

Subject: IP 0002/05/E – Application for the renewal and variation of IP 0002/05/E for Medichem Manufacturing Malta Ltd & Combino Pharma (Malta) Ltd., Hal Far, Birzebbugia

Date: 5th January 2020

To: ERA Board

From: Environment Resources Directorate

Case officer: Gabriella Grima

1. Background

This report has been prepared for the determination of IP 0002/05/E (renewal and variation of IP 0002/05/E) for Medichem Manufacturing Malta Ltd & Combino Pharma (Malta) Ltd., submitted both by Dr. Dino Mangion on behalf of both installations. In this regard, the application was received on 5th March 2019 and a consolidated application was submitted on 17th November 2020.

2. Case Officer Report

2.1 Proposal

The application for renewal and variation of IP 0002/05/E proposes the following additions to the current operations:

1. The consideration of both Medichem Manufacturing Malta Ltd and Combino Pharma (Malta) Ltd. as a multi-operator permit;
2. The removal of the Quality control laboratory from Medichem Manufacturing Ltd. and relocation to Combino Pharma (Malta) Ltd.

2.2 Proposed Emissions and Mitigation

Table 1 : Emission points for Medichem Manufacturing Malta Ltd		
Emission point reference	Source	Mitigation Measures
1	Production area	Wet scrubber
2a	Vent atmospheric tank	

2b	Vent atmospheric tank	The vent of each tank passes through a condenser to minimise the emissions.
2c	Vent atmospheric tank	
3	Boiler	Stack height in accordance with regulations, 3 m above roof level.
4a	HVAC plant exhaust	HEPA filters
4b	HVAC exhaust from HPAPI isolator chambers	All chambers have double HEPA filters system in their exhaust.
5	Cooling Towers	Biocide treatment
6	Generator	N/A
7	Blowdown Tank	The blowdown tank is in itself a mitigation measure
8	R&D Fumehoods vent	G4 & carbon active F7 filters

Table 2 : Emission points to air Combino Pharma (Malta) Ltd

Emission reference (Schedule 3)	point	Source	Mitigation Measures
PS1		Boiler	N/A
PS2		Generator	N/A
PS3a		HVAC production process room	HEPA Filters (H13 99.95% efficiency)
PS3b		HVAC production room	N/A
PS3c		HVAC production room	N/A
PS3d		HVAC packaging room	N/A
PS3e		Fluid bed drier	HEPA Filters (H13 99.95% efficiency)
PS3f		Fluid bed drier emergency stack	Polyester filter
PS3g		Coater	2-stage HEPA Filter (H14 99.995% efficiency)
PS4		Fumehood vent	N/A
PS5		Fumehood vent	N/A
PS6		Fumehood vent	N/A

Table 3: Emission limits and monitoring for Medicchem			
Emission point reference	Parameter	Limit	Minimum Monitoring Frequency
PS1	VOC (total organic carbon)	150 mgC /Nm ³	Annual
PS1	Particulate matter	5 mg/ Nm ³	Annual
PS1	Ammonia	10 mg/ Nm ³	Annual, if process generates such emissions
PS1	HCl	7.5 mg/ Nm ³	
PS1	Cl ₂	1 mg/Nm ³	
PS1	HBr	1 mg / Nm ³	
PS3	NOx	200 mg / Nm ³	Every three years
PS3	SOx	200 mg / Nm ³	Every three years
PS3	CO	-	Every three years
E1	Volume per year	-	Yearly
	Temperature	-	Each batch
	pH	-	Each batch
	Settleable solids	-	Yearly
	Suspended solids	-	Yearly
	Total Kjeldahl Nitrogen	-	Yearly
	Sulphides and compounds releasing hydrogen sulphide on acidification	-	Yearly
	Free and emulsified grease	-	Yearly
	Free Chlorine	-	Yearly
	Chloride	-	Each batch
	Total Sulphates	-	Yearly
	Total Boron	-	Yearly
	Chemical Oxygen Demand	-	Quarterly
	Biological Oxygen Demand	-	Quarterly
Total Phosphorous	-	Yearly	

2.3 Supporting documents recommended for approval

Documents: IP 0002/05/E
IP 0002/05/Ei
IP 0002/05/Eii

Drawings: IP 0002/05/Ei/DOC1

2.4 Applicable law/ policy

Medichem Manufacturing Malta Ltd. carries out of activities which fall within scope of the Industrial Emissions (Integrated Pollution Prevention and Control) Regulations, in particular Activity 4.5:

“Production of basic pharmaceutical products including intermediates”

