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# VIETNAM GUIDANCE DOCUMENT

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# Content

# Vietnam Guidance Document

## Vietnam Clinic - Feb.15, 2022

Update on Apr 18, 2022 after receiving MOST Dispatch No. 517 and 870/TĐC-QLCL

| Questions | Response from Vietnam team (Update information) | Information/Remark (Update information) |
|---|---|---|
| **Decree 111**<br>How other companies comply to Decree 111, particularly on meeting the COO IF their original label does not have COO printed. | • Will revise the original label.<br>• Put English COO sticker on label before importing into VN<br>• Put Vietnamese sublabel covering COO before importing into Vietnam<br><br>• The required COO content in original label before importation has been allowed a transition time of 2 years since 15 Feb 2022.<br>• However, products circulated in Vietnam market should have Vietnamese sub-label according to local regulation (decree 43 and decree 111). | |
| **Article 24 (Transition Clause)**<br>How can companies justify meeting this clause - "labels and commercial packages… been produced or printed before the effective date of this Decree may be used for manufacture of goods for up to 2 more years from the effective date of this Decree"? | • The required contents in original label before importation have been allowed a transition time of 2 years since 15 Feb 2022.<br>• However, products circulated in Vietnam market should have Vietnamese sub-label according to local regulation (decree 43 and decree 111). | |
| **Article 15 (Origins of Goods)**<br>a. It is stated in point 4 that "The name of the country or territory where the goods are manufactured or the place where the final stage of finishing the goods is performed must not be abbreviated."<br>b. Does this mean those widely understood country codes such as "US", "UK" is not accepted?<br>d. What about lesser-used country codes such as "MX", "FI", "CH" etc.? | a. & b. & c. If the abbreviations are according to the ISO 3166-1, they are accepted for original label. Please refer to ISO 3166-1. But country name must not be abbreviated on Vietnamese sub-label. | Refer to item 4, clause 15 (page 4) |
| **Article 1 (Scope)**<br>a. Any item that could be out of scope (E.g. spare parts for medical equipment? Accessories (E.g. CD-Rom?) | Scope covers all goods, except for property, temporary import/export goods, … | Refer to item 2 clause 1 |

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| **COO requirement** | a. Yes, COO sticker can be applied for Sale Unit/Carton box before importing into Vietnam. | |
| a. Can companies affix supplementary/additional COO sticker on the sales unit/carton box to meet the COO requirement?<br>b. What is the level of labelling for the COO? Is it the sales unit?<br>c. Also by affixing additional COO sticker, Will there be issues later with product registration/renewal with Decree 98?<br>d. Also, just curious, how ready are VN's customs in enforcing the Decree 111 since the effective date is tomorrow (15 Feb)? | b. Level of COO requirement before importation is shipping carton of each product. Level of COO requirement before selling in Vietnam is selling unit.<br>c. No. Please describe more, provide specific case<br>d. Early to have experience the reaction from Custom. However, if imported products do not comply with local requirement by random checking, Custom will "hold" shipment at custom clearance stage. | |
| **Free Trade Zone**<br>Are there any free trade zone in VN where #4 (i.e. additional COO) can be pasted prior to clearance to VN? | Yes, border warehouse | |
| **Industry representation**<br>I understand there are various industry representations and/or queries by industry submitted to MOH on this Decree. Any meeting minutes or documents that recorded the discussions and answers from authorities? | • Yes. RAWG has been working and influencing since 2020<br>• There were several meetings/workshop and Association position letters since 2020 – still present<br><br>On March 10, 2022, the MOST made a response to the MDDSC, agreeing to allow abbreviations of the origin of goods in accordance with global practice or as specified in ISO 1366-1. The MOST also clarified that the Decree stipulates a transition period of 2 years from the effective date so that enterprises can make new labels instead, during transition time enterprises continue to use printed goods labels according to the production plan. In case the goods labels have been produced and printed according to the provisions of Decree No. 43 according to the enterprise's plan, they will continue to be used for production, ensuring no more than 02 years from the effective date of Decree 111. If the original label does not comply with the provisions of Decree No. 111, the enterprises may continue to use it but must fully label the secondary label in accordance with the provisions of Decree 43 and Decree 111. In short, all concerns/ unclear points related to the labeling requirement are solved. | - Eurocham position letter in Aug 2020, Sep 2021 and Jan 2022)<br><br>- Eurocham Position Letter No. 2501/2022/OOG/EUC-MDDSC<br><br>- MOST Dispatch No. 517 and 870/TĐC-QLCL |

