

Report on the review of regulatory flexibilities/agilities as implemented by National Regulatory Authorities during Covid-19 pandemic –December 2020

Disclaimer: This report is meant to inform discussion amongst ICMRA authorities and authorities of other WHO members states on regulatory flexibilities/agilities in the context of COVID-19, other pandemics/emergency situations and routine regulatory conditions. It is not meant to infer WHO or ICMRA endorsement of the examples described herein, including Appendix 2.

1. Background

The Covid-19 pandemic has created unprecedented demand on World Health Organization (WHO) Member States' health care systems and has led to an urgent need for access to health products. In addition, while necessary to combat the pandemic, restrictions and public health measures have impacted the usual processes that National Regulatory Authorities (NRAs) and manufacturers use to support development and access to medical products that are needed for Covid-19 and other public health programmes. In response, NRAs and regional regulatory systems (RRS) have acted quickly to implement agile regulatory processes that enable continued routine regulatory oversight while facilitating timely access to Covid-19 and non-Covid-19 related products.

2. Objectives

The objective of the review exercise was to provide options to facilitate regulatory responses to the COVID-19 pandemic by identifying and collecting the practices on regulatory flexibilities/agilities from the published and implemented documents by different NRAs to:

- 2.1 facilitate development and access to Covid-19 related commodities.
- 2.2 facilitate access to other health commodities and managing shortages during the COVID-19 pandemic period and related restrictions.
- 2.3 facilitate continuity of regulatory services during Covid-19 related restrictions.

3. Scope and limitations

- 3.1 The review was limited to regulatory flexibilities/agilities for therapeutics/medicines, vaccines and medical devices (including in-vitro diagnostics (IVDs)).
- 3.2 The review focused on documents that were published in English or with English-translated versions
- 3.3 The review focused on documents that were published between February and June 2020.
- 3.4 The exercise did not involve asking all WHO Member States to share their flexibilities/agilities but only those that were published including those from some well-functioning and advanced (former SRAs¹ and/or WHO GBT²-Maturity Level 3) NRAs.
- 3.5 The review did not include comparisons of flexibilities within the same product type and/or regulatory function and/or among NRAs.
- 3.6 This exercise did not include the review of the effectiveness of the measures and the related challenges in implementing them. Apart from discussions within the committee, the review team didn't conduct any interviews with the NRAs to collect and assess their feedback on the experiences and lessons learnt from implementing the flexibilities/agilities.

¹ SRAs: As defined by ICH membership before October 2015

² GBT: Global Benchmarking Tool

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3.7 *Disclaimer:* The agilities that are presented here are not necessarily endorsed by WHO and ICMRA nor applicable in all jurisdictions.

4. Process and methodology

The review exercise was performed in the following 3 phases between May and September 2020 through virtual meetings (teleconferences):

4.1 **Phase 1:** Identification of the relevant published documents and related web links.

4.2 **Phase 2:**

- Reviewing and summarizing the flexibilities/agilities using a custom designed MS Excel template.
- Categorizing the regulatory flexibilities/agilities into different product types (medicines/therapeutics, vaccines and medical devices+ In-vitro diagnostics) and regulatory functions/activities (such as GMP, GDP, Clinical trial oversight).

4.3 **Phase 3:**

- Identification of practices from the different documents using principles of the WHO Good Regulatory Practices (GRP) guidance and collective experiences of group members.
- Validation review by the group members to ensure that the work done met the 3 objectives of the exercise.

