

## Sugam Portal checklist for PSUR Submission of Vaccines already approved for Manufacturing or Import in India

Item No	Item Description	Item Type
1.	Covering Letter	File Upload
2.	Executive Summary	File Upload
3.	Marketing status of the proposed product in India	File Upload
<b>4.</b>	<b>Licence Information</b>	<b>Label</b>
4.1.	CLAA Permission/ Approval letter	File Upload
4.2.	Amendments / Post Approval Change approvals (if any)	File Upload
4.3.	Product Labels	File Upload
4.4.	Summary of Product Characteristics (SmPC)	File Upload
<b>5.</b>	<b>Dossier</b>	<b>Label</b>
5.1.	PMS Report/ Phase IV Report if any during the PSUR period	File Upload
5.2.	Safety Summary Report	File Upload
<b>6.</b>	<b>PSUR Report:</b>	<b>Label</b>
6.1.	Title Page	File Upload
6.2.	Introduction	File Upload
6.3.	Current worldwide marketing authorization status	File Upload
6.4.	Actions taken in reporting interval for safety reason	File Upload
6.5.	Changes to reference safety information	File Upload
6.6.	Estimated patient exposure	File Upload
6.6.1	(i) Cumulative and interval subject exposure in clinical trial	File Upload
6.6.2.	(ii) Cumulative and interval patient exposure from Marketing Experience from India	File Upload
6.6.3.	(iii) Cumulative and interval patient exposure from Marketing Experience from rest of the world	File Upload
6.7.	Presentation of individual case histories	File Upload
6.7.1.	(i) Reference prescribing information	File Upload
6.7.2.	(ii) Individual cases received from India	File Upload
6.7.3.	(iii) Individual cases received from rest of the world	File Upload
6.7.4.	(iv) Cumulative and interval summary tabulations of serious adverse events from clinical investigations.	File Upload
6.7.5.	(v) Cumulative and interval summary tabulations from post-marketing data sources	File Upload
6.8	Studies	File Upload
6.8.1.	(i) Summaries of significant safety findings from clinical trials during the reporting period	File Upload
6.8.2.	(ii) Findings from non-interventional Studies	File Upload
6.8.3.	(iii) Findings from non-Clinical Studies	File Upload

6.8.4.	(iv) Findings from literature	File Upload	
6.9.	Other information	File Upload	
6.9.1.	(a) Signal and risk evaluation	File Upload	
6.9.2.	(b) Risk management plan	File Upload	
6.10	Overall Safety Evaluation	File Upload	
6.10.1	(i) Summary of safety concerns	File Upload	
6.10.2.	(ii) Benefit evaluation	File Upload	
6.10.3.	(iii) Benefit risk analysis evaluation	File Upload	
6.11	Conclusion	File Upload	
7	<b>Appendix</b>	<b>Label</b>	
7.1.	Approved Prescribing Information Leaflet	File Upload	
7.2.	ICSRs	File Upload	
7.3.	ICSRs Line listing in xl. / E2B R2/R3 format	File Upload	
7.31	Listed ADR's/AEFI's	File Upload	
7.32	Non-Listed ADR's/AEFI's		
7.4.	SAE CIOMS	File Upload	
8	<b>Warning</b>	<b>Label</b>	
8.1	Drug Alerts/Recalls if any	File Upload	
8.2	Contraindications	File Upload	
8.3	Drug Interactions	File Upload	
8.4	Box Warning	File Upload	
8.5	Indicate whether change shall be made to product information in order to optimize the use of products		
	Assessment by CDSCO of PSUR Data submitted by the applicant	<b>Upload by CDSCO</b>	
<b>Pharmacovigilance Checklist</b>			
9		<b>Pharmacovigilance Inspection</b>	<b>Label</b>
9.1.	Pharmacovigilance System Master File	File Upload	
9.2.	Pharmacovigilance SOPs (Data Collection, Entry, QA- QMS, Signal, Training & Data Management)	File Upload	
9.3.	Pharmacovigilance Internal Audit Report	File Upload	
9.4.	NRA Pharmacovigilance Inspection Report (if available)	File Upload	
9.5.	CAPA Report (if applicable)	File Upload	
10.	AEFI/ADR collected through firm's Pharmacovigilance System		
11	<b>Action taken/safety updates on basis of recommendation of National AEFI committee/Signal Review Panel</b>	<b>Download</b>	
12	<b>Recommendation by CDSCO &amp; comments if available</b>	<b>Download</b>	

