Annex 2

Guidelines on regulatory preparedness for the oversight of pandemic or other emergency use vaccines in importing countries

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Guidelines published by the World Health Organization (WHO) are intended to be scientific and advisory in nature. Each of the following sections constitutes guidance for national regulatory authorities (NRAs) and for manufacturers of biological products. If an NRA so desires, these WHO Guidelines may be adopted as definitive national requirements, or modifications may be justified and made by the NRA.
Abbreviations

AEFI  adverse event(s) following immunization
COVID-19  coronavirus disease 2019
CTD  Common Technical Document
EUL  WHO emergency use listing
GRelP  good reliance practices
GMP  good manufacturing practice(s)
NCL  national control laboratory
NRA  national regulatory authority
PQ  WHO prequalification
RMP  risk-management plan
tWLA  transitional WHO Listed Authority
VIRAT  vaccine introduction readiness assessment tool
VRAF  vaccine readiness assessment framework
WLA  WHO Listed Authority
1. Introduction

Pandemics and other large-scale disease outbreaks caused by newly emerging or known pathogens affecting many people may result in severe disease burden and can claim millions of lives globally. Pandemics are usually caused by respiratory viruses – however, as such events may in future be caused by other pathogens, WHO continually reviews and updates its list of priority pathogens based on global scientific consensus (1).

Pandemic influenza viruses and newly emerging coronaviruses differ significantly from seasonally circulating viruses. Such viruses may evolve from viruses that previously only circulated in animals (for example, severe acute respiratory syndrome coronavirus 2) or from virus subtypes already circulating in humans (for example the 2009 A(H1N1) influenza (swine flu) virus). Due to lack of previous exposure to such viruses, the human population is considered to be immunologically naïve to them. As a result, pandemics and other large-scale disease outbreaks (such as the recent Ebola, Zika and cholera outbreaks) result in an urgent need for medical countermeasures, including vaccines, to limit their spread.

One of the highest priorities in ensuring global health security and protecting public health is to identify strategies that shorten the time required between the emergence of a pandemic virus or other human pathogen and the availability of safe and efficacious vaccines. Therefore, in the event of a pandemic or other public health emergency, the national regulatory authorities (NRAs) of vaccine-importing countries are strongly encouraged to apply procedures based on recognition of, or reliance on, the product evaluation and decisions made by reference NRAs, which may include the NRA of the vaccine-producing country.

The WHO Guidelines on regulatory preparedness for human pandemic influenza vaccines (2) were adopted in 2007 on the recommendation of the WHO Expert Committee on Biological Standardization. Following the subsequent 2009 H1N1 influenza pandemic, a lack of regulatory preparedness was identified as one of the factors that had delayed or in some cases prevented the deployment of pandemic influenza vaccines in importing countries. This was especially the case for vaccines intended for donation or deployed by United Nations agencies in response to the pandemic (3, 4). Therefore, the WHO Guidelines on regulatory preparedness for provision of marketing authorization of human pandemic influenza vaccines in non-vaccine-producing countries (5) were developed to provide guidance on appropriate regulatory approaches to the marketing authorization of such vaccines, and on their lot release during a public health emergency. These guidelines were developed in the context of the Pandemic Influenza Preparedness (PIP) Framework’s Partnership contribution implementation plan 2013–2016 for regulatory capacity-building and strengthening of pandemic preparedness and response (6).
Following the subsequent Ebola epidemic and coronavirus disease 2019 (COVID-19) pandemic, a need was identified to update the published guidelines and expand their scope to cover all vaccines used in pandemics or other public health emergencies, and to draw on the lessons learned during these emergencies. Furthermore, WHO global benchmarking tool assessments used to objectively evaluate national regulatory systems indicated a need to strengthen regulatory preparedness in countries for the timely approval of medical products during public health emergencies (7). Recently published or updated WHO guidelines and other guidance documents include:

- Good regulatory practices in the regulation of medical products (8);
- Good reliance practices in the regulation of medical products: high level principles and considerations (9);
- Guidelines on import procedures for medical products (10); and
- Guidance on development and implementation of a national deployment and vaccination plan for pandemic influenza vaccines (11).

Many of the principles outlined in these and other guidance documents have been incorporated into the current Guidelines.

2. Purpose and scope

This document provides guidance to NRAs of vaccine-importing countries (including countries supplied with vaccines through United Nations agencies, programmes and funds and/or other international/regional mechanisms, countries receiving donations of vaccines and countries which self-procure vaccines) on the regulatory oversight of vaccines used during pandemics or other public health emergencies. However, the principles set out may also apply to other medical products urgently needed during a pandemic or other public health emergency.

The aim of the document is to help such countries in preparing and establishing processes to expedite the provision of an authorization or emergency approval to use a hitherto unauthorized vaccine in an emergency, as well as to manage post-authorization procedures.

It is recognized that countries will already have national legislation and policies on the regulation of vaccines. Some countries may also have regulations in place on accepting donations of vaccines and ancillary products. Therefore, the current document is intended to provide general guidance and principles to the NRAs (or other bodies with appropriate legislative powers) of importing countries for evaluating vaccines specifically for use during a pandemic or other
public health emergency, and on establishing authorization procedures for the use of such vaccines.

A strong emphasis has been placed on the need to put in place risk-based decision-making processes that minimize duplication and make life-saving vaccines available for use without unnecessary delays during pandemics or other public health emergencies.

The document is intended for use by NRAs but will also be of interest to national immunization technical advisory groups, as well as to manufacturers and authorities in the private and public sectors responsible for importing, planning and managing vaccine deployment and vaccination operations at all levels. The current document should be used together with other relevant WHO guidelines.

3. Terminology

The following definitions apply to the terms as used in these WHO Guidelines. These terms may have different meanings in other contexts.

Authorization: an umbrella term which includes all types of authorization that may be given by an NRA regarding the use of a vaccine during a pandemic or other public health emergency. The authorization may refer to a marketing authorization or to an emergency authorization as defined below.