5. Summary of the observations on implemented flexibilities/agilities

- The exercise reviewed 52 published guidance notes/documents (Appendix 1) from 19 NRAs and other health institutions including ministries of health. The 19 NRAs and other institutions represented Member States from 5 WHO regions (AFRO, AMRO/PAHO, EURO, SEARO and WPRO).
- The majority (about 63%) of the regulatory flexibilities/agilities were targeted at facilitating production and access to Covid-19 medical products of which about 50% focused on medical devices including IVDs and the other 50% on medicines and vaccines.
- Clinical trials oversight and marketing authorisation/approval (MA) were the most targeted regulatory functions/activities across the different product types.
- The review showed that there has been an increase in the level and scope of regulatory oversight for quality, safety and performance of medical devices/products particularly for personal protective equipment (PPE) and other products such as disinfectants and hand sanitizers.
- The review also observed an introduction of remote monitoring in clinical trials and remote/virtual inspections for manufacturing and clinical trial sites as part of flexibilities/agilities to continue providing regulatory services covering Covid-19 and non-Covid-19 products.
- The review observed an increase in the involvement and/or functions of NRAs in early detection, management and communication of possible shortages. Some NRAs have implemented flexibilities/agilities to allow importation and/or use of unregistered alternative products and also allow risk-based postponement of certain post MA changes, deviations, qualifications and validations with justifications to ensure continuity of supply chains and avoid possible shortages.
- The review observed an increase in the adoption, implementation and use of registration pathways involving reliance and mutual recognition for Covid-19 products.
- The review also showed that NRAs have implemented flexibilities/agilities to encourage manufacturers in early engagement with the authorities such as through pre-submission briefs/meetings as well as allow for “rolling submissions” of applications for MA.
- The review had also observed increased communication by NRAs to stakeholders with technical information related to quality, safety and efficacy/performance of products.

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- The review saw an increased implementation of Emergency Use Authorization (EUA) pathways to facilitate time-limited use of unlicensed/non-prequalified medical products having inadequate data to support full licensing/approval/prequalification. Applicants and sponsors have been requested to assure continued, robust product monitoring and commitment to continue generating evidence towards full licensing or prequalification.

6. Examples of agilities/flexibilities for consideration

The summarized and collated examples of the flexibilities/agilities that have been implemented and may be considered by other NRAs for adoption and adaption to their respective regulatory frameworks and systems are presented in Appendix 2.

7. Recommendations and future steps

The following are the recommendations and proposed future (next) steps that may be considered going forward as observed from the review exercise:

7.1 Share experiences and knowledge gained on the effectiveness of regulatory agilities put in place following an adequate period of implementation. Agilities may fall into three categories:

7.1.1 Measures/workarounds that are unique to the current pandemic, including those deemed to be of limited or no added value in facilitating access to COVID-19 therapeutics/vaccines/devices or facilitating non COVID-19 regulatory activities.

7.1.2 Best practices that may also be applicable for other potential pandemics or crisis scenarios.

7.1.3 Best practices that may also be effective in the context of normal regulatory activities, for possible inclusion in official WHO written standards or guidance documents.

7.2 Without prejudging the value of certain practices beyond the current pandemic, the following practices were identified as further deep dives:

- ✓ Remote inspections and virtual approaches, (*in progress – ICMRA*³)
- ✓ Acceleration of timelines for approvals (regulatory activities), (*Initiated by WHO/ICMRA*)
- ✓ Reduction of local requirements (sealing, signatures, paper documents), (*under consideration by ICH*)
- ✓ Shortage monitoring, (*in progress – WHO/ICMRA*)
- ✓ Emergency procedures for access to medicines (off label authorized/not authorized), (*Initiated- WHO/ICMRA*)

8. Appendices

- Appendix 1: Reference guidance notes/documents from NRAs and other health institutions
- Appendix 2: Examples of agilities/flexibilities for consideration

9. Contributors

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³ ICMRA: International Coalition of Medicines Regulatory Authorities

APPENDIX 1: REFERENCE GUIDANCE NOTES/DOCUMENTS FROM NRAS AND OTHER HEALTH INSTITUTIONS
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Disclaimer: The review team didn't conduct any interview with the NRAs below to collect and assess their feedback on the experiences and lessons learnt from implementing the flexibilities/agilities within their respective jurisdictions.

