

SENT BY EMAIL

Québec City, July 11, 2024

TO BUYERS AND/OR PROCUREMENT OFFICERS OF PUBLIC HEALTH AND SOCIAL SERVICES INSTITUTIONS

TO SURGEONS WHO USE HUMAN TISSUE PRODUCTS

TO OPERATING SUITE STAFF MEMBERS

Subject: Upcoming changes and measures to be taken by December 2, 2024 – Preparing for the entry into force of Héma-Québec's sole human tissue distributor mandate

To whom it may concern:

On April 11, 2024, we announced that Héma-Québec's sole human tissue distributor mandate will officially enter into force on December 2, 2024. As of that date, Héma-Québec will be solely responsible for supplying and distributing human tissue across the entire Québec health care network, thereby consolidating its role in delivering human tissue products.

Héma-Québec was granted the sole distributor mandate following a recommendation from Québec's biovigilance committee. The goal is to simplify supply management and improve the traceability of human tissue products.

To ensure a smooth transition, it is essential for all network members to align with the Ministère de la Santé et des Services sociaux directives regarding the exclusive procurement of human tissue by Héma-Québec, which put an end to hospitals' direct purchases from other suppliers. Please read on for some important information and measures you should take to guide your institution as it prepares for the December 2, 2024, deadline.

INVENTORY MANAGEMENT

UPCOMING CHANGES / EXPLANATIONS

MEASURES TO TAKE

1. END OF SUPPLIER PRODUCT CONSIGNMENT INVENTORY IN HOSPITALS

Within its mandate as the sole human tissue distributor, Héma-Québec is implementing a quality assurance process involving supplier qualification and finished product distribution on the market.

Consignment inventory refers to situations in which a supplier can store their products in hospitals while retaining ownership of the inventory until the hospitals use the products.

However, when consignment inventory is used, Héma-Québec cannot guarantee the quality of the products prior to use because neither Héma-Québec nor the suppliers control the storage conditions. Therefore, in the interests of maintaining the integrity of the products Héma-Québec will distribute under its mandate, the practice of consignment inventory will end on December 2, 2024.

Suppliers who have products in hospital inventory will be asked to remove them, and hospitals will have to maintain appropriate minimum stock levels to counteract any procurement delays for the products in question.

While Héma-Québec will contact suppliers about this matter directly, we encourage you to inform your tissue suppliers that this practice will be ending on December 2, 2024, and discuss an appropriate transition phase with them, if applicable.

2. STORAGE SPACES / EQUIPMENT

It is a common practice for suppliers to provide or loan storage units to hospitals for some types of products.

Over the course of this transition, some suppliers may decide to terminate these agreements or practices.

We suggest that you plan to acquire storage units, if needed, to meet your specific needs.

INVENTORY MANAGEMENT

UPCOMING CHANGES / EXPLANATIONS

MEASURES TO TAKE

1. END OF AGREEMENTS WITH EXTERNAL SUPPLIERS

Hospitals can no longer enter into new agreements with external human tissue suppliers. As the new human tissue supplier for the health care network, Héma-Québec will handle all calls for tenders and supplier audits to ensure product quality and compliance.

As a reminder, current contracts between hospitals and suppliers will be honoured until their planned expiry dates, and contracts ending before September 30, 2024, can be extended with the same conditions until no later than December 31, 2024, if needed.

If you have any questions or want to clarify the expiry dates of your current contracts, please contact Héma-Québec's human tissue supply team at approvisionnement.tissushumains @hema-quebec.qc.ca

ORDERING PROCESS / TERMS AND CONDITIONS

UPCOMING CHANGES / EXPLANATIONS

MEASURES TO TAKE

1. TISSUE ORDERS PLACED BY SUPPLIERS FOR HOSPITALS

Under the current procurement process, it seems to be a common practice for some supplier representatives to place orders for hospitals with their company.

Héma-Québec would like to clarify that only official orders from hospitals (and its own staff) will be processed as of December 2, 2024.

None

2. STANDARD DELIVERY TIMES AND CONFIRMATIONS

Some tissue products will continue to be procured from Héma-Québec's tissue bank, while other products will come from other suppliers.

Tissue from other suppliers will not pass through Héma-Québec's facilities. Instead, we have opted for a direct delivery approach commonly known as dropshipping, which involves delivering products directly to customers. Estimated delivery times for all products that appear in Héma-Québec's product catalogue will be sent to hospitals before December 2, 2024.

All orders from Héma-Québec will receive a confirmation based on standard delivery times. Héma-Québec customer service agents will then confirm whether the orders or products can be delivered any sooner (in emergency situations).

None

3. TERMS AND CONDITIONS

All human tissue orders from Héma-Québec will be subject to Héma-Québec's terms and conditions. The terms and conditions will be distributed shortly, but please note the following:

O Return of compliant products: Will not be possible, except in exceptional situations and with Héma-Québec's approval. Charges will apply.

O Emergency room delivery charges: As delivery charges will not be known at order confirmation, they will be charged to hospitals in full on the invoice.

None

PRODUCT OFFERING

UPCOMING CHANGES / EXPLANATIONS

1. IMPROVED PRODUCT OFFERING

Héma-Québec's catalogue will be usable starting on December 2, 2024, and will be sent to hospitals in September 2024.

The catalogue will present all products distributed by Héma-Québec and by its tissue bank, as well as products delivered under contracts between Héma-Québec and other human tissue suppliers.

Héma-Québec is working with experts in the health care network to choose the right products that comply with defined quality standards and meet the needs of the health care network.

Update your ordering

MEASURES TO TAKE

Update your ordering systems with Héma-Québec catalogue codes for all products that will be distributed.

PRODUCT OFFERING (CONT.) UPCOMING CHANGES / EXPLANATIONS MEASURES TO TAKE With the exception of certain tissues, procurement sources will not be detailed in the catalogue. Additionally, hospitals will no longer be able to order a particular brand or tissue from suppliers, save for some specific products. Pursuant to Héma-Québec's procurement policy, tissue procurement sources will continue to be Héma-Québec's responsibility, in order to ensure a safe supply of human tissues for the health care network.

Information sessions about the entry into force of Héma-Québec's sole human tissue distributor mandate will be held in fall 2024. At these sessions, we will officially present the product offering and give you more information to make this transition a success. You will have the opportunity to ask questions and speak with our team of experts.

In the meantime, if you would like to receive more information or share your comments or concerns, feel free to contact us at our centralized email address, tissushumains@hema-quebec.qc.ca, which will put you in direct contact with the managers of our human tissue team.

Kindly pass along this information to the medical staff at your institution, whether or not they deal with suppliers of human tissue products. Please note that this letter was also sent to presidents and CEOs, directors of professional services and procurement managers at public health and social services institutions.

Sincerely,

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Héma-Québec