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| The current Decree 98 requires Class B devices (including those exempted previously for import license) to obtain the publication of applicable standards (similar to Class A) before they can be imported into Vietnam. This requirement is effective from 1 Jan 2022. Is there is alternative or transition period for this group of devices. We heard that the Vietnam custom is requesting to see the approval during shipment clearance? | • Class B with import license exempted have to obtain the publication of applicable standards from 1 Jan 2022<br>• Class B with import license can be continuously imported until 31 Dec 2022 | |
| Local label requirements | Refer to presentation | |
| Upcoming price disclosure | Under discussion for development declaration template and how to implement. | |
| Marketing material approval process | Self-declaration for promotional material will be effective from 01 Jul 2022 | |
| **Business**<br>a. Can license be transferred? If so what is the timeframe and requirement?<br>b. What is the requirements to bring in a research only product into Vietnam? Is import license required as stated in Decree 98? is required IL. Is this import license product specific? | a. No, new submission<br>b.<br>• MDD can be imported for research purpose ⟶ Import License is required.<br>• RUO (Not IVD or MD yet) is out of scope of Decree 98, is under chemical law ⟶ special import permission required depends on the substance and composition. | |
| **Risk classification**<br>a. Understand that we are going to self-assign a risk class of a product based on Circular 39/2016 but is there a need to check with MOH again prior to the registration submission?<br>b. Please clarify on Article 6 and 7. When will these happen?<br>c. Under Article 76 clause 2d, it mentioned that for Class C and D not in the list of circular 30, they have to be classified and announced by the MOH on the portal. Please advise how is this done? Is this "listing" on MOH portal also applicable to other products other than the above-mentioned Class C and D not in the list of circular 30? | a. No. It is applicant responsibility ⟶ MOH does not check prior to the registration. MOH may check during the review process for class C and D registration and post check for class A and B.<br>b. Effective Jan 1, 2022. When MOH detects wrong classification of MD with decreasing risk level such as C instead of B risk<br>c. For class C and D not required Import License, they have to be classified and published on MOH portal by the importer.<br><br>For other products, it does not require to classify risk certificate/document signed for submission purpose according to Decree 98. However, it is recommended to classify and publish on MOH portal for customs and tender purpose later. | |
| **Document requirement** | | |

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| a. Is this required document "certificate of product quality inspection or assessment/ Quality assessment certificate" referring to the local evaluation report/certificate? If not please advise.<br>b. Any Vietnam-specific content needed for "CSDT dossier"?<br>c. Any minimum performance requirement of the products especially for higher risk products like Covid-19 test kit?<br>d. Is amendment and notification required for changes to the secondary label?<br>e. Besides single use products, are reagents and solutions exempted from Certificate of Warranty? What are the other applicable products?<br>f. Should there be a change in distributor, can we continue to distribute and exhaust inventory bearing the old distributor details in market? Is there a timeframe accepted? Is over-labeling acceptable in Vietnam in this case?<br>g. Does hardcopy of original legalized LOA and CFS be submitted? Does legalization need to come from the Country of Origin?<br>h. There are different requirements between instrument and reagent. What if the device does not fall within either scope, which should we follow?<br>i. What is the realistic timeframe for approval of Class A and B devices now, and amendment notification to MOH?<br>j. Is CFS from chamber of commerce acceptable besides the authority in registration or tender?<br>k. Can we include English text in Vietnamese product name? Is this acceptable and any impact to the tender? | a. Not clear the question. Which article???<br>b. Yes, refer to CSDT decision 2426/QD-BYT<br>c. No specific performance requirement for registration purpose.<br>d. Yes for all level of commercial packaging label.<br>e. Reagents/solutions/other products can be exempted with confirmation/justification letter from manufacturer<br>f. Not a clear question.<br>g. No need to submit hard copy, electronic copy to be submitted. Yes, legalization needs to come from the CoO of LOA and CFS.<br>h. Different requirements between 2 product groups:<br>- Reagent/calibrator/control<br>- Other products including instruments<br>i. Around one month from completion of submission with payment receipt.<br>j. Not experience. It may be accepted if chamber of commerce is authorized by Government.<br>k. No. except for several specific cases such as real-time PCR,… | |
| If the COO is detailed within the UDI on the label – is this acceptable? | Not acceptable. | Revision of Article 15 by Decree 111:<br>2. Origin of goods on the label shall be expressed as: "sản xuất tại" ("made in"); "chế tạo tại" ("manufactured in"); "nước sản xuất" ("country of origin"); "xuất xứ" ("country"); "sản xuất bởi" ("manufactured by"); "sản phẩm của" ("product of") followed by the country's name or region in which the goods are produced or presented in accordance with the regulations of the Law on origin of goods. |

