Polski Bank Komórek Macierzystych
FamiCord Group

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PBKM Famicord

statement on the draft *Guidelines on Good Manufacturing Practice for Advanced Therapy Medicinal Products*

Submitted in the framework of the public consultation of the European Commission launched on 28 June 2016

ABOUT

Famicord Group, established by Polski Bank Komorek Macierzystych (PBKM), is one of the largest stem cells banks in Europe collecting and storing human stem cells isolated from cord blood and other tissues taken after childbirth. To date, over 130.000 families in Europe have decided to store their children's umbilical cord blood at Famicord, its subsidiaries and related companies. In addition to the family banking activity, the Famicord Group runs a public bank with an inventory of ~3000 units.

Additionally, PBKM possesses 6 permissions from Polish Main Pharmaceutical Inspectorate to produce ATMP based on mesenchymal stem cells for use in Hospital Exemption procedure.

Famicord Group owns and operates 7 laboratories located in Hungary, Poland, Romania, Spain and Turkey, out of which 3 are AABB-accredited and 2 are GMP-class. Famicord Group hires over 300 people and consolidated revenue in 2015 reached 25m Euro. The mother company, PBKM, is listed on the Warsaw Stock Exchange.

22 cord blood transplantations have been performed so far with units stored at the Famicord banks, and more than 200 patients were treated with mesynchemal stem cells.

Addresss
Polski Bank Komórek Macierzystych S.A.
Famicord Group
Aleja Jana Pawla II 29
00 – 867 Warsaw
Poland

Contact Person: Mr. Jakub Baran, CEO
Tel: + 48 600 023 971

Polski Bank
Komórek Macierzystych
FamiCord Group

FamiCord.eu

PBKM, member of the Famicord® Group welcomes the development of the draft Guidelines on Good Manufacturing Practice for Advanced Therapy Medicinal Products.

PBKM Famicord is following with great amount of interest the EU regulatory developments related to Advanced Therapy Medicinal Products. Indeed, the future legislative outlook and regulatory environment will not only influence the degree of development of such products but also the access to stem cells and other human material as a source for ATMP products.

PBKM agrees with the Guidelines on Good Manufacturing Practices for ATMP. However, PBKM thinks that member states' and EU authorities could do more to reach the definition of the same standards and requirements in all member states.

As such, we would encourage the European Commission to mention in the introduction/ preamble of the guidelines that, in time, the adoption and application of the same standards in all European countries is highly desirable. This would help create a level playing field for ATMP developers in all member states, would avoid market distortions, equal access to health services for all EU citizens as well as avoidance of medical tourism.

The experience of - now more than 20-year old - family cord blood banking sector shows us the less positive consequences of too high variations between member states' legislation and standards. When, for example, some national authorities want to impose standards that are significantly much stricter than the EU legislation, business tend to relocate in other EU (or even non-EU) countries triggering also an issue related to cross-border services for customers and likely patients.

We trust that, when developing guidelines related to the ATMP sector, the European Commission will consider and potentially apply some of the lessons learnt from other relatively new sectors - yet old enough to be able to assess the consequences of the lack of harmonisation.

We thank you for the opportunity to participate in this stakeholder consultation and remain at the European Commission's disposal for further consultations.

Best regards,

PBKM Famicord

aa Accredited

Member of Cord Blood Europe

Biuro
al. Jana Pawła II 29
00-867 Warszawa
tel./fax 22 436-40-50

Laboratorium Centralne PBKM
ul. Działkowa 85
02-234 Warszawa

biuro@pbkm.pl
www.pbkm.pl
Infolinia: 608 200 777

NIP: 525-22-39-973 REGON: 017452559 KRS: 0000166106 Sąd Rejonowy dla Miasta Stołecznego Warszawy XII Wydział Gospodarczy Kapitał Zakładowy: 2 367 410 PLN