Emergency Use Pathways (EUPs):

applying regulatory flexibility in the age of COVID-19

A review of EUPs for marketing authorisations, made available by 7 major regulatory authorities and the WHO.

Common findings across the 7 authorities and the WHO:

Type of pathway

35 established pathways that can be used in the context of a pandemic or public health emergency

4 pathways created specifically for COVID-19

Type of product

38 used for vaccines and therapeutics

Advantages of EUPs:

For sponsors, authorities and ultimately bringing the treatments to patients

Facilitates development

Expedites authorisation

Timely patient access

Mechanism

- Exempt from certain submission requirements
- More interactions with sponsor pre-submission
- Option to use rolling submission

- Reliance
- Formal priority review
- Notification (not formally reviewed)
- Conditional
- Exceptional

R&D BRIEFING 75

CIRS Centre for Innovation in Regulatory Science

Introduction to Emergency Use Pathways

Infectious pandemic events require extraordinary responses. From the earliest times until today with the most recent global outbreak of COVID-19, countries have marshalled their resources to face the challenges posed by these events. With every response, our understanding has increased of how best to combat the infection while ensuring that quality, accurate diagnostics, safe and effective treatments, and life-saving support systems are made available through the application of increasingly robust, yet flexible regulatory approaches.

Among these regulatory approaches, special pathways have evolved that are designed to facilitate the rapid availability of diagnostics, vaccines, therapies and medical devices while applying principles of scientific rigour that support quality, safety and efficacy. Regulatory agencies currently facing COVID-19 have already learned through the experiences of addressing the unique needs of outbreaks of polio, Human Immunodeficiency Virus (HIV), Influenza A virus subtype H1N1 (H1N1), Severe Acute Respiratory Syndrome (SARS), Middle East Respiratory Syndrome (MERS), Zika and Ebola, that during pandemic infections standard assessment and approval pathways may not meet rapidly evolving healthcare needs. In response, the leading agencies have developed a toolbox of flexible pathways that could be used during times of emergency. We collectively term these 'Emergency Use Pathways (EUPs).'

Emergency Use Pathway (EUP)

For the purposes of this Briefing, EUPs are risk-based pathways with which regulatory agencies assess and authorise new medical interventions during a time of emergency.

EUPs encompass a wide range of regulatory pathways, including some that are used routinely in non-pandemic situations. Examples include compassionate use, reliance, specific government mandates as well as an agency's usual pathways for medicines of high unmet need.

EUPs can be applied to diagnostics, vaccines, therapeutics and devices and play a key role in managing an infectious pandemic as well as other health emergencies. Accordingly, each EUP has a distinct emphasis; some focus on accelerating the development of new therapies or technologies, while others speed the assessment and authorisation process. Across all EUPs is the recognition that rapid decisions about these technologies are counterbalanced by a degree of uncertainty about the product's use amongst the general population, the state of pandemic in a given jurisdiction and the ability of its health services to employ the product.

An underlying premise for these pathways is that in times of infectious pandemic crises, both the public and government administrators are willing to take increased risks in the face of the potential benefits of rapid access to technologies deemed of critical societal importance. An assessment of a technology's benefits and risk will take into consideration the material threat posed by the pandemic event. The benefit-risk assessment will depend on the category of product; therapeutic products including vaccines for sick patients will have a different threshold of acceptance than prophylactic products that will be given to healthy people. In addition, the quality, consistency and reliability of batches must be assured, and changes during product development must be properly controlled, evaluated, justified, and documented[1].

Despite there being consultation and calls from the World Health Organisation (WHO) for regulatory agencies to be prepared for pandemic and other public health emergencies including the development of EUPs[2], many pathways have grown out of local needs and experiences and therefore agencies appear to be heterogenous in their approaches. However, upon closer inspection, EUPs seem to share some common characteristics. In view of the recent pandemic caused by COVID-19, we have conducted this integrated analysis of the key attributes of EUPs available in major regulatory agencies around the world to better understand the characteristics and value of such pathways. We

[1] Kieny M. & Rägo L. (2016) Regulatory policy for research and development of vaccines for public health emergencies. *Expert Reviews of Vaccines* 15(9);1075-1077. Accessed from: https://www.tandfonline.com/doi/full/10.1080/14760584.2016.1188695

[2] WHO (2017) WHO Informal Consultation on options to improve regulatory preparedness to address public health emergencies [Meeting Report, 17-19 May 2017]. Available at: https://www.who.int/medicines/news/2017/PHEmeeting-reportIK-EG16_Nov_2017.pdf

recognise that this is a very dynamic, rapidly changing field, with new approaches being developed almost daily. Therefore, this analysis is intended to provide an overview of the types of pathways that are available for vaccines and therapeutics and may not be exhaustive. When viewed holistically, we believe that this analysis will provide insights into ways that experiences with EUPs can be shared among experienced agencies and that can also serve as a guide to agencies that may have only recently recognised the need to implement EUPs in their jurisdiction.

The pandemic environment

Pandemics have occurred periodically during the history of human existence including the plague of Justinian (6th Century, ~30-50m deaths), the Black Death (14th Century, ~ 200m), and Spanish Flu (1918, ~ 40-50m) and in more recent memory polio, HIV, H1N1, SARS and MERS (see Table 1).

With globalisation and the increased connections through trade as well as frequent travel between countries, there is an increased likelihood of rapid and widely disseminated outbreaks of infectious disease, although these are not easily predicted. Such outbreaks cause substantial disruption not only to healthcare systems but also to the political, economic and social fabric of the countries affected.

Pandemic

"an epidemic occurring worldwide, or over a very wide area, crossing international boundaries and usually affecting a large number of people"[3].

More simply put, a pandemic is the worldwide spread of a new infectious disease that has increased mortality and morbidity as most people do not have immunity.

That said, improved healthcare systems in many countries appear to generally reduce the number of deaths, so the key issue is how to ensure that the systems do not get overwhelmed. Measures are required to help flatten the curve of infections, such as social distancing, along with public health campaigns to increase awareness around increased hand washing and coughing protocols. A better understanding of pandemics and how they spread has led the WHO to increase surveillance and develop action plans, policies and measures on how best to mitigate and manage pandemics. Indeed, the WHO has indicators regarding emergency procedures within its Global Benchmarking Tool, which are requisites for an agency reaching a certain 'maturity' level.

