

EMBRYO PROTECTION AUTHORITY

PUTTING PATIENTS FIRST

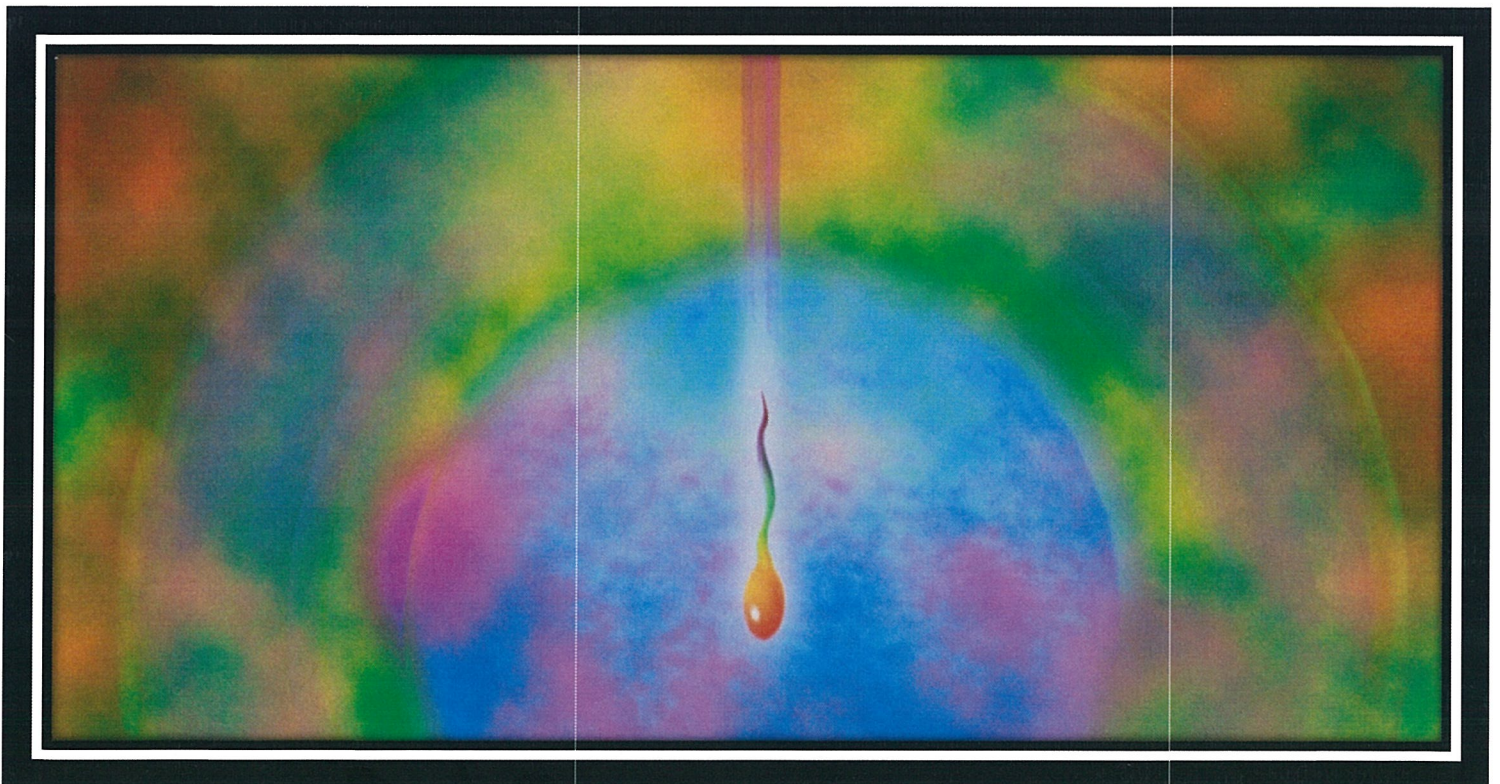
ANNUAL WORK REPORT

AND

TRENDS AND FIGURES OF

FERTILITY TREATMENTS

IN MALTA FOR 2014



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Presented to Minister for Energy and Health Hon Konrad Mizzi and
to Parliamentary Secretary for Health Hon Chris Fearne

as per Embryo Protection Act 2012 and
Embryo Protection Authority Regulations, LN 32 of 2015