Emergency authorization: an early access mechanism with time limitation used by regulatory authorities to expedite the availability of new investigational/unauthorized vaccines during a pandemic or other public health emergency. In principle, this is granted if the known and potential benefits of the vaccine are considered to outweigh the known and potential risks, and upon meeting certain criteria (for example, that no alternative products are approved or available). In some jurisdictions, this is referred to as “emergency use authorization” or “conditional approval”.

Emergency use listing (EUL): a risk-based procedure used by WHO to assess and list unlicensed vaccines with the aim of expediting their availability during a pandemic or other public health emergency. It is expected that a manufacturer that applies for WHO EUL assessment of a vaccine will complete the development of the product prior to its submission for full marketing authorization and WHO prequalification (PQ) in the future.

Import authorization: the process undertaken by the NRA or designated institution to approve or authorize the importation of a vaccine into the country.

Importing country: a country that imports a vaccine produced in another country.

Interpandemic phase: the period between pandemics (12).
Joint review: a form of work-sharing in which a regulatory task such as the review/assessment of a vaccine is conducted by two or more NRAs in collaboration.

Marketing authorization: a procedure that is conducted by an NRA for the approval of a vaccine for marketing and use in the country, and which includes a process of evaluation to determine the quality, safety and efficacy of the product, the benefit–risk ratio and the appropriateness of the product information. This term may also be referred to as “licensing” or “registration” in other documents (13).

National pandemic preparedness plan: a national plan that aims to set out country-specific priorities and actions, and to identify the major components that must be put in place (for example, coordination, resource identification and allocation, and capacity-building) along with the capacities that should be strengthened to respond to a pandemic (14).

Pandemic phase: the period of global spread of a disease caused by a new virus (or new virus strain) or other pathogen. Progression from the interpandemic phase to the pandemic phase may occur quickly or gradually, as indicated by the global risk assessment principally based on virological, epidemiological and clinical data (12).

Pandemic preparedness vaccine: a vaccine developed and tested in anticipation of a pandemic, and manufactured using a virus strain believed to have similar characteristics to a potential pandemic virus strain (also referred to as “mock-up pandemic vaccine” or “vaccine against a novel virus” in other documents) (2, 15, 16).

Pandemic vaccine: a vaccine designed for use against a virus or other pathogen identified by WHO as the causative agent of a pandemic.

Prequalification (PQ): a procedure in which WHO applies international standards to comprehensively evaluate and determine whether vaccines are safe, effective and of adequate quality in order to advise United Nations agencies and countries on the suitability and acceptability, in principle, of vaccines being considered for purchase.

Public health emergency: an extraordinary event that is determined, as provided in the International Health Regulations (17), to: (a) constitute a public health risk to other States through the international spread of disease; and (b) potentially require a coordinated international response.

Recognition: a specific and formalized type of reliance in which an NRA (the relying NRA) accepts the regulatory decision of another NRA (the reference NRA) or the recommendation of a trusted institution (such as WHO). Recognition should be based on evidence that the regulatory requirements of the reference NRA or recommendations given by a trusted institution are sufficient to meet the regulatory requirements of the relying NRA. Recognition between NRAs may be unilateral or mutual and may, in the latter case, be the
subject of a mutual recognition agreement. The relying NRA remains responsible and accountable for decisions taken even when it recognizes the regulatory decisions of the reference NRA or the recommendations of a trusted institution.

**Reference NRA**: an NRA whose work or decisions are relied upon by the NRA of an importing country for the authorization and life-cycle management of vaccines used during a pandemic or other public health emergency. The choice of a reference NRA could be based on WHO Listed Authority (WLA) status, including transitional WLA (tWLA) listing (18), the designation of WHO maturity level 3 or 4 status, consultation with WHO, or other criteria acceptable to the NRA of the importing country. The WLA and tWLA listings can be found on the WHO website.⁷

**Reliance**: the act whereby a relying NRA takes into account and gives significant weight to assessments performed by another NRA (the reference NRA) or to recommendations given by a trusted institution (such as WHO), or to any other authoritative information, in reaching its own decision. The relying NRA remains independent, responsible and accountable for the decisions taken by it, even when it relies on the decisions, recommendations, assessments and information of the reference NRA or other trusted institution.

**Relying NRA**: an NRA that accepts, takes into account and/or gives significant weight to the decisions of a reference NRA, the recommendations of a trusted institution (such as WHO) and/or to the assessments performed by them, in reaching its own regulatory decisions.

**Risk-management plan (RMP)**: a plan containing information on a vaccine’s safety profile and on the measures to be taken to prevent or mitigate any risks associated with its use. The RMP is submitted by manufacturers as part of the marketing authorization dossier that is evaluated by regulatory authorities before a vaccine can be authorized, and is regularly updated by the manufacturer as new information becomes available.

**Variant**: an evolved virus that differs in its genetic information (that is, in its genome sequence) compared to the original virus.

**WHO Listed Authority (WLA)**: a regulatory authority globally recognized to be operating at an advanced level of performance, thereby replacing the procurement-oriented concept of “stringent regulatory authority”. The tWLA is a list of all regulatory authorities on the public WHO List of transitional WLAs (18). These NRAs are recognized by WHO to have achieved levels of operation necessary for the regulation of vaccines. The WHO List of tWLA is valid for 5 years from the date of publication of the final WLA Operational Guidance, during which time authorities will be evaluated against

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the requirements for designation as a WLA. A regulatory authority will move from tWLA to permanent WLA status upon successful completion of the WLA evaluation process.

4. General considerations

Countries should have a legal framework in place that requires all vaccines to be approved for use. However, marketing authorization of vaccines is not always possible during emergency situations and thus NRAs may need to authorize the use of vaccines following an expedited risk-based assessment of their public health needs. In the interpandemic phase, countries should review, and if necessary amend, existing legislation to allow for flexibility by the NRA in choosing an authorization pathway that addresses public health needs. The legal framework should be flexible enough to enable the NRA to apply recognition of, or reliance on, the decisions and work of reference NRAs and/or WHO recommendations for prequalification and/or emergency use listing (PQ/EUL), or to conduct a risk-based review of available safety, efficacy and quality data (see section 5 below for more details on each of these approaches).

