Annex - Template of the National Display of the Risk Management Plan (RMP) in Lebanon - for MAH/Applicant having EU RMP (Rev.1)

Active substance(s) (INN or common name):	
Pharmaco-therapeutic group (ATC Code):	
Name of Marketing Authorization Holder or Applicant:	
Name of the pharmacovigilance representative (if applicable):	
Number of medicinal products to which this National display of RMP refers (i.e. number in Lebanon):	Choose one of the following: 1 2 3 4 5 6
Product(s) concerned (brand name(s)):	<list>

Version number of National Display < Enter a version n° >

Date of final sign off <Enter a date>

For the EU RMP which is the reference of this National Display (referenced EU RMP):

Version number <Enter a version n° >

Table of content of National Display of the RMP

Provide here the table of content of the National display of RMP and its annexes (hyperlink) as showing the page number

Risk management is a global activity. However, because of differences in indication and healthcare systems, target populations may be different across the world and risk minimization activities will need to ***be tailored*** *to the system in place in a particular country or global region. In addition, differences in disease prevalence and severity, for example, may mean that the benefits of a medicinal product may also vary between regions. Therefore a product may* ***need different or supplementary activities in the RMP*** *for each region although there will be core elements which are common to all. For example much of the safety specification will be the same regardless of where the medicinal product is being used but the epidemiology of the disease may vary between e.g. Africa and Europe, and there may be* ***additional or fewer safety concerns*** *depending upon the target population and indication.*

Furthermore, individual countries may have different health systems and medical practice may differ between countries so the conditions and restrictions in the marketing authorization may be implemented in different ways depending upon national customs.

MAH/ Applicants are required to submit RMP to the medicines authority of Lebanon in the situations described in Module V section V.C.3.

Taking into consideration that the core elements of the product's RMP are common and as this guideline was based on the European Good Pharmacovigilance Practice, thus for simplification; MAH/Applicants having EU RMP in place submit both of the following:

1. *the most updated version of the EU RMP (referenced EU RMP including its annexes); altogether with*
2. *the National Display of the RMP (including its annexes).*

In these circumstances (submitting the National Display and the EU RMP), the following conditions apply:

- *When the referenced EU RMP is subject to update the National Display of RMP should be updated in accordance.*
- *Minor differences may exist between this guidance and the EU RMP, in this case MAH/Applicant may be asked by the national medicines authority in Lebanon to submit additional information, use different tables, and/or provide clarification…. etc.*
- *The submitted EU RMP shall be the most updated version.*
- *The EU RMP shall be submitted with its annexes and reference materials.*
- *Generally, it is required that all the risk management activities applied globally/in the EU to be applied in Lebanon as well, especially the risk minimization measures including the measurement of their effectiveness. Accordingly, all activities, action plans and details especially the risk minimization ones (including the measurement of their effectiveness) stated in the submitted EU RMP are expected by default to apply to Lebanon and the MAH is required to adhere to them, EXCEPT otherwise clearly stated and justified by the MAH/Applicant in the "National Display of the RMP" and agreed by the national competent authority. Please pay attention in filling in the National Display of RMP and do not skip any*

activity which was in the reference EU RMP without highlighting whether it will be implemented or not on the national level according to the tables below. Any unjustifiably skipped activity will be considered as "apply to national level" and the MAH is required to adhere to.

The purpose of the "National Display of the RMP" is:

- *To highlight to what extent the risk management activities proposed to be implemented nationally adhere to the globally implemented plan and;*
- *To provide justification for any difference (apart from what implemented in EU) whenever exist including the needed national tailoring if any.*
- *In addition it should include an assessment whether there are any additional national/ region-specific risks or not, describing the added activities that may be added to manage those additional risks.*
- *It provides good evidence that the LSR has clear understanding and commitment about the activities that will be implemented on the national level and how they will be implemented.*

Contacts

Local Safety Responsible (LSR) name ……

LSR signature……

Contact person for this RMP……

E-mail address or telephone number of contact person……

……

Section I: Product(s) Overview

For each product in the RMP

Indication(s)	Current (if applicable) **in Lebanon**
	Current of the medicinal product in the EEA
	Proposed (if applicable) **in Lebanon**
	That of the medicinal product in the EEA
Posology and route of administration in Lebanon	Current (if applicable) **in Lebanon**
	Current of the reference medicinal product in the EEA
	Proposed (if applicable) **in Lebanon**
	That of the reference medicinal product in the EEA
Pharmaceutical form(s) and strengths	Current (if applicable) **in Lebanon**
	Current of the reference medicinal product in the EEA
	Proposed (if applicable) **in Lebanon**
	That of the reference medicinal product in the EEA

Date of first authorization (if authorized) in Lebanon <Enter a date>

Section II: Summary table of Safety concerns

Copy table from Part II: SVIII of the referenced EU RMP and add to the list any risk which may be specific to the region or Lebanon (to which this display will be submitted).