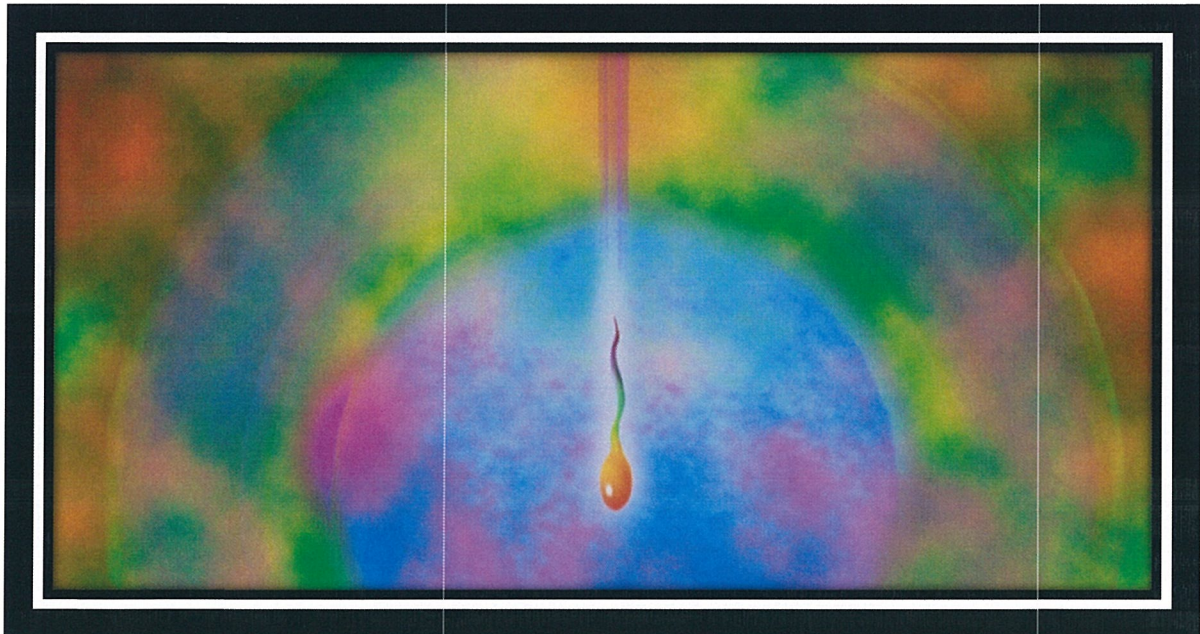
May 2015

EMBRYO PROTECTION AUTHORITY

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ANNUAL WORK REPORT

FOR 2014



EMBRYO PROTECTION AUTHORITY (EPA)

The Embryo Protection Authority is the sole Regulator of all Assisted Reproductive Technology Fertility Treatments using oocytes and sperm that are carried out in Malta and performed in both private and public licenced centres. The Authority sets the standards and determines the policy framework (Protocol) as per established in the Embryo Protection Act. The Authority also provides information to stake holders, the general public and especially to couples seeking treatment.

Our Principles – PATIENTS FIRST

The Embryo Protection Authority treats all couples referred by the Clinics with dignity and respect, all information provided to the Authority is sensitive and highly confidential.

All decisions taken by the Embryo Protection Authority are taken in the best interest of the couples and also the welfare of the child that will be conceived after any assisted reproductive technology procedure.

Our Principles – Working closely with Stake Holders

The Authority works closely with all stakeholders in the Fertility Field and ensures that it listens to and learns from the Service Providers whilst at the same time ensures that the highest level of standards are being kept by all as specified in the Laws governing this fertility sector.

The Authority also performs its functions consistently and fairly with all clinics as per the established Laws and Regulations.

Laws and Regulations governing the Fertility Sector:

- Embryo Protection Act 2012 (Cap 524) and
- Embryo Protection Authority Regulations, LN 32 of 2015

Functions of the EPA

- To ensure that high standards of ethics are maintained by all medical practitioners, paramedics and other personnel involved in procedures of medically assisted procreation;
- To request and obtain, in cases of reasonable suspicion that the provisions of the Embryo Protection Act are not being followed, information and copies, in any form, of documents required by the Commission Directive

2004/23/EC of the European Parliament and of the Council of 31 March, 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells to ensure traceability of human cells;

- To carry out inspections in order to ensure that the standards of best practice are being respected and implemented and that all information and documentation required under article 18 of the Embryo Protection Act is being kept appropriately and for this purpose to access clinics and any other places as necessary;
- To maintain a statement of the general principles which, in its opinion, should be followed:
 - in carrying out its activities under the Embryo Protection Act; and
 - in carrying out its functions in relation to such activities under the Embryo Protection Act;
- To ensure, in relation to activities under the Embryo Protection Act, compliance with:
 - the obligations and requirements imposed by or under the Embryo Protection Act; and
 - the codes of practice established under paragraph (a) of the Embryo Protection Act;
- To perform such other functions as may, from time to time, be prescribed by regulations made under the Embryo Protection Act.

Board of Directors and Meetings

The Authority Board is composed of Judge Dr Philip Sciberras as Chairman, Ms Simone Attard as Vice Chairperson, and Ms Pauline Baldacchino, Ms Mariella Meachen and Dr Patrick Sammut as members. All members on the board were appointed on the 17th May 2013 as per Article 3 of the Embryo Protection Act. The Authority also had the services of a Secretary to the Board during 2014, however the assigned secretary resigned and to date no replacement has been made.