Following the 2003 SARS outbreak and the growing threats from avian flu, many countries developed pandemic plans. In 2005 the WHO updated their International Health Regulations regarding specific standards that member states needed to have regarding detection, response to and reporting of outbreaks. This framework enabled a more coordinated response to the H1N1 pandemic of 2009. However, the response to the 2014 Ebola outbreak in West Africa brought to light the ongoing challenges and implications for coordinating pandemic responses. The WHO, using lessons learned from the Ebola outbreak, then developed the WHO R&D Blueprint in 2016, identifying how to decrease the time taken to develop and authorise new diagnostics, vaccines and therapeutics[4]. The impact of the WHO R&D Blueprint has been demonstrated in subsequent Ebola and Zika outbreaks[5][6].

As shown in the next section, countries have risen to the challenge of strengthening regulatory capacity for public health emergencies by having in place a number of EUPs to enable the timely development and authorisation of vaccines and therapeutics.

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[3] Last JM, editor. (2001) *A dictionary of epidemiology*, 4th edition. New York: Oxford University Press.

[4] WHO (2016) An R&D blueprint for action to prevent epidemics – plan of action, May 2016. Accessed from: https://www.who.int/blueprint/about/r_d_blueprint_plan_of_action.pdf?ua=1

[5] Piot P., Soka MJ, Spencer J (2019) Emergent threats: lessons learnt from Ebola, *International Health*, 11(5); 334–337. Available at: https://doi.org/10.1093/inthealth/ihz062

[6] Chua A et al (2017) Update on Zika Diagnostic Tests and WHO's Related Activities. *PLoS Negl Trop Dis* 11(2): e0005269. https://doi.org/10.1371/journal.pntd.0005269

Disease	Year of first detection	Number of countries affected	Cases	Deaths	Comment/reference
COVID-19 (SARS-CoV-2)	2019	213	2,591,015	178,686	Ongoing as of 24 April 2020[7]
Zika virus	2015	76 [8]	223,477 confirmed in the Americas[9]	20 in the Americas[9]	Reported until July 2019
Ebola (West Africa epidemic)	2014	10	28,652	11,325	Reported until 2016[10]
MERS	2012	27	2494	858	Cases reported up to 30 November 2019[11]
H1N1 avian flu	2009	>214	Studies estimate 60.8m cases in the US alone[12] and 11 to 21 percent of the global population may have become infected[13]	At least 18,449 confirmed (estimated to be between 150,000-575,000[14])	Reported up to August 2010[15]
SARS	2002	26	8098	774	Ended July 2003[16]
HIV	1981	Global	74.9m infected with HIV[17]	32m AIDS-related deaths[17]	Ongoing

Table 1 – Examples of pandemics and epidemics

[7] WHO (2020) Coronavirus (COVID-19) situation dashboard. Accessed on 24 April 2020 at: https://covid19.who.int/

[8] WHO (2019) Zika Epidemiology Update July 2019. Accessed from: https://www.who.int/emergencies/diseases/zika/zika-epidemiology-update-july-2019.pdf?ua=1

[9] Pan American Health Organization / World Health Organization (2018) Zika suspected and confirmed cases reported by countries and territories in the Americas Cumulative cases, 2015-2017. Accessed from: https://www.paho.org/hq/index.php?option=com_content&view=article&id=12390:zika-cumulative-cases&Itemid=42090&lang=en

[10] Center for Disease Control and Prevention 2014-2016 Ebola Outbreak in West Africa. Accessed from https://www.cdc.gov/vhf/ebola/history/2014-2016-outbreak/index.html

[11] WHO (2019) MERS situation update November 2019. Accessed from: http://applications.emro.who.int/docs/EMRPUB-CSR-241-2019-EN.pdf?ua=1&ua=1&ua=1

[12] Shrestha SS et al (2011) Estimating the burden of 2009 pandemic influenza A (H1N1) in the United States, April 2009-April 2010, *Clinical Infectious Diseases* 52(Suppl. 1): S75-S82. Available at: https://doi.org/10.1093/cid/ciq012

[13] Kelly H et al (2011) The Age-Specific Cumulative Incidence of Infection with Pandemic Influenza H1N1 2009 Was Similar in Various Countries Prior to Vaccination, *PloS One* 6(8): e21828. Available at: https://doi.org/10.1371/journal.pone.0021828

[14] Dawood FS et al (2012) Estimated global mortality associated with the first 12 months of 2009 pandemic influenza A H1N1 virus circulation: a modelling study, *The Lancet Infectious Diseases* 12(9); 687-695. Available at: https://doi.org/10.1016/S1473-3099(12)70121-4

[15] WHO Pandemic (H1N1) 2009 – update 112, 6 August 2010. Accessed from https://www.who.int/csr/don/2010_08_06/en/

[16] WHO (2004) Guidelines for the global surveillance of severe acute respiratory syndrome (SARS) – updated recommendations, October 2004. Accessed from: https://www.who.int/csr/resources/publications/WHO_CDS_CSR_ARO_2004_1.pdf?ua=1

[17] UNAIDS (2019) Factsheet - World Aids Day 2019. Available at: https://www.unaids.org/sites/default/files/media_asset/UNAIDS_FactSheet_en.pdf

An analysis of regulatory EUPs

EUPs can deploy the full range of regulatory pathways available, from compassionate use through to reliance or specific government mandates, which provide an exemption from the need to seek marketing authorisation e.g. interim orders in Canada, emergency exceptions in Australia and ordinances in Switzerland. EUPs can also include an agency's usual pathways used in non-emergency situations for medicines of high unmet need. Indeed, many EUPs are allowing exemptions from the usual regulatory requirements, with the risk managed by requiring alignment with specific standards, guidances and strict medical oversight.

The regulatory landscape and myriad of different EUPs that can be used has been summarised in this Briefing to provide a high-level view of the similarities across agencies in terms of pathways available as well as routes specific for an agency. The agencies that have been reviewed are: US Food and Drugs Authority (FDA); European Medicines Agency (EMA) (Centralised procedure); Therapeutic Goods Administration, Australia (TGA); Health Canada, Canada; Swissmedic, Switzerland; Pharmaceutical and Medical Devices Agency, Japan (PMDA); National Medical Products Administration, China (NMPA) and the WHO.