Summary of safety concerns	
Important identified risks	• < > List • Lebanon/ region-specific risk (if any): < > List
Important potential risks	• < > List • Lebanon/ region-specific risk (if any): < > List
Missing information	• < > List • Lebanon/ region-specific risk (if any): < > List

Section III: Summary of the Risk Management Plan by activity

III.1. Activities included in the referenced EU RMP

The following table should summarize all the activities stated in the referenced EU RMP, separate table for each medicinal product included in the National Display of RMP may be provided as appropriate. It should be organized **in terms of the activities/actions** to be undertaken rather than by safety concern. The reason for this is that one proposed activity (e.g. a prospective safety cohort study) could address more than one of the safety concerns.

All the activities of the following types should be covered in the table; in addition indicate the corresponding type in the second column:

- routine pharmacovigilance activities,
- ongoing & planned additional pharmacovigilance activities,
- ongoing & planned post authorization efficacy studies
- routine risk minimization measures
- additional risk minimization measures

Those activities as stated in the referenced EU RMP should be displayed in comparison with those proposed by the MAH/Applicant to be implemented in Lebanon (i.e. on the national level); any difference should be clearly justified. Ideally the following **activity comparison table** can be used to present the needed data.

Activities as stated in the referenced EU RMP	Type of the activity	Safety Concern/ efficacy issue	Action plan in the referenced EU RMP	Action plan in the National Display of the RMP	Highlight differences if any (even minor difference)	Justification

a) If the MAH/Applicant proposes **not to implement** in Lebanon any of the **activities** stated in the EU referenced RMP; this should be clearly highlighted in the above table and comprehensive justification should be supplied, in addition explanation of how the safety concern intended by this activity will then be managed in Lebanon.

b) If the MAH/Applicant proposes some differences (even minor ones) in the action plan of **specific activity** to be followed in Lebanon other than those described in the referenced EU RMP; the differences should be clearly highlighted in the table and comprehensive justification should be supplied as well.

III.2. Supplementary activities on the national level

If the MAH/Applicant will implement in Lebanon additional activities over those stated in the referenced EU RMP (e.g. due to country-specific/region-specific safety concern/s or due to other justified reason); this should be presented in details according to the below tables (for details see Module V parts III and V), as appropriate **any relevant documents should be annexed**. It is also important to realize that for activities already exist in the referenced EU RMP but different action plan in Lebanon is proposed by MAH/Applicant this action plan cannot be included in this section as if it is plan for additional activity, instead the difference should be described in the above table.

a) Supplementary national pharmacovigilance activity(s)

If the supplementary activity is a specific questionnaire is planned for collecting structured data on a safety concern of special interest on the national level this is still considered to be routine but should be mentioned and a mock up provided in this National Display of RMP

annex 7. If the supplementary activity(ies) is of additional pharmacovigilance type (i.e. additional pharmacovigilance activity); fill in the following table, and protocols should be provided in Annex 6 of this National Display of RMP.

Study/activity Type, title	**Objectives**	**Safety concerns addressed (country/region specific)**	**Status (planned, started)**	**Date for submission of interim or final reports (planned or actual)**
<E.g. CRUCIAL Cancer Registry at University College Liver unit (non-interventional cohort,)>	<E.g. To investigate long term survival, time to progression, safety profile and QoL in patients with primary liver cancer or solid tumor metastases>	<E.g. Bradycardia, thrombosis, leukopenia, use in patients with renal impairment, long term safety>	<E.g. Protocol submitted to <<authority name>>	<E.g. Interim reports planned June 2014& 2017. Final study report Dec 2020>
<E.g. Validation of antibody test (non-clinical,>	<E.g. Comparison of Supertest kit with current gold standard>	<E.g. Development of antibodies>	<E.g. Planned start March 2014>	<E.g. Final study report December 2014>

b) Supplementary national post-authorization efficacy study(s)

If the supplementary activity(s) is a post-authorization study fill in the following table. The protocols should be provided in Annex 8 of this National Display of RMP.

