ENVIRONMENTAL STATEMENT

Installation of prefabricated modular facilities at Medichem Manufacturing (Malta) Ltd. factory

Tracking Number: 00148783

Technical Report

30 October 2012

ERSLI

Assignment	Environmental Statement (Statement)		
Project Title	Installation of prefabricated modular facilities at Medichem Manufacturing (Malta) Ltd. factory		
Location	Medichem Manufacturing (Malta) Ltd. HF61, Qasam Industrijali, Hal Far, Birzebbugia, Malta		
Applicant	Dr Dino Mangion obo Medichem Manufacturing (Malta) Ltd		
Perit	Perit Wallace Farrugia (Wallace Farrugia & Associates)	**Statement Consultant**	Dr Paul Gauci (ERSLI Consultants Ltd)
Perit Ref	85/12	**MEPA Ref**	Tracking Number: 00148783

Revisions

No	Date	By	Reason for Revision
00	30 October 2012	PG	Submitted Draft

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GLOSSARY

Abbreviation	Full text
2005-EIS	Environmental Impact Statement: Installation of a Manufacturing Plant for the Production of Active Pharmaceutical Ingredients at Ħal Far - Technical Report: Coordinated Assessment (Gauci, 2005)
cGMP	current good manufacturing practice
EIA	Environmental Impact Assessment
EMS	environmental management system
FDA	U.S. Food and Drugs Administration
GMP	good manufacturing practice
IPPC	Integrated Pollution Prevention and Control
Medichem	Medichem Manufacturing (Malta) Limited
MEPA	Malta Environment and Planning Authority
PDS	project description statement (Farrugia, 2012)
R&D	research and development
S.L.	Subsidiary Legislation
Statement	Environmental Statement

0.1 Background

0.1.1 This *Environmental Statement* (Statement) was commissioned by *Medichem Manufacturing (Malta) Limited* (Medichem) in response to a part of the screening letter (dated 04 September 2012) issued under Legal Notice 514 of 2010 (S.L. 504.103)[1] by the *Malta Environment and Planning Authority* (MEPA), with reference to the proposal for the *[i]nstallation of prefabricated modular facilities at Medichem Manufacturing (Malta) Ltd. factory*, submitted by Dr Dino Mangion (Applicant). The Medichem factory is located at HF61 in the Ħal Far Industrial Estate (see Figure 1 below).

0.1.2 The proposed laboratory is designed for research and development (R&D) activities connected with the production of Potent Compounds, and, in the event that the Medichem proposal is approved by the MEPA, it would be additional to the existing R&D laboratory in the factory. The laboratory would be located in the eastern side of the factory grounds, as is also indicated in Figure 1.

Figure 1: Locations of the Medichem factory in the Ħal Far Industrial Estate and of the proposed laboratory

0.2 The assignment

0.2.1 The part of the above-mentioned screening letter to which this ES refers states that:

Since it is not clear how the proposed development will affect the site's intended liquid waste management, a detailed justification/statement from the EIA Coordinator that carried out the original EIS for the existing development is required. This statement should confirm or otherwise whether the proposed changes are such that they may have a significant impact on the environment and thus change the nature of the EIA undertaken for PA4257/04.

0.2.2 Given that in 2004/2005 the undersigned coordinated preparation of the *Environmental Impact Assessment* (2005-EIS), which identified and examined the likely environmental impacts of the original proposals for the present operations that formed part of development application PA/04257/04 (Gauci, 2005), he was commissioned by Medichem with the preparation of this Statement.

