

Annex I: Comments regarding the IPPC application – Medichem Manufacturing (Malta) Ltd.

Form A

Section	Duly made?	ERA Comments 15 April 2019	Comments by MML	Duly made?	ERA	Comments by MML
Application Reference Number	✗	This is to be referred as IP 0002/05/E	Done	✓	Noted	/
A1.1	✓	Noted.	/	✓		
A1.2	✓	Noted.	/	✓		
A1.3	✓	Noted.	/	✓		
A1.4	✗	<p>Document: IPPC Permit IP 0002/05 (last issued on 20 December, 2013) Annex A-1</p> <p>Noted as part of the consolidated application the entire permit is to be enclosed.</p>	Done. Annex A-1 amended to include all the permit details	✓	Noted, kindly update Annex A-1 with EP102/20.	Done. Both documents merged together.

		<p>Document: Public Sewer Discharge Permit DMU-5574 (last issued on 7 August, 2017) Annex A-2</p> <p>Noted, kindly provide an updated and valid sewer discharge permit.</p>	<p>Attached last Permit issued on 14th January 2020</p>	✓	<p>Annex A-2 still related to the 2017 version. kindly update</p>	<p>Done. Document Updated</p>
		<p>Kindly include list of any developments permit including the decision notice for:</p> <ol style="list-style-type: none"> 1. DNO 957/18 [Internal alterations and extension of room at first floor, and including sanctioning of existing alterations which are not in accordance to latest approved drawings.] 2. PA/02877/12 [Installation of prefabricated modular laboratory facilities at Medichem manufacturing (Malta) Ltd. Factory] 3. PA/01792/04 [Alterations to existing 	<p>Decision notices for each PA attached as Annex A-4 to Annex A-7</p>	✓	<p>Noted, no further comments.</p>	/

		factory] 4. PA/04257/04 [Installation of manufacturing plant for production of active pharmaceutical ingredients (AP1) in a facility/factory already covered by permit PA 1792/04]				
A2.1	✓	Noted	/			/
A2.2	✗	Noted, however kindly note that usually Ms. Selina Zerafa is typically the operational contact point. Operator to verify.	Included details for Ms Selina Zerafa	✓	Noted	/
A3.1	✓	Noted	/			/
A3.2	N.A	Noted	/			/
A3.3	N.A	Noted	/			/
A3.4	N.A	Noted	/			/
A3.5	✓	Document: Annex A-3 Company Certificate Noted	/			/

A3.6	✓	Noted	/			/
A4	✓	Noted	/			/

Form C

Section	Duly made?	ERA Comments 15 April 2020	Comments by MML	Duly made?	ERA replies	Comments by MML
C1.1	✓	Noted	/			/
C1.2	Duly made?	<u>Document: Annex C-1</u> Noted	/			/
C1.3	✓	<u>Document: Annex C-1</u> Noted, kindly details in terms of timeframes for the proposed changes. With respect to the variation in terms of conditions of the permit, whereby it is indicated that no changes are required. Kindly specify whether the proposed variation will bring about changes with respect to waste generation, air emissions etc. Kindly confirm	The changes were already carried out and finalised in April 2019. The removal of the Quality Control Laboratories from Medichem site will have an insignificant impact on the amount of waste generation and air emissions compared to the amount of waste generated from the	✓	Noted, confirmed during inspection held in July 2020.	/

		whether Emission Point 4b is still in operation on site as thus should be retained in the permit?	<p>Production area. In addition, the Research and development laboratory is still present on site so a small amount of laboratory waste will still be generated.</p> <p>The extraction system previously available for the QC lab is no longer present.</p> <p>Point 4b is referring to the HVAC system present at the HPAPI laboratory hence it will be retained in the permit.</p>			
C1.4	✓	Noted.	/	✓		/
C1.4.1	✖	Kindly include risk assessment, which was drafted for the installation. Kindly specify whether the RA will need to be updated in view of the changes.	<p>Noted. RA for the groundwater and land risk assessment attached as Annex C-2.</p> <p>The Quality Control Laboratory was not considered as a potential source of contamination in the RA. Therefore we do not believe the RA should be updated in this regards.</p>	✓	Noted and agreed with the conclusion of the report that baseline testing is not required.	/