During 2014 the Authority held 11 Board Meetings, and in all sittings the established quorum was reached. Attendance by members to these Board meetings is as stated hereunder:

Member	Attended	Excused
Chairman - Hon Judge Philip Sciberras	9	2
Vice Chairperson - Ms Simone Attard	10	1
Member - Ms Pauline Baldacchino	8	3
Member - Ms Mariella Meachen	9	2
Member - Dr Patrick Sammut	8	3

During 2014 the Authority also held 3 additional Board Meetings together with the representatives of the Obstetrics and Gynaecology Association and The Paediatric Association in Malta to decide over the requests for additional fertilisations of oocytes (Article 6 of the Embryo Protection Act gives the power to the Authority in consultation with the mentioned Associations to approve the fertilisation of three oocytes instead of two allowed by law.) These requests are made by the respective clinicians treating the couple. Attendance by members to these Board meetings is as stated hereunder:

Member	Attended	Excused
Chairman - Hon Judge Philip Sciberras	3	0
Vice Chairperson - Ms Simone Attard	3	0
Member - Ms Pauline Baldacchino	2	1
Member - Ms Mariella Meachen	3	0
Member - Dr Patrick Sammut	2	1

The Authority also held two additional meetings with the Superintendency of Public Health (SPH) prior to visiting Clinics for Inspection, these meetings were attended by the Vice Chairperson Ms Simone Attard, Ms Mariella Meachen and Dr Patrick Sammut who also formed part of the Inspectorate Team visiting clinics.

Inspections for Licencing

The Authority jointly with the Superintendency of Public Health (SPH) made two separate inspections one in a private fertility Centre namely St James Hospital and also another inspection at the Public fertility Clinic namely Mater Dei Hospital. These inspections were held in order to ensure that the standards of best practice are being respected and implemented and that all information

and documentation required under article 18 of the Act is being kept appropriately. Both inspections were spread on several days each and both led to the issuing of a Licence to both Centres.

Appointments on Other Committees

- **National Health Service IVF Project Team**

Since March 2013, the Government was constantly seeing how the IVF Services would be offered for free on the NHS from Mater Dei Hospital. To this effect an IVF Project Team was appointed to see to all the needs that these services will require, the Authority is represented by its Vice Chairperson Ms Simone Attard on this Project Team. Ms Attard was also appointed as an Advisor offering consultation services to the Ministry of Energy and Health for the setup and running of the IVF Service at Mater Dei Hospital.

- **ART Prioritisation Committee**

The Ministry of Energy and Health has taken into account that couples requiring IVF cannot be put on a waiting list on a first come first serve basis, as according to the criteria established both by the NHS and also by the Authority, a maximum maternal age limit was established, thus such patients needed priority.

To this effect the Health Ministry appointed an ART (Assisted Reproductive Technology) Prioritisation Committee with the aim to objectively rank in order of precedence the couples who are seeking assistance at the ART Clinic at

Mater Dei Hospital. Priority of treatment was given to the couples where the women's age is an issue, since delays in providing an opportunity to treatment, may actually make the couple ineligible for future treatment. Other criteria are also taken into account. The Authority is represented on this ART Prioritisation Committee by its Vice Chairperson Ms Simone Attard and by Dr Patrick Sammut, member of the Authority. This committee meets regularly as prioritization is needed continuously as new cases are registered each week at Mater Dei Hospital.

Annual Remuneration to Board Members

The Authority Board Members are not fully employed by the Embryo Protection Authority and receive only a remuneration package for the work done. The Remuneration received by each member is as per listed hereunder:

Member	Annual Remuneration in Euros
Chairman - Hon Judge Philip Sciberras	13,954
Vice Chairperson - Ms Simone Attard	6,000
Member - Ms Pauline Baldacchino	3,494
Member - Ms Mariella Meachen	3,494
Member - Dr Patrick Sammut	3,494

Other Work by the Authority

Apart from the normal processing of all applications for treatment, requests for additional fertilisations and the cryopreservation of gametes – oocytes and sperm, (a detailed description of these works will be given in the section entitled

“TRENDS AND FIGURES OF FERTILITY TREATMENTS IN MALTA FOR 2014” together with the respective statistics).

The Authority was continuously in collaboration with the Ministry of Energy and Health in assisting in answering the several Parliamentary Questions being made repeatedly on the Assisted Reproductive Technology procedures especially on the IVF services to be offered at Mater Dei and also on the Eligibility Criteria as established in the Embryo Protection Authority’s Protocol.

Moreover the Authority was also giving guidance both to the existing clinics offering the IVF service in the private sector and also to the new service provider who will now offer the services from Mater Dei Hospital.

The Authority also held several meetings with the Competent Authorities to finalise the Legal Notice that led to the “Embryo Protection Authority Regulations, LN 32 of 2015”. This Legal Notice is in line with the Government’s Manifesto proposal to ensure that the IVF Authority will have all the necessary resources. The need of adding new provisions to the Act was two-fold:

- To provide EPA with the necessary tools for its operations, and
- To bring it in conformity with other statutory Acts establishing the setting up of the different Authorities.