0.2.3 This Statement refers to the following two sources of information:

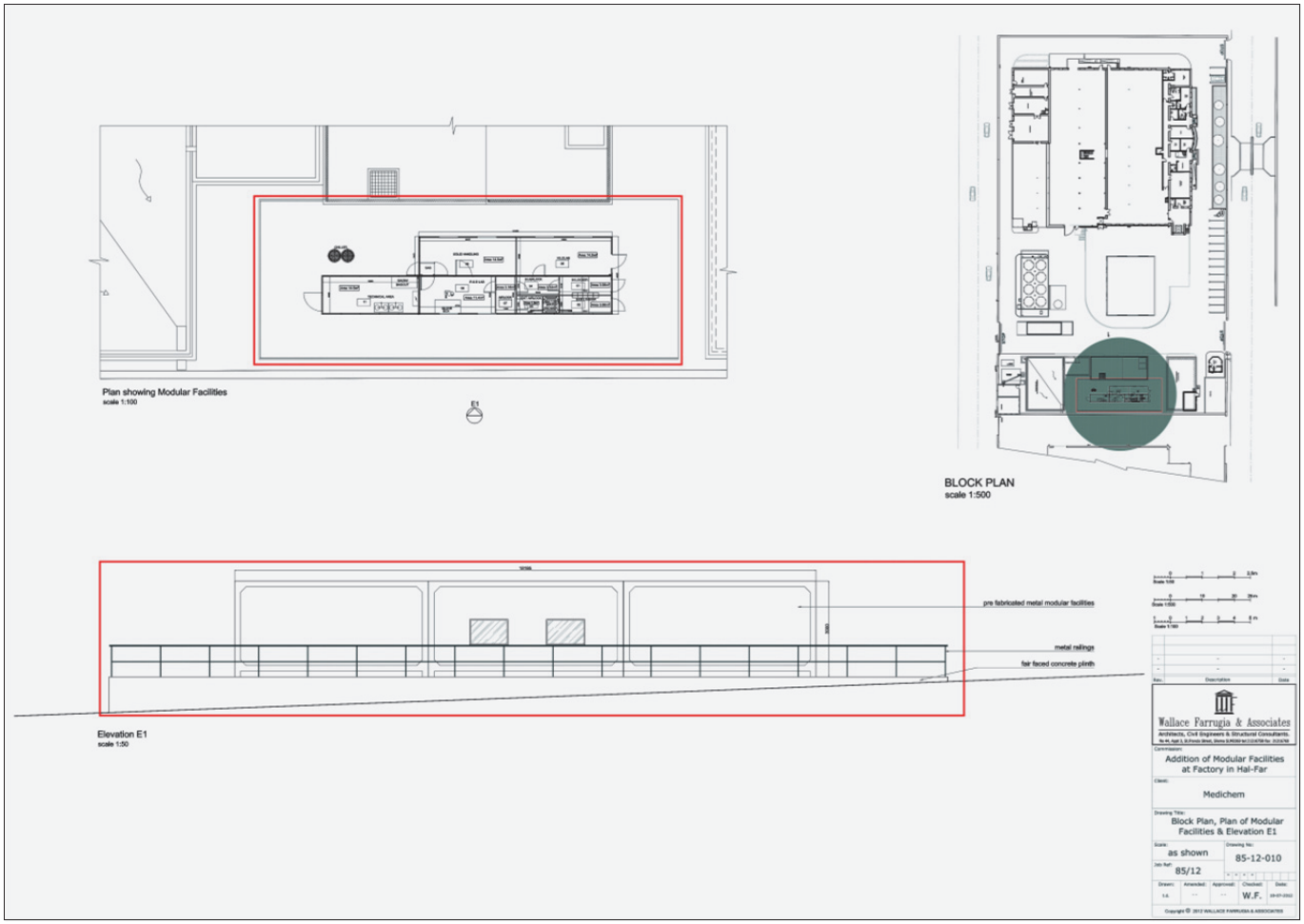
- *project description statement* (PDS) regarding the proposed laboratory (Farrugia, 2012), and
- interview with Ing Mark Debono, the Medichem *Head of Environmental Protection, Health & Safety*, regarding the workings of the *environmental management system* (EMS) adopted by Medichem, with respect to waste management.

1.1 General description

1.1.1 The works connected with the proposed laboratory are in the hands of Perit Wallace Farrugia (Wallace Farrugia & Associates) (Architect), who is responsible for the overall coordination of the proposed project, together with the architectural and civil engineering aspects.

