Regenerative Medicine
- Using Pluri-potential Stem Cell-
(Japan's Example)

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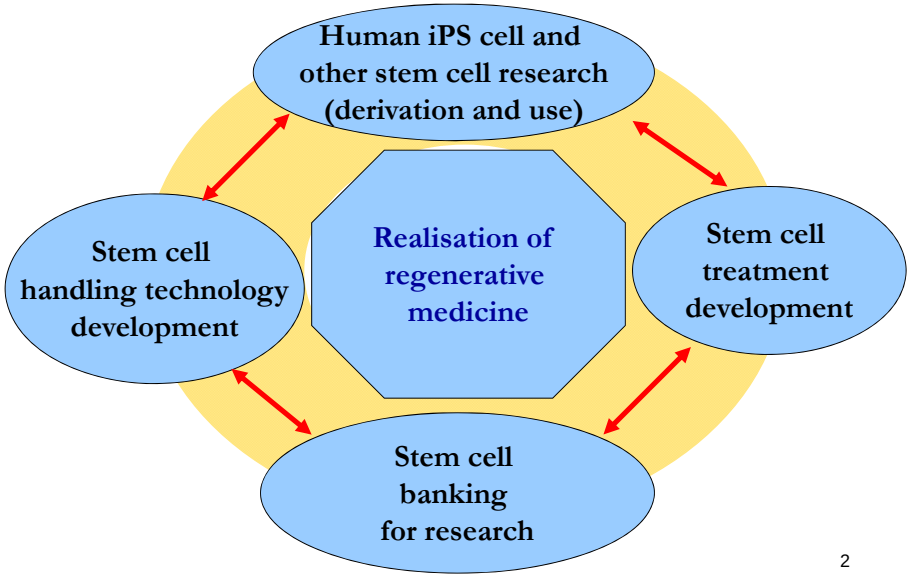
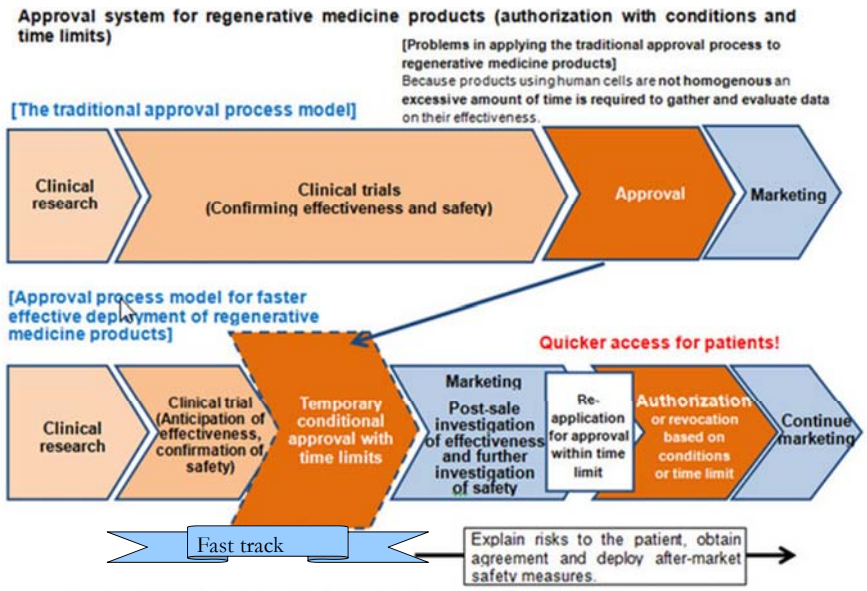
資料４－２