Meanwhile operations at Combino Pharma (Malta) Ltd.’s involve the production of solid pharmaceutical finished dosage forms which do not fall within scope the Industrial Emissions (Integrated Pollution Prevention and Control) Regulations

The proposal is to comply with:

Applicable to both installations:

- Environment Protection Act (CAP. 549);
- The Waste Regulations (SL 549.63)

Applicable to Medichem Manufacturing Malta Ltd.:

- Industrial Emissions (Framework) Regulations (S.L. 549.76)
- Industrial Emissions (Integrated Pollution Prevention and Control) Regulations (S.L. 549.77)
- Commission Implementing Decision (EU) 2016/902 of 30 May 2016 establishing best available techniques (BAT) conclusions, for common waste water and waste gas treatment/management systems in the chemical sector, under Directive 2010/75/EU of the European Parliament and of the Council
- Best available techniques (BAT) specified in the BREF for Manufacture of Organic Fine Chemicals (published August 2006)

2.5 Site Description and Constraints

Medichem Manufacturing (Malta) Ltd is located in Hal Far Industrial Estate in which the predominant land uses in the surrounding area are industrial predominantly manufacturing (including other pharmaceutical facilities) and goods / freight terminals. The site is also adjacent to Wied Żnuber valley which is located south of the installation. The site is also located around 15 m north of the mouth of the Wied Żnuber valley; this watercourse discharges at sea level. The cliffs located along the coast just south of the site (starting from the southern boundary of the site) are designated as part of a Special Protected Area (SPA), a Natura2000 Special Area of Conservation (SAC) – Site of International Importance, and scheduled as an Area of Ecological Importance (AEI). The site is located outside the Groundwater Safeguard Zone.

2.6 Site History

The following permitting history is noted on site:

Facility	Number	Title	Status
MML	PA1792/04	alterations to existing factory	<i>Approved (22/7/2004) and completed</i>
MML	PA4257/04	Installation of manufacturing plant for production of active pharmaceutical ingredients (API) in facility/factory already covered by permit PA 1792/04	<i>Approved (14/9/2005) and completed</i>
CPL	PA4695/04	Internal and external alterations to existing factory in Hal Far industrial estate	<i>Approved (16/11/2004) and completed</i>
CPL	PA1825/05	Internal and external alterations to existing factory as approved by PA4695/2004, and addition of sub-station on property	<i>Approved (16/04/2005) and completed</i>
CPL	PA2174/06	Addition of workshop to existing factory	<i>Approved (2/01/2007) and completed</i>
CPL	EP0036/09/A	Environmental Permit for Operations	<i>Granted (19/7/2010) superseded by EP0036/09/B</i>
CPL	PA6006/06	Additional storey onto office-factory HF60	<i>Approved (1/9/2010) and completed</i>
MML	PA2877/12	Installation of prefabricated modular laboratory facilities at Medichem manufacturing (Malta) Ltd. factory.	<i>Approved (12/4/2013) and completed</i>
CPL	PA4360/15	Renewal of approved permit PA60006/06 (additional storey onto office-factory hf60) and including minor alterations approved layouts	<i>Approved (24/02/2016) and completed</i>
MML	DN 00957/18	Internal alterations and extension of room at first floor, and including sanctioning of existing alterations which are not in accordance to latest approved drawings.	<i>Approved (14/12/2018) and completed</i>

2.7 Consultations

i. Intra-ERA feedback

For both installations the Biodiversity and Water Unit did not have any comments in view that that any waste water generated is treated and discharged to the sewerage system.

The Ambient Quality and Waste Unit provided feedback on various aspects. With respect to noise emissions, in which no variation in noise sources was declared by Medichem Manufacturing (Malta) Ltd, the noise team queried whether the proposal could result in a reduction in the noise levels emitted from the site. This was clarified from the Operator that the quality control laboratory was never considered as a significant noise source on site compared to other equipment present which was verified in the Noise Monitoring Report carried out in 2016.

With respect to Combino Pharm (Malta) Ltd, it was suggested that a first noise monitoring study is to be carried out to assess the noise levels emitted from the site operations as an impact on the outside environment and where relevant on the nearest sensitive receptors, in accordance with the latest revision of BS 4142. Such a request has been reflected in the proposed permit.

The waste team, requested a number to a number of clarification with respect the designation of an EWC code which the Operator/s agreed to update their waste disposal procedure.

The Environmental Assessment Unit had no comments since in view that the proposal did not warrant a new development application, and that both installation will retain their permitted operations.