SN	NRA	DOCUMENT TITLE	WEB LINK
1	SING-HSA	Import of Hand Sanitisers, Masks, Thermometers and Protective Gear	https://www.hsa.gov.sg/announcements/regulatory-updates/import-of-hand-sanitisers-masks-thermometers-and-protective-gear
2	USFDA	Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the FD&C Act	www.fda.gov/media/136486/download
3	JP_PMDA	Handling on adverse drug reaction reports of medical products in dealing with COVID-19 (Administrative Notice dated March 9, 2020) → The notice permits that adverse drug reaction reports can be simplified (including omission of seal) during COVID-19 pandemic.	https://www.pmda.go.jp/files/000238327.pdf
4	SAHPRA	SAHPRA responds to coronavirus (COVID-19): Medicines/medical devices supply challenges	http://www.sahpra.org.za/wp-content/uploads/2020/03/Report-Shortages_FINAL_17March.pdf
5	ANSM	COVID-19 Inspections	https://www.ansm.sante.fr/Activites/Processus-d-inspection/COVID-19-Inspections-Mesures-administratives/(offset)/0#med
6	AU_TGA	COVID-19 limits on dispensing and sales at pharmacies	https://www.tga.gov.au/media-release/covid-19-limits-dispensing-and-sales-pharmacies
7	JP_PMDA	Handling on clinical trial notifications of COVID-19 (Administrative Notice dated March 19, 2020) → The notice permits that clinical trials on COVID-19 can be started without waiting 30 days after the submission of clinical trial notification if investigation by PMDA is completed	https://www.mhlw.go.jp/hourei/doc/tsuchi/T20032310040.pdf
8	AU_TGA	Exemption for coronavirus (COVID-19) medical devices	https://www.tga.gov.au/exemption-coronavirus-covid-19-medical-devices
9	SING-HSA	HSA Expedites Approval of COVID-19 Diagnostic Tests in Singapore via Provisional Authorisation	https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-expedites-approval-of-covid-19-diagnostic-tests-in-singapore-via-provisional-authorisation
10	IN-CDSO	Circular regarding procedure for lot release of Human vaccine in view of prevailing COVID-19 pandemic	*

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11	CA_HC	Exceptional Access to Drugs	https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/covid19-interim-order-drugs-medical-devices-special-foods/information-provisions-related-drugs-biocides.html
12	CA_HC	Diagnostic Devices	https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19.html
13	CA_HC	Exceptional Access to Medical Devices	https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/covid19-interim-order-drugs-medical-devices-special-foods/medical-device-exceptional-import.html
14	UK_MHRA	Exceptional GMP flexibilities for medicines imported from third countries during the coronavirus (COVID-19) outbreak	https://www.gov.uk/guidance/exceptional-gmp-flexibilities-for-medicines-imported-from-third-countries-during-the-coronavirus-covid-19-outbreak
15	AU_TGA	Expedited COVID-19 medical device application process	https://www.tga.gov.au/expedited-covid-19-medical-device-application-process
16	UK_MHRA	Exceptional good distribution practice (GDP) flexibilities for medicines during the coronavirus (COVID-19) outbreak	https://www.gov.uk/guidance/exceptional-good-distribution-practice-gdp-flexibilities-for-medicines-during-the-coronavirus-covid-19-outbreak
17	JP_PMDA	Handling on review of COVID-19 clinical trials by Institutional Review Board (IRB) (Administrative Notice dated April 1, 2020)	https://www.pmda.go.jp/files/000234902.pdf
18	Swissmedic	Federal Council introduces measures to counter shortages of essential medical supplies for combating the COVID-19 pandemic	https://www.swissmedic.ch/swissmedic/en/home/news/coronavirus-covid-19/br-versorgungsengepaesse.html
19	JP_PMDA	Handling on the storage of informed consent forms during clinical trials (Administrative Notice dated April 7, 2020) → The notice permits that alternative method can be used when signed informed consent forms are difficult to be stored because of infection etc. in clinical trials for patients with infectious disease.	https://www.mhlw.go.jp/hourei/doc/tsuchi/T20040810010.pdf
20	INDO-BADAN POM	Establishment of Drug Guidelines in the Handling of Corona Virus Disease 2019 (COVID-19)	**