1.1.2 The exact location and layout of the laboratory are shown in the Architect's drawing submitted to the MEPA, which is shown in Figure 2 (below). As is noted in the Introduction, it is needed by Medichem for R&D connected with the development of processes for the preparation of Potent Compounds.

Figure 2: Exact location and layout of the laboratory



1.2 Justification of the need for the proposed laboratory

1.2.1 The proposed laboratory constitutes the initial part of a long term plan, which should lead to the location of a larger plant for the production of Potent Compounds in the near vicinity of the existing factory. It would be dismantled once the principal objective, i.e. the installation and operation of the new production plant, is attained.

1.2.2 As is normally done is such facilities, Medichem scientists will be carrying out small-scale experimental trials involving minimal amounts of substances in order to understand the complexities of and develop specific processes for the manufacturing stage of the product cycle. This work is similar to that carried out in the existing R&D laboratory, but it has to be carried out separately because of the risk of contamination given that the two laboratories would be focusing on different issues. This is a basic good manufacturing practice (GMP) principle.[2]

1.2.3 Once a synthetic route is optimised and proven to function in a reliable, safe and reproducible manner, the process will be scaled up under *current good manufacturing practice* (cGMP) regulations,[3] in a separate section of the laboratory. Medichem would then be in position to supply customers with initial quantities for their assessments, which quantities would be at the sub-kilogram scale.

1.3 Spatial organisation of the proposed laboratory

1.3.1 The design of the laboratory provides for five prefabricated/portable modular compartments, which cover an overall area of 75m^2. The flexibility of a mobile, modular, prefabricated system would enable Medichem to be in a position to respond quickly and effectively to patent changes (relocation of the facilities), and to have rapid access to the research and development of Potent Compounds by expanding the existing operations into the part of the HF61 factory grounds that are earmarked for the proposed laboratory without affecting the operations in the rest of its facility (due to cGMP requirements). As is noted above, the results of the R&D activities in the laboratory would indicate whether investment in another pharmaceutics plant in the Hal Far Industrial Estate would be viable.

Table 1: Spaces within the proposed laboratory

Space		Floor Area (m^2)
1	Technical area	14.50
2	R&D laboratory	11.40
3	Air locks	9.68
4	Locker rooms	7.84
5	Kilo lab	14.60
6	Solid handling	14.90

Source: (Farrugia, 2012)

2.1 Waste types

2.1.1 The following table lists the types of waste, listed by the waste code in the *European Waste Catalogue* (ECW) (European Commission, 2002) that would be generated in the proposed laboratory:

Table 2: Waste types that would be generated by the work carried out in the laboratory

Code	Description in the EWC	Relevant examples
07	Wastes from organic chemical processes	
07 07	Waste from the MSFU of fine chemicals and chemical products not otherwise specific	
07 07 04	Other organic solvents, washing liquids and mother liquors	Mixtures of waste solvents, aqueous waste containing organic substances, aqueous phase waste containing corrosive substances, acidic/alkaline laboratory waste
07 07 10	Other filter cakes and spent absorbents	Solids from processes using non-halogenated solvents, Contaminated filters and filter cakes

2.1.2 Both waste types are considered hazardous, with their likely adverse environment impacts, in the absence of appropriate management systems, being as follows:

- impact on air quality by virtue of air borne contamination,
- impact on land resulting from the fall out of particulates, and
- impact on the quality of aquatic environments resulting from chemical release into controlled waters.

The receptors would be terrestrial and marine flora and fauna, and human beings all of which are highly sensitive to the contaminants in question.

2.1.3 The magnitude and level of significance of the impacts would depend on the quantities and concentrations of the contaminants in question.