All countries should prepare for public health emergencies, including pandemics, that may cause high morbidity and mortality, and lead to considerable social disruption. In 2013, WHO published updated pandemic preparedness guidance to reflect experience gained and lessons learned from the 2009 H1N1 influenza pandemic, and to support further preparedness efforts at national and subnational levels (12). The updated guidance sets out a risk-based approach that: (a) enables a more flexible response to different scenarios; (b) emphasizes the key importance of multisectoral and whole-of-society involvement in planning; and (c) uses a simplified pandemic phase structure that includes the interpandemic and pandemic phases.

Regulatory preparations for a pandemic or other public health emergency should be undertaken in order to strengthen the legal and regulatory framework, and to enable flexibility in the enforcement of requirements for importing and approving or authorizing a vaccine in emergency situations. This would include clearly defining the regulatory pathways to be used for the emergency authorization or marketing authorization of a new vaccine under emergency conditions (11). The WHO global benchmarking tool, whether through a formal process or a self-assessment process, can be used to identify gaps in the regulatory system and to ensure that countries have adequate oversight and capacities to regulate vaccines. This tool can be used in addition to other mechanisms for evaluating capacities under emergency situations such as the COVID-19 vaccine introduction readiness assessment tool (see section 4.1 below).
NRAs together with national immunization programmes, marketing authorization holders and other stakeholders should also develop strategies for enhanced post-authorization surveillance to monitor the safety and minimize the risks of vaccines used during a pandemic or other public health emergency. Such strategies should include considerations on risk communication and risk-management plans (RMPs), which are requirements of the marketing or emergency authorization process and often include post-authorization studies to further characterize important potential risks and to evaluate safety in special populations (for example, children, pregnant women, lactating women, immunocompromised individuals and people with pre-existing health conditions). As RMPs would also usually include reference to all ongoing studies including those in other countries, vaccine-importing countries should in the interpandemic phase evaluate legislative/regulatory requirements for post-authorization safety studies with the aim of reducing duplication and allowing for risk-based determination of the adequacy of data from other countries during a pandemic or other public health emergency. Detailed WHO guidance on safety monitoring and post-authorization surveillance procedures is provided in:

- Guidelines on regulatory preparedness for human pandemic influenza vaccines (2);
- Global manual on surveillance of adverse events following immunization (19);
- COVID-19 vaccines: safety surveillance manual (20); and
- Causality assessment of an adverse event following immunization (AEFI): user manual for the revised WHO classification (21).

The emergency procedures should also include processes for ensuring information management and effective communication, as well as cooperation, between different branches of the NRA and relevant stakeholders such as public health authorities, the national immunization programme, disease management programmes, the marketing authorization holder and others. (11, 22). Communication with other NRAs may also be necessary.

Plans should be developed and transparently shared with all stakeholders to address the need for official communication from the NRA relevant to specific audiences such as the general public, health care workers, national and subnational authorities, industry and international collaborators when needed. The principles set out in relevant WHO guidelines (23–25) should be followed. Communication and information-sharing systems should be established and implemented for all stakeholders (11). Prior to a pandemic or other public health emergency, these systems should be tested to build trust with the population and other audiences.
4.1 **The role of the NRA in the national pandemic and emergency preparedness plan**

A national pandemic and emergency preparedness plan should be developed and endorsed before a pandemic or other public health emergency arises. The plan should include acknowledgement of the roles and responsibilities of the NRA in the regulatory oversight of vaccines (11, 26).

Most countries developed and published their national pandemic influenza preparedness plans in 2005 and 2006, and updated them following the 2009 H1N1 influenza pandemic. During the COVID-19 pandemic, countries also used the vaccine introduction readiness assessment tool (VIRAT) to develop a roadmap to prepare for vaccine introduction and to identify gaps and areas for potential support – along with the vaccine readiness assessment framework (VRAF) to obtain granular information on gaps and associated costs, thus enabling the programming of financial resources for vaccine deployment. The VIRAT and VRAF tools have now been consolidated into the comprehensive COVID-19 vaccine introduction readiness assessment tool (VIRAT/VRAF 2.0) developed in 2020 (27).

Where necessary, countries should expand the scope of their national pandemic and emergency preparedness plans to cover any potential regulatory activities during a pandemic or other public health emergency. The national plan should be aligned with any existing regional or continent plans where possible. The plan should include strategies to facilitate the timely availability, distribution and administration of vaccines, while ensuring their quality, safety and efficacy.

4.2 **Considerations for national regulatory preparedness**

The NRA should be responsible for developing and implementing the following procedures to support the national pandemic and emergency preparedness plan and national vaccine deployment plan before a pandemic or other public health emergency arises (11).

4.2.1 **Strengthening the regulatory system**

- Mapping of existing regulatory processes and capacities in relation to recommended international standards such as the WHO global benchmarking tool, and implementing interventions to close identified gaps and strengthen the importing country’s regulatory system, particularly the sub-indicators related to regulatory preparedness.

- Developing a robust quality management system articulating risk-based thinking (28) and good reliance practices (GRelP) including information-sharing procedures, as appropriate, between the
importing country’s NRA and selected reference NRAs in the event of a pandemic or other public health emergency.

- Mapping of existing national, legal and regulatory frameworks for research, including other organizations that collaborate with the NRA in the approval of clinical trials (for example, an ethics committee) to support the conducting of such trials for novel vaccines, if required.

- Allocating resources to be used when a pandemic alert or other public health emergency has been declared by WHO and/or the responsible national authority.

4.2.2 Accelerating review and authorization

- Identifying potential reference NRAs/trusted institutions (for example, WHO) and establishing partnerships and collaboration with them as far as possible, for example through the signing of memoranda of understanding.

- Developing a system to accelerate the authorization of pandemic or other emergency use vaccines, and ensure the optimization of available resources in response to the pandemic or other public health emergency, that includes:
  - definition of regulatory pathways for review and/or approval (see section 5.1 below);
  - definition of requirements for the dossier or supporting documents required for evaluation by the NRA under the different regulatory pathways (see section 5.2 below);
  - a process allowing for recognition of the decision of, or reliance upon the expertise of, a reference NRA;
  - a process for granting emergency authorization of vaccines, including reliance on the WHO EUL procedure, when appropriate;
  - a process for expediting marketing authorization of vaccines recommended under WHO PQ, when appropriate;
  - a procedure for marketing authorization or emergency authorization of the pandemic or other emergency use vaccine through an independent review by the NRA of the vaccine-importing country if recognition or reliance cannot be implemented;
  - preparation of templates for emergency benefit–risk consideration and assessment reports during an emergency; and
a procedure for granting authorization to pandemic preparedness vaccines, if applicable.
• Developing procedures for joint review within established collaboration networks or through collaboration with reference NRAs and WHO.

