CENTER FOR DRUG REGULATION AND RESEARCH
LIST OF REQUIREMENTS FOR REGISTRATION OF STEM CELL PRODUCTS

1) Integrated Application Form
2) Copy of Certificate of Accreditation from BHFS
3) Copy of Marketing Authorization from the National Regulatory Authority (NRA) of the exporting country or the country of origin
4) List of countries where the product is already approved and the date(s) of approval
5) Valid agreements between the manufacturer, trader, importer, distributor, where applicable
6) Copy of GMP Certificate of the stem cell-based product manufacturer
7) Scientific evidence to support each claimed indication
8) Information on the product and its manufacture/production
9) Claimed shelf-life and stability studies undertaken
10) Description of the cold-chain procedures employed
11) Certificate of Analysis (CA) of Finished Product
12) Labeling Materials (facsimile labels)
13) Name of the person who will be responsible for any eventuality resulting from the use of the product

Additional Requirements:

1) For products in plastic container:
   (a) Certificate of Analysis for Test of Migratable Substances/ Leachability
2) For imported products:
   (a) Foreign GMP Clearance

Notes:

- All documentary requirements must be in PDF format to be submitted to PAIR
- Image files should be at least 150 dots per inch (dpi)
- A hard copy of the integrated application form is required