## Sugam Portal checklist for PSUR Submission of New Drugs already approved for Manufacturing or Import in India

Item No	Item Description	Item Type
5.	Covering Letter	File Upload
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<b>8.</b>	<b>Licence Information</b>	<b>Label</b>
4.1.	CLAA Permission/ Approval letter	File Upload
4.2.	Amendments / Post Approval Change approvals (if any)	File Upload
4.3	Product Labels	File Upload
4.4.	Summary of Product Characteristics (SmPC)	File Upload
<b>5.</b>	<b>Dossier</b>	<b>Label</b>
5.1.	CTD Module V	File Upload
5.2.	Phase III Clinical Trial Report/ PMS Report/ Phase IV Report	File Upload
5.3.	Safety Summary Report	File Upload
<b>6.</b>	<b>PSUR Report:</b>	<b>Label</b>
6.1.	Title Page	File Upload
6.2.	Introduction	File Upload
6.3.	Current worldwide marketing authorization status	File Upload
6.4.	Actions taken in reporting interval for safety reason	File Upload
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6.6.	Estimated patient exposure	File Upload
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8	<b>Warning</b>	<b>Label</b>
8.1	Drug Alerts/Recalls if any	File Upload
8.2	Contraindications	File Upload
8.3	Drug Interactions	File Upload
8.4	Box Warning	File Upload
	Assessment by CDSCO of PSUR Data submitted by the applicant	<b>Upload by CDSCO</b>

## Sugam Portal checklist for PSUR Submission of Subsequent New Drugs already approved for Manufacturing or Import in India

Item No	Item Description	Item Type
9.	Covering Letter	File Upload
10.	Executive Summary	File Upload
11.	Marketing status of the proposed product in India	File Upload
<b>12.</b>	<b>Licence Information</b>	<b>Label</b>
4.1.	CLAA Permission/ Approval letter	File Upload
4.2.	Amendments / Post Approval Change approvals (if any)	File Upload
4.3	Product Labels	File Upload
4.4.	Summary of Product Characteristics (SmPC)	File Upload
<b>5.</b>	<b>Dossier</b>	<b>Label</b>
5.1.	CTD Module V	File Upload
5.2.	Phase III Clinical Trial Report/ PMS Report/ Phase IV Report	File Upload
5.3.	Safety Summary Report	File Upload
<b>6.</b>	<b>PSUR Report:</b>	<b>Label</b>
6.1.	Title Page	File Upload
6.2.	Introduction	File Upload
6.3.	Current worldwide marketing authorization status	File Upload
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8.3	Drug Interactions	File Upload
8.4	Box Warning	File Upload
	Assessment by CDSCO of PSUR Data submitted by the applicant	<b>Upload by CDSCO</b>

## Sugam Portal checklist for PSUR Submission of Fixed Dose Combinations already approved for Manufacturing or Import in India

Item No	Item Description	Item Type
13.	Covering Letter	File Upload
14.	Executive Summary	File Upload
15.	Marketing status of the proposed product in India	File Upload
<b>16.</b>	<b>Licence Information</b>	<b>Label</b>
4.1.	CLAA Permission/ Approval letter	File Upload
4.2.	Amendments / Post Approval Change approvals (if any)	File Upload
4.3	Product Labels	File Upload
4.4.	Summary of Product Characteristics (SmPC)	File Upload
<b>5.</b>	<b>Dossier</b>	<b>Label</b>
5.1.	CTD Module V	File Upload
5.2.	Phase III Clinical Trial Report/ PMS Report/ Phase IV Report	File Upload
5.3.	Safety Summary Report	File Upload
<b>6.</b>	<b>PSUR Report:</b>	<b>Label</b>
6.1.	Title Page	File Upload
6.2.	Introduction	File Upload
6.3.	Current worldwide marketing authorization status	File Upload
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6.5.	Changes to reference safety information	File Upload
6.6.	Estimated patient exposure	File Upload
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## Sugam Portal checklist for PSUR Submission of New Medical Devices [approved for Manufacturing or Import in India

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2.	Executive Summary	File Upload
3.	Marketing status of the proposed product in India	File Upload
<b>4.</b>	<b>Licence Information</b>	<b>Label</b>
4.1.	CLAA Permission/ Approval letter	File Upload
4.2.	Amendments / Post Approval Change approvals (if any)	File Upload
4.3	Product Labels/ IFU's	File Upload
4.4.	Summary of Product Characteristics (SmPC)	File Upload
<b>5.</b>	<b>Dossier</b>	<b>Label</b>
5.1.	Clinical Investigation Report/PMS Report	File Upload
5.2.	Safety Summary Report	File Upload
<b>6.</b>	<b>PSUR Report:</b>	<b>Label</b>
6.1.	Title Page	File Upload
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8	<b>Warning</b>	<b>Label</b>
8.1	Medical Device Alerts/Recalls if any	File Upload
8.2	Contraindications	File Upload
8.3	Box Warning	File Upload
	Assessment by CDSCO of PSUR Data submitted by the applicant	<b>Upload by CDSCO</b>