2.2 Quantities

2.2.1 The waste types identified in the previous section had also been singled out in the 2005 EIS, though at the time it was difficult for exact quantities to be predicted (Gauci, 2005, p. 76). The following table lists the annual quantities of the said waste types in the existing operation and the amounts that are foreseen for the proposed laboratory:

Table 3: Current annual quantities of waste types produced by the Medichem operations

Code	Total produced (kg)	Re-used internally (kg)	Re-used externally (kg)	Balance exported for treatment (kg)
07 07 04	332,567	62,983	90,564	179,020
07 07 10	5,770	-	-	5,770

Note to Table 3
The production system at the Medichem factory is designed to re-use a proportion of the 07 07 04 waste type. The proportion of this waste type that is used externally is sold to third-party buyers based in Malta for use in their operations.

2.2.2 Medichem predict that the experimental work and small-scale production of the substances which would be carried out in the proposed laboratory would generate less than 1% of what the manufacturing plant produces.

2.3 Waste disposal or treatment

2.3.1 Medichem have indicated to the undersigned that, given the small quantities of the above-mentioned waste types produced in the proposed laboratory, separate recovery will not be an option. These wastes would therefore be registered, stored temporarily on-site and then handed over to registered brokers to be exported for specialized treatment within the regulatory framework described in Chapter 3 (on page 17).

2.3.2 Currently, Medichem exports hazardous wastes to Magma Tratamientos SLU in Valencia, Spain (MAGMA Group, 2012), through the registered brokers PT Matic Environmental Services Ltd (2012)

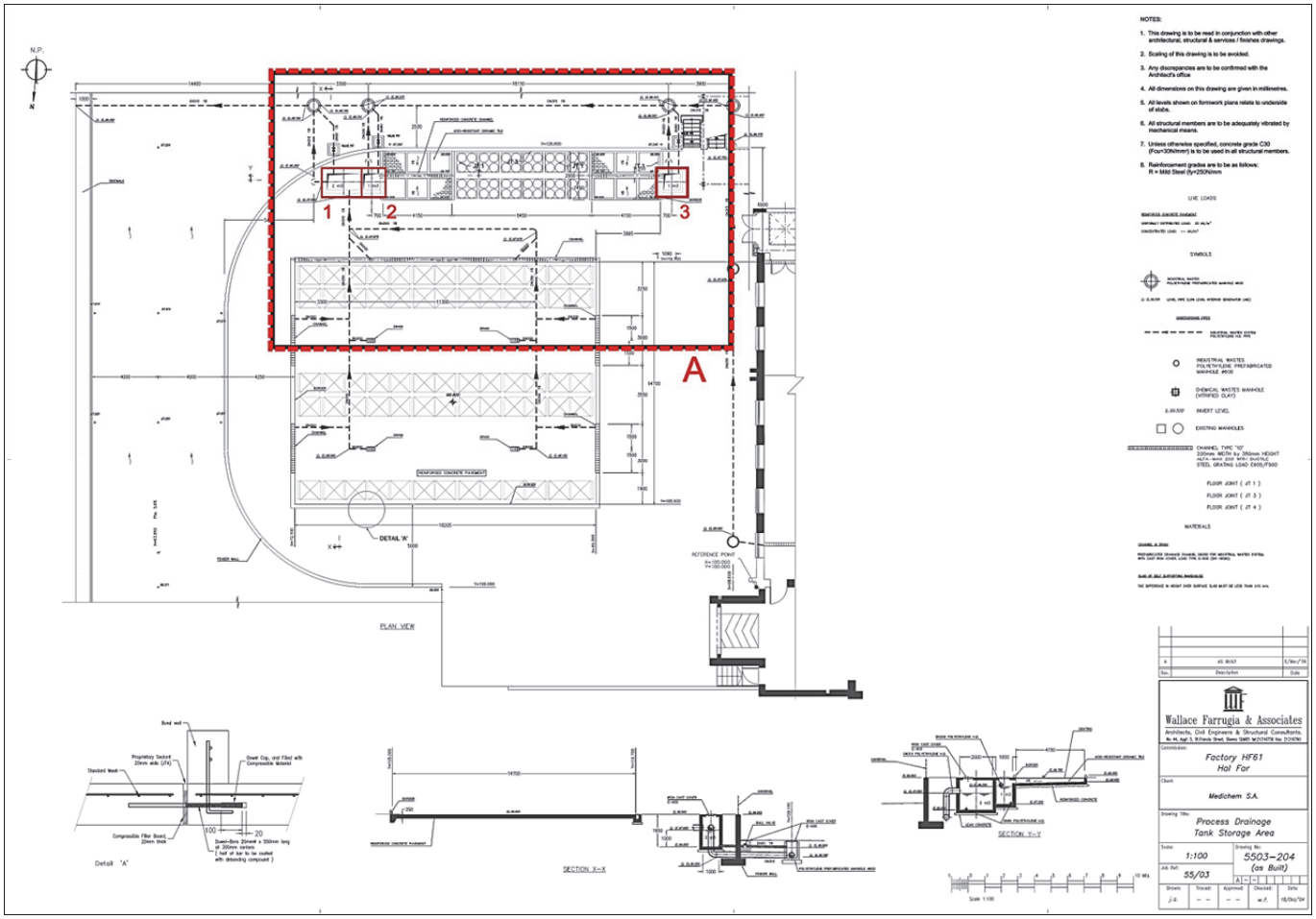
2.3.3 In the 2005-EIS, the above-mentioned approach to the treatment/disposal of hazardous waste was considered an option together with the possibility of some of the treatment taking place in Malta. For this reason the procedures to be followed for the export of such waste types and the regulatory framework for such procedures were described in some detail (Gauci, 2005). As is noted above, the regulatory framework which is currently in place is discussed in Chapter 3.

