Preparation: National Legislation Implementing the IHR(2005)

Prepared by the Institute of Health Law (University of Neuchâtel, Switzerland) Staff

February 2019
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This codebook should be used in conjunction with the statistical data extract that can be downloaded from the dataset homepage by clicking on the Data button. There are four standard variables in every LawAtlas dataset. They are:

**JURISDICTION:**
This is a dropdown selection in each coding form. It includes the jurisdictions coded in the dataset.

**EFFECTIVE DATE:**
This date (MM/DD/YYYY) is the most recent effective date of the legal text captured for this place. The effective date represents the date the policy coded was put into effect.

**VALID THROUGH DATE:**
This date (MM/DD/YYYY) is the last date the policy was in effect as reflected by the legal text captured to code this policy.

**LEGAL TEXT:**
This is a text box that captures all legal text relevant to the coding questions. This will not download into Microsoft Excel.
### Questions

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<tr>
<th>Question 1:</th>
<th>Is there a law that regulates response to emergency situations?</th>
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Question 8: What are these authorities?

Question Type: Categorical - check all that apply

Variable Name: Support_SpecificAuthorities_Sub-national authority
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Question 9: What are these authorities?

Question Type: Categorical - check all that apply

Variable Name: Support_SpecificAuthorities_Expert commission
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Question 10: What diseases should be covered by preparedness plans?

Question Type: Categorical - check all that apply

Variable Name: Support_Diseases_Plague
Variable Values: 0, 1
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Question 11: What diseases should be covered by preparedness plans?

Question Type: Categorical - check all that apply

Variable Name: Support_Diseases_Anthrax
Variable Values: 0, 1
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Question 12: What diseases should be covered by preparedness plans?

Question Type: Categorical - check all that apply

Variable Name: Support_Diseases_Pandemic Influenza
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Question 13: What diseases should be covered by preparedness plans?

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Question 21: **What diseases should be covered by preparedness plans?**
Question Type: Categorical - check all that apply
Variable Name: Support_Diseases_Rift valley fever
Variable Values: 0, 1
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Question 22: **What diseases should be covered by preparedness plans?**
Question Type: Categorical - check all that apply
Variable Name: Support_Diseases_Viral hemorrhagic fevers
Variable Values: 0, 1
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Question 23: **What diseases should be covered by preparedness plans?**
Question Type: Categorical - check all that apply
Variable Name: Support_Diseases_Marburg
Variable Values: 0, 1
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Question 24: **What diseases should be covered by preparedness plans?**
Question Type: Categorical - check all that apply
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Variable Values: 0, 1
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Question Type: Categorical - check all that apply
Variable Name: Support_Diseases_Lassa
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Question Type: Categorical - check all that apply
Variable Name: Support_Diseases_Junin
Variable Values: 0, 1
Value Label: 0 = No
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Question 27: **What diseases should be covered by preparedness plans?**
Question Type: Categorical - check all that apply
Variable Name: Support_Diseases_Machupo
Variable Values: 0, 1
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Question 28: **What diseases should be covered by preparedness plans?**

Question Type: Categorical - check all that apply
Variable Name: Support_Diseases_Meningococcal infection
Variable Values: 0, 1
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Question 29: **What diseases should be covered by preparedness plans?**

Question Type: Categorical - check all that apply
Variable Name: Support_Diseases_Smallpox
Variable Values: 0, 1
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Question 30: **What diseases should be covered by preparedness plans?**

Question Type: Categorical - check all that apply
Variable Name: Support_Diseases_Poliomyelitis
Variable Values: 0, 1
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Question 31: **What diseases should be covered by preparedness plans?**

Question Type: Categorical - check all that apply
Variable Name: Support_Diseases_Diphtheria
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Question 32: **What diseases should be covered by preparedness plans?**

Question Type: Categorical - check all that apply
Variable Name: Support_Diseases_Measles
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Question 33: **What diseases should be covered by preparedness plans?**