This high-level analysis has identified and evaluated the routes that could be deployed to facilitate development or speed authorisation and access to address important medical countermeasures for public health emergencies as well as pandemics like COVID-19. In practice, not all of these pathways might be used for COVID-19. We have tabulated key pathways, outlining some of their characteristics and potential advantages regarding their use in development, submission, regulatory process and the type of decision. Further information about each specific pathway can be found using the links provided and each pathway should be reviewed by the reader as to its current state of use and requirements. The tables below show for each agency the following information:

Characteristics of EUP in terms of:

- Type of pathway - is it a pathway created specifically for COVID-19 or an existing Facilitated Regulatory Pathway (FRP) that can be used in the context of a pandemic or for general public health emergencies? FRPs can facilitate the development, review of and access to medicines, particularly where there is an unmet medical need by providing alternatives to standard regulatory review routes.
- Type of product that can use the pathway – vaccines or therapeutics (including small molecules and biologics)

Advantages of EUP that facilitate development:

- Exemption from certain submission requirements
- More agency-sponsor interactions pre-submission
- Option for rolling submission, allowing for sections of the application to be considered for review as they are completed

Advantages of EUP that expedite authorisation:

- Reliance – where a regulatory authority in one jurisdiction may take into account and give significant weight to evaluations performed by another regulatory authority or trusted institution in reaching its own decision. Reliance pathways can involve a Verification or Abridged review of the application.
- Formal priority review to accelerate the regulatory review of the application
- A Notification procedure - where the agency is notified that the technology has been made available but the application does not undergo a formal regulatory review
- Conditional - where the applicant can demonstrate the positive benefit-risk balance, based for example on early evidence. It is revisited in the future to consider conversion to a standard authorisation.
- Exceptional – where the applicant is unable to provide comprehensive data on the efficacy and safety under normal conditions of use. Also revisited in the future through provision of information on the use of the product but will normally not lead to the completion of a full dossier.
- Other

As described herein, the EMA has numerous pathways that can be of value to address pandemics and public health emergencies. When applied during a pandemic, these may encourage agency-sponsor interactions, which can facilitate development, authorisation or both.

	Characteristics				Advantages								
Name of EUP	**Type of EUP**		**Type of product**		**Facilitates development**			**Expedites authorisation**					
	Pathway created specifically for COVID-19	An established FRP that can be used in the context of a pandemic or public health emergency	Vaccines	Therapeutics (small molecules / biologics)	Exempt from certain submission requirements	More interactions with sponsor pre-submission	Option to use rolling submission	Reliance	Formal priority review	Notification (not formally reviewed)	Conditional	Exceptional	Other
Accelerated assessment		X	X	X	(x)	(x)	(x)		X				*
	https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/accelerated-assessment *Depends on the evidence												
Conditional approval		X	X	X	(x)	(x)	(x)		On request		X		
	https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/conditional-marketing-authorisation												
Exceptional Approval		X	X	X	(x)	(x)	(x)		On request			X	
	https://www.ema.europa.eu/en/glossary/exceptional-circumstances												
Compassionate use		X		X	X	(x)	(x)						Fast turnaround time*
	https://www.ema.europa.eu/en/human-regulatory/research-development/compassionate-use *The European Medicines Agency (EMA) provides recommendations through the Committee for Medicinal Products for Human Use (CHMP), but these do not create a legal framework. Compassionate use programmes are coordinated and implemented by Member States, which set their own rules and procedures.												
PRIME		X	X	X		X			X				*
	https://www.ema.europa.eu/en/human-regulatory/research-development/prime-priority-medicines *Depends on the evidence												
Pandemic influenza vaccine		X	X			X							
	https://www.ema.europa.eu/en/influenza-vaccines-submission-procedural-requirements												

Table 2 – EMA EUPs
(x) Specific for COVID-19 therapeutics

As described herein, Health Canada has numerous pathways that can be of value to address pandemics and public health emergencies. When applied during a pandemic, these may encourage agency-sponsor interactions, which can facilitate development, authorisation or both.

	Characteristics				Advantages								
Name of EUP	**Type of EUP**		**Type of product**		**Facilitates development**			**Expedites authorisation**					
	Pathway created specifically for COVID-19	An established FRP that can be used in the context of a pandemic or public health emergency	Vaccines	Therapeutics (small molecules / biologics)	Exempt from certain submission requirements	More interactions with sponsor pre-submission	Option to use rolling submission	Reliance	Formal priority review	Notification (not formally reviewed)	Conditional	Exceptional	Other
Notice of compliance with conditions		X	X	X							X		
	https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/pdf/prodpharma/applic-demande/guide-ld/compli-conform/noccg_accd-eng.pdf												
Priority Review		X	X	X					X				
	https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodpharma/prfs_tpfd-eng.pdf												
Urgent Public Health Need (UPHN) List		X	X	X	X			X		X			X
	https://www.canada.ca/en/health-canada/services/drugs-health-products/access-drugs-exceptional-circumstances/questions-answers.html												
Extraordinary Use New Drugs (EUND) pathway		X	X	X	X	X			*				
	https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/applications-submissions/guidance-documents/submission-information-requirements-extraordinary-drugs-eunds.html#a26 *May be considered for pandemic												
Special Access Programme (SAP)		X	X	X									
	https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/hpfb-dgpsa/pdf/acces/sapg3_pasg3-eng.pdf												
Interim Orders (including specific to COVID-19)	(X)	X	X	X	X					X			
	https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/legislation-guidelines/interim-orders.html Interim Order Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in Relation to COVID-19: https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/covid19-interim-order-drugs-medical-devices-special-foods.html												

Table 3 – Health Canada EUPs
(x) Specific for COVID-19 therapeutics

As described herein, the FDA has numerous pathways that can be of value to address pandemics and public health emergencies. When applied during a pandemic, these may encourage agency-sponsor interactions, which can facilitate development, authorisation or both. In addition to FDA pathways reviewed here, some states have enacted Right-to-Try laws that can accommodate specific requests driven by patients to access unapproved therapies.

