FEASIBILITY OF PRODUCTION OF INTRAVENOUS FLUIDS IN MALTA

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INTRODUCTION

Intravenous infusions are sterile aqueous solutions or emulsions with water as the continuous phase intended for large volume administration to replenish and maintain the body's normal fluid and electrolyte levels. [1] Intravenous infusions must comply with the following pharmacopoeial tests: 2.6.14 test for bacterial endotoxins, 2.9.19 particulate contamination: sub visible particles, 2.6.1. test for sterility and where justified and authorised, 2.6.8 test for pyrogens. [2]

Currently Malta imports intravenous fluids at relatively high costs which increase due to transportation expenses. The setting up of a Medical Solutions Production Center, with the objective to manufacture a wide range of intravenous infusions at a lower cost would benefit the National Healthcare System (NHS).

OBJECTIVES

1. To review the production and testing of intravenous fluids using Blow-Fill-Seal technology.
2. To conduct a feasibility study to assess the viability of setting up a Blow-Fill-Seal plant locally.

Figure 1: The production of Intravenous Fluids using Blow-Fill-Seal Technology

DESIGN

A database of the intravenous fluids used in Malta was compiled and the annual consumption of each product was obtained from the Government Hospital Pharmaceutical Stores (GHPS). The requirements of composition, sterility and microbiological testing established by the European Pharmacopoeia were studied. An in-depth literature review of intravenous fluid production using Blow-Fill-Seal technology was carried out.

A feasibility study was conducted to gauge the feasibility of the project. The demand for intravenous fluids in the neighbouring countries of Libya, Algeria, Morocco and Tunisia were estimated by extrapolating the consumption per capita in Malta onto their population parameters.

The capital investment required to purchase and import a self-contained production facility was obtained by contacting a turnkey supplier of such facilities. Estimates of fixed costs (salaries, utilities and rent) were calculated based on the 2008 Malta Economic Survey, the Enemalta (electricity) and the Water Services Corporation tariffs, and the Malta Enterprise quotations respectively. Price quotations for raw materials were obtained from suppliers of chemicals, plastics and water.

RESULTS

Table 1: Results of Feasibilty Study - Financial Prediction for the first 4 years operating at the maximum output capacity of 2.5 million units per year. Figures in brackets represent expenditure. Net Cashflow indicates the profit or loss made.

	Year 1 (1,000s €)	Year 2 (1,000s €)	Year 3 (1,000s €)	Year 4 (1,000s €)
Fixed Costs				
Salaries	(335)	(335)	(335)	(335)
Rent	(25)	(25)	(25)	(25)
Miscellaneous	(15)	(15)	(15)	(15)
Variable Costs				
Water	(4)	(4)	(4)	(4)
Electricity	(115)	(115)	(115)	(115)
Raw Materials	(875)	(875)	(875)	(875)
Capital				
Plant & Equipment	(2172)	0	0	0
Tax Credit (30% on Plant)	652	0	0	0
Grant on Salaries	51	0	0	0
Sales (at €1 per unit)	2500	2500	2500	2500
Net Cashflow	(338)	1131	1131	1131

CONCLUSION

Local demand stands at 700,000 units per year. The foreign markets' demand was estimated to be 144 million units per year. The financial analysis indicates that the domestic demand is not enough to warrant the construction of this facility. Production at maximum capacity would make the project feasible, provided that surplus units are exported. The profit margin could be expanded by increasing product output, or by widening the product range to include other sterile pharmaceutical solutions including irrigation fluids, cardiology solutions and small volume sterile solutions such as eyedrops. An EU fund for research and development of up to €100,000 could be made use of if research on new technology is conducted at the facility.

1. British Medical Association; Royal Pharmaceutical Society of Great Britain. British National Formulary. 58th ed. London: Pharmaceutical Press; 2009.
2. European Directorate for the Quality of Medicines. Monographs on dosage forms – Parenteral Preparations. In: EDQM. European Pharmacopoeia. 5th ed. Council of Europe, Strasbourg, France: EDQM; 2004. p. 3144–46.