With respect to Medichem Manufacturing (Malta) Ltd 's application, the Compliance and Enforcement Directorate, queried whether any wastes were produced in the conversion of this lab into offices (with particular attention to contaminated equipment and chemical wastes) and how these were disposed of. Following clarification from the Operator, CED had no further comments on the replies from the first round of consultation on this application.

With respect to Combino Pharm (Malta) Ltd.'s application a number of minor clarification were requested and clarified in subsequent submissions. The time period for the submission of Improvement Program Items for the noise monitoring and waste gas inventory required by BAT was considered to be too short.

Annual Environmental Reports for 2016-2019 have all been submitted for both by Medichem Manufacturing (Malta) Ltd and Combino Pharm (Malta) Ltd. With respect Medichem Manufacturing (Malta) Ltd. for each year the fugitive emissions were below the 5% of total solvent consumed.

ii. Feedback from External consultees

The **Water Services Corporation (WSC)** commented that both entities had their permit renewed on 14th January 2020. WSC recommended that the discharge Permit Unit is notified in the event that the operators intended to cease activities. WSC stated that there was no objection from the discharge Permit Unit.

The **Regulator for Energy and Waster Services (REWS)** requested clarification pertaining to fuel storage of both installations. REWS has confirmed, that Medichem Manufacturing (Malta) Ltd.'s, an application for necessary REWS authorization has been submitted.

The **Environmental Health Directorate (EHD)** provided generic comments with respect to nuisances and complaints which are reflected in both the proposed permits. EHD requested that in the case of Medichem Manufacturing (Malta) Ltd, any water supply that was being used in the QC Laboratory that will not be needed in the new office space is to be cut back to the main supply pipe for both hot and cold. This was confirmed by the operator to already have been carried out.

With respect to Combino Pharm (Malta,) Ltd. the directorate recommended the construction of the rainwater reservoir. It was noted by the Operator that rain water is not harvested and whilst the option has been reconsidered for its construction the infrastructure of the facility as built does not offer a feasible solution. EHD has no further comments on the permit.

The **Occupational Health and Safety Authority (OHSA)** provided general requirements in relation to XXVII of 2000 and relevant occupational health and safety regulations which are to be adhered to by both installation. Conditions of such were already included in Medichem Manufacturing (Malta) Ltd 's permit (IP002/05/D) and are thus now being retained in the proposed permit and extended to apply also to Combino Pharma (Malta) Ltd. OHSA requested a verification for a list of dangerous substances with their classification under the Control of Major Accident Hazards regulations, L.N. 179 / 2015. Following such submissions it transpired that neither installation falls within the COMAH threshold.

The **Civil Protection Directorate (CPD)** commented that numerous familiarization visits have taken place and are satisfied with the up keeping of the installations. Continuation of training to all the staff in basic firefighting and spillage control training to their staff alike was recommended. The Operator noted that all employees are trained on basic fire fighting on an annual basis. Spill response training is being provided to quality control personnel and will be provided to production personnel.

The **Malta Competition and Consumer Affairs Authority** had no comments with respect to Medichem Manufacturing (Malta) Ltd.'s application. With respect to Combino Pharm (Malta) Ltd. had no further comments following a clarification on the importation of F-gases in relation to the quota system as per Regulation 517/2014.

The **Energy and Water Agency, Planning Authority** and the **Malta Resources Authority** did not provide feedback.

iii. Feedback from the operator

Consultation regarding the permit was carried out with the Applicant following which comments were received by the Authority. Of particular note the following pertinent points were provided:

- a) Requested that HEPA Filter efficiency certification for exhaust filters is to be submitted every two-years as opposed to an annual basis
- b) Requested that since LPG is the main source of fuel for the boilers, consideration needs to be made in the event that diesel is utilised as a back-up fuel in the cases of damage to the supply of LPG. Did not agree with having a stricter ELV set for NOx which is set for gas oil. To consider amendment, and to change the ELV back to 250 from 200.
- c) On the notification procedure for the production of any new Active Pharmaceutical Ingredient other than those approved by the Authority, the Operator requested to have this condition applied only to products which are introduced for manufacturing on a large scale (around 5T) and on a continuous production routine.
- d) On the permit condition stating that bulk storage tanks for liquids and associated bunding and pipe work shall be visually inspected and documented at least twice a month, the Operator recommended a replacement to this condition that instead of visual inspections every two weeks it would be more adequate to perform ultrasonic tests on the bulk storage tanks every 10 years.

Updated approved documents were provided as requested by the Authority. Some updates to conditions were made.