C1.4.2	✖	Kindly provide layout plans for the changes with respect to the QC lab.	Attached as Annex C-15	✓	Noted	/
C1.4.3	✖	Kindly provide block plans for the changes with respect to the QC lab.	Please refer to Annex C-15	✓	Noted	/
C2.1	✖	Noted, kindly advise whether the ISO14001 is still in place for the facility in question. Kindly include latest accreditation certification.	Yes confirmed. ISO 14001 certificate attached as Annex C-3	✓	Noted	/
C2.2.1	✓	<u>Document: Annex C-1</u> Noted	/			
C2.2.2	N/A	Noted	/			/
C2.2.3	N/A	Noted	/			/
C2.2.4	✖	Kindly note that the BAT assessment on Common Waste Water and Waste Gas Treatment was requested for Medichem and is to be submitted.	Done. Attached as Annex C-11	✓	Noted kindly not comments therein.	Noted
C2.2.5	✖	To be re-evaluated once submission of CWWWT BAT is submitted.	Submitted as Annex C-11	✓	This is considered not to be applicable in view of latest submissions and nature of variation requested.	/

C2.3	✖	In view of the relocation of the QC lab kindly indicate whether there will be any changes in terms of raw materials utilized on site. Also kindly clarify as to whether there have been any changes in terms of the production of APIs from those declared in the first application and subsequent IPPC applications thereafter.	<p>No the relocation of the new QC Lab will not have an impact on the raw materials used on site for production. In addition any other materials required for laboratory works would still be required at a less amount for the Research and Development laboratory still present on site.</p> <p>Yes, the type of APIs which are produced on site has changed over the years. An updated list of APIs which are allowed to be produced in Medichem Malta are listed in Annex C-4.</p>	✓	Updated list is noted	/
C2.4	✓	Noted	/			/
C2.5	✓	Noted	/			/
C2.6.1	✖	Kindly specify whether there will be any changes to the annual energy consumption in view of the proposed relocation of the lab. If it is not-significant kindly indicate as such.	There are no significant changes in Energy consumption. This has been confirmed in the Energy Audit carried out in 2019. Report of latest Energy Audit is attached in Annex C-5	✓	Noted	/
C2.6.2	✖	Noted it is understood that there are no changes in terms of energy	Confirmed. Please see comment in C2.6.1	✓	Noted	/

		efficiency onsite. Kindly confirm.				
C2.7	✖	Kindly specify whether there any changes to the annual water consumption in view of the proposed variation.	There are no significant changes in Energy consumption. This has been confirmed in the Energy Audit carried out in 2019. Report of latest Energy Audit is attached in Annex C-5	✓	Noted	/
C2.8	✖	Kindly clarify whether the emergency plan will be updated in view of the proposed variation.	Emergency Response Plan updated in 06/12/2019. Attached as Annex C-6a and C-6b	✓	Noted	/
C2.9	✓	Noted	/			
C2.10	✓	Noted	/			
C2.11	✖	Kindly provide requested details. 1. Kindly provide details on processes which may be interlinked with Combino-Pharma Ltd., by providing a flow diagram. 2. Kindly provide details on infrastructural interlinkages shared with Combino-Pharma Ltd. such as the shared LPG supply, the waste-water treatment plant on site, shared waste management area and	Interlinked Processes as shown in Annex C-14 LPG supply layout plan from Combino as shown in Annex C-12 a and C12b Combino Drain Water system layout plan as shown in Annex C-13	✓	Noted	/

		associated pipework jointly managed by both Operators Layout plans are to be provided (where applicable).				
C3.1.1	✓	Noted	/			
C3.1.2	✓	Noted	/			
C3.1.3	✓	Noted	/			
C3.2	✓	Noted	/			
C3.3.1	✗	Noted, kindly verify whether that no changes have been carried to the drain connection in the former QC lab.	The drain connection which remains present is only for the air conditions.	✓	Noted no further comments.	/
C3.3.2	✓	Noted, kindly provide updated sewer discharge permit.	Attached			
C3.3.3	✓	Noted	/			
C3.3.4	✓	Noted	/			
C3.4	✓	Noted	/			
C3.5	✓	Noted	/			
C3.6	✗	<ol style="list-style-type: none"> Kindly confirm whether EP4b in the permit is to be retained? Kindly provide a list of all exhaust HVACs in the facility. Kindly indicate in a site layout plan. Kindly note that as per the requirements of the limitations of emissions of certain pollutants into the air from medium combustion plants 	<p>The previous extraction system present at the lab is no longer present. EP4b is to be kept as this refers to the HVAC exhaust of the High Potency unit.</p> <p>Form for Medium Combustion Plant filled in for Medichem Boiler. Generator on site has an energy power output of</p>	✓	Noted, however kindly note we require the rated thermal input for the generator not the output.	Rated Thermal Input Calculated: 0.98MW

