the UN Secretary General under the Mechanism for Investigation of Alleged Use of Chemical and Biological Weapons.

[33] https://www.recoverytrial.net/results
[34] https://www.principletrial.org/results
[35] https://www.panoramictrial.org/
[36] https://www.recoverytrial.net/results
[37] https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/solidarity-clinical-trial-for-covid-19-treatments

31. The implications of scientific and technological issues related to the COVID-19 pandemic for the BTWC underline how essential it will be to draw in knowledge and expertise from those closely involved in the relevant fields to assist in our review of advances in science and technology. They also emphasise the need for a structured and systematic ongoing process for the review of relevant advances, with the flexibility to address emerging issues as they arise, and accurately assess their implications for the full and effective implementation of particular provisions of the Convention. This ought to be reflected in the final report of the Ninth Review Conference on the future role of scientific and technological reviews.