Project for realization of regenerative medicine

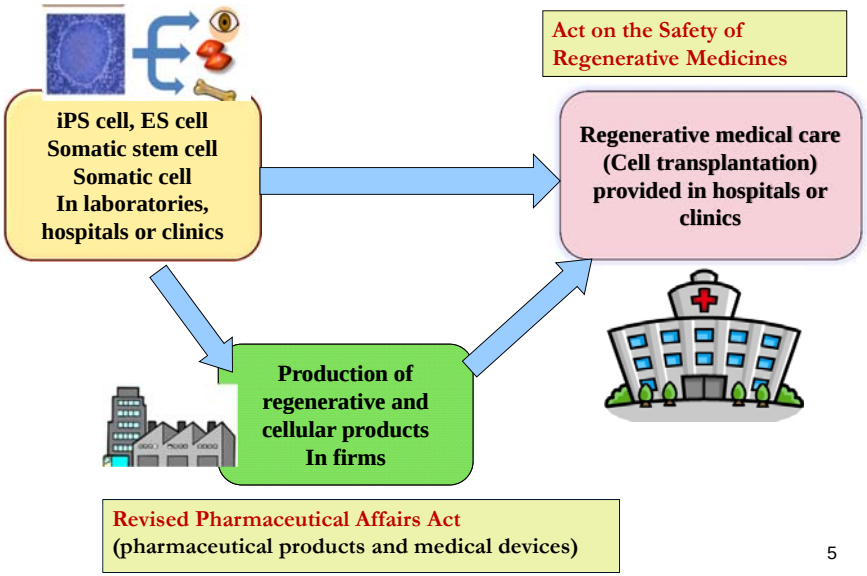


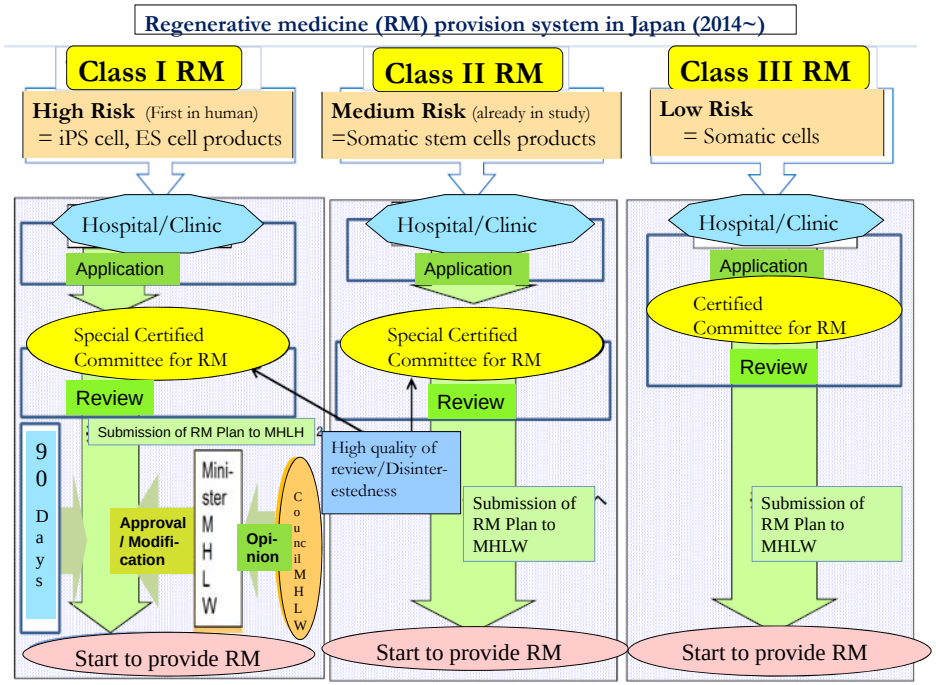
Historical development of regulations

1996 Birth of Dolly
1997 Establishment of National Bioethics Committee
1998 First derivation of human ES cell (Thomson, Wisconsin, US)
1999 Report "Basic conception on reproduction of human being through cloning technology"
2000 Report "Basic Conception on research on human embryo, including human ES cell"
Law on regulation of cloning technology on human being
2001 Guidelines on derivation and use of human ES cell (MEXT)
Guidelines on the research on certain kinds of embryos (MEXT) (therapeutic cloning ban)
2004 Report "Basic conception on handling of human embryo"
2006 Ethical guidelines on clinical trials using human stem cells (MHLW)
2009 Revised Guidelines on research on certain kinds of embryos (therapeutic cloning)
Guidelines on derivation of human ES cell / Guidelines on use of human ES cell (MEXT)
2010 Guidelines on research of creation of gametes from human iPS cell an human stem cell (MEXT)
Revised Ethical guidelines on clinical trials using human stem cells (iPS cell only)
2013 Approval of a protocol using iPS cell for a clinical research
Act on Promotion of Regenerative Medicine
Act on the Safety of Regenerative Medicine
Revised Act on Pharmaceutical Affairs



Regenerative medicine system





Remaining Issues of RM Safety Act

1) Will each RM treatment plan be appropriately classified and reviewed according to the three risk levels ?

