Guidance for registers of manufacturers, importers, distributors and medical products authorized by Member States

Prioritised Activity A – Develop and promote training material and guidance documents to strengthen the capacity of national/regional regulatory authorities for the prevention and detection of and response to substandard and falsified medical products

Action: Develop recommendations regarding national registers of manufacturers, importers distributors and medical products authorized by Member States

INTRODUCTION

1. The protection of the entire supply chain against the penetration of substandard, unregistered/unlicensed and falsified medical products is essential, as any weak point in the distribution processes provides opportunities for these products to enter the supply chain and reach patients. The methods by which such products enter the supply chain have become increasingly complex, resulting in the development of thriving secondary and grey markets throughout the world.

2. The involvement of unauthorized/unapproved entities and the introduction of unauthorized products in the supply chain are of particular concern, as these facilitate the distribution of substandard, unregistered/unlicensed and falsified products. That is why the ability to identify the legal agents authorized/approved by national/regional regulatory authorities (NRRAs), as well as authorized medical products, is essential so that any agent of the supply chain may, through the pertinent verifications, ensure that the medical products are authorized and sourced only from approved suppliers and distributed by approved entities.

3. For these reasons, and in line with the workplan of the Member State mechanism (MSM) adopted in 2013, the list of the MSM Prioritized Activities for the period 2018–2019 has included as a new action “Develop recommendations regarding national registers of manufacturers, importers, distributors,1 and medical products authorized by Member States”, understanding “registers” as any official list or database maintained by NRRAs with information on licensed entities and authorized medical products in a given territory. To address this task, the Working Group convened for

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1 The survey considered distributors and wholesalers in the same category.
Prioritized Activity A conducted a survey about the current situation of these registers in Member States, their content and the access to their information.

4. Forty-one (41) responses have been received from health organizations in different countries. The distribution by WHO region is as follows: five, African Region; 12, Region of the Americas; one, South-East Asia Region; 15, European Region; two, Eastern Mediterranean Region; and six, Western Pacific Region. Although the results of this survey might represent a global view of the current situation in Member States, the results of each regional group may be biased because of the uneven engagement of NRRAs in the survey. Most survey respondents represent regulatory authorities (73.3%), all the rest of them represent ministries of health.

5. Annex 1 of this document presents links to national and regional registers, as informed by those who have replied to the survey. This guidance is considered to be a “living document”, and Member States may suggest modifications to Annex 1 at any time.

ANALYSIS OF THE RESPONSES

6. From the analysis of the responses received, it can be concluded that 93.3% of the responding countries currently have a database/register of manufacturers and authorized medical products (medicines and vaccines); 88.9% of them have registers for importers and distributors and 86.7% have a marketing authorization holders’ database. However, the number of registers for in vitro diagnostic devices is remarkably lower (51.1%).

7. Regarding the public accessibility of these registers, either directly or through the website of the competent authority, most of them are publicly accessible: 68.9% databases of manufacturers, 62.2% of importers, 66.7% of distributors and 77.8% of authorized medical products (medicines and vaccines). For medical devices (in vitro diagnostic) registers, the percentage is significantly lower (35.6%). In some cases, information can be provided by the health authority upon request (around additional 15–30% for each category) and only a small percentage of registers are not publicly available: 6.7% databases of manufacturers; 2.2% of importers; 4.4% of distributors; 4.4% of authorized medical products (medicines and vaccines) and licenced in vitro diagnostic medical devices.

8. An analysis of the current situation shows clearly that there is room for improving the accessibility of these registers and databases, mainly through the NRRAs’ websites.

9. Concerning the information contained in the registers/databases, details about company name, address and authorized activities are almost always provided for those relating to manufacturers, importers, distributors. However, contact details of the entity listed in the registers/databases, such as telephone number or e-mail address are provided only in half of the cases (57.8% and 45% respectively).

10. Regarding authorized medicines’ databases, product name, active substances and dosage forms are included in most cases, along with information about the licence holder (86.7%). However, other relevant information – such as excipients or classification as per the Anatomical, Therapeutic, Chemical classification system (ATC code) as defined by WHO – is less common (64.4%). Once more, information availability for in vitro diagnostic products is lower: for example, only 68.9% of existing databases for these products present the name of the product as available information.
11. Concerning the frequency of updates of the information available, most databases of manufacturers, importers, distributors are updated practically every day or in a continuous manner (around 45% of the cases). A similar situation is observed for databases of authorized medicines (51.1%). The frequency observed in the updates for databases of in vitro diagnostic medical devices is remarkably lower (33.3%).