2.8 Representations from public

- i. **Public consultation dates:** 18th November 2020 to the 2nd December 2020
- ii. **Responses received:** No public comments received.

2.9 Discussion

Medichem Manufacturing (Malta) Ltd. (MML) and Combino Pharm (Malta) Ltd. (CPL) are two adjacent pharmaceutical installations located in the Hal Far Industrial Park (HHF61 and HHF 60 respectively). Both facilities are owned by the same corporate body.

The operations of the Medichem Manufacturing Malta Ltd. fall within scope of the Industrial Emissions (Integrated Pollution Prevention and Control) Regulations (S.L. 549.77) in view that the main activity on site is the manufacture of Active Pharmaceutical Ingredients (APIs). MML, are regulated by an IPPC permit which was issued for the first time in 2005 and which was varied and renewed throughout the years. The current permit (IP0002/05/D) with three subsequent extensions, expires on 24 January 2020.

On the other hand, Combino Pharma (Malta) Ltd. which does not produce Active Pharmaceutical ingredients and thus does not require an IPPC Permit has been issued an environmental permit for the manufacturing activities of solid pharmaceutical dosage forms at their facility. The environmental permit was issued for the first time in 2013 and the current permit (EP 0102/20) expires on 24 January 2020.

On 5th March 2019, both operators submitted a request for a renewal and variation of the IPPC permit. In this request, the operator is proposing the following additions to the current operations:

1. The removal of the QC lab from Medichem Manufacturing (Malta) Ltd;
2. The incorporation of operation of Combino Pharma (Malta) Ltd's environmental permit with Medichem Manufacturing (Malta) Ltd's IPPC permit in view that CPL will now be carrying out directly associated activities as prescribed in IPPC legislation;

The application did not contain the required detail necessitated by the application form and was thus resubmitted. This was submitted on 15 May 2020. Following a number of changes to the documentation, the consolidated application was received on the 17th November 2020.

Medichem Manufacturing (Malta) Ltd. has also submitted a comparison with the Best Available Techniques for common waste water and waste gas treatment/management systems in the chemical sector published in 2016 upon which the improvement programme item is being proposed to be addressed in stages during the first year of the permit.

Since an independent noise assessment is required to be carried out for both operators, a noise plan is being requested to be submitted within three months of the granting of the permit taking into consideration that this had already been done in the past but needs to be revised to consider revised monitoring requirements.

On the requested that HEPA Filter efficiency certification for exhaust filters is to be submitted every two-years as opposed to an annual basis, ERD recommends the annual requirement is to remain in the permit.

On the disagreement with having a stricter ELV set for NO_x which is set for gas oil, ERD recommends in view that both fuels can be used the strictest emission limit values shall apply.

On the notification procedure for the production of any new Active Pharmaceutical Ingredient other than those approved by the Authority, ERD does not recommend any changes to the condition, in view that the IED interpretation does not contemplate a threshold for what is considered industrial production

On the suggested replacement of the permit condition stating on bulk storage tanks for, ERD recommends that the documented visual checks shall take place every three months and additional condition for 10 yearly ultrasonic tests shall also be included. In addition ERD recommends that an additional IP item is to be included with the first ultrasonic testing to be carried out within the first four years prior to renewal.

The Statutory Consultation process as required by S.L. 549.77 (Industrial Emissions (Integrated Pollution Prevention and Control) Regulations) was started on 23rd March 2020. A consolidated application submitted on the 18th November 2020, which enabled initiation of the public consultation between the 18th November and 2nd December 2020.

Medichem Manufacturing (Malta) Ltd. has fulfilled the improvement programme item in IP0002/05/D, whilst there were no improvement programme in the environmental permit covering operations of Combino Pharma (Malta) Ltd.

Furthermore, should the IPPC permit be favorably determined, the current Environmental Permit (EP 0102/20) for Combino Pharm Ltd will be superseded

2.10 Financial Matters

Application Fee	€9000 - PAID
Other Fee (MCP renewal)	€125 - PENDING
Financial guarantee	<p>For Medichem Manufacturing (Malta) Ltd. financial guarantee of € 15,025 is being assigned to secure the obligations under this permit. The previous financial guarantee amounted to €14,900.</p> <p>For Combino Pharma (Malta) Ltd. financial guarantee of € 11,850 is being assigned to secure the obligations under this permit. No financial guarantee was previously assigned.</p>
Annual Fee	<p>For Medichem Manufacturing (Malta) Ltd €750 per year since year 2016 and an additional €200 for each inspection carried out since 2016 (2 in total) totaling €4900</p> <p>For Combino Pharma (Malta) Ltd. €1500 per year (covering 2021) and an additional €200 for each inspection carried out in 2020 (1 pre-permit inspection) totaling €1700</p>