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21	JP_PMDA	Handling on regulatory reviews of drugs, medical devices, IVDs, and regenerative medical products for the time being associated with COVID-19 (Administrative Notice dated April 13, 2020) → The notice writes that medical products related to COVID-19 are subject to priority review.	https://www.mhlw.go.jp/hourei/doc/tsuchi/T200415I0010.pdf
22	ANSM	Ce document fournit certaines orientations aux demandeurs et titulaires d'autorisations de mise sur le marché de médicaments à usage humain sur les attentes réglementaires ainsi que les adaptations possibles pendant la pandémie de COVID-19 en complément des adaptations déjà prévues au niveau européen et qui s'appliquent pour les procédures nationales. (French)	https://+K43+C42:L43+K43+C42:L43+C42:M43+C42:N43+C42:M43
23	swissmedic	Pharmacovigilance: change in procedure for requesting follow-up information for individual case safety reports	https://www.swissmedic.ch/swissmedic/en/home/news/coronavirus-covid-19/pharmakovigilanz-geaendertes-vorgehen-follow-up-info.html
24	JP_PMDA	Handling on regulatory reviews of disinfectant as newly designated quasi-drugs for the time being associated with COVID-19 (Administrative Notice dated April 24, 2020)	https://www.pmda.go.jp/files/000234940.pdf
25	USFDA	Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency	www.fda.gov/media/136238/download
26	USFDA	Post marketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic	www.fda.gov/media/72498/download
27	swissmedic	Placing on the market of important medical devices for combating the COVID-19 pandemic	https://www.swissmedic.ch/swissmedic/en/home/medical-devices/market-surveillance-of-medical-devices/announcements-on-market-control-issues/inverkehrbringung-lebenswichtiger-beatmungsgeraete.html
28	Swissmedic	Australia, Canada, Singapore, Switzerland Consortium regulators pledge support to tackle COVID-19	https://www.swissmedic.ch/swissmedic/en/home/news/coronavirus-covid-19/durchfuehrung-inspektionen-waehrend-covid.html
29	swissmedic	Inspections in Switzerland during the COVID-19 pandemic	https://www.swissmedic.ch/swissmedic/en/home/news/coronavirus-covid-19/durchfuehrung-inspektionen-waehrend-covid.html
30	Public Works and Government Services Canada	Specifications for COVID-19 Products	https://buyandsell.gc.ca/specifications-for-covid-19-products
31	Swissmedic	Update on inspections in Switzerland during the COVID-19 pandemic	https://www.swissmedic.ch/swissmedic/en/home/news/coronavirus-covid-19/durchfuehrung-inspektionen-waehrend-covid.html

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32	SING-HSA	Guidance on 3-D Printing of Essential Medical Devices and Accessories for Use in COVID-19 (Coronavirus Disease 2019) Situation	https://www.hsa.gov.sg/announcements/regulatory-updates/guidance-on-3-d-printing-of-essential-medical-devices-and-accessories-for-use-in-covid-19-%28coronavirus-disease-2019%29-situation
33	UK_Health and Social	Technical Specifications for Personal Protective Equipment (PPE)	https://www.gov.uk/government/publications/technical-specifications-for-personal-protective-equipment-ppe
34	JP_PMDA	Handling on regulatory reviews of medical products against COVID-19 (PSEHB/PED Notification No. 0512-4, PSEHB/MDED Notification No.0512-1 May 12, 2020)	https://www.pmda.go.jp/files/000235010.pdf
35	JP_PMDA	Handling of implementation guidelines for document-based conformity inspection and GCP on-site inspection for the time being associated with COVID-19 (Administrative Notice dated May 12, 2020)	https://www.pmda.go.jp/files/000235011.pdf
36	EMA	Guidance on remote GCP inspections during the COVID-19 pandemic	https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guidance-remote-gcp-inspections-during-covid-19-pandemic_en.pdf
37	MHRA	Guidance on Managing clinical trials during Coronavirus (COVID-19)	https://www.gov.uk/guidance/managing-clinical-trials-during-coronavirus-covid-19
38	EU_EMA	Regulatory flexibility guidance	https://ec.europa.eu/health/sites/health/files/human-use/docs/guidance_regulatory_covid19_en.pdf
39	JP_PMDA	Q&A on clinical trial of drugs, medical devices, and regenerative medical products under the influence of COVID-19 → The notice permits flexibility in handling investigational products and having IRB.	https://www.pmda.go.jp/files/000235164.pdf
40	DMA	Several actions taken to ensure the supply of medicine during COVID-19	https://laegemiddelstyrelsen.dk/en/news/2020/several-actions-taken-to-ensure-the-supply-of-medicine-during-covid-19/
41	CA_HC	Hard Surface Disinfectants and Hand Sanitizers	https://www.canada.ca/en/health-canada/services/drugs-health-products/disinfectants/covid-19.html
42	AU_TGA	Post market review of COVID-19 point-of-care tests	https://www.tga.gov.au/post-market-review-covid-19-point-care-tests
43	UK_MHRA	MHRA regulatory flexibilities resulting from coronavirus (COVID-19) – covering: Blood components for transfusion; Clinical trials; Inspections and good practice; Medical Devices; Medicines regulation; Pharmacovigilance.	https://www.gov.uk/guidance/mhra-regulatory-flexibilities-resulting-from-coronavirus-covid-19