PURPOSE

12. In the light of the results obtained, this document has been drafted to outline some of the elements to be considered by NRRAs in respect to maintaining registers, aiming at strengthening the supply chain and gaining supervisory effectiveness. These recommendations have as a starting point the consideration that a comprehensive system of registers of manufacturers, importers, distributors and medical products will enable an efficient surveillance of the legal supply chain.

Establishing well-defined and detailed registers

13. Most Member States who have responded to the survey have set up registers for manufacturers, importers, distributors and authorization holders, as well as databases for authorized medicines. Similar systems for in vitro diagnostic products are still underdeveloped.

14. These registers should be comprehensive and include all the entities or products authorized by the NRRA, in order to allow the uncomplicated identification of those entities and products that present themselves as authorized when they are not.

15. Therefore, the recommendation is that all Member States promote the creation of registers for different categories of actors (manufacturers, importers, distributors) and medical products.

Registers’ contents

16. All registers should provide enough information to identify the entities or products authorized.

17. The recommendation is that Member States’ registers include, as a minimum, the following information:

Registers for manufacturers, importers, distributors and marketing authorization holders

- Company name
- Full address
- Authorized/approved activities
- Date of expiration of authorization given to the company (if applicable)
- Contact telephone number/fax
- Contact e-mail address
Registers for medicines and vaccines

• Name of product
• Name of active pharmaceutical ingredient(s)*
• Dosage and dosage form
• ATC code*
• Marketing authorization holder name
• Excipients
• Date of expiration of authorization given to the product (if applicable)
* not applicable to vaccines

Registers for in-vitro diagnostic medical devices

• Name of product
• Main intended use
• Name of company responsible for placing the product in the market
• Date of expiration of authorization given to the product (if applicable)

18. For registers of products, the inclusion of photographs of the authorized packaging is also highly recommended.

Maintaining the information up to date

19. Maintaining up-to-date registers is key for effective verification by public and private stakeholders. Nearly half of the current databasesregisters provide information that is updated daily, which boosts the usage of the implemented system.

20. The recommendation is that Member States opt for a frequency of updating registers that reflects the current situation of their markets, taking into consideration the intended use of the registers.

Ensuring convenient access to information

21. Making registers’ information accessible to the public, including private stakeholders, is key to ensure the protection of the legal supply chain at all levels. If private entities can have easy access to the adequate information, this may support their due diligence checks and make them less prone to be victims of deceit or fraud.

22. In a similar way, having registers’ information in other foreign language(s), in addition to the official national language(s), will help to strengthen the legal chain beyond national borders. The use
of foreign languages enables registers to be consulted faster by other NRRAs or international stakeholders, helping the exchange of information between authorities and private entities inside and outside a region or country.

23. In this regard, it is essential to identify the authority responsible for managing the register and provide its contact information as well.

24. The recommendation is that Member States consider giving the highest level of transparency and accessibility to their registers, and provide, when possible, information in foreign languages.

**Final remarks**

25. Public registers are an essential tool for activities developed by NRRAs in the prevention, detection and response to substandard, unregistered/unlicensed and falsified medical products. NRRAs not having yet established their own registers should consider the experiences of other competent authorities when designing their national/regional databases. Promoting public access to such registers is essential for NRRAs and stakeholders to verify the legitimacy of products that are available and entities that operate in the supply chain, assisting in maintaining its integrity.
ANNEX 1

LINKS TO NATIONAL AND REGIONAL REGISTERS

ALGERIA

Links to authorized medicines register:
http://sante.gov.dz/index.php/telecharger

ARGENTINA

Links to distributors (including wholesalers) register:
Links to manufacturers register:
Links to importers register:
Links to authorized medicines register:
https://servicios.pami.org.ar/vademecum/views/consultaPublica/listado.zul

AUSTRALIA

Links to importers register:
Links to marketing authorization holders register:
Links to authorization medicine
Links to in vitro diagnostics medical products register:

AUSTRIA

Links to marketing authorization holders register:
https://aspregister.basg.gv.at/aspregister/faces/aspregister.jspx?_afrLoop=84497819333389754&_afrWindowMode=0&_adf.ctrlstate=dq4aprt04_4
Links to authorized medicines register:
https://aspregister.basg.gv.at/aspregister/faces/aspregister.jspx?_afrLoop=84497819333389754&_afrWindowMode=0&_adf.ctrlstate=dq4aprt04_4
Links to in vitro diagnostics medical products register:
http://www.medizinproduktregister.at/de/english-version