	Characteristics				Advantages								
Name of EUP	**Type of EUP**		**Type of product**		**Facilitates development**			**Expedites authorisation**					
	Pathway created specifically for COVID-19	An established FRP that can be used in the context of a pandemic or public health emergency	Vaccines	Therapeutics (small molecules / biologics)	Exempt from certain submission requirements	More interactions with sponsor pre-submission	Option to use rolling submission	Reliance	Formal priority review	Notification (not formally reviewed)	Conditional	Exceptional	Other
Breakthrough Designation		X	X	X	X	X	X		X				
	https://www.fda.gov/files/drugs/published/Expedited-Programs-for-Serious-Conditions-Drugs-and-Biologics.pdf												
Fast Track		X	X	X		X	X						
	https://www.fda.gov/files/drugs/published/Expedited-Programs-for-Serious-Conditions-Drugs-and-Biologics.pdf												
Priority Review		X	X	X					X				
	https://www.fda.gov/files/drugs/published/Expedited-Programs-for-Serious-Conditions-Drugs-and-Biologics.pdf												
Accelerated Approval		X	X	X									X
	https://www.fda.gov/files/drugs/published/Expedited-Programs-for-Serious-Conditions-Drugs-and-Biologics.pdf												
Animal Rule		X	X	X		X							X
	https://www.fda.gov/media/88625/download												
Corona Virus Treatment Acceleration program (CTAP)	X		X	X		X			X				Time limited
	Post-approval evidence generation will be required using real world evidence https://www.fda.gov/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap												

Table 4 – FDA EUPs

	Characteristics				Advantages								
Name of EUP	**Type of EUP**		**Type of product**		**Facilitates development**			**Expedites authorisation**					
	Pathway created specifically for COVID-19	An established FRP that can be used in the context of a pandemic or public health emergency	Vaccines	Therapeutics (small molecules / biologics)	Exempt from certain submission requirements	More interactions with sponsor pre-submission	Option to use rolling submission	Reliance	Formal priority review	Notification (not formally reviewed)	Conditional	Exceptional	Other
Drug repurposing "Abbreviated Pathway" via 505(b)(2) pathway		X		X	X								X
	https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/abbreviated-approval-pathways-drug-product-505b2-or-anda-september-19-2019-issue												
Emergency Use Authorization (EAU)		X	X	X					X				X
	Post-approval commitments will likely be required https://www.fda.gov/media/97321/download												
Expanded access program		X	X	X	*				X				X
	https://www.fda.gov/news-events/public-health-focus/expanded-access https://www.govinfo.gov/content/pkg/FR-2009-08-13/pdf/E9-19005.pdf * Emergency Investigational New Drug Application (eIND) for Antiviral products can be used; 21 CFR 312.310: https://www.fda.gov/drugs/investigational-new-drug-ind-application/emergency-investigational-new-drug-eind-applications-antiviral-products												

Table 4 – FDA EUPs (cont.)

As described herein, TGA has numerous pathways that can be of value to address pandemics and public health emergencies. When applied during a pandemic, these may encourage agency-sponsor interactions, which can facilitate development, authorisation or both.

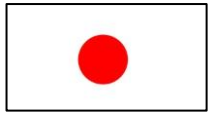
	Characteristics				Advantages								
Name of EUP	**Type of EUP**		**Type of product**		**Facilitates development**			**Expedites authorisation**					
	Pathway created specifically for COVID-19	An established FRP that can be used in the context of a pandemic or public health emergency	Vaccines	Therapeutics (small molecules / biologics)	Exempt from certain submission requirements	More interactions with sponsor pre-submission	Option to use rolling submission	Reliance	Formal priority review	Notification (not formally reviewed)	Conditional	Exceptional	Other
Priority		X	X	X					X				
	https://www.tga.gov.au/priority-review-pathway-prescription-medicines												
Provisional Approval		X	X	X							X		
	https://www.tga.gov.au/provisional-approval-pathway-prescription-medicines												
Special Access Scheme (Categories A, B and C)		X		X					X	*			**
	https://www.tga.gov.au/form/special-access-scheme *for SAS A and SAS C; **SAS B is an approval												
Comparable overseas regulators (CORs)-A/B approach		X	X	X				X	X				X
	CORs= EMA, FDA, HAS, Health Canada, PMDA, MHRA, Swissmedic https://www.tga.gov.au/comparable-overseas-regulators-cors-timeframes-and-milestones#cora												
COVID-19 Emergency Exemption of 2020	X		X	X						X			
	Three exemptions from registration requirements (as of 16 April 2020): Hydroxychloroquine and chloroquine https://www.legislation.gov.au/Details/F2020N00041 Lopinavir and Ritonavir https://www.legislation.gov.au/Details/F2020N00039 Remdesivir https://www.legislation.gov.au/Details/F2020N00040												

Table 5 – TGA EUPs

As described herein, Swissmedic has numerous pathways that can be of value to address pandemics and public health emergencies. When applied during a pandemic, these may encourage agency-sponsor interactions, which can facilitate development, authorisation or both.

	Characteristics				Advantages								
Name of EUP	**Type of EUP**		**Type of product**		**Facilitates development**			**Expedites authorisation**					
	Pathway created specifically for COVID-19	An established FRP that can be used in the context of a pandemic or public health emergency	Vaccines	Therapeutics (small molecules / biologics)	Exempt from certain submission requirements	More interactions with sponsor pre-submission	Option to use rolling submission	Reliance	Formal priority review	Notification (not formally reviewed)	Conditional	Exceptional	Other
Ordinance on Measures to Combat the Coronavirus (COVID-19)	X		X	X	X					X		X	
	https://www.admin.ch/opc/en/classified-compilation/20200744/index.html												
Streamlining of the review procedure for specific medicinal product categories on request (Art. 13)		X	X	X				X					
	https://www.swissmedic.ch/swissmedic/en/home/news/mitteilungen/ae-zlpraxis-uebertragbare-infektonskrankheiten.html https://www.swissmedic.ch/swissmedic/en/home/humanarzneimittel/authorisations/information/wl-zl-ham-nach-art13hmg.html												
Conditions for the rolling submission of data during ongoing proceedings, handling unlicensed drugs (Art. 9)		X	X	X			X				X		
	https://www.admin.ch/opc/en/classified-compilation/20002716/index.html#fn-#a9-9 https://www.bag.admin.ch/dam/bag/en/dokumente/mt/k-und-i/hygiene-pandemiefall/influenza-pandemieplan-ch.pdf.download.pdf/foph-swiss-influenza-pandemic-plan.pdf												
Fast track		X	X	X					X		*		
	https://www.swissmedic.ch/dam/swissmedic/en/dokumente/zulassung/zl_hmv_iv/zl109_001wlbefristetezulassung.pdf.download.pdf/zl109_00_001e_wltemporary%20authorisationforhuman.pdf *May include temporary authorisation												

Table 6 – Swissmedic EUPs



As described herein, PMDA has numerous pathways that can be of value to address pandemics and public health emergencies. When applied during a pandemic, these may encourage agency-sponsor interactions, which can facilitate development, authorisation or both.