2.4 Temporary on-site storage of wastes

2.4.1 Medichem plan to have all the waste generated by the laboratory treated through the same procedures that are currently in use in the existing R&D Laboratory. The waste would be segregated, registered, and temporarily stored (prior to being transported away from the factory) in designated areas within an 'external warehouse', which is located as shown in the map in Figure 3 (below). The space available in the warehouse is sufficient for the amounts involved; in other words no changes to the existing infrastructure would be required in the event that the laboratory proposal is accepted by the MEPA.

Figure 3: Zoning within the grounds of the Medichem factory (HF61) in the Hal Far Industrial Estate

Figure 4: Location of pits and bunds and sections through bunds in the external warehouse



2.4.2 The warehouse is equipped with spillage containment pits and bunds to mitigate the risks associated with damage to the environment. The Architect's 'as-built' drawing in Figure 4 (above) highlights zone 'A' within the external warehouse where the following pits are located:

- the warehouse pit .....(marked "1" – 2m^3)
- the base pit .....(marked "2" – 1m^3)
- the acid pit .....(marked "3" – 1m^3).

This drawing also provides information about the design of the bunds, which act as barriers between the storage areas and the rest of the Medichem factory grounds. The designs presented in this drawing formed part of the proposals which were presented with the application for the IPPC permit, which is referred to in para 3.1.1 (on page 17).

2.4.3 As is noted earlier the storage space for the hazardous wastes which would be produced by the proposed laboratory, would be available within the existing external warehouse. In other words, no modifications to this warehouse would be required.

2.5 Environmental management system

2.5.1 The procedures described above would be carried out within the framework of an EMS which is certified by IQNet (IQNet, 2012) and AENOR (AENOR, 2012) as being in fulfilment of the ISO 14001:2004 standard. The certificate (registration number: ES-2009/0366) was issued in June 2009 and was renewed in June of this year. The next renewal is set for 2015.

3.1 Introduction

3.1.1 Medichem is registered as a waste producer (also applies to packaging waste) through the IPPC permit IP 0002/05/C issued under the *Integrated Pollution Prevention and Control Regulations* (Legal Notice 234 of 2002, S.L. 504.54), which transpose into Maltese Law *Council Directive 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control* (European Commission, 2010a), also known as the IPPC Directive. By January 2014 *Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control)* (European Commission, 2010b) should be transposed into the statute books of European Union Member States in order to replace the IPPC Directive.