1 The information available in Annex 1 was notified by the competent authorities and correspond to the links available as of September 2018. If you wish to update the information, please contact rapidalert@who.int.
BELGIUM

Links to distributors (including wholesalers) register:
https://www.fagg.be/nl/menselijk_gebruik_0
Links to authorized medicines register:
http://bijsluiters.fagg-afmps.be/?localeValue=nl
https://banquededonneesmedicaments.fagg-afmps.be/#/
Links to manufacturers register:
http://eudragmdp.ema.europa.eu/
Links to importers register:
http://eudragmdp.ema.europa.eu/

BELIZE

Links to manufacturers register:
Links to distributors (including wholesalers) register:

BRAZIL

Links to manufacturers register:
http://portal.anvisa.gov.br/consulta-empresas-autorizadas
Links to importers register:
http://portal.anvisa.gov.br/consulta-empresas-autorizadas
Links to marketing authorization holders register:
http://portal.anvisa.gov.br/consulta-empresas-autorizadas
Links to distributors (including wholesalers) register:
http://portal.anvisa.gov.br/consulta-empresas-autorizadas
Links to authorized medicines register:
http://portal.anvisa.gov.br/medicamentos/consultas
Links to in vitro diagnostics medical products register:
http://portal.anvisa.gov.br/noticias/-/asset_publisher/FXrp9qY7FbU/content/banco-de-dados-fragmentacao-de-produtos-para-saude/219201
(https://dados.anvisa.gov.br/dados/TA_PRODUTO_SAÚDE_SITE.csv)

CHILE

Links to distributors (including wholesalers) register:
http://www.ispch.cl/anamed/establecimientos_farmaceuticos/produccion
http://www.ispch.cl/anamed/establecimientos_sanitarios/eda
Links to authorized medicines register:
http://registrosanitario.ispch.gob.cl/
Links to marketing authorization holders register:
http://registrosanitario.ispch.gob.cl/
COLOMBIA

Links to manufacturers register:
https://www.invima.gov.co/aseguramiento-sanitario
Links to importers register:
https://www.invima.gov.co/aseguramiento-sanitario
Links to authorized medicines register:
http://consultaregistro.invima.gov.co:8082/Consultas/consultas/consreg_encabcum.jsp
Links to in vitro diagnostics medical products register:
http://consultaregistro.invima.gov.co:8082/Consultas/consultas/consreg_encabcum.jsp

COSTA RICA

Links to manufacturers register:
https://registrelo.go.cr
Links to importers register:
https://registrelo.go.cr
Links to marketing authorization holders register:
https://registrelo.go.cr
Links to distributors (including wholesalers) register:
https://registrelo.go.cr
Links to authorized medicines register:
https://registrelo.go.cr
Links to in vitro diagnostics medical products register:
https://registrelo.go.cr

CROATIA

Links to manufacturers register:
Links to importers register:
Links to distributors (including wholesalers) register:
Links to authorized medicines register:
http://www.halmed.hr/en/Lijekovi/Baza-lijekova/
http://www.halmed.hr/en/Medicinski-proizvodi/Baza-medicinskih-proizvoda/
Links to in vitro diagnostics medical products register:
ECUADOR

Link to manufacturers register:
http://www.controlsanitario.gob.ec/base-de-datos/

Link to importers register:
http://www.controlsanitario.gob.ec/base-de-datos/

Links to marketing authorization holders register:
http://www.controlsanitario.gob.ec/base-de-datos/

Links to distributors (including wholesalers) register:
http://www.controlsanitario.gob.ec/base-de-datos/

Links to authorized medicines register:
http://www.controlsanitario.gob.ec/base-de-datos/

EL SALVADOR

Links to authorized medicines register:

Links to distributors (including wholesalers) register:
http://www.medicamentos.gob.sv/index.php/es/servicios-m/listados/listados-de-establecimientos/listado-de-droguerias

Links to marketing authorization holders register:

Links to importers register:
http://www.medicamentos.gob.sv/index.php/es/servicios-m/informes/unidad-juridica/listado-de-importadores

Links to manufacturer register:

ESTONIA

Links to manufacturers register:
http://rkav.sm.ee/rkav/faces/pages/tegevuslubaForm/tegevuslubaOtsing.jspx

Links to importers register:
http://rkav.sm.ee/rkav/faces/pages/tegevuslubaForm/tegevuslubaOtsing.jspx

Links to distributors (including wholesalers) register:
http://rkav.sm.ee/rkav/faces/pages/tegevuslubaForm/tegevuslubaOtsing.jspx