Question Type: Categorical - check all that apply
Variable Name: Support_Diseases_Botulism
Variable Values: 0, 1
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Question 34: What diseases should be covered by preparedness plans?
Question Type: Categorical - check all that apply
Variable Name: Support_Diseases_SARS
Variable Values: 0, 1
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Question 35: What diseases should be covered by preparedness plans?
Question Type: Categorical - check all that apply
Variable Name: Support_Diseases_Seasonal influenza
Variable Values: 0, 1
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Question 36: What diseases should be covered by preparedness plans?
Question Type: Categorical - check all that apply
Variable Name: Support_Diseases_Zika
Variable Values: 0, 1
Value Label: 0 = No
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Question 37: What diseases should be covered by preparedness plans?
Question Type: Categorical - check all that apply
Variable Name: Support_Diseases_CCHF
Variable Values: 0, 1
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Question 38: What diseases should be covered by preparedness plans?
Question Type: Categorical - check all that apply
Variable Name: Support_Diseases_Not designated in the law
Variable Values: 0, 1
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Question 39: What other entities are mandated to establish preparedness plan to respond to outbreaks of communicable diseases?
Question Type: Categorical - check all that apply
Variable Name: Support_OtherEntities_Airports
Variable Values: 0, 1
Value Label: 0 = No
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Question 40: What other entities are mandated to establish preparedness plan to respond to outbreaks of communicable diseases?
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**Question 41:** What other entities are mandated to establish preparedness plan to respond to outbreaks of communicable diseases?

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**Question 42:** What other entities are mandated to establish preparedness plan to respond to outbreaks of communicable diseases?

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**Question 43:** What other entities are mandated to establish preparedness plan to respond to outbreaks of communicable diseases?

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**Question 44:** What other entities are mandated to establish preparedness plan to respond to outbreaks of communicable diseases?

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**Question 45:** What other entities are mandated to establish preparedness plan to respond to outbreaks of communicable diseases?

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**Question 46:** Is there a law regulating the declaration of a state of emergency?
Question 47: Is the declaration of state of emergency a condition to respond to an outbreak of communicable disease?

Question 48: Are there provisions on the organization of simulation exercises to test the preparedness plans at the national level?

Question 49: Who is responsible for initiating simulation exercises?

Question 50: Who is responsible for initiating simulation exercises?

Question 51: Who is responsible for initiating simulation exercises?

Question 52: Who is responsible for initiating simulation exercises?
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Question 53: **Who is responsible for initiating simulation exercises?**
Question Type: Categorical - check all that apply
Variable Name: Testing_Responsive_Non-governmental organizations
Variable Values: 0, 1
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Question 54: **Who is responsible for initiating simulation exercises?**
Question Type: Categorical - check all that apply
Variable Name: Testing_Responsive_Sub-national level organizations
Variable Values: 0, 1
Value Label: 0 = No
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Question 55: **Who is responsible for initiating simulation exercises?**
Question Type: Categorical - check all that apply
Variable Name: Testing_Responsive_Health care institutions
Variable Values: 0, 1
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Question 56: **Who is responsible for initiating simulation exercises?**
Question Type: Categorical - check all that apply
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Question 57: **Is the timing of simulation exercises regulated?**
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Question 58: **Are professionals required to participate in simulation exercises?**
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Question 59: **Does the law regulate debriefings following emergency responses?**
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Question 60: **Who is in charge of initiating the review?**
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- **Variable Name:** Testing_Review_National public health authority
- **Variable Values:** 0, 1
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Question 61: **Who is in charge of initiating the review?**
- **Question Type:** Categorical - check all that apply
- **Variable Name:** Testing_Review_Government
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Question 62: **Who is in charge of initiating the review?**
- **Question Type:** Categorical - check all that apply
- **Variable Name:** Testing_Review_Specialized department of the Government
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Question 63: **Who is in charge of initiating the review?**
- **Question Type:** Categorical - check all that apply
- **Variable Name:** Testing_Review_Specialized expert committee
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Question 64: **Who is in charge of initiating the review?**
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Question 65: **Who is in charge of initiating the review?**
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Question 79: **What medicines are stockpiled?**
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Value Label: 1 = Yes
Question 80: **What medicines are stockpiled?**
Question Type: Categorical - check all that apply
Variable Name: Shortage_Medicines_Botulinic antitoxin
Variable Values: 0, 1
Value Label: 0 = No
Value Label: 1 = Yes
Question 81: **What medicines are stockpiled?**
Question Type: Categorical - check all that apply
Variable Name: Shortage_Medicines_Antirabies antitoxin
Variable Values: 0, 1
Value Label: 0 = No
Value Label: 1 = Yes
Question 82: **What medicines are stockpiled?**
Question Type: Categorical - check all that apply
Variable Name: Shortage_Medicines_Not designated in the law
Variable Values: 0, 1
Value Label: 0 = No
Value Label: 1 = Yes
Question 83: **Are there provisions on the principles regulating priority distribution of medicines stockpiles?**
Question Type: Binary - mutually exclusive
Variable Name: Shortage_PriorityMedicines
Variable Values: 0, 1
Value Label: 0 = No
Value Label: 1 = Yes
Question 84: **Is there a law that regulates the marketing of new pharmaceutical products?**
Question Type: Binary - mutually exclusive
Variable Name: Shortage_Marketing
Variable Values: 0, 1
Value Label: 0 = No
Value Label: 1 = Yes
Question 85: **Must the new product be authorized before marketing?**
<table>
<thead>
<tr>
<th>Question Type:</th>
<th>Binary - mutually exclusive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variable Name:</td>
<td>Shortage_AuthorizedMarketing</td>
</tr>
<tr>
<td>Variable Values:</td>
<td>0, 1</td>
</tr>
<tr>
<td>Value Label:</td>
<td>0 = No</td>
</tr>
<tr>
<td>Value Label:</td>
<td>1 = Yes</td>
</tr>
</tbody>
</table>