3.2 Waste management regulations

3.2.1 The Medichem waste management operations are in line with the following:

- *Waste Regulations* (Legal Notice 184 of 2011; S.L. 504.37).
- *Waste Management (Activity Registration) Regulations* (Legal Notice 106 of 2007: S.L. 504.78). The above-mentioned PT Matic Environmental Services Ltd (see para 2.3.2on page 14) is a registered waste broker under these regulations (permit number. GBR 00699/09) (MEPA, 2012).
- *Waste Management (Packaging and Packaging Waste) Regulations* (Legal Notice 277 of 2006; S.L. 504.72)

3.2.2 All waste is classified into the various streams according to an internal classification system, and is traceable to the process generating it. It is adequately packaged, labelled, registered and stored temporarily on site as described above. Furthermore, wherever possible and reasonably practicable, a portion of the liquid waste generated is recovered to be re-used internally or externally.

3.3 Discharges into the public sewerage system

3.3.1 All discharges to the sewer are regulated through a Sewer Discharge Permit issued under the *Sewer Discharge Control Regulations* (Legal Notice 139 of 2002; S.L. 423.15).

3.3.2 None of the activities taking place in the proposed laboratory will produce discharges that end up in the Water Services Corporation sewerage network.

3.4 Transport and export of hazardous waste

3.4.1 All hazardous waste generated in the Medichem factory is transported away from the factory for external re-use or for export (see Table 3 on page 13), under the following regulations:

- *Motor Vehicles (Carriage of Dangerous Goods by Road) Regulations* (Legal Notice 211 of 2003; S.L. 65.11), through which Malta's commitments with respect to the *European Agreement concerning the International Carriage of Dangerous Goods by Road* (ADR) (UNECE, 2011) are put into force in Malta.
- Waste Management (Shipment of Waste) Regulations (Legal Notice 285 of 2011; S.L. 504.15) which transposes into Maltese Law *Council Regulation (EC) No 1013/2006 of the European Parliament and of the Council of 14 June 2006 on shipments of waste* (European Commission, 2011).

3.4.2 The same regulations would evidently be applicable to the wastes generated by the laboratory operations.

4.1 Given that

- the quantities of hazardous wastes that would be produced by the laboratory would be small when compared to the amounts of the same waste types produced by the current operations;
- no changes to the existing Medichem factory and its infrastructure, in addition to the placement of the proposed laboratory in the allocated area, would be required in the event that the MEPA approves the Applicant's proposal;
- the 2005 EIS took into consideration the waste management regime that is currently adopted and would be adopted in the event that the proposed laboratory is approved by the MEPA; and
- the ISO 14001:2004 certification implies that all the environmental [including waste management] regulations, to which the Medichem operations are subject to, are being conformed to,

the undersigned submits that one can safely assume that the proposed laboratory would not extend the scope and validity of the 2005-EIA.

Dr Paul Gauci (PG)
30 October 2012

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ENDNOTES

[1] Legal documents discussed in this Statement have been retrieved from the website of the Ministry for Justice, Dialogue and the Family (MJHA, 2012).

It should be noted that in this reference is always made to the principal document (Act, Legal Notice). This reference however would be inclusive of all enactments or legal notices through which the principal document would have been amended.

[2] In Malta GMP is regulated under the *Good Manufacturing Practice in Respect of Medicinal Products and Investigational Medicinal Products for Human Use Regulations* (Legal Notice 485 of 2004, S.L 458.42), which transpose into Maltese Law, Commission Directive 2003/94/EC of 8 October 2003 *laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use* (European Commission, 2007).

[3] cGMP regulations are issued by the *Food and Drug Administration* of the United States (FDA) for medicinal-products companies to comply with, in order for them to be in a position to register their products with the same FDA (FDA, 2012).