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| 1. If the COO is detailed within the UDI on the label – is this acceptable? | Not acceptable. | Revision of Article 15 by Decree 111:<br>2. Origin of goods on the label shall be expressed as: "sản xuất tại" ("made in"); "chế tạo tại" ("manufactured in"); "nước sản xuất" ("country of origin"); "xuất xứ" ("country"); "sản xuất bởi" ("manufactured by"); "sản phẩm của" ("product of") followed by the country's name or region in which the goods are produced or presented in accordance with the regulations of the Law on origin of goods. |
| It's written in Decree 111 that the COO could be present on the original label in a foreign language, so we just want to confirm that it's acceptable for the COO to be written in any foreign language (not necessarily have to be English or the language of the COO territory). If we follow the decree closely, it should be alright if, let's say, a product is produced in Germany, the legal manufacturer is in the USA, but the "Made in Germany" statement on the label is written in Hindu because the big market for that product is India, is that right ? | Your understanding is correct. It is acceptable for COO to be presented in any foreign language and Vietnamese language. | Revision of Article 10 by Decree 111:<br>2. The following information on the original label of goods imported into Vietnam must be written in Vietnamese or foreign language while following customs clearance procedures:<br><br>c) Origin of the goods; In case of unknown origin of goods, the country from which the last stage of finishing the goods is performed;<br><br>Revision of Article 15 by Decree 111:<br>4. The country's name or region in which the good is produced or from which the last stage of finishing the goods is performed shall not be abbreviated forms. |

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| What is the exact definition of COO per Vietnam trade law and how it is aligned with local regulation. There could be huge difference between "the region in which the goods are produced" versus "the region where the last stage of finishing the goods is performed" – both are applicable per Article 10 of Decree 111; however, trade law definition might be different. | 1. What is the exact definition of COO per Vietnam trade law and how it is aligned with local regulations.<br>➡ Reply:<br>Definition of ""Origin of good" – Decree 31/2018/ND-CP<br>1. "Origin of good" means a country, group of countries or territory where such good has been wholly obtained or where the last substantial transformation has been carried out when more than one country, group of countries or territory is concerned in the production of the good.<br>2. There could be huge difference between "the region in which the goods are produced" versus "the region where the last stage of finishing the goods is performed" – both are applicable per Article 10 of Decree 111; however trade law definition might be different.<br>➡ Reply: "the region where the last stage of finishing the goods is performed" is applicable in case the origin of goods in accordance with the regulations in Clause 1 of this Article is unknown. | Revision of Article 15 by Decree 111:<br>3.In case of unknown origin of goods in accordance with the regulations in Clause 1 of this Article, write the country in which the last stage of finishing the goods is performed. |
| Per Article 10; it seems it is acceptable to have the name or abbreviated of the manufacturer or the entity responsible for the goods. If it is acceptable to abbreviate the entity name, I do not see why abbreviation of countries is not acceptable?It is actually much easier to understand the countries abbreviation rather than guessing the entity name abbreviation! | The origins of goods which are abbreviated as specified in ISO 3166-1 are accepted. | Dispatch No. 517:<br>For the origins of goods of which abbreviations are specified in the ISO 3166-1 globally recognized, the enterprise can use these abbreviations as specified in ISO 3166-1 in the original labels. However, the products circulated in Vietnam market should have Vietnamese sub-label according to local regulation. This means the country name on Vietnamese label must not be abbreviated. |
| Would Decree 111 apply for all level of packaging [ie shipper labels, immediate packaging labels and secondary packaging labels]? If not, this needs to be clearly stated. Flexibility is required for smaller size labels due to space issue | Definition of Label – Decree 43:<br>1. Label means any manuscript, printed copy, drawing, photocopy of words, pictures, images that is stuck, printed, attached to, casted, or carved, a container of good or on other kinds of materials to be attached to the good or **commercial container;**<br>➡ Decree 111 apply for packaging level of **commercialized container**<br>For examples:<br>When goods is commercialized in individual box, so the box has to be complied with Decree 43/111;<br>When goods is commercialized in smaller unit, so each unit has to be complied with Decree 43/111; | |