	Characteristics				Advantages								
Name of EUP	**Type of EUP**		**Type of product**		**Facilitates development**			**Expedites authorisation**					
	Pathway created specifically for COVID-19	An established FRP that can be used in the context of a pandemic or public health emergency	Vaccines	Therapeutics (small molecules / biologics)	Exempt from certain submission requirements	More interactions with sponsor pre-submission	Option to use rolling submission	Reliance	Formal priority review	Notification (not formally reviewed)	Conditional	Exceptional	Other
Exceptional approval		X	X	X	X					X	X	X	
	https://www.who.int/biologicals/vaccines/Annex_2_WHO_TRS_963-3.pdf?ua=1 (p.87), Article 14-3 of the Pharmaceutical and Medical Device Act												
Priority review		X	X	X					X				
	https://www.who.int/biologicals/vaccines/Annex_2_WHO_TRS_963-3.pdf?ua=1 (p.87) https://www.pmda.go.jp/files/000212491.pdf												

Table 7 – PMDA EUPs

As described herein, NMPA has numerous pathways that can be of value to address pandemics and public health emergencies. When applied during a pandemic, these may encourage agency-sponsor interactions, which can facilitate development, authorisation or both.

	Characteristics				Advantages								
Name of EUP	**Type of EUP**		**Type of product**		**Facilitates development**			**Expedites authorisation**					
	Pathway created specifically for COVID-19	An established FRP that can be used in the context of a pandemic or public health emergency	Vaccines	Therapeutics (small molecules / biologics)	Exempt from certain submission requirements	More interactions with sponsor pre-submission	Option to use rolling submission	Reliance	Formal priority review	Notification (not formally reviewed)	Conditional	Exceptional	Other
The Special Review and Approval Procedure for Drug Registration of the State Food and Drug Administration		X	X	X		X	X		X				
	The guidance is used for medicines for the prevention and treatment of public health emergencies (issue date 18 November 2005): State Food and Drug Administration (2005) Article No. 21: http://www.nmpa.gov.cn/WS04/CL2174/300621.html On 21 January 2020, CDE launched an emergency review mechanism; medicines for prevention and treatment of COVID-19 will be reviewed under the emergency review process, with fast track process, early intervention/interaction, expedited review and approval, to ensure the early access of these medicines: http://www.samr.gov.cn/xw/zj/202002/t20200214_311641.html												
Breakthrough		X	X	X		X	X		X				
	8th Nov 2019 - Draft for comments http://www.cde.org.cn/attachmentout.do?mothed=list&id=800 http://www.gov.cn/zhengce/zhengceku/2020-04/01/content_5498012.htm												
Priority review		X	X	X		X	X		X				
	8th Nov 2019 - Draft for comments: http://www.cde.org.cn/attachmentout.do?mothed=list&id=8006 http://www.gov.cn/zhengce/zhengceku/2020-04/01/content_5498012.htm												
Conditional approvals		X	X	X		X					X		
	Issued 20 December 2017 “The Guideline on Conditional Approvals for Urgently Needed Drugs: http://www.nmpa.gov.cn/WS04/CL2095/229373.html http://www.gov.cn/zhengce/zhengceku/2020-04/01/content_5498012.htm												

Table 8 – NMPA EUPs

The WHO's broad mandate includes advocating for universal healthcare, monitoring public health risks and coordinating responses to health emergencies. In relation to public health matters, the WHO provide leadership and guidance. Utilising lessons learned from previous public health risks the WHO developed a Research and Development Blueprint[4]. This identifies how to strengthen regulatory systems globally as well as decease the time taken to develop and authorise new diagnostics, vaccines and therapeutics. The WHO also has a number of EUPs that enable medicines once available to be expedited to low- and middle-income countries (LMICs).

	Characteristics				**Advantages**								
Name of EUP	**Type of EUP**		**Type of product**		**Facilitates development**			**Expedites authorisation**					
	Pathway created specifically for COVID-19	An established FRP that can be used in the context of a pandemic or public health emergency	Vaccines	Therapeutics (small molecules / biologics)	Exempt from certain submission requirements	More interactions with sponsor pre-submission	Option to use rolling submission	Reliance	Formal priority review	Notification (not formally reviewed)	Conditional	Exceptional	Other
WHO Emergency Use Listing (EUL) mechanism		X	X	X		X	X	X	X		*		
	https://www.who.int/diagnostics_laboratory/eual/emergency/en/ https://www.who.int/medicines/news/2017/reg_prep_key-to-addressing_ph_emergencies/en/ https://www.tandfonline.com/doi/full/10.1080/14760584.2016.1188695 https://www.who.int/news-room/detail/09-01-2020-emergency-use-listing-procedure-and-roadmap-health-emergencies *EUL could result in a conditional approval												
WHO pre-qualification pathway		X	X	X		X		X	X				
	https://www.who.int/medicines/regulation/prequalification/prequal-vaccines/about/en/ https://academic.oup.com/cid/article/61/suppl_5/S428/417512												

Table 9 – WHO EUPs

WHO EUP-enabling authorisations and availability in LMICs

National Regulatory Authorities (NRA), whether they are from well-resourced countries or LMICs, play a vital role in the health care system by providing regulatory oversight of all medical products. The WHO has an ongoing action plan to help build effective and efficient regulatory systems globally and during a public health crisis. For COVID-19 "WHO is working closely with global experts, governments and partners to rapidly expand scientific knowledge on this new virus and to provide timely advice on measures to protect people's health and prevent the spread of this outbreak"[18].

To further strengthen not just regulatory systems, but also the environment for evaluating and making available medicines in preparedness for public health crisis including pandemics, the WHO, following the West African Ebola epidemic from 2014-2016, developed an R&D Blueprint with input from a global coalition of medical, scientific and regulatory experts. This blueprint is a global strategy and preparedness plan that allows the rapid activation of R&D activities. Its aim is to fast-track the availability of effective tests, vaccines and medicines that can be used to save lives and avert large scale crisis. During the Ebola epidemic, the WHO developed the Emergency Use Assessment and Listing procedure (EUAL) to assess the performance, quality and safety of medical technologies during emergency situations.

The Emergency Use Listing (EUL) was established in 2017 and in January 2020 the WHO published the EUL procedure and roadmap to streamline the process by which new or unlicensed products can be used during public health emergencies. This procedure replaces the EUAL procedure[19]. The EUL is a risk-based procedure for assessing and listing unlicensed vaccines, therapeutics and in vitro diagnostics with the aim of expediting the availability of these products to people affected by a public health emergency. It is intended to assist interested UN procurement agencies and Member States in determining the acceptability of using specific products, based on an essential set of available quality, safety, and efficacy and performance data.

The WHO set up the prequalification process for vaccines in 1987 and in 2001 established the Prequalification Programme, which is a service to facilitate access to medicines that meet unified standards of quality, safety and efficacy for HIV/AIDS, malaria and tuberculosis. Prequalification includes a fast-track option that can be implemented when a vaccine needs to be used as part of an emergency response (see Ebola case study below).