4.2.3 Establishing an advisory group/committee that includes external experts

• Establishing procedures for the identification and timely appointment of an emergency evaluation task team for pandemic or other emergency use vaccines comprising experts in the country (and if possible, in the region and continent) in different fields (for example, virologists, immunologists and disease experts) from academia, the ministry of health and/or the private sector to:
  – support the evaluation of the candidate vaccine(s);
  – recommend appropriate regulatory authorization of suitable vaccines and provide advice to decision-makers; and
  – allow for the regular review of task team appointments and procedures (for example, during the interpandemic phase).
• Developing a procedure for the expedited approval of the NRA recommendation by other authorities within the country (for example, the ministry of health or a national advisory committee), if required.

4.2.4 Establishing post-authorization procedures

• Developing mechanisms for approving and communicating post-authorization changes for vaccines authorized in a pandemic context – for example, through labelling indicating extension of shelf-life, language(s) available, safety, dosage, age, indication and other information (13).
• Establishing a robust system and procedure for the importation of pandemic or other emergency use vaccines, including incorporation of importation pre-advice from the NRA to importers where possible (for example, proposed target timeline of not more than 5 working days).
• Establishing procedures and requirements for lot release of pandemic or other emergency use vaccines by the NRA during the pandemic phase or public health emergency by adopting recognition mechanisms (see section 6.4 below).
- Establishing a procedure for keeping a record of the distribution of product batches, regardless of the route of acquisition, to facilitate traceability – this may include the use of a 2D barcode on the secondary packaging.

- Outlining post-authorization surveillance procedures, which should include special provisions for post-authorization surveillance of the pandemic or other emergency use vaccine, including any AEFI, in accordance with the RMP.

- Ensuring system preparedness for implementing potential RMP elements and/or meeting the conditions of product approval (for example, a requirement for post-approval trials in special populations, if applicable).

### 4.2.5 External communications

- Selecting an NRA contact point for communications with WHO, other regulatory authorities and other stakeholders (including national immunization programmes and marketing authorization holders) on public health/regulatory issues.

- Developing a public communications plan summarizing the basis for decision-making.

- Establishing procedures for interacting with the public health agencies that will procure, deploy and administer the vaccines, including discussion of options for the appropriate sourcing of vaccines.

The national pandemic and emergency preparedness plan and national vaccine deployment plan should be reviewed and tested regularly to ensure that they are up to date.

### 4.2.6 Labelling requirements

Although legal requirements for labelling vary at the national level, the NRAs of vaccine-importing countries are encouraged to exercise flexibility during a pandemic or other public health emergency to enable the timely distribution of vaccines – for example, by waiving requirements for the inclusion of local languages. NRAs are also encouraged to allow the use of a common international label for pandemic or other emergency use vaccines carrying the following minimum information, as recommended in the WHO Model packaging for COVID-19 vaccines (29) to ensure the safe use of the vaccines:

- Name of the vaccine
- Type of vaccine
- Method/route of administration
- Dose/concentration
- Storage information
- Lot number
- Name of marketing authorization holder/manufacturer
- Manufacture date
- Expiry date (to be confirmed using a QR code).

NRAs may also consider allowing inclusion of the statement “For Pandemic or Emergency Use Only” on labels to differentiate a vaccine approved under the emergency authorization procedure from vaccines with regular marketing authorization.

While the use of a QR code is recommended to confirm the expiry date during a pandemic or other public health emergency, it is acknowledged that in some regions, legislation requires the printing of expiry dates on the label (30). Therefore, to avoid premature disposal and wasting of vaccines during a pandemic or other public health emergency, the NRA should have a mechanism in place (based on use of a QR code or other approach) for communicating up-to-date information on the expiry date in a timely manner to the national immunization programme, health care professionals and the public, as the shelf-life of the vaccine may be extended after initial authorization of the vaccine following the generation of real-time stability data. Further guidance on leveraging technologies for automated product traceability and information sharing can be found in the relevant WHO guidelines (30).

5. Risk-based considerations for regulatory evaluation and authorization

The NRAs of vaccine-importing countries are strongly encouraged to exhibit flexibility and to apply a risk-based approach to ensure the timely evaluation and authorization of quality assured vaccines during a pandemic or other public health emergency. A risk-based approach takes into consideration factors such as whether a vaccine has been approved by a reference regulatory authority or recommended by other trusted institutions (such as WHO), the phase of a pandemic (if applicable) and the risk to the population based on the potentially limited quality, safety and efficacy data available for a vaccine during an emergency situation. Such an approach also supports the optimizing of resources, which are often stretched during a pandemic or other public health emergency.

The NRA of an importing country should consider relying on the product evaluation and decisions made by reference NRAs, which may include
the NRA of the vaccine-producing country, or on the recommendations of WHO or other trusted institution. The sameness of the product being submitted to the relying authority and the product approved by the reference regulatory authority should always be considered as part of the evaluation process. All relevant aspects of sameness should be considered, including same qualitative and quantitative composition, same strength, same pharmaceutical form, same intended use, same manufacturing process, same suppliers of active pharmaceutical ingredient and same excipient quality. Additionally, the results of supporting studies of vaccine quality, safety and efficacy, indications and conditions of use should in general match those obtained by the NRA upon which the importing country NRA is relying (9). Depending on the level of reliance, the NRA may also require further data to confirm the applicability of the assessment outcome in their national context, or may perform an abridged assessment (9).