3 Environment Officer Recommendation:

The Environment and Resources Directorate recommends the GRANTING of the Permit for a period of four (4) years subject to the following post-decision requirements:

- Submission of a bank guarantee of €15,025 by Medichem Manufacturing (Malta) Ltd.
- Submission of an annual fee of €4,900 covering the period 2016 - 2021 (€750 per year) and 2 inspections carried out to date (rated at €200 per inspection) by Medichem Manufacturing (Malta) Ltd.

- Submission of payment of € 125 for the renewal of a medium combustion plant as per S.L.549.122 by Medichem Manufacturing (Malta) Ltd.
- Submission of a bank guarantee of €11,850 by Combino Pharma (Malta) Ltd.
- Submission of an annual fee of €1,700 covering the period 2021 (€1,500 per year) and 1 inspection carried out to date (rated at €200 per inspection) by Combino Pharma (Malta) Ltd.

The proposed permit conditions include:

- Standard conditions for each sector;
- Site specific condition for Medichem Manufacturing (Malta) Ltd.:
 - Emissions to air from two combustion plants (generator & boiler) on site are allowed. The boiler falls within the threshold for medium combustion plants regulations (S.L.549.122).
 - Various conditions prescribing the Best Available Techniques (BAT) for the activities of this facility.
 - Prior to the production of any new Active Pharmaceutical Ingredients other than those approved by the Authority, the Operator is notify the Authority 1 months prior to the start of production and submit the necessary documentation.
 - An inventory of solvent usage shall be maintained on site.
- Site specific conditions Combino Pharma (Malta) Ltd.:
 - Emissions to air from two combustion plants (generator & boiler) on site are allowed. The combustion plants do not fall within the threshold for Medium Combustion plants.
 - Wastewaters from Combino Pharm should result in any exceedance of the limits set in the Water Services Corporation Sewer Discharge Permit for Medichem
 - Specific conditions in relation to the fluid bed drier emergency stack.
 - In the event that the VOC solvent consumption threshold exceeds 50 tonnes/year as per Activity 20 in Schedule II of S.L.549.79 the operator is to notify the Authority.
- Improvement programme items:

Improvement programme for Medichem Manufacturing Malta Ltd.		
Reference	Requirement	Date

7	a) Identification of waste gas pollutants and implementation of a waste gas stream inventory in line with the requirements of BAT 2 and BAT 16 of the CID 2016/902 [Establishing best available techniques (BAT) conclusions, under Directive 2010/75/EU for common waste water and waste gas treatment /management systems in the chemical sector	a) Within six months of the granting of the permit
	b) Depending on the outcome of item (a), a revised monitoring proposal to reflect established best available techniques, as applicable	b) Within nine months of approval of 7a)
	c) Depending on the outcome of item (a), submission of a monitoring results to reflect established best available techniques.	c) Within twelve months of 7b)
8	Submission of a noise monitoring plan in line with Schedule 2 of IP002/05/E	Within three months of granting of the permit
	Implementation of a noise monitoring exercise and submission of the report.	By end 2021
9	Submission of the monitoring proposal for a one-time air emission monitoring exercise from the fume hood exhaust vent (PS 8)	By 31 December 2021
10	Ultrasonic testing of shell thickness on tanks and pipework.	By end 2024

Improvement programme for Combino Pharma (Malta) Ltd.		
Reference	Requirement	Date
1	Submission of a noise monitoring method statement in line with Schedule 2 of the Framework permit	Within three months from the granting of the permit
	Implementation of a noise monitoring exercise and submission of the report.	Within one year from the

		granting of the permit
2	Submission of an addendum to the land and groundwater risk assessment for the consideration of Combino Pharm Ltd. site.	Within one year from the granting of the permit
3	Submission of the monitoring proposal for a one-time air emission monitoring exercise from the fume hood exhaust vents (PS4-6)	By 31 December 2021

This report [to the ERA Board] has been prepared, reviewed and endorsed by:	
Case Officer: Gabriella Grima	Reviewed by: Simon Farrugia
Env. Protection Officer (Permitting)	Senior Env. Protection Officer (Permitting)
Signature:	Signature:
Date:	Date:
Endorsed by: Nathalie Ellul	
Team Manager (Permitting)	
Signature:	
Date:	