**Question 86:** What are the conditions to obtain the authorization for marketing?

<table>
<thead>
<tr>
<th>Question Type:</th>
<th>Categorical - check all that apply</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variable Name:</td>
<td>Shortage_ConditionsMarketing_Quality of the product</td>
</tr>
<tr>
<td>Variable Values:</td>
<td>0, 1</td>
</tr>
<tr>
<td>Value Label:</td>
<td>0 = No</td>
</tr>
<tr>
<td>Value Label:</td>
<td>1 = Yes</td>
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</tbody>
</table>

**Question 87:** What are the conditions to obtain the authorization for marketing?

<table>
<thead>
<tr>
<th>Question Type:</th>
<th>Categorical - check all that apply</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variable Name:</td>
<td>Shortage_ConditionsMarketing_Safety of the product</td>
</tr>
<tr>
<td>Variable Values:</td>
<td>0, 1</td>
</tr>
<tr>
<td>Value Label:</td>
<td>0 = No</td>
</tr>
<tr>
<td>Value Label:</td>
<td>1 = Yes</td>
</tr>
</tbody>
</table>

**Question 88:** What are the conditions to obtain the authorization for marketing?

<table>
<thead>
<tr>
<th>Question Type:</th>
<th>Categorical - check all that apply</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variable Name:</td>
<td>Shortage_ConditionsMarketing_Efficiency of the product</td>
</tr>
<tr>
<td>Variable Values:</td>
<td>0, 1</td>
</tr>
<tr>
<td>Value Label:</td>
<td>0 = No</td>
</tr>
<tr>
<td>Value Label:</td>
<td>1 = Yes</td>
</tr>
</tbody>
</table>

**Question 89:** What are the conditions to obtain the authorization for marketing?

<table>
<thead>
<tr>
<th>Question Type:</th>
<th>Categorical - check all that apply</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variable Name:</td>
<td>Shortage_ConditionsMarketing_Prior delivery of an authorization to produce</td>
</tr>
<tr>
<td>Variable Values:</td>
<td>0, 1</td>
</tr>
<tr>
<td>Value Label:</td>
<td>0 = No</td>
</tr>
<tr>
<td>Value Label:</td>
<td>1 = Yes</td>
</tr>
</tbody>
</table>