Importing countries should select, and where possible establish links with, suitable reference NRAs and other trusted institutions during the interpandemic period. The NRA of the importing country should establish mechanisms and procedures for relying on the authorization decisions of the NRA of the country producing the vaccine, or other reference NRA, or on WHO recommendations for PQ/EUL, as appropriate, when considering approving a vaccine for use in a pandemic or other public health emergency. Such reliance mechanisms and procedures may involve the signing of a memorandum of understanding or recognition agreement during the interpandemic phase, and may include information-sharing procedures between the importing country NRA and selected reference NRAs. Countries may also rely on the outcome of the review of vaccines assessed by WHO and recommended under the PQ/EUL procedures.8

The unredacted assessment reports, public assessment reports, inspection reports and RMPs from other NRAs may provide valuable insights depending on the level of reliance, and may inform the decision-making processes of NRAs in importing countries. Manufacturers and reference NRAs are encouraged to share, in line with their national laws, relevant unredacted assessment and inspection reports, as well as RMPs, with the NRAs of importing countries to facilitate the use of reliance pathways. If these reports are not readily available, direct communication with the relevant NRA or WHO (in the case of WHO PQ/EUL vaccines) is strongly encouraged.

Another risk-based approach that countries may use is work-sharing through joint reviews. Procedures for joint review of a pandemic or other

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8 More information on the WHO EUL procedure for vaccines can be found at: https://www.who.int/teams/regulation-prequalification/eul/eul-vaccines.
emergency use vaccine dossier by countries participating in established collaboration networks or in collaboration with reference NRAs should be developed as part of regulatory preparedness. This may include forecasting the use of an accelerated form of an existing joint review model and/or the signing of advance agreements with potential new collaborators during the interpandemic phase.

Even when using reliance, NRAs should have access to all available quality, safety and efficacy data, RMPs, and reference assessment and inspection reports to facilitate informed decision-making and to strengthen regulatory oversight of the vaccine after its introduction. When reliance cannot be implemented, a pre-submission meeting with the manufacturer may be useful in expediting the availability of a pandemic or other emergency use vaccine as this will provide an opportunity for the manufacturer to receive technical advice from the NRA when compiling their submission, thereby reducing the review time once a dossier is submitted. The NRA should also conduct an appropriate review of the documentation submitted and document the extent of the available evidence on which the recommendation to approve or reject was based, even during a pandemic or other public health emergency. However, every effort should be made to do this in a timely manner.

As was noted during the COVID-19 pandemic, it may not be possible for manufacturers to submit applications for authorization to all countries in the midst of a public health emergency. During that event, WHO acted as a “facilitator” for the provision of relevant quality, safety and efficacy data to NRAs under relevant confidentiality agreements between WHO and the manufacturers, and between WHO and the NRAs. RMPs, and assessment and inspection reports were provided to NRAs to facilitate decision-making and future regulatory oversight of the vaccine. A similar model should be considered for use during any future pandemic or other public health emergency.

5.1 Selection of an appropriate regulatory pathway
As summarized in Fig. 1, a risk-based approach should be taken when selecting the appropriate regulatory pathway for authorization of pandemic or other emergency use vaccines. In some situations, an application for authorization of such vaccines may be submitted in parallel to the reference NRA or WHO and to the NRA of the importing/relying country. Under these circumstances, the NRA of the importing countries are encouraged to take into consideration the findings or outcomes of the review of the reference NRA or WHO when conducting their own review.
5.2 Documentation required according to regulatory pathway

Reliance ranges from full recognition of the decision of a reference NRA or of the recommendation of a trusted institution such as WHO, using minimum documentation, to the use of full unredacted assessment reports and/or additional data or information to make an independent decision. The extent of reliance applied and documentation required will be decided upon by countries in line with their regulatory capacities and legal frameworks. Guidance on the documentation to be requested under the various pathways available for the approval of pandemic or other emergency use vaccines is provided below and summarized in Table 1. It is possible that not all documentation for a vaccine will be available at the time of application, and many NRAs allow applicants to submit evidence as it becomes available, for example, using written commitments. Although reliance is not limited to marketing authorizations and inspections, the current section focuses on reliance for these functions.

5.2.1 Recognition

This approach is the process of recognizing the decision of a reference NRA or the recommendation for PQ/EUL by WHO, supported by verification of product sameness (9) but without further technical evaluation. This approach can also be referred to as a verification review. Where it has been agreed (as defined in the approved NRA pandemic or other public health emergency procedures) that the
decision of a reference NRA or WHO recommendation for PQ/EUL can be used as the basis of a recommendation for authorization, this approach would involve acceptance based on the use of the evaluation and terms of authorization from the reference NRA or WHO. The relying NRA retains sovereignty of, and has responsibility for, the final decision, and therefore some degree of difference (for example, in product information) is possible.

5.2.1.1 Documentation required

- certificate or other evidence of the reference NRA’s authorization decision, or the WHO recommendation for PQ/EUL;
- (public) assessment and inspection reports (if available);
- unredacted assessment and inspection reports of the reference NRA as far as possible, and in accordance with its national laws or with WHO PQ/EUL (and if required by the importing country’s legal framework); and
- any other documentation required by the importing country’s legal framework.

5.2.1.2 Applicability

During an emergency situation, this approach would be applicable for a pandemic or other emergency use vaccine authorized by a reference NRA or recommended by WHO for PQ/EUL. It may also be applicable during the pandemic phase to a pandemic vaccine authorized by the NRA of the producing country regardless of maturity level.

5.2.2 Reliance

This approach involves relying on the assessments, inspections and/or decisions of other competent NRAs or on a WHO recommendation for PQ/EUL in order to conduct abridged reviews. Reliance may be placed on reference NRAs or trusted institutions using, for example, assessment reports. Where it has been agreed (as defined in the approved NRA pandemic or other public health emergency procedures) that the decision, recommendation or work from another NRA or trusted institution can be considered and used as the basis of a recommendation for authorization by importing countries, this approach would involve the abridged review and use of the terms of authorization of the reference NRA or recommendation by WHO. The vaccine supplied should be the same as that approved by the reference NRA (9). The relying NRA retains sovereignty of, and has responsibility for, the final decision, and therefore some degree of difference is possible.
5.2.2.1 **Documentation required**

- certificate or other evidence of the reference NRA’s authorization decision, or the WHO recommendation for PQ/EUL;
- (public) assessment and inspection reports (if available);
- unredacted assessment and inspection reports of the reference NRA as far as possible, and in accordance with its national laws or with WHO PQ/EUL; and
- Common Technical Document (CTD) dossier or documentation essentially the same as that submitted to the reference NRA or WHO as specified in published WHO guidance on GreIP (9).