Links to authorized medicines register:

Links to marketing authorization holders register:
EUROPEAN UNION

Links to distributors (including wholesalers) register:
http://eudragmdp.ema.europa.eu
Links to manufacturers register:
http://eudragmdp.ema.europa.eu
Links to importers register:
http://eudragmdp.ema.europa.eu
Links to marketing authorization holders register:
Links to authorized medicines register:

FINLAND

Links to manufacturers register:
http://eudragmdp.eudra.org/inspections/logonGeneralPublic.do
Links to importers register:
http://eudragmdp.eudra.org/inspections/logonGeneralPublic.do
Links to distributors (including wholesalers) register:
http://eudragmdp.eudra.org/inspections/logonGeneralPublic.do
Links to marketing authorization holders register:
Links to authorized medicines register:

HUNGARY

Links to manufacturers register:
http://portal.nebih.gov.hu/manufacturers
Links to importers register:
Links to marketing authorization holders register:
https://www.ogyei.gov.hu/lists/
https://atiportal.nebih.gov.hu/
Links to distributors (including wholesalers) register:
https://www.ogyei.gov.hu/lists/
http://portal.nebih.gov.hu/gyogyszergyartok
Links to authorized medicines register:
https://atiportal.nebih.gov.hu/
https://www.ogyei.gov.hu/lists/
IRAN, ISLAMIC REPUBLIC OF

Links to manufacturers register:
http://fda.gov.ir/
http://support.ttac.ir/

Links to importers register:
http://fda.gov.ir/
http://support.ttac.ir/

Links to marketing authorization holders register:
http://fda.gov.ir/
http://support.ttac.ir/

Links to distributors (including wholesalers) register:
http://fda.gov.ir/
http://support.ttac.ir/

Links to authorized medicines register:
http://fda.gov.ir/
http://support.ttac.ir/

Links to in vitro diagnostics medical products register:
http://fda.gov.ir/

IRELAND

Links to manufacturers register:
http://www.hpra.ie/homepage/medicines/regulatory-information/manufacturers

Links to importers register:
http://www.hpra.ie/homepage/medicines/regulatory-information/manufacturers

Links to marketing authorization holders register:
http://www.hpra.ie/homepage/medicines/regulatory-information/medicines-authorisation

Links to distributors (including wholesalers) register:

Links to authorized medicines register:
http://www.hpra.ie/homepage/medicines/regulatory-information/medicines-authorisation

ITALY

Links to manufacturers register:
http://eudragmdp.ema.europa.eu

Links to importers register:
http://eudragmdp.ema.europa.eu

Links to distributors (including wholesalers) register:
http://eudragmdp.ema.europa.eu
www.ministerodellasalute.it

Links to marketing authorization holders register:
www.aifa.gov.it

Links to authorized medicines register:
www.aifa.gov.it

Links to in vitro diagnostics medical products register:
www.ministerodellasalute.it
NIGERIA

Links to manufacturers register:
https://www.nafdac.gov.ng/our-services/registered-products/
Links to importers register:
https://www.nafdac.gov.ng/our-services/registered-products/
Links to marketing authorization holders register:
https://www.nafdac.gov.ng/our-services/registered-products/
Links to authorized medicines register:
https://www.nafdac.gov.ng/our-services/registered-products/
Links to in vitro diagnostics medical products register:
https://www.nafdac.gov.ng/our-services/registered-products/

NORWAY

Links to marketing authorization holders register:
https://www.legemiddelsok.no/
Links to authorized medicines register:
https://www.legemiddelsok.no/
Links to manufacturers register:
http://eudragmdp.ema.europa.eu
Links to importers register:
http://eudragmdp.ema.europa.eu
Links to distributors (including wholesalers) register:
http://eudragmdp.ema.europa.eu

PERU

Links to marketing authorization holders register:
http://observatorio.digemid.minsa.gob.pe/PortalConsultas/Consultas/ConsultaEstablecimientos.aspx
Links to distributors (including wholesalers) register:
http://www.digemid.minsa.gob.pe/conpro.asp
Links to authorized medicines register:
http://www.digemid.minsa.gob.pe/conpro.asp
Links to in vitro diagnostics medical products register:
http://www.digemid.minsa.gob.pe/conpro.asp

PHILIPPINES

Links to manufacturers register:
Links to importers register:
Links to marketing authorization holders register:

Links to distributors (including wholesalers) register:

Links to authorized medicines register:

Links to in vitro diagnostics medical products register:

