Drugs and Health Products

Record of Decisions

Cell Therapy Stakeholders Group (CTSG) and the Biologics and Genetic Therapies Directorate (BGTD)

April 21, 2015
1:00 pm to 4:00 pm
Tunney's Pasture, Ottawa, ON

Attendance:

Health Canada Participants

Catherine Parker, DGO
Liz Anne Gillham-Eisen, OPIC
Georgette Roy, ORA
Agnes Klein, CERB
Lindsay Elmgren, CBE
Anthony Ridgway, CERB
Francisca Agbanyo, CBE
Patrick Bedford, OPIC
Scott McCash, OPIC
Paul Gustafson (by phone), HPFB-Inspectorate
Kenneth Joly, OPIC

CTSG Participants

Sowmya Viswanathan, CellCAN-Univerty Health Network, ISCT NA LRA
David Courtman, CellCAN- Ottawa Hospital Research Institute
Samantha Hodgins, CellCAN- Ottawa Hospital Research Institute
Martin Giroux, CellCAN-Centre d'Excellence en Thérapie Cellulaire-Hôpital Maisonneuve Rosemont
Rosario Isasi, CellCAN-McGill University
Friederike Pfau, CellCAN-Laval University/LOEX
Gayle Piat, CellCAN-University of Alberta
Anne-Marie Alarco, CellCAN
Howard Kim, CCRM
Olive Sturtevant , ISCT NA LRA
Deborah Griffin, ISCT NA LRA
Shirley Bartido (by phone), ISCT NA LRA
Kara Wacker (by phone), ISCT NA LRA
Karen Nichols (by phone), ISCT NA LRA
Michael Mendicino (by phone), ISCT NA LRA
William Janssen (by phone), St. Jude’s

1.0 Welcome and Introductions

The meeting was co-chaired between BGTD and the CTSG. Liz Anne Gillham-Eisen co-chaired on behalf of BGTD and Sowmya Viswanathan and Olive Sturtevant co-chaired on behalf of CTSG.

C. Parker provided introductory remarks on behalf of BGTD, and identified cell therapies as a Branch priority.

2.0 Review and Approval of the Agenda

L. Gillham-Eisen explained that the agenda for bilateral meetings are co-developed, meaning that both groups (BGTD and CTSG) are free to propose agenda items. CTSG proposed a number of agenda items for the inaugural meeting, and a number of them were deferred to future meetings. This first agenda focused on Health Canada Updates (Guidance and International Activities); Gene Therapies; and autologous cell therapy issues.

The agenda was accepted without changes.

3.0 Overview of CTSG and Ratification of Terms of Reference

O. Sturtevant provided a background on the Terms of Reference document. The document was drafted in cooperation between ISCT and CellCan.

D. Courtman Question/Comment on the distinction between “Industry” & “Academia”, and encouraged the use of “cell therapy community” instead. The group agreed.

S. Viswanathan asked to amend the Terms of Reference to allow for the bilateral meetings to occur twice per year. BGTD agreed with the change. It was also suggested to add a definitions section to the Terms of Reference.

There was also a question around formally drafting a document to layout the timelines and expectations between BGTD and the CTSG. It was agreed that this would be a separate document, outside of the Terms of Reference

It was made clear that the results of the bilateral meetings are public, meaning that either side is free to use the Meeting Reports for communication purposes, and they could be posted online.

4.0 Overview of Health Canada Activities

P. Bedford provided an update on Health Canada Activities, with particular focus on the

status of (1) the *Draft Guidance for Sponsors: Preparation of Clinical Trial Applications for use in Cell Therapy Products in Humans* consultation process and (2) International collaborative activities. A final guidance for cell therapy clinical trials can be expected this Spring. The outcomes of international discussions will be presented at the International Society of Cellular Therapies on May 27, and should be available on the International Pharmaceutical Regulator's Forum shortly thereafter. The presentation acknowledged the importance of enabling appropriate cell therapy research and use in Canada, and the need to develop strategic action plan & discuss next policy development steps in consultation with the cell therapy community.

D. Courtman explained that industry is hesitant to call Health Canada for basic guidance. A. Klein responded that cell therapy stakeholders are encouraged to contact Health Canada with questions (for example, the Management of Drug Submissions Guidance describes how to organize pre-submission meetings, and the Office of Regulatory Affairs remains available to discuss submission questions), and a group such as this (the BGTD-CTSG bilateral meeting program) can work to demystify the process overall.

P. Bedford acknowledged that there is a need to develop policy so the community can move forward.
F. Agbanyo added that blood is a good example of how the application of the Food and Drug Regulations can evolve over time to address human materials. A. Klein also added that a similar evolution occurred with insulins.

5.0 Cellular Therapy Trials (status on Gene Therapies)

D. Courtman presented an overview of CellCAN Gene Therapy trials. Following that, O. Sturtevant presented on ISCT Gene Therapy Trials, including the use of Genetically Modified Cells.

O. Sturtevant asked is there is an equivalent to the US FDA's RAC.
A. Ridgway responded that creating such a committee was considered by the Health Products and Foods Branch in the late-90s, but it was decided that if needed, other, existing, advisory committees could be employed with ad hoc additions. The need for a specific committee has proven unnecessary to date.

6.0 Future Policy Considerations for minimally manipulated autologous products (with implications on EL)

S. Viswanathan indicated that the cell therapy community would like to know how Health Canada is looking to regulate autologous products. In particular, how would manufacturing sites be regulated? Having each site require an Establishment license seems onerous. Or would it be closer to the CTO process?

L. Gillham-Eisen responded that BGTD is aware of this issue, and is currently

considering options.

P. Bedford acknowledged the significant cost implications of regulating autologous cell therapies under typical GMP regulations for other drugs, and added that challenges associated with autologous cells are not unique internationally. Every regulatory authority seems to have different approaches (many involving specific exemptions). This is an area that would benefit from further discussions with other regulators to determine what may work best for Canada.

A. Ridgway responded that we try to be flexible early in product development since no process is immediately GMP compliant, but patient safety will be paramount.
B. F. Agbanyo again cited that regulations for autologous cell therapy products might eventually be separated into a sub-group, similar to how blood and blood products, and their processing facilities are regulated

7.0 Roundtable

P. Bedford informed the groups that BGTD hopes to post the final Guidance in May and that the CTSG will be notified.

M. Giroux had a question regarding GMP, specifically when it is needed, especially for early Phase I/II trials. What consistutes GMP-approval by Health Canada, and can a facility claim it has “GMP status” for early phase trials. P. Gustafson suggested leaving the topic to the next meeting to provide greater clarity.

Meeting Adjourned 3:50 PM.