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| **What about the pack insert or IFU?**<br>Does the IFU need to be in Vietnamese language only or would English language be acceptable? | Regarding medical devices:<br>Vietnamese IFU is required and has to be registered before circulation.<br>English IFU does not accept for circulation. | |
| **What about the pack insert or IFU?**<br>If a product is supplied in a pack of xxxx units, what are the requirements for the outer and inner labelling requirements. I would like also to understand what are the requirements for the provision of pack insert. Sometimes a pack of xxx units can only have one insert because this is how it is commercialised globally, what would be the impact if Vietnam has a different arrangement and wants to sell by individual units? | Please refer to the answer of question 5. | |
| Flexibility is definitely required for performing local relabelling to comply with certain local requirements and this should also be taken into consideration by customs procedures in case the original label is not in alignment with certain requirements (such as COO or country abbreviation). | By law, the original label of goods imported into Vietnam is required to show 3 below contents in foreign or Vietnamese when carrying out customs clearance procedures:<br>a) Name of the goods;<br>b) Origin of the goods;<br>c) The name or abbreviated name of the manufacturer or the entity responsible for the goods in the foreign country;<br><br>If the original labels of goods imported into Vietnam are written in a foreign language as prescribed in points a, b, c, after completing the customs clearance procedure and transfer goods to storage, the importer shall add Vietnamese labels with 4 below contents before putting such goods into circulation in domestic market:<br><br>a) Name of the goods;<br>b) Name and address of the entity responsible for the goods (hereinafter referred to as "responsible entity");<br>c) Origins of goods; In case of unknown origin of good, the country in which the last stage of finishing the goods is performed;<br>d) Other mandatory information shall be displayed on the label according to the characteristics of the goods prescribed in Appendix I issued together with this Decree and relevant regulations.<br><br>In summary:<br>• Origins of goods which are abbreviated as specified in ISO 3166-1 are accepted.<br>• The required COO content in original label has been allowed a transition time of 2 year since 15 Feb 2022.<br>However, the products circulated in Vietnam market should have Vietnamese sub-label according to local regulation. | |
| What is the authority's intention on imposing Decree 111 on medical device industry.<br>Given that Country of Origin (COO) are often declared in shipping documents already and what is more important for user/patient are safety and quality related information, unclear of the need to impose additional labelling before customs clearance. | The authority found a gap in labelling regulation Decree 43, not controlling original labels. That resulted in enterprise could import products with blank label and then re-dressing with their own Vietnamese labels.<br>The Decree 111 is issued to control the information on original labels for all kinds of goods, not only MD.<br>For more information, Vietnam's had a big experience enterprise cheating the COO of electronics goods. | |

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| With regards to current custom clearance via Green, Yellow and Red lanes; would it be possible for companies/importers to know which lane they are assigned to by customs.<br>Some companies may then wish to prepare for disruption in supply, say if a company/importer is assigned to the Red lane and is unable to meet the additional Decree 111 requirements. | 1. Would it be possible for companies/importers to know which lane they are assigned to by customs.<br>➡ Reply:<br>By declaration, companies/importers will know which lane they are assigned to by customs. But, company does not know the lane of other companies. | |
| "MADE IN….." to stamp on origin labels, can this proposal be accepted by Custom Office? | Definition of Label:<br>Label means any manuscript, printed copy, drawing, photocopy of words, pictures, images that is stuck, printed, attached to, casted, or carved, a container of good or on other kinds of materials to be attached to the good or commercial container;<br><br>According to "Label" definition, stamped "MADE IN….." is acceptable. | Article 3 – Decree 43:<br>1. Label means any manuscript, printed copy, drawing, photocopy of words, pictures, images that is stuck, printed, attached to, casted, or carved, a container of good or on other kinds of materials to be attached to the good or commercial container; |
| Do standalone software require registration application in Vietnam? According to article 3 of decree 98 (below), the classification, grant of free-sale registration numbers and announcement of eligibility for trading are not applicable to 'software used for medical equipment' | Software does not require to register. | |
| Would like to confirm VN language require for accessories & software? | Yes | Article 10 – Decree 111:<br><br>1. Goods label of goods circulated in Vietnam shall present the following contents in Vietnamese language:<br><br>a) Name of the goods;<br><br>b) Name and address of the entity responsible for the goods (hereinafter referred to as "responsible entity");<br><br>c) Origins of goods; In case of unknown origin of good, the country in which the last stage of finishing the goods is performed;<br><br>d) Other mandatory information shall be displayed on the label according to the characteristics of the goods prescribed in Appendix I issued together with this Decree and relevant regulations. |

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