   = Providers might tend to characterise their plans to an easier level or submit them to a softer review committee.

2) Will each review be effectively done ?

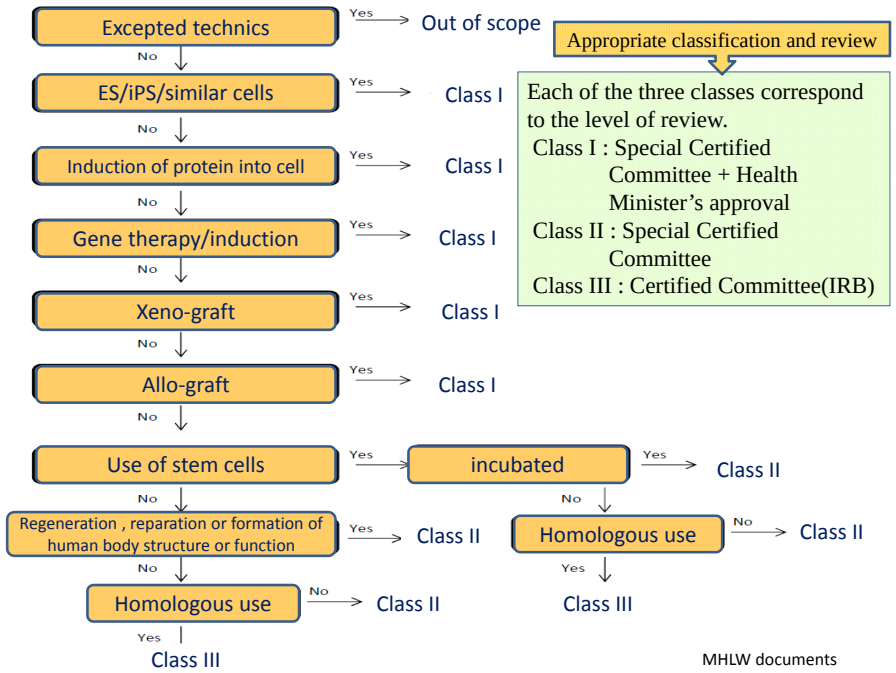
   =Quality of each certified review committee and assurance of effectiveness

3) Will the control on the third level work effectively ?

   =Effective control on free treatment

4) How to assure the effectiveness of each regenerative treatment ?

   = Law provisions are written with general terms and limited to the assurance of the safety of each RM. The effectiveness of the treatment is not included.



MHLW documents

Quality of review and review committees

1) Establishment of certified review committees
   composition of members, review work,
   transparency of review, secretarial support
2) Membership of each committee (esp. Class III)
   independent, multi-disciplinary, multiplicity
3) Review process
   democratic management of work,
   transparent and free discussion,
   independence, preservation of records

Effectiveness of RM

Effectiveness of treatment is out of scope.

1) RM is a treatment expected to be.
   RM is in fact a kind of cell therapy.
   RM involves invasiveness. ⇒ **Safety first!**
2) Control of effectiveness may be done through nonbinding administrative instructions, which may be beyond the limit of legislative control.
3) Limit of governmental control
   Dichotomy of safe and effective medical care and freedom of research

Perspective of Japan's framework of RM

RM = Most of new RM are yet on clinical research stage
= Freedom of research vs. Protection of patients
⇒ The RM Act is based on risk – benefit theory.
How effective may the control be?
Problem 1 = assurance of effectiveness

New system of review committee
No more IRB review system
= Limited number of qualified review committee system
Problem 2 = Reform of IRB system
⇒ New type of review committee system
Transition to European type regional (local) committee system

ありがとう。(“Arigatou”)
Thank you !
Muchas Gracias !
Muito Obrigado !