		regulations (S.L.549.122), any combustion plants on site will need to be renewed. Kindly fill in form attached for each MCP on site.	496kW.			
C3.7	✓	Noted	/			
C3.8	✓	Noted	/			
C3.9	✗	Kindly verify that the proposed changes will not significantly effect the noise levels emitted from the site.	The Quality Control laboratory was not a source of noise at Medichem in the Noise Monitoring Report carried out in 2016, hence there are no significant changes in noise levels emitted from site.	✓	Noted	/
C3.10	✓	Noted	/			
C3.11	✓	Noted	/			
C4.1	✓	Noted	/			
C4.2	✓	Noted	/			
C5.1	✓	Noted	/			
C6.1	✓	Noted	/			
C6.2	✓	Noted	/			
C6.3	✓	Noted	/			
C7.1	✗	Kindly include developments permits in this section	Noted. Annex C-7 attached	✓	Noted	/
C8.1	✗	Kindly provide details of nominated operational contact and provide a copy of the CV.	Annex C-8 and Annex C-9	✓	Noted	/
C8.2	✗	It is our understanding that the TCP for Medichem is the same as	Noted. Done	✓	Noted	/

		that of Combino Pharm (Malta) Ltd., therefore this section is to be marked as yes.				
C9.1	✘	Kindly re-confirm in view of clarifications requested above section and in statutory consultation feedback.	Annex C-10 attached.	✓	Noted	/

Annex I: Comments regarding the IPPC application – Combino Pharm (Malta) Ltd.

Form A

Section	Duly made?	ERA Comments 15 April 2020	Comments by CPL		ERA	Comments by CPL
Application Reference Number		Kindly include IP0002/05/E		✓	Noted	/
A1.1	✓	Noted	/			
A1.2	✓	Noted	/			
A1.3	✓	Noted	/			
A1.4	✘	Document: Environmental Permit EP 0036/09 (last	Noted. Annex A-1 amended	✓	Noted, however kindly include	Done. Documents merged together.

		<p>issued on 17 December, 2014) - Annex A-1</p> <p>Kindly note that a complete version will be required as part of the consolidated application.</p>			EP102/20 permit in this document	
		<p>Document: Waste Carrier Permit Class A4 GBR 320/12 (last issued on 26 March, 2018) – Annex A-2</p> <p>Kindly remove from this section</p>	Noted – Removed	✓	Noted	/
		<p>Document: Waste Carrier Permit Class D2 GBR 277/12 (last issued on 8 March, 2018) – Annex A-3</p> <p>Kindly remove from this section</p>	Noted – Removed	✓	Noted	/
		<p>Document: Public Sewer Discharge Permit DMU-5887 - Annex A-4</p> <p>Kindly provide updated and valid permit.</p>	Annex A-4 Amended accordingly	✓	Noted	/

		Document: LPG Storage LPG-00545-SS (SS-72) Kindly provide updated and valid authorization.	Annex A-5 Amended accordingly	✓	Noted	/
		Kindly include any relevant Planning Authority permits onsite.	Included Annex 7 to Annex 11	✓	Noted	/
A2.1	✓	Noted	/			
A2.2	✓	Noted, however kindly note that usually Ms. Selina Zerafa is typically the operational contact point. Operator to verify.	/			
A3.1	✓	Noted	/			
A3.2	N.A	Noted	/			
A3.3	N.A	Noted	/			
A3.4	N.A	Noted	/			
A3.5	✓	Document: Annex A-6 Company certificate Noted	/	✓	Noted	/
A3.6	✓	Noted	/			

A 4	✓	Noted	/			
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Form B


Section	Duly made?	ERA Comments 15 April 2020	Comments by CPL		ERA	Comments by CPL
B1.1	✓	The activity indicated as 4.5 is to be to be removed. Activities in the “stationary technical unit” should be left blank. Under directly associated activities, kindly include the manufacture of finished dosage forms in this section.	Noted. Amended Noted – Included	✓	Noted	/
B1.2	✓	Document: Annex B-1 Noted.	/			
B1.3	✗	Kindly tick option 2.	Noted. Amended	✓	Noted	/
B1.4.1	✗	Kindly note that risk assessment that was drafted for Medichem will need to be updated to include the CPL site, this was already communicated to the Applicant.	The current Groundwater and land risk assessment only takes into consideration the Medichem site. A groundwater and land risk assessment for	✓	Noted, item will be include as Improvement programme item.	Noted