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44	SING-HSA	Guidance on Medical Devices for Decontamination of Single Use Respirators during the COVID-19 (Coronavirus Disease 2019) Situation	https://www.hsa.gov.sg/announcements/regulatory-updates/guidance-on-medical-devices-for-decontamination-of-single-use-respirators-during-the-covid-19-%28coronavirus-disease-2019%29-situation
45	swissmedic	Clinical trials on medicinal products - Pandemic by SARS-CoV-2	https://www.swissmedic.ch/swissmedic/en/home/news/coronavirus-covid-19/klv-cov-2-pandemie-2.html
46	swissmedic	Ordinance on Measures to Combat the Coronavirus (COVID-19 Ordinance):	https://www.admin.ch/opc/en/classified-compilation/20200744/index.html
47	Swissmedic	Joint Guidance of Swissmedic and swissethics on the management of clinical trials with medicinal drug products in Switzerland during the COVID-19 pandemic	https://www.swissmedic.ch/swissmedic/en/home/news/coronavirus-covid-19/klv-cov-2-pandemie-2.html
48	swissmedic	COVID-19: Exceptions from import provisions for medicinal products	https://www.swissmedic.ch/swissmedic/en/home/news/coronavirus-covid-19/covid-19-ausnahmen-einfuhrbestimmungen-am.html
49	SP_EMPS	Guidance on exceptional measures on clinical trials and observational studies to handle problems arising from COVID-19 emergency. - Dedicated webpage with the repository of guidance and updates regarding COVID19	https://www.aemps.gob.es/la-aemps/ultima-informacion-de-la-aemps-acerca-del-covid%E2%80%9119/
50	TGA	Discontinuation of Nardil (phenelzine sulfate)	https://www.tga.gov.au/sites/default/files/phenelzine-nardil-discontinuation.pdf
51	SING-HSA	HSA's Regulatory Position on Respiratory Devices: Supply for Management of COVID-19 Patients	https://www.hsa.gov.sg/announcements/regulatory-updates/hsa-regulatory-position-on-respiratory-devices-supply-for-management-of-covid-19-patients
52	SAHPRA	Guidance on good practice (GXP) inspections during emergencies/disasters including the COVID- 19 pandemic	Guidance-on-Good-Practice-GxP-Inspections-During-the-Pandemic.pdf (sahpra.org.za)

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https://cdsco.gov.in/opencms/opencms/system/modules/CDSKO.WEB/elements/download_file_division.jsp?num_id=NTgxNg==

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https://jdih.pom.go.id/produk/KEPUTUSAN%20KEPALA%20BPOM/Kep%20KBPM%20tentang%20Pedoman%200bat%20dalam%20Penanganan%20COVID%2019_Lengkap.pdf

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The following are the summarized and collated examples of the flexibilities/agilities that have been implemented and may be considered by other NRAs for adoption and adaption to their respective regulatory frameworks and systems.