5.2.2.2 **Applicability**

This approach would be applicable during the interpandemic and pandemic phases for a pandemic vaccine authorized by a reference NRA or recommended by WHO for PQ/EUL. It may also be applicable during the pandemic phase to a pandemic vaccine authorized by the NRA of the producing country regardless of maturity level.

5.2.3 **Emergency authorization**

Emergency authorization is an early access mechanism used to expedite the availability of new investigational/unauthorized vaccines during a public health emergency. It is granted if it is reasonable to believe that: (a) the vaccine may be effective based on the totality of evidence available; (b) the known and potential benefits outweigh the known and potential risks; and (c) certain criteria have been met – for example, the absence of approved or available alternatives.

Emergency authorization is a fast-track process based upon review of the information available at the time, or reliance on the decision of a reference NRA or WHO EUL recommendation. If a fast-track review is deemed appropriate (as defined in the approved NASA pandemic or other public health emergency procedures), the documents listed below should be reviewed.

A vaccine is given an emergency authorization for a limited period and with certain conditions, mostly related to obtaining post-authorization data such as AEFI and other quality, safety and efficacy data for further extension of the authorization period (if required). Once adequate data have been generated, the full application dossier should be provided for review and authorization.
5.2.3.1 Documentation required
If recognition or reliance is to be used:

- unredacted assessment and inspection reports of the producing country’s NRA or reference NRA as far as possible, and in accordance with national laws, or the WHO EUL recommendation; and
- CTD dossier or documentation essentially the same as that submitted to the reference NRA or WHO as specified in published WHO guidance on GrelP (9).

If a fast-track independent review is to be conducted:

- evidence of quality (certificate of analysis or lot release) and good manufacturing practice (GMP) certificate; and
- the available documentation or format of a dossier necessary to demonstrate that vaccine quality, safety and efficacy are acceptable in the context of a public health emergency if the CTD dossier is not available.

5.2.3.2 Applicability
This approach would be applicable during a pandemic or other public health emergency for a vaccine given a WHO EUL or authorized by the producing country’s NRA or by a reference NRA.

5.2.4 Independent review of the full dossier
This is the standard process of evaluation of the full dossier for marketing authorization for vaccines that are new applications or that were previously authorized by NRAs other than a reference NRA.

5.2.4.1 Documentation required
The documentation should be complete, as legally required in each country – for example, Modules 1–5 of the CTD dossier.

5.2.4.2 Applicability
Independent full review would usually be applicable to vaccines authorized in the interpandemic phase. During a pandemic phase, if a full review is performed, adequate resources should be made available to ensure that the review is completed in a timely manner. This would require evaluation of the documentation of product quality, as well as of the results of nonclinical and clinical studies to demonstrate safety and efficacy in the target population. The documentation reviewed should be in line with national legal requirements.
The review will result in the issuance of marketing authorization if all conditions are met.

It is possible that not all documentation for a vaccine will be available at the time of application, and many NRAs allow applicants to submit evidence as it becomes available. This approach is generally known as a “rolling review” (31) and is intended to shorten the time to market for novel vaccines.

Where applicable, and in the interpandemic period, the NRA of an importing country may conduct a full pandemic preparedness vaccine dossier review to ensure familiarity with the characteristics of such vaccines prior to the next pandemic phase.

Table 1
Summary of the documentation required for the different pathways available for the authorization of pandemic or other emergency use vaccines

<table>
<thead>
<tr>
<th>Pathway</th>
<th>Documentation required</th>
</tr>
</thead>
</table>
| Recognition | • Certificate or other evidence of the reference NRA’s authorization decision, or the WHO recommendation for PQ/EUL.  
• (Public) assessment and inspection reports (if available).  
• Unredacted assessment reports of the reference NRA in accordance with its national laws or with WHO PQ/EUL (and if required by the importing country’s legal framework).  
• Any other documentation required by the importing country’s legal framework. |
| Reliance | • Certificate or other evidence of the reference NRA’s authorization decision, or the WHO recommendation for PQ/EUL.  
• (Public) assessment and inspection reports (if available).  
• Unredacted assessment and inspection reports of the reference NRA as far as possible, and in accordance with its national laws or with WHO PQ/EUL  
• CTD dossier or documentation essentially the same as that submitted to the reference NRA or WHO as specified in published WHO guidance on GReIP (9). |
Table 1 continued

<table>
<thead>
<tr>
<th>Pathway</th>
<th>Documentation required</th>
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<tbody>
<tr>
<td>Emergency authorization</td>
<td>If recognition or reliance is to be used:</td>
</tr>
<tr>
<td></td>
<td>• Unredacted assessment and inspection reports of the producing country’s NRA or reference NRA as far as possible, and in accordance with national laws, or the WHO EUL recommendation.</td>
</tr>
<tr>
<td></td>
<td>• CTD dossier or documentation essentially the same as that submitted to the reference NRA or WHO as specified in published WHO guidance on GReIP (9).</td>
</tr>
<tr>
<td>If a fast-track independent review is to be conducted:</td>
<td></td>
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<tr>
<td></td>
<td>• Evidence of quality (certificate of analysis or lot release) and GMP certificate.</td>
</tr>
<tr>
<td></td>
<td>• The available documentation or format of a dossier necessary to demonstrate that vaccine quality, safety and efficacy are acceptable in the context of a public health emergency if the CTD dossier is not available.</td>
</tr>
</tbody>
</table>

| Independent review of the full dossier | • Modules 1–5 of the CTD dossier. |

5.3 Decision-making

Before a regulatory decision to recommend authorization of a pandemic or other emergency use vaccine is taken, the NRA should ensure that the following conditions are met:

- The benefit–risk ratio is deemed favourable – that is, the known and potential benefits outweigh the known and potential risks based on evaluation of the available data – and this can be communicated in a comprehensive and transparent manner.
- An adequate document package was provided, and a commitment obtained from the manufacturer to provide any outstanding information related to vaccine quality, safety or efficacy post authorization as it becomes available.
- An RMP has been reviewed and approved.
- The packaging, label and package insert meet national requirements and are in line with the guidance provided in section 4.2.6 above.