			Combino is to be performed by Q3 2021			
B1.4.2	✖	Document: Annex B-3 Kindly provide clearer map showing the full site boundary as requested in the form.	Annex B-3 amended with highlighted site boundary.	✓	Submissions Noted	/
B1.4.3	✓	Document: Annex B-4 –First Floor Noted Document: Annex B-4 – Ground Floor Noted	/			
B2.1	✓	Noted	/			
B2.2.1	✓	Document: Annex B-1 Noted	/			
B2.2.2	✓	Annex B-6 Noted	/			
B2.2.3	✓	Document: Annex B-7 Noted	/			
B2.2.4	✖	Document Annex B-8 Kindly note that the BAT Assessment was not	Annex B-8 can be removed from submission.	✓	Changes noted	/

		required was the current and proposed operations of CPL. The non-requirement is to be made clear in the application.				
B2.2.5	✖	<p><u>Document :Annex B-8</u></p> <p>Kindly indicate whether alternative technology other than to the existing and proposed have been considered.</p>	No. In case of a change in equipment or procurement of new equipment we will evaluate the options available, considering BAT techniques, infrastructure requirements and other factors.	✓	Agreed.	/
B2.3	✖	<p><u>Document: Annex B-9</u></p> <p>Kindly clarify whether there is any changes to the raw material list and storage as provided in EP form. Kindly provide information to the required detail, including details of the following</p> <ol style="list-style-type: none"> 1. Exhaustive list of raw materials utilised on site. 2. For each substance indicated the maximum storage capacity and 	<p>Updated Annex B-9 with list of APIs and raw materials which may be stored on site. There is no maximum capacity of material which is stored. Material is procured according to the final dosage form which will be produced. Containment is explained in Annex B-9 'General' Section</p> <p>Annex B-4 is indicating</p>	✓	Noted, however MSDS sheets are to be provided	Noted. MSDS sheets included in Annex B-9b and c

		containment measures (including bunding capacity, where applicable); 3. The raw material storage should be identified clearly on a site layout plan.	the Warehouse area where raw materials are stored by a red line marking the area concerned.			
B2.4	✓	Noted.	/			
B2.5	✗	Kindly provide maintenance plan. In the event of confidentiality issues, kindly note that the document will not be made public.	Attached procedure as Annex B-20. Please note this is an internal procedure which should be kept confidential.	✓	Noted no further comments	/
B2.6.1	✗	Document: Annex B-11 With respect to the recommendation of the report, will any of the proposed suggestion be carried out. If so kindly, provide timeframes.	Attached updated Energy Audit report carried out in 2019 as Annex B-21 which provides feedback on the recommendations carried out in 2016. New recommendations are still being evaluated for implementation and by when.	✓	Noted, improvements will be included as IP item.	/
B2.6.2	✓	Document :Annex B-11 Noted.	/			

B2.7	✖	Document :Annex B-11 See comments above also breakdown of the proposed annual water consumption by source and end-use is to be provided.	Water consumption main sources are for use in production processes; cleaning; sanitization; and other administration and sanitary use.	✓	Noted	/
B2.8	✖	Document: Annex B-12 Kindly submit emergency response plan.	Noted. Attached as Annex B-22a and B-22b	✓  Annex B-22a Emergency Plan Full T	Noted	/
B2.9	✖	Document: Annex B-5 Kindly provide training SOPs.	Annex B-5 updated to reflect reference to current procedure accordingly. Attached training procedure as Annex B-23. Please treat as confidential.	✓	Noted	/
B2.10	✖	Document: Annex B-13 Cessation Plan is to be updated with the required information requested in the form.	The Cessation Plan requirements listed refers to the need to have a qualitative assessment of the potential for contamination of land and groundwater pollution which might arise from the historical and current processes carried out at the installation which	✓	Noted, requirement included as IP item.	/