***Disclaimer:** The effectiveness of the example of agilities listed here has not been reviewed and the examples are not necessarily endorsed by WHO and ICMRA nor applicable in all jurisdictions. However, the examples are provided as options for consideration by NRAs for implementation with or without adaptation to their respective needs.*

10. Clinical trial oversight flexibilities/agilities through:

- Expedited review of clinical trials facilitated by:
 - Simplification of submission procedures. For example, in Japan, the “Handling on clinical trial notifications of COVID-19 (Administrative Notice dated March 19, 2020)” permits that clinical trials on COVID-19 can be started without waiting 30 days after the submission of clinical trial notification if investigation by PMDA is completed.
 - Allowing for virtual meetings of institutional review board (IRB)/ independent ethics committee (IEC)/ ethical review board (ERB), where appropriate.
- Prioritizing reviews and authorizations of actionable studies which are nationally or regionally or globally sponsored for COVID-19 research.
- Mitigating the receiving processes of the investigational products.
- Accepting signed copies or electronic signatures on original documents instead of “legal seals”.
- Allowing remote monitoring of trials.
- Allowing some justified protocol deviations without Authority notification. However, sponsors are required to properly maintain the documentation to enable appropriate evaluation of trials.
- Allowing home delivery of IMP where participants cannot attend trial site without amendments.
- Rescheduling or postponing clinical visits by authorities with risk-based justifications.
- Substituting GCP on-site inspection in clinical trial sites with relying on the confirmation of the management on clinical trial sites by sponsors.
- Facilitating quicker alternative routes of communication with regulatory bodies, for example increased use of electronic communication than meeting and surface mails.
- Allowing alternative means of obtaining patient consent such as remote written or non-written informed consent.
- Broadening criteria of qualified health professionals who can carry out investigator duties, including at remote sites.
- Introducing or strengthening the ability of the authorities to suspend or cancel a trial in whole or in part, and the power to add Terms and Conditions to manage or mitigate risk.
- Reducing notification requirements for non-significant changes to authorized trials.

11. Registration and Market authorization flexibilities/agilities which:

- Promote the use of IT measures and electronic exchange of information between the NRA and applicants.

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- Allow applicants to submit clinical trial data from platform trials (e.g. SORIDATY, RECOVERY, REMAP-COVID, ANTICOV, COMMUNITY), funded by public sector instead of the clinical trial data conducted by sponsor in compliance with the related law.
- Provide for the expedited review/authorization of priority products for the management of on current pandemic, e.g. COVID-19.
- Allow for the increased implementation of rolling submission procedures.
- Promote the use of consortiums or work-sharing initiatives to review applications for priority products.
- Suspend time limits for response to assessment questions.
- In the EU, promoting zero-day mutual recognition/repeat use procedure that expands/extends the granted Market Authorization (MA)/registration from one Member State to others who need the medicinal products for COVID-19 patients in their countries.
- Allow for justified postponement of submitting complete dossiers by MAH for those MAs that are about to end and are having challenges to submit renewal applications.
- Provide for the postponement of “Sunset clause” or similar requirement based on justified requests from the MAH. This is where MAHs may not be able to place the authorized product on the market within the period of three consecutive years before the authorization for that product ceases to be valid.
- Allow for EUA pathway which is conditional, time limited and may be revoked by the issuing Authority.
 - The EUA pathway requires robust safety and efficacy monitoring and continued progress generating evidence to support full licensure/registration or prequalification.
- Provide for the implementation of “Compassionate use” or exceptional authorization of the distribution and use of unlicensed medicinal product.
- Enable the national public health authority to import promising COVID-19 drugs for placement in facilities before they are authorized.