**Question 90:** What are the conditions to obtain the authorization for marketing?

<table>
<thead>
<tr>
<th>Question Type:</th>
<th>Categorical - check all that apply</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variable Name:</td>
<td>Shortage_ConditionsMarketing_Prior delivery of an authorization to import</td>
</tr>
<tr>
<td>Variable Values:</td>
<td>0, 1</td>
</tr>
<tr>
<td>Value Label:</td>
<td>0 = No</td>
</tr>
<tr>
<td>Value Label:</td>
<td>1 = Yes</td>
</tr>
</tbody>
</table>

**Question 91:** What are the conditions to obtain the authorization for marketing?

<table>
<thead>
<tr>
<th>Question Type:</th>
<th>Categorical - check all that apply</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variable Name:</td>
<td>Shortage_ConditionsMarketing_Skills of the producer</td>
</tr>
<tr>
<td>Variable Values:</td>
<td>0, 1</td>
</tr>
<tr>
<td>Value Label:</td>
<td>0 = No</td>
</tr>
</tbody>
</table>
Value Label: 1 = Yes
Question 92: What are the conditions to obtain the authorization for marketing?
Question Type: Categorical - check all that apply
Variable Name: Shortage_ConditionsMarketing_Favourable risk-benefit balance
Variable Values: 0, 1
Value Label: 0 = No
Value Label: 1 = Yes

Question 93: What are the conditions to obtain the authorization for marketing?
Question Type: Categorical - check all that apply
Variable Name: Shortage_ConditionsMarketing_Not designated in the law
Variable Values: 0, 1
Value Label: 0 = No
Value Label: 1 = Yes

Question 94: What authority grants the authorization?
Question Type: Categorical - check all that apply
Variable Name: Shortage_GrantAuthority_Ministry of health
Variable Values: 0, 1
Value Label: 0 = No
Value Label: 1 = Yes

Question 95: What authority grants the authorization?
Question Type: Categorical - check all that apply
Variable Name: Shortage_GrantAuthority_Separate public health national authority
Variable Values: 0, 1
Value Label: 0 = No
Value Label: 1 = Yes

Question 96: What authority grants the authorization?
Question Type: Categorical - check all that apply
Variable Name: Shortage_GrantAuthority_Specific national vaccines authority
Variable Values: 0, 1
Value Label: 0 = No
Value Label: 1 = Yes

Question 97: What authority grants the authorization?
Question Type: Categorical - check all that apply
Variable Name: Shortage_GrantAuthority_Specific national medicine authority
Variable Values: 0, 1
Value Label: 0 = No
Value Label: 1 = Yes

Question 98: What authority grants the authorization?
Question Type: Categorical - check all that apply
Variable Name: Shortage_GrantAuthority_Single national therapeutic products authority
Variable Values: 0, 1
Value Label: 0 = No
Value Label: 1 = Yes

Question 99: What authority grants the authorization?

Question Type: Categorical - check all that apply
Variable Name: Shortage_GrantAuthority_Expert committee
Variable Values: 0, 1
Value Label: 0 = No
Value Label: 1 = Yes

Question 100: What authority grants the authorization?

Question Type: Categorical - check all that apply
Variable Name: Shortage_GrantAuthority_Not designated in the law
Variable Values: 0, 1
Value Label: 0 = No
Value Label: 1 = Yes

Question 101: Are there provisions on an accelerated procedure in times of emergency?

Question Type: Binary - mutually exclusive
Variable Name: Shortage_AcceleratedProcedure
Variable Values: 0, 1
Value Label: 0 = No
Value Label: 1 = Yes

Question 102: Is there a specific procedure to be used in an outbreak of communicable disease to market pharmaceutical products that have been approved abroad?

Question Type: Binary - mutually exclusive
Variable Name: Shortage_ApprovedAbroad
Variable Values: 0, 1
Value Label: 0 = No
Value Label: 1 = Yes

Question 103: Does the law grant WHO oversight in the assessment of quality, safety and performance documentation of the pharmaceutical product in the case of a public health emergency?

Question Type: Binary - mutually exclusive
Variable Name: Shortage_WHOOversight
Variable Values: 0, 1
Value Label: 0 = No
Value Label: 1 = Yes

Question 104: Is the importation of medicines regulated?