The evaluation may need to be based upon minimal and incomplete documentation, and this should be acknowledged in the recommendation. An evaluation report should be produced by the NRA under all the review pathways.
in line with published WHO guidance on good regulatory practices in the regulation of medical products (8). During a pandemic or other public health emergency, emergency approval procedures may be used. Approval may be based upon limited clinical and/or quality data (for example, stability data) and upon expedited evaluation of the available evidence. Therefore, the approval may include one or more special conditions for use, including:

- use only during the period of the pandemic or other public health emergency;
- use only in certain specified groups at high risk;
- special conditions for post-authorization safety reporting; and
- requirement for evidence generation to address knowledge gaps.

In some countries, the NRA may have the authority to approve the use of a vaccine without reference to another national authority, while in other countries a final approval or directive (for example, from the ministry of health or a national advisory committee) may be required in addition to the NRA review.

6. Post-authorization activities

6.1 Post-authorization changes

Vaccines typically undergo numerous changes after authorization for reasons such as better understanding of the product and manufacturing process, the scale-up of batch quantities, additional manufacturing sites, and the availability of additional data or information resulting from product use in wider populations. One common change submitted after authorization is the extension of use of the vaccine to other groups or populations that were not included in the initial clinical indication.

As with all newly approved vaccines there will be changes submitted to the NRA following the initial authorization of pandemic or other emergency use vaccines. NRAs and manufacturers are encouraged to follow the guidance provided in the WHO Guidelines on procedures and data requirements for changes to approved vaccines (13). The review and approval process should be prioritized, and timelines reduced in a pandemic or other public health emergency, and existing global initiatives leveraged to streamline reviews. Manufacturers should always be requested to supply the updated or latest version of the product information with the vaccine, and to publish the same on their website so that the end users in the importing country have access to all updates, changes or variations to the product information that may have been made since the initial authorization.
Changes that may be of crucial importance to importing countries during a pandemic or other public health emergency include safety and efficacy changes, as well as changes in the shelf-life and “in use” stability of the vaccine. Continued evaluation of the benefit–risk profile of the vaccine should be undertaken beyond the pandemic phase based on emerging data and information.

As real-time data on vaccine stability are incrementally generated, there should be effective information exchange between the reference NRA or WHO, vaccine manufacturers and importing countries to ensure that updated shelf-lives are communicated in a timely manner to avoid the needless destruction of vaccines.

Transparency should be promoted through the publishing and sharing of regulatory information to facilitate information exchange among NRAs. In a pandemic or other public health emergency, it is particularly important that the reference NRAs and WHO publish their decisions and recommendations on authorized vaccines, and highlight any alerts.

### 6.1.1 Pathways for the review of post-authorization changes

Reliance pathways used for the initial authorization should also be applied to post-authorization changes as far as possible. Therefore, during a pandemic or other public health emergency, the NRAs of importing countries are encouraged to recognize or rely on the decisions of the reference NRA or on WHO recommendations for PQ/EUL with regard to post-authorization changes. Major or critical manufacturing process changes that impact the safety or use of a vaccine should be reported to the NRAs of importing countries.

If recognition of WHO EUL has been used for the initial authorization, the NRA of the importing country may want to refer to the terms of authorization as defined by the WHO EUL decision, if their national legal framework allows for such reference, to facilitate maintenance of the emergency use. This will allow for a prompt and appropriate response to any updates to the WHO EUL, such as new manufacturing sites, new indication, extension of shelf-life and so on.

### 6.1.1.1 Documentation required

If recognition or reliance is to be used:

- evidence of the reference NRA's approval or WHO PQ/EUL recommendation of the post-approval change(s);
- unredacted assessment reports of the reference NRA or WHO PQ/EUL (as far as is possible); and
- documentation essentially the same as that submitted to the reference NRA or WHO PQ/EUL, as specified in published WHO guidance on GRelP (9).
If an independent review is to be conducted:

- full supporting documentation with the relevant quality, safety and efficacy data applicable to the proposed change(s) in accordance with national guidelines.

As highlighted above, reliance ranges from the full recognition of the decision of a reference NRA or trusted institution such as WHO (using minimum documentation) to the use of full unredacted assessment reports to make an independent decision. The extent of reliance to be applied, and documentation required, will be determined by countries in line with their national legal frameworks. In an emergency situation, an independent review should only be considered if recognition or reliance cannot be used.

6.2 Importation and market surveillance and control

6.2.1 Import authorization

Once authorization has been granted for a vaccine, countries should have a procedure in place for approving its importation within 5 working days from the date of receipt of the import authorization application. The WHO Guidelines on import procedures for medical products (10) provide guidance for NRAs, trade ministries, customs authorities, port authorities and importing agents on simplifying the checking and handling of vaccines for import. During importation, the vaccine is checked to verify compliance with the authorization, for example with regard to labelling. To protect vaccine recipients and ensure that no substandard or falsified products enter the country, it is vital that existing national legislation relating to importation covers all vaccines, including donations (32).

NRAs are encouraged to follow the principles outlined in WHO operational guidance on the legal and regulatory framework facilitating vaccine deployment (32).

Some NRAs with no or very limited capacity to conduct reviews for authorization may use the import permit as a form of authorization of the vaccine. Countries should ensure that such vaccines have been approved by a reference NRA or trusted institution such as WHO. This procedure should be clearly defined by the NRA in the importing country during the interpandemic phase, including applicable timelines to prevent delays in the importation of the vaccine.

6.2.1.1 Documentation required

As a prerequisite for border and customs clearance, the importing agency or agent should be equipped to furnish the customs authority with the following documentation in respect of each consignment:
- documents issued by the NRA in the importing country attesting
  that the importer is duly authorized to import the vaccines and that
  the products are duly authorized to be marketed or permitted to be
  imported into the importing country;
- a batch release certificate issued by the manufacturer;
- a safety data sheet, where applicable;
- a relevant invoice, bill or delivery slip for the batch, including the
  product name, batch number, quantity, and expiry or manufacture
  date;
- lot/batch release certificate issued by the NRA in the country/
  territory of origin; and
- any other documentation required by national or regional legislation
  for customs clearance.