SAUDI ARABIA

Links to manufacturer register:
https://mdel.sfda.gov.sa/PublicModule/LicensedApplicants.aspx

Links to importers register:
https://mdel.sfda.gov.sa/PublicModule/LicensedApplicants.aspx

Links to distributors (including wholesalers) register:
https://mdel.sfda.gov.sa/PublicModule/LicensedApplicants.aspx

Links to in vitro diagnostics medical products register:
https://www.sfda.gov.sa/ar/medicaldevices/Authorized/Pages/Authorized-Medical.aspx

Links to marketing authorization holders register:
https://www.sfda.gov.sa/ar/medicaldevices/Authorized/Pages/Authorized-Medical.aspx

Links to authorized medicines register:
https://www.sfda.gov.sa/ar/medicaldevices/Authorized/Pages/Authorized-Medical.aspx

SENEGAL

Links to manufacturer register:
http://www.dirpharm.net/

Links to importers register:
http://www.dirpharm.net/

Links to marketing authorization holders register:
http://www.dirpharm.net/

Links to distributors (including wholesalers) register:
http://www.dirpharm.net/

Links to authorized medicines register:
http://www.dirpharm.net/

Links to in vitro diagnostics medical products register:
http://www.dirpharm.net/
SINGAPORE

Links to manufacturers register:

Links to importers register:

Links to marketing authorization holders register:

Links to distributors (including wholesalers) register:

Links to authorized medicines register:

Links to in vitro diagnostics medical products register:

SLOVAKIA

Links to marketing authorization holders register:
ftp://www.sukl.sk/Zoznam_liekov/

Links to authorized medicines register:
ftp://www.sukl.sk/Zoznam_liekov/

SPAIN

Links to manufacturers register:
https://www.aemps.gob.es/industria/regLabFarma/home.htm

Links to importers register:
https://www.aemps.gob.es/industria/regLabFarma/home.htm

Links to marketing authorization holders register:
https://www.aemps.gob.es/industria/regLabFarma/home.htm

Links to distributors (including wholesalers) register:
https://www.aemps.gob.es/industria/distribucion_medicamentos/home.htm

Links to authorized medicines register:
https://cima.aemps.es/cima/publico/home.html
SWEDEN

Links to distributors (including wholesalers) register: http://eudragmdp.ema.europa.eu
Links to manufacturer register: http://eudragmdp.ema.europa.eu
Links to importers register: http://eudragmdp.ema.europa.eu
Links to marketing authorization holders register: https://lakemedelsverket.se/LMF/
Links to authorized medicines register: https://lakemedelsverket.se/LMF/

SWITZERLAND

Links to manufacturers register: https://www.swissmedic.ch/swissmedic/fr/
Links to importers register: https://www.swissmedic.ch/swissmedic/fr/
Links to marketing authorization holders register: https://www.swissmedic.ch/swissmedic/fr/
Links to distributors (including wholesalers) register: https://www.swissmedic.ch/swissmedic/fr/

UNITED REPUBLIC OF TANZANIA

Links to manufacturers register: www.tfda.go.tz
Links to importers register: www.tfda.go.tz
Links to marketing authorization holders register: www.tfda.go.tz
Links to distributors (including wholesalers) register: www.tfda.go.tz
Links to authorized medicines register: www.tfda.go.tz
Links to in vitro diagnostics medical products register: www.tfda.go.tz
UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND

Links to distributors (including wholesalers) register:
http://eudragmdp.ema.europa.eu

Links to manufacturers register:
http://eudragmdp.ema.europa.eu

Links to importers register:
http://eudragmdp.ema.europa.eu

Links to authorized medicines register:
https://www.gov.uk/pil-spc (patient information leaflets and summaries of product characteristics)

UNITED STATES OF AMERICA

Links to distributors (including wholesalers) register:
https://www.accessdata.fda.gov/scripts/cder/wdd3plreporting/index.cfm

Links to authorized medicines:
https://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/default.htm
https://www.fda.gov/BiologicsBloodVaccines/ucm121134.htm

Links to marketing authorization holders register:
https://www.accessdata.fda.gov/scripts/cder/druls/default.cfm
https://www.accessdata.fda.gov/scripts/cder/druls/default.cfm
https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EstablishmentRegistration/TissueEstablishmentRegistration/ucm148002.htm

Links to medical devices and medical device manufacturers register:
https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053199.htm
https://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm

URUGUAY

Links to authorized medicines register:
https://listadomedicamentos.msp.gub.uy/ListadoMedicamentos/servlet/com.listadomedicamentos.lista
domicilios