Question Type: Binary - mutually exclusive
Variable Name: Shortage_Importation
Variable Values: 0, 1
Value Label: 0 = No
Value Label: 1 = Yes

Question 105: **Must an authorization be obtained to import medicines?**
Question Type: Binary - mutually exclusive
Variable Name: Shortage_AuthObtained
Variable Values: 0, 1
Value Label: 0 = No
Value Label: 1 = Yes

Question 106: **What are the minimal requirements must an importer meet to obtain authorization?**
Question Type: Categorical - check all that apply
Variable Name: Shortage_ImportConditions_Professional qualification of the importer
Variable Values: 0, 1
Value Label: 0 = No
Value Label: 1 = Yes

Question 107: **What are the minimal requirements must an importer meet to obtain authorization?**
Question Type: Categorical - check all that apply
Variable Name: Shortage_ImportConditions_Organization of the business
Variable Values: 0, 1
Value Label: 0 = No
Value Label: 1 = Yes

Question 108: **What are the minimal requirements must an importer meet to obtain authorization?**
Question Type: Categorical - check all that apply
Variable Name: Shortage_ImportConditions_Equipment in the premises
Variable Values: 0, 1
Value Label: 0 = No
Value Label: 1 = Yes

Question 109: **What are the minimal requirements must an importer meet to obtain authorization?**
Question Type: Categorical - check all that apply
Variable Name: Shortage_ImportConditions_Good manufacturing practices in the country of origin similar to the country of importation
Variable Values: 0, 1
Value Label: 0 = No
Value Label: 1 = Yes

Question 110: **What are the minimal requirements must an importer meet to obtain authorization?**
Question Type: Categorical - check all that apply
**Variable Name:** Shortage.ImportConditions._Authorization to produce the medicine/vaccine in the country of origin  
**Variable Values:** 0, 1  
**Value Label:** 0 = No  
**Value Label:** 1 = Yes

**Question 111:** What are the minimal requirements must an importer meet to obtain authorization?  
**Question Type:** Categorical - check all that apply

**Variable Name:** Shortage.ImportConditions._Prior authorization for marketing the medicine/vaccine in the country of origin  
**Variable Values:** 0, 1  
**Value Label:** 0 = No  
**Value Label:** 1 = Yes

**Question 112:** What are the minimal requirements must an importer meet to obtain authorization?  
**Question Type:** Categorical - check all that apply

**Variable Name:** Shortage.ImportConditions._Not designated in the law  
**Variable Values:** 0, 1  
**Value Label:** 0 = No  
**Value Label:** 1 = Yes

**Question 113:** Under what circumstances can these requirements be waived?  
**Question Type:** Categorical - check all that apply

**Variable Name:** prev.requir._Scientific research  
**Variable Values:** 0, 1  
**Value Label:** 0 = No  
**Value Label:** 1 = Yes

**Question 114:** Under what circumstances can these requirements be waived?  
**Question Type:** Categorical - check all that apply

**Variable Name:** prev.requir._Emergency  
**Variable Values:** 0, 1  
**Value Label:** 0 = No  
**Value Label:** 1 = Yes

**Question 115:** Under what circumstances can these requirements be waived?  
**Question Type:** Categorical - check all that apply

**Variable Name:** prev.requir._Orphan diseases  
**Variable Values:** 0, 1  
**Value Label:** 0 = No  
**Value Label:** 1 = Yes

**Question 116:** Under what circumstances can these requirements be waived?  
**Question Type:** Categorical - check all that apply
Variable Name: prev_requir_Not designated in the law
Variable Values: 0, 1
Value Label: 0 = No
Value Label: 1 = Yes

Question 117: Must an authorization for marketing of an imported medicine be obtained before marketing?
Question Type: Binary - mutually exclusive
Variable Name: Shortage_AuthMarketingBefore
Variable Values: 0, 1
Value Label: 0 = No
Value Label: 1 = Yes

Question 118: Is the importation of vaccines regulated like medicines?
Question Type: Binary - mutually exclusive
Variable Name: Shortage_ImportVaccinesMeds
Variable Values: 0, 1
Value Label: 0 = No
Value Label: 1 = Yes