			requires the land and groundwater risk assessment. It is therefore suggested for this plan to be submitted with the land and ground water risk assessment by Q3 2021			
B2.11	x	<p>Kindly provide requested details.</p> <p>3. Kindly provide details on processes which may be interlinked with MML, via a flow diagram.</p> <p>4. Kindly provide details on infrastructural interlinkages shared with MML such as the shared LPG supply, the waste-water treatment plant on site, shared waste management area and associated pipework jointly managed by both Operators</p>	<p>Interlinked Processes as shown in Annex B-26</p> <p>LPG supply layout plan from Combino as shown in Annex B-27a and B-27b.</p> <p>Combino Drain Water system layout plan as shown in Annex B-28</p>	<p>✓</p>  <p>Annex B-26 Interlinked Processes.</p>	Noted	/

		Layout plans are to be provided (where applicable).				
B3.1.1	✖	<u>Document: Annex B-14</u> Kindly clarify whether there any changes to the waste produced on site as that declared in the EP applications. Kindly provide information the required detail.	Annex B-14a and B-14b updated accordingly	✓	Noted, kindly note comments in statutory consultation on waste EWC codes.	Noted.
B3.1.2	✖	<u>Document: Annex B-14</u> The document provided lacks the required details.	Annex B-14a and B-14b updated accordingly	✓	Noted	/
B3.1.3	✖	<u>Document: Annex B-14</u> The document provided lacks the required details.	Annex B-14a and B-14b updated accordingly	✓		
B3.2	✓	Noted	/			
B3.3.1	✖	Kindly elaborate on the connections to sewer in the MML and provide a site drainage layout.	Annex B-28 attached		Noted	/
B3.3.2	✓	Noted	/			
B3.3.3	✖	<u>Document: Annex A-2 of IPPC Form A</u>	Annex A-4 updated with latest permit	✓	Noted	/

		Kindly provide updated sewer discharge permit				
B3.3.4	✓	Noted	/			
B3.4	✓	Noted	/			
B3.5	✗	Kindly provide requested information	No rainwater is harvested or stored at Combino Pharm Malta Ltd. There is not the infrastructure in place for storage of rainwater.	✓	Noted	/
B3.6	✗	<p><u>Document: Annex B-15</u></p> <p>Noted however, kindly supplement information with that already provided in the EP application.</p> <p>Kindly clarify whether the medium combustion plants on site fall within scope of the S.L. 549.122 <i>Limitation of Emissions of Certain Pollutants into the air from Medium Combustion Plants Regulations</i>. Kindly provide Rated thermal input for any MCP on site. If any MCP on site falls within scope, annex III for each MCP is to be provided.</p>	<p>Noted. Annexes B-15a and B-15b amended to include further information on air emission points.</p> <p>Both boiler and generator do not have a rated Thermal Input greater than 1MW therefore they do not fall under SL 549.122 regulation. Details of boiler and generator are also provided in Annex B-15a.</p> <p>Site Layout plan included in B-15b</p>	✓	Noted, Kindly include figure of RTI of the medium combustion plants in annex B-15.	Done.

		Kindly provide a list of all exhaust HVACs in the facility. Kindly indicate in a site layout plan.				
B3.7	✓	Noted	/			
B3.8	✓	Noted	/			
B3.9	✗	<u>Document: Annex B-16</u> Kindly see comments on noise provided by the statutory consultees	No environmental noise measurement survey is available for Combino. This can be carried out by Q3 2021.	✓	Noted to be included as IP item	/
B3.10	✗	<u>Document: Annex B-15</u> Kindly provide requested information.	Information included in Annex B-15a	✓	Noted	/
B3.11	✗	Kindly provide	Annex B-24	✓	Noted	/
B4.1	✓	Noted	/			
B4.2	✓	Noted	/			
B5.1	✓	Noted	/			
B6.1	✓	Noted	/			
B6.2	✗	Kindly mention Medichem here.	Done.	✓	Amendment noted.	/
B6.3	✓	Noted	/			
B7.1	✗	<u>Document: EP 0036/09</u> Kindly provide list of applicable development permits	Removed reference to Environmental Permit and included list of development permits available for Combino.	✓	Noted	/
B8.1	✓	Document: Annex B-17 Noted	/			

B8.2	✓	<u>Document Annex B-18</u> Noted	/			
B8.3	✓	<u>Document: Annex B-19</u> Noted	/			
B9.1	✗	Kindly provide requested plan	Annex B-25 attached.	✓	Noted	/