The high demand for vaccines during a pandemic or other public
health emergency, whether due to shortages or inaccessibility, may result in the
circulation of substandard and falsified vaccines or unapproved vaccines in both
the legal and illegal distribution channels. NRAs in importing countries are
particularly encouraged to ensure that their market control systems can prevent
and detect substandard and falsified vaccines, and that the appropriate response
capabilities are in place, including information sharing and reporting to the
WHO global surveillance and monitoring system\(^9\) which provides information
on substandard and falsified medicines to countries. In addition, the principles
set out in published WHO guidance on good storage and distribution practices
for medical products (33) should be followed to ensure that the integrity of
vaccines is not compromised. Regardless of the lot release procedure applied,
a record must also be kept of all lots received in the country to facilitate their
traceability.

6.3 Pharmacovigilance

NRAs are encouraged to follow the procedures for post-authorization
surveillance of adverse events as described in the national pandemic and
emergency use vaccine deployment plan. This should follow the principles set
out in the WHO Guidelines on regulatory preparedness for human pandemic
influenza vaccines (2), the WHO Global manual on surveillance of adverse
events following immunization (19) and internationally recognized guidelines
on good pharmacovigilance practices – see for example (34). The national

pharmacovigilance system should ensure that all stakeholders (including manufacturers, regulatory authorities, immunization programmes, vigilance centres and others) closely coordinate and share the information they require to meet their responsibilities.

A crisis management plan and RMP for pandemic or other emergency use vaccines should be developed and monitored by the manufacturer with input from the NRA and the national immunization programme (if needed) to enable continuous monitoring and management of the benefit–risk profile of the vaccine during marketing and use.

At the time of initial authorization, trials (including safety studies) may not have been conducted in special populations such as children, pregnant women, lactating women, immunocompromised individuals, people with pre-existing health conditions and other groups of interest (which may differ from country to country). Special consideration may therefore need to be given to the inclusion of post-authorization Phase IV studies by manufacturers in the RMP.

National systems for post-authorization surveillance, including the reporting of AEFI and causality assessment of serious adverse events, should not be compromised by the implementation of a pandemic or other emergency use vaccination campaign. NRAs are strongly urged to identify AEFI of interest as soon as they emerge and to use tools such as VigiFlow\(^{10}\) and VigiMobile\(^{11}\) to facilitate AEFI reporting and management.

NRAs should take timely regulatory action in relation to any safety issues identified post-authorization, including approval changes in the reference NRA country, some of which may require the communication of important risks to the public and other stakeholders through changes in the product information. NRAs should also actively engage with stakeholders (such as professional associations) to ensure the adequate and effective communication and minimization of any identified risks.

NRAs are encouraged to use reliance in pharmacovigilance – for example, by adapting existing warnings and precautions published by reference NRAs to the local context. These may appear in product information sheets, RMPs, direct health care professional communications (“dear doctor” letters) and patient information sheets. For this purpose, NRAs should closely monitor the information produced by reference NRAs and other sources.

The NRA, in collaboration with the local marketing authorization holder, should also plan and implement active surveillance studies, including pregnancy registries if resources are available.

\(^{10}\) For more information see: https://who-umc.org/pv-products/vigiflow/vaccine-safety-surveillance-in-vigiflow/.

\(^{11}\) For more information see: https://who-umc.org/pv-products/vigiflow/vigimobile/.
6.4 Lot release

NRAs should have the flexibility in their legal framework to waive requirements for independent testing in an emergency situation and to instead use recognition/reliance mechanisms. In a pandemic or other public health emergency, lot release and quality control of vaccines by the NRA and/or national control laboratories (NCLs) of importing countries should follow the guidance set out in relevant WHO documents (26, 35–38) and be completed within the shortest possible time.

Vaccines received by importing countries should be produced in compliance with GMP and tested for quality and safety by the vaccine manufacturer. Typically, such vaccines are also subjected to independent quality control testing and released by the producing country’s NRA/NCL in accordance with the WHO Guidelines for independent lot release of vaccines by regulatory authorities (26). Recognition of the lot release certificate of the NRA/NCL of the producing country is strongly recommended by WHO in accordance with national laws (26). For vaccines supplied through United Nations agencies, it is recommended that further release testing by the NRA/NCL of receiving countries should not be performed because such vaccines are prequalified or listed by WHO and released by the producing country’s NRA/NCL. For self-procured WHO PQ/EUL vaccines or vaccines approved by a reference NRA, it is not recommended that further release testing by the NRA/NCL of receiving countries be performed because such vaccines have been prequalified or listed by WHO and released by the producing country’s NRA/NCL.

For self-procured pandemic or other emergency use vaccines that do not have a WHO PQ/EUL recommendation and are not approved by a reference NRA, the NRA/NCL of the procuring country may, in the event of a pandemic or other public health emergency, conduct lot release through review of the summary lot protocol. Further laboratory testing by the NRA/NCL of the receiving country is normally not necessary, based on risk assessment.

The procedures adopted should ensure the deployment of vaccines without undue delay. Where NRA lot release has not been conducted for a pandemic or other emergency use vaccine (such as a vaccine approved using the emergency authorization procedure of the NRA of the producing country), importing countries with limited capacity or resources (including time) to conduct laboratory testing may rely on the batch release certificate issued by the quality control unit of the manufacturer. Some countries do not issue a lot release certificate even though the vaccine has been granted marketing authorization. In this scenario, the NRA/NCL of the producing country may be requested to produce a document to certify the quality of the batch and facilitate a summary lot protocol review. The model summary protocol may not be available on the WHO website for some vaccines and in such instances the manufacturer’s template should be used.
Appropriate and adequate supply chain procedures should be followed for all types of vaccines, including the capturing of lot distribution and critical lot information. Product monitoring becomes more important when the NRA of the importing country is not conducting quality testing through their NCL and is relying on the lot release of other NRAs.

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References