In addition, the WHO has developed the Monitored Emergency Use of Unregistered and Investigational Interventions (MEURI) that provides countries with an ethical framework in which they can make a local jurisdictional decision on whether an unproven treatment can be used on an individual patient basis in a public health emergency[20]. This framework enables an expert panel to be convened so that the member states, including an appropriately qualified ethics committee, can assess whether to make the medicine available under "compassionate use" or "expanded access" in their jurisdiction.

The WHO tools help facilitate registration of medicines and vaccines globally. These tools not only include EUPs, but also regulatory strengthening programmes that help to build capacity within NRAs and enable agencies to make their own regulatory decisions. An example is a reliance mechanism on a regulatory decision, where the initial review is conducted by another competent regulatory agency. Ultimately, a reliance approach aims to help reduce the workload of the agency while still allowing an independent decision-making process.

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[18] WHO (2020) Coronavirus Disease (COVID-19) Outbreak: Rights, roles and responsibilities of health workers, including key considerations for occupational safety and health. Accessed on 23 April 2020 at: https://www.who.int/docs/default-source/coronaviruse/who-rights-roles-respon-hw-covid-19.pdf?sfvrsn=bcabd401_0

[19] WHO (2020) WHO publishes Emergency Use Listing procedure and roadmap to make new medical products more readily available during health emergencies [Press release, 9 January 2020]. Available at: https://www.who.int/news-room/detail/09-01-2020-emergency-use-listing-procedure-and-roadmap-health-emergencies

[20] WHO (2016) Guidance For Managing Ethical Issues In Infectious Disease Outbreaks. Available at: https://www.who.int/ethics/publications/infectious-disease-outbreaks/en/

Global effort to develop a vaccine: Ebola case study

Like the COVID-19 virus, Ebola has been a challenging emerging disease. First detected in 1976, the Ebola virus has been studied since the 1990s and laboratory research to establish a vaccine was initiated in 2001. The 2014–2016 outbreak in West Africa was the largest and most complex Ebola outbreak since the virus was first discovered, and that is when clinical development to produce a vaccine was largely started. Although this outbreak, like others including Zika, MERS, and SARS, came under control through physical rather than therapeutic means, many lessons have been learned. Since 2014, regulatory authorities around the world worked together to support the WHO in combating outbreaks of Ebola, with first worldwide vaccine approval in 2019 by EMA, followed closely by that in the USA. Despite taking five years from IND to first approval, the vaccine became available quickly in LMICs through the WHO prequalification procedure.

1976

First detection of Ebola

March 2014

Ebola outbreak identified in West Africa

8 Aug 2014

WHO declared the epidemic a "public health emergency of international concern"

Aug-Sep 2014

- Ad hoc expert group at **EMA** created; joint discussion with **US FDA and WHO**
- Early dialogue with companies to identify the most effective development pathway

In response to the 2014-2016 Ebola outbreak, the WHO developed the **Emergency Use Assessment and Listing (EUAL)** mechanism, a risk-based procedure for assessing and listing unlicensed vaccines, therapeutics and in vitro diagnostics for use in public health emergencies.

Metrics and pathways for Ebola vaccine (V290; Ervebo)

Aug 2014 IND submitted ~150 days after Ebola outbreak identified

June 2016
- Granted PRIME by EMA
- Granted Break-through by FDA

NDA/MAA submitted **March 2019** to EMA

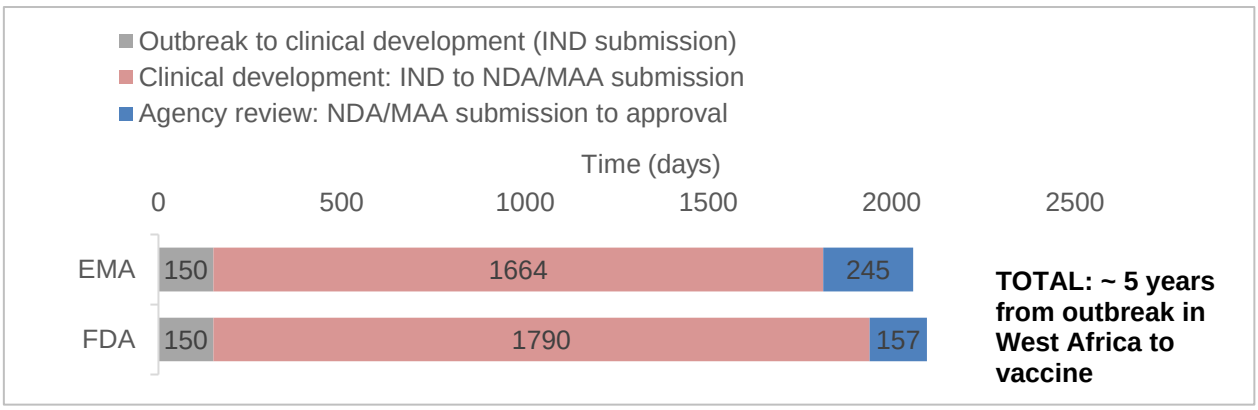
July 2019 to FDA

Mar-Dec 2019 EMA and FDA expedited review

Nov 2019 Approved by EMA (Conditional)

Dec 2019 Approved by FDA (Traditional)

36hrs post-EMA approval, WHO pre-qualifies the vaccine and it becomes available in ~6 countries within 90 days



Expedited review = EMA accelerated assessment/FDA priority review; IND = investigational new drug; NDA = new drug application; MAA = marketing authorisation applications

Observations

At the time of writing, there were over 2.5 million worldwide recorded cases of COVID-19, and approximately 178,000 deaths across 213 countries[5]. This has led to a worldwide scientific research and development push to identify how to rapidly detect infected persons, provide an acute treatment for those infected, as well as a race to find a vaccine and shorten both its development and time to authorisation. Indeed, more than 80 vaccines are currently in the development pipeline[21]. This has not only put pressure on and disrupted the clinical development space, with non COVID-19 related trials being put on hold or slowed[22] but has also heightened regulatory agency activity to provide timely authorisation to begin COVID-19-related clinical trials. This need has seen new pathways being developed to ensure that specific medical countermeasures can be developed in a timely manner e.g. the US FDA CTAP programme. These pathways have been supported by specific task forces within agencies and used alongside existing authorisation pathways to ensure timely evaluation and resource coordination.