12. Inspections (GMP, GCP, GDP/Import & Export, GLP) flexibilities/agilities through:

- Relaxing of import control procedures by leveraging on the existing administrative processes for enforcement discretion.
- Developing and using of a List of Drugs for Exceptional Importation and Sale.
- Implementing fast-track procedures for the certification of manufacturing facilities producing drugs to treat Covid-19.
- Extending the validity of GxP compliance based on risk management principles.
- Allowing distant or virtual (remote) inspections.
- Accepting signed copies or electronic signatures instead of legal seals or original signatures.
- Allowing for time-limited qualification of premises and equipment with risk-based justifications.
- Allowing supplier/vendor requalification through risk-based approaches and third-party reliance approaches.
- Waiving of pre-/post-shipment testing of imported products.
- Allowing vaccines lot release based on review of summary lot protocol only (risk-based testing for lot release function).
- Applying qualified pharmacist/personnel (QP) discretion in dealing with minor deviations that do not affect the safety and efficacy of products during certification and release.
- Using QRM for the relaxation of post-MA changes/amendments obligations.
 - Allowing “small changes as defined by NRA” based on QRM to be implemented without waiting for approval from the NRA.
- Leveraging on existing administrative processes for enforcement discretion (e.g., non-compliant labelling, shelf-life extension, and authorization in other countries)

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- Allowing the over-labelling & extending the permitted implementation period.

13. Post approval activities and Pharmacovigilance flexibilities/agilities by:

- Using QRM for relaxation of post-MA changes/amendments obligations.
 - Exceptional change management process or similar approaches made available to MAHs of crucial medicines such as changes to suppliers and/or manufacturing/control sites that are necessary to reduce the risks of shortages.
- Allowing supplier/vendor requalification through risk-based approaches on third party reliance and distributors to perform risk-based qualifications including retrospectively.
- Introducing modifications in mandatory post-marketing adverse event reporting procedures, including deadlines and route of reporting.
- Relaxing of the requirement for a seal on submissions, for example, accepting adverse drug reaction reports with a handwritten signature in lieu of a seal of the representative.
- Reducing number of requests for follow-up information when relevant details for assessing the case are missing.

14. Flexibilities/agilities facilitating access and managing shortages through:

- NRAs to update national legislations and regulations to provide for measures to address shortages.
- Introduction of requirement for early notification of potential shortages by manufacturers and other stakeholders
- Implementing controls and impose limits on purchase of certain medicines and other products to avoid out-of-stock situation.
- Implementing priority and expedited assessments for national variations for authorizations impacting supply chains.
- Allowing access to unlicensed and “NRA” specified products through alternative pathways.
- Recommending the switch to alternative treatments where continued supply of required medicines cannot be guaranteed for new and existing patients.
- Providing detailed clinical advice on switching treatments and key points to consider.
- Promoting joint regional initiatives on pool procurements of large consignments of certain medicines.
- Approving the importation of essentially identical medicinal products as a short-term solution.

15. Medical Devices (including PPE) and Sanitizers flexibilities/agilities to:

- Expedite authorization of biocide drugs (e.g. hard surface disinfectants and hand sanitizers), which are critical to irreversibly destroy or reduce viruses.
- Waive MA requirement for hand sanitizers.
- Waive import licenses (permits) for identified and published PPEs and other related products.
- Waive requirements to submit any notification of importation of identified and published medical devices for personal use against COVID-19 up to defined limits.
- Allow certain devices that may not fully meet regulatory requirements but are manufactured according to comparable standards to be included on the list of medical devices for exceptional importation and sale.
- Allow importers to bring designated medical devices into countries without meeting some of the requirements under the Medical Devices Regulations with risk-based justifications.
- Grant exemptions for the import and authorization of medicinal products and for non-CE-certified medical devices whenever the epidemiological situation demands it and based on the applicable risk-benefit analyses.

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- Allow the placement on the market of unauthorized medical devices as long as their effectiveness and performance are proven (with documented evidence).
- Waive evaluations/assessments of PPEs for use against COVID-19 by way of reliance for quality as long as safety of the product can be guaranteed.
- Publish on the website of detailed technical specifications of various medicals devices and PPEs.
- Waive MA or post-MA change requirements for the use of approved/registered anesthesia machines and positive airway pressure devices as emergency ventilators through national risk-benefit approaches based on safety and performance.