Study (type and study number)	Objectives	Efficacy uncertainties addressed	Status (planned, started)	Date for submission of interim or final reports

c) Supplementary national risk minimization activity(s)

If the supplementary activity(ies) is of risk minimization type (i.e. risk minimization activity); fill in the following tables. Details should be provided in Annexes 10 & 11 of this National display of RMP.

Safety concern	
Objective(s) of the risk minimization measures	
Routine risk minimization measures	(Proposed) text in SmPC <E.g. Dose reduction for ……. in section 4.2 of the SPC…… Warning in section 4.4 to…… Listed in section 4.8>
	Comment (e.g. on any differences between SmPCs)
	Other routine risk minimization measures <E.g. Prescription only medicine Use restricted to physicians experienced in the treatment of…….>
Additional risk minimization measure(s)1	Objective and justification of why needed.
	Proposed actions/components and rationale
Additional risk minimization measure(s) 2 (repeat as necessary)	Objective and justification of why needed.
	Proposed actions/components and rationale

Effectiveness of risk minimization measures	
How effectiveness of risk minimization measures for the safety concern will be measured	*If a study is planned, this should also be included in Part III.2 Additional PhV activities to assess effectiveness of risk minimization measures*
Criteria for judging the success of the proposed risk minimization measures	
Planned dates for assessment	
Results of effectiveness measurement	Provide latest assessment at each update of the RMP. For risk minimization measures where formal studies are planned, any results should be mentioned in Part III.2 with the implications discussed here and any remedial actions in V.2
Impact of risk minimization	
Comment	

Section IV: National Display of RMP Annexes

Provide here a list of the annexes of the National Display of the RMP

List of annexes of the National Display of RMP

Annex 1 – should submitted only upon request of Lebanon

Annex 2 - SmPC & Package Leaflet

Annex 3 - N.A. (submitted already in the referenced EU RMP)

Annex 4 - N.A. (submitted already in the referenced EU RMP)

Annex 5 - N.A. (submitted already in the referenced EU RMP)

Annex 6 - Protocols for proposed & ongoing supplementary additional pharmacovigilance activities in National Display of RMP section III.2.a (if applicable)

Annex 7 - Specific adverse event follow-up forms section III. 2.a (if applicable)

Annex 8 - Protocols for proposed and ongoing studies in National Display of RMP section III.2.b (if applicable)

Annex 9 - Synopsis of newly available study reports in National display Section III.2.a. & b.

Annex 10 - Details of proposed additional risk minimization measures (if applicable)

Annex 11 - Mock-up of proposed additional risk minimization measures (if applicable)

Annex 12 - Other supporting data (including referenced material)

Annex 2 - SmPC & Package Leaflet

Current (or proposed if product is not authorized) local (of Lebanon) summary of product characteristics (SmPC) and package leaflet(s) for each product in the RMP.

If multiple versions are included for a product, they should show in which Country(ie) they are applicable. In addition, if available, a core SmPC should be provided with an overview of the changes applicable to the SmPC in Lebanon.

Annex 6 - Protocols for proposed & ongoing supplementary additional pharmacovigilance activities in National Display of RMP section III.2.a

Overview of included protocols

Study title	**Protocol status** *	**Version of protocol**	**Date of protocol version**
	Choose one of the following: • Draft • Approved		<Enter a date>

*Draft = not approved

Approved = when agreed by national authority as appropriate

Annex 7 - Specific adverse event follow-up forms section III. 2.a

Provide forms

Annex 8 - Protocols for proposed and ongoing studies in National Display of RMP section III.2.b

Study title	Protocol status *	Version of protocol	Date of protocol version
	Choose one of the following: • Draft • Approved		<Enter a date>

*Draft = not approved

Approved = when agreed by Authority

Annex 9 - Synopsis of newly available study reports in National display Section III.2.a. & b.

Include the study abstract. For non-interventional studies use the abstract format detailed in Module: VIII Post Authorization Safety Studies of Good Pharmacovigilance Safety Studies

Annex 10 - Details of proposed additional risk minimization measures (if applicable)

Annex 11 - Mock-up of proposed additional risk minimization measures (if applicable)

Mock up examples in English (unless other language is requested by the medicines authority of Lebanon) (of the material provided to healthcare professionals and patients. For those materials directed to patients, in addition to the English version, Arabic translation of the mock up shall be included as well.

Annex 12 - Other supporting data (including referenced material)

Index of included material with regard to the National Display of RMP