Stakeholder knowledge sharing in the age of COVID-19

The current pandemic has promoted coordination and convergence across agencies, and this has been demonstrated by the International Coalition of Medicines Regulatory Authorities (ICMRA), which held a regulatory workshop (virtually) on 2 April 2020 to discuss the ongoing COVID-19 pandemic and agreed to regular exchanges between agencies. It brought together 28 medicines regulatory authorities and experts from the WHO to discuss the available knowledge on possible treatments (drugs and biologics) for COVID-19. The group agreed to exchange information about studies and results from COVID-related research to help support a coordinated global approach. The group also agreed that trials appropriately designed to meet regulatory requirements i.e. randomised controlled trials (RCTs) with an appropriate control arm, would be best for generating data that could lead to timely regulatory approval decisions and could guide clinicians in promptly identifying the best treatment options for COVID-19. To support these studies, the United States Pharmacopeia (USP) recommends developing guidelines for pragmatic clinical trials and design of real-world evidence studies to support the repurposing of approved products during health emergencies[23].

Although in the regulatory space coordination and information sharing has been initiated, in the development space there are concerns that different trials with the same medical intervention are being conducted and the lack of collaboration or coordination is resulting in possible duplicative efforts and the inefficient use of limited resources. However, a number of companies that are working on COVID-19 vaccines have come together through the WHO, committing to share data and strengthen cooperation to ensure a reduction in duplication of effort and improve efficiencies. Indeed, the WHO and partners have instigated the “Solidarity” trial, which is an international trial to help find an effective treatment for COVID-19; as of 21 April 2020, over 100 countries are working together to find effective therapeutics as soon as possible[24]. Such an endeavor is also planned for vaccines[25].

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[21] Bioworld (2020) Biopharma products in development for COVID-19. Accessed on 24 April 2020 at: https://www.bioworld.com/COVID19products#vac

[22] Bioworld (2020) Clinical trials of biopharma and med-tech products affected by COVID-19. Accessed on 22 April 2020 at: https://www.bioworld.com/COVID19clinical-affect

[23] USP (2020) Pandemic Preparedness for Regulators in Low- and Middle-Income Countries: Mitigating medical product shortages, preparing the public, and protecting patients during the COVID-19 pandemic and beyond. Available at: https://www.usp.org/sites/default/files/usp/document/our-work/global-public-health/gph-guidance-to-regulators-paper.pdf

[24] WHO (2020) “Solidarity” clinical trial for COVID-19 treatments. Accessed on 30 April 2020 at: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/solidarity-clinical-trial-for-covid-19-treatments

[25] WHO (2020) Update on WHO Solidarity Trial – Accelerating a safe and effective COVID-19 vaccine. Accessed on 30 April 2020 at: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/solidarity-trial-accelerating-a-safe-and-effective-covid-19-vaccine

Application of EUPs globally to tackle pandemics

As has been documented in this Briefing, EUPs to support public health constitute a broad range of diverse yet flexible regulatory pathways designed to address not only COVID-19 but also new unpredicted emerging diseases. These pathways can facilitate the development phase of new therapeutics and vaccines or can accelerate the assessment and access processes. The speed with which some of these COVID-19-specific pathways have emerged and how other established pathways are being used judiciously demonstrates that regulatory flexibility combined with political will can ensure that in pandemic situations, there are risk-based pathways to assure that all potential treatments can be developed, fairly assessed and ultimately made available to patients[26]. Indeed, within regulatory agencies such as EMA, an "open door policy" has been enacted for COVID-19 therapeutics explicitly addressing: informal acceptance of submissions to be either assessed by CHMP or forwarded to the EMA pandemic task force or Scientific Advice Working Party (SAWP) as appropriate; early rapporteur assignment; and the opportunity to benefit from rolling submissions. In March 2020 the G7 supported the launch of joint research projects for COVID-19 treatments and vaccines. Such high-level political participation will hopefully ensure synergistic efforts and global access to COVID-19 vaccines. For example, on 24 April 2020 the WHO launched the Access to COVID-19 tools (ACT) accelerator, which is a collaboration between the WHO and groups such as BMGF, CEPI, Gavi, Global Fund, UNITAID, Wellcome Trust, to speed up development, availability and equitable distribution of diagnostics, therapeutics and vaccines for COVID-19.

Over the last decade the regulatory landscape has seen an increase in pathways enabling the clinical development process i.e. increased interactions with regulators (such as with the US FDA Breakthrough Therapy Designation and the EU PRIME designation) to ensure efficient and effective development decisions. Many are also designed to expedite product authorisation using flexible concepts such as real-time, rolling reviews, priority assessments and conditional approvals.
This means that the pathways that agencies have in place can be used effectively to facilitate access to promising treatments for high unmet medical need in times of heightened public health need.

Applicability of EUPs to LMICs

These considerations are equally important for LMICs where regulatory systems may not be able to address the immediate needs posed by infectious pandemics. Indeed, the USP has identified five strategies that LMICs can use to address these emergency situations. Among these and consistent with the observations in our report, the USP has advised that guidances must be developed on regulatory preparedness for emergency use authorisation and ethical principles for ensuring medical product quality assurance during disease outbreaks. Many countries currently do not have the regulatory tools to use new products or formulations during health emergencies. USP recommends that regulators should continue to seek guidance from the WHO on emergency use of medical products during public health emergencies and that regulatory authorities in LMICs should build on previous collaborations to share both confidential and public information expeditiously, enabling timely local decision making[19]. We concur that such reliance models represent efficient and effective EUP approaches to addressing critical needs, especially in poorly-resources regulatory agencies. In addition, enhanced monitoring and post-EUP risk management processes are important components to mitigate potential risks associated with EUPs.

These considerations also apply to the systems put in place by the WHO. For example, the prequalification route showed its benefits with regard to Ebola. Although the Merck vaccine Ervebo took about five years to develop, the WHO prequalified the vaccine approximately 36 hrs after the EU approval decision and had a procedure for regulatory cooperation to fast-track the vaccine in-country licensing. This achieved registration in about half a dozen countries within 90 days of the WHO decision. Countermeasures developed for COVID-19 must also be fast-tracked to LMICs; using the WHO EUPs will be critical to enable LMICs to have access to new vaccines and other quality, safe and effective counter measures.

[26] Mak Tippi K et al (2020) Global regulatory agility during covid-19 and other health emergencies, *BMJ* 369 :m1575. Available at: https://doi.org/10.1136/bmj.m1575

The importance of HTA considerations to enable access to pandemic treatments

In addition to our analysis of EUPs, we sought to understand how the Health Technology Assessment (HTA) bodies are addressing pandemic issues. It must be noted that when it comes to vaccines HTAs in many countries have different assessment pathways as their model, and in particular for pandemic vaccines, will be evaluating the benefits and effectiveness at a population level.

Our review of the reimbursement landscape demonstrated that HTA agencies are learning and providing proactive guidance on how to manage access to technologies associated with the COVID-19 pandemic. Many have launched dedicated online platforms containing evidence, tools and resources on a range of COVID-19 topics. The National Institute of Health and Care Excellence (NICE) has developed its first COVID-19 guidelines, which cover a range of topics including critical care in adults, the management of severe asthma and approaches to systemic anticancer treatment[27]. These are being developed using an interim approach and method for rapid guideline processing. In order to publish these guidelines quickly, they are kept under review as new evidence is generated. The rapidly developed guidelines and evidence summaries are also exempt from overseas reuse application, which will allow other agencies to adopt and adapt the guidelines in their local healthcare context. In addition, NICE is offering free fast-track advice for researchers developing novel diagnostics or therapeutics for COVID-19 and has produced a draft guide to COVID-19 clinical evidence generation[28]. To address the most critical needs, NICE is revising timelines for non COVID-19 related recommendations or therapeutically critical products.

Final reflections

Our analysis has found that there are numerous regulatory routes that can be used to assess the multitude of new therapies and vaccines that emerge in response to a pandemic. In the case of COVID-19, the pandemic identified potential gaps in regulatory approaches, which can be addressed through the implementation of both COVID-19-specific pathways and general FRPs. Once we move into post-pandemic times, a new normal may emerge and the main issues that will have been highlighted by this pandemic will require countries and governments to confront how well were they prepared. Countries will also face lessons to be learned that could for a future pandemic, which will occur, help to mitigate the upheaval seen by this event.

"In any crisis, leaders have two equally important responsibilities: solve the immediate problem and keep it from happening again"

Bill Gates[29]

It will also be important for regulators to reflect on how their role affected the course of the pandemic. Based on the findings of this study, all of the agencies studied have the capacity to use flexible pathways for emergency authorisations. Indeed, within regulatory agencies such as EMA an open-door policy has been enacted for COVID-19 therapeutics. Although our analysis did not focus on medical devices or diagnostics, we recognise that countries must ensure timely access to qualified diagnostics for the infectious agent. The availability of effective tests has been widely divergent across jurisdictions and this will be one area in terms of the regulatory processes and procedures to be evaluated to ensure that the availability of fit-for-purpose tests can be expedited. Could a better understanding of the lessons learned lead to new models for other non-pandemic healthcare imperatives? How effectively these pathways will have been used will be the subject of future scrutiny.

The ultimate solution for a pandemic, as was observed with influenza and polio, is the availability of an efficacious vaccine. Because of the unpredictable nature of infectious transmissions, a pandemic vaccine will be challenging to develop in advance. Although some agencies have developed pathways that allow registration of 'pandemic preparedness vaccines' for influenza, which mimic future pandemic vaccines in terms of composition and manufacturing but contain a different virus

[27] NICE (2020) Coronavirus (COVID-19). Accessed on 22 April 2020 at: https://www.nice.org.uk/covid-19

[28] NICE (2020) NICE Scientific Advice Guide for COVID-19 evidence collection – April 2020. Accessed on 22 April 2020 at: https://www.nice.org.uk/Media/Default/About/what-we-do/Scientific-advice/COVID-19-scientific-advice-for-evidence-collection.pdf

strain, unfortunately these cannot be directly used for COVID-19. The need to accelerate the development of a vaccine is seen as critical, not only regarding the direct health benefits but also as social and economic imperatives of the global community.

Currently the majority of medical countermeasures being considered for COVID-19 are repurposed medicines that can be developed more rapidly. The delay between the onset of a pandemic and the emergence of an effective countermeasure or herd immunity can be serious disincentives to the development of innovative new therapeutics. However, the global nature of this pandemic is seeing efforts to accelerate the development of a novel vaccine.

In final analysis, the novel pathways for the registration of pandemic-related therapies must be fully tested and refined. Based on our review we have found that many agencies have in place mechanisms to enable quick decision making to ensure the quality and the benefit-risk balance of new pandemic-related treatments. In addition, we are seeing that the mechanisms put in place for technical cooperation amongst regulators prior to the pandemic are helping facilitate experience sharing and cooperation across agencies during the pandemic. Will this cooperation continue when it comes to ensuring rapid regulatory review of new treatments, will regulators and companies be willing to work together on simultaneous regulatory evaluation of products, or will there be a delay built in utilising current sequential models? In a post-pandemic setting could this lead to expanded models of cooperation, either through work sharing or trust mechanisms to help leverage comparable agencies decisions? One test of this cooperation will be regarding how well-resourced countries were able to support LMICs either directly or through collaboration with the WHO. We will learn through the passage of time as agencies consider what is needed to authorise a therapy for their jurisdiction.

As governments and regulatory agencies tackle the challenge recently raised by Bill Gates[29] to solve the immediate problem, from the regulatory perspective in the countries studied, we conclude that emergency use pathways are in place. A number of these have evolved based on the call from the WHO over the last decade to prepare for pandemics, as well as those early access pathways built in by agencies to ensure flexibility so as to meet unmet medical needs. Implementing learning from the use of these pathways by well-resourced countries and LMICs, will be up to the WHO, society, scientists, epidemiologists and governments to put investment in long-term strategies, so these learnings are not forgotten when the current turmoil recedes. For the regulatory systems it will be important to ensure that when the next pandemic occurs, the processes and procedures are in place to prevent delays in responding appropriately.

[29] Gates B. (2020) Perspective: Responding to Covid-19 – A Once-in-a-Century Pandemic? *New England Journal of Medicine.* DOI: 10.1056/NEJMp2003762

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About CIRS

The Centre for Innovation in Regulatory Science (CIRS) is a neutral, independently managed UK-based subsidiary company, forming part of the Clarivate Analytics group. CIRS' mission is to maintain a leadership role in identifying and applying scientific principles for the purpose of advancing regulatory and HTA policies and processes. CIRS provides an international forum for industry, regulators, HTA and other healthcare stakeholders to meet, debate and develop regulatory and reimbursement policy through the innovative application of regulatory science and to facilitate access to medical products through these activities. This is CIRS' purpose. CIRS is operated solely for the promotion of its purpose. The organisation has its own dedicated management and advisory boards, and its funding is derived from membership dues, related activities, special projects and grants.

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