



NATIONAL ASSEMBLY

SECOND SESSION

THIRTY-FIFTH LEGISLATURE

Bill 438

An Act respecting Héma-Québec and the haemovigilance committee

Introduction

**Introduced by
Mr Jean Rochon
Minister of Health and Social Services**

**Québec Official Publisher
1998**

EXPLANATORY NOTES

This bill entrusts Héma-Québec with the mission of providing a supply of blood and blood products and components to the population.

The bill specifies that Héma-Québec is not a mandatory of the Government and that no public servant may be a member of its governing board. However, it confers on the Minister of Health and Social Services certain powers of intervention if, for instance, the Minister finds that the quality or safety of the products distributed by Héma-Québec is not sufficient.

The bill provides that the operations of Héma-Québec are to be financed, in particular, by means of the amounts paid to it by the health and social services institutions in consideration for the supply of its products.

The bill also creates the haemovigilance committee, the chief function of which is to advise the Minister of Health and Social Services concerning current risks related to the use of blood and blood products and components. The haemovigilance committee will consist of persons appointed by the Minister.

Lastly, the bill provides measures to determine the time at which Héma-Québec is to begin its product collection, processing and distribution operations.

LEGISLATION AMENDED BY THIS BILL :

- Labour Code (R.S.Q., chapter C-27);
- Act respecting the process of negotiation of the collective agreements in the public and parapublic sectors (R.S.Q., chapter R-8.2).

Bill 438

AN ACT RESPECTING HÉMA-QUÉBEC AND THE HAEMOVIGILANCE COMMITTEE

THE PARLIAMENT OF QUÉBEC ENACTS AS FOLLOWS :

CHAPTER I

HÉMA-QUÉBEC

DIVISION I

CONTINUATION AND NATURE

1. Héma-Québec, constituted on 26 March 1998 by letters patent issued under Part III of the Companies Act (R.S.Q., chapter C-38), is continued in accordance with the provisions of this Act.

2. Héma-Québec is a legal person not established for pecuniary gain.

Héma-Québec is not a mandatary of the State.

DIVISION II

MISSION

3. The mission of Héma-Québec is to provide the health and social services institutions in Québec and the population with a sufficient supply of blood, blood products and blood components.

In the pursuit of its mission Héma-Québec shall, in particular,

(1) develop and enforce strict quality and safety standards in order to earn the trust of the general public and of the recipients of the products it distributes ;

(2) recruit blood and plasma donors and work in partnership with those donors and volunteer blood donor clinic organizers ;

(3) assume responsibility for the collection of blood and plasma ;

(4) manage the records of blood and plasma donors in accordance with strict standards of accuracy, security and confidentiality ;

(5) process the products collected ;

(6) assume responsibility for the storage, distribution and management of provincial stocks;

(7) supply, in particular to health and social services institutions, the blood, blood products and blood components required by those institutions;

(8) at the request of a body managing joint supplies to institutions that has been designated by the Minister of Health and Social Services, obtain, store and supply to the institutions the fractionated products or substitute products required by those institutions;

(9) engage in research and development for the purpose of developing new methods, new technologies and new products that meet the needs of Québec's health system;

(10) maintain links to ensure collaboration and the exchange of information with counterpart organizations in Canada and elsewhere, in order to be informed of and share expertise;

(11) work in close collaboration with the authorities of the Canadian supply service so as to enable each system to benefit from the services and products of the other if necessary;

(12) exercise any other function related to the supply system that is entrusted to it by the Minister of Health and Social Services.

The Minister may also entrust similar duties or functions to Héma-Québec in connection with bone marrow or any other human tissue.

4. Héma-Québec may, in exercising its functions, enter into an agreement according to law with a government other than the Government of Québec, a department of such a government, an international organization, or an agency or body of such a government or organization.

Héma-Québec may also accept gifts, bequests, subsidies or other contributions, provided that any attached condition is compatible with the exercise of its functions.

5. Héma-Québec must enter into an agreement with the Canadian supply service to exchange information on blood or plasma donors with a view to reducing the risk of product contamination.

DIVISION III

ORGANIZATION

6. The head office of Héma-Québec shall be located at the place determined by the Government. Notice of the location and of any change in location of the head office shall be published in the *Gazette officielle du Québec*.

Héma-Québec may hold its meetings at any place in Québec.

7. The governing board of Héma-Québec shall be composed of the following persons who shall become members of the board as and when they are appointed by the Government :

(1) one person selected from among the persons proposed by associations representing recipients of blood components or blood products ;

(2) two persons selected from among the persons proposed by the association of Québec hospitals known as Association des hôpitaux du Québec ;

(3) one person selected from among the persons proposed by blood or plasma donors and volunteer blood donor clinic organizers ;

(4) two members selected from among the persons proposed by the Québec specialists' federation known as Fédération des médecins spécialistes du Québec ;

(5) one member from the university biotechnology sector, selected from among the persons proposed by university-level teaching institutions ;

(6) one member selected from among the persons proposed by the public health directors appointed under the Act respecting health services and social services (R.S.Q., chapter S-4.2) ;

(7) two members from the private enterprise sector selected from among the persons proposed by various socio-economic groups.

The director general, appointed by the members in office, is also a member of the governing board of Héma-Québec.

8. No public servant within the meaning of section 1 of the Public Service Act (R.S.Q., chapter F-3.1.1) may be a member of the board.

9. The director general is appointed for a term of not more than five years and the other members of the governing board are appointed for a term of not more than three years.

Upon the expiry of their term, the members of the board shall remain in office until reappointed or replaced.

10. The members of the governing board shall designate a chair and a vice-chair from among their number ; the vice-chair shall chair the board when the chair is absent or unable to act.

The director general shall act as the secretary of Héma-Québec.

11. The chair shall preside at meetings of the board, oversee its operation and assume the other functions conferred on the chair by Héma-Québec.

12. The quorum at meetings of the governing board is a majority of its members, including the chair or, as the case may be, the vice-chair.

In the case of a tie-vote, the chair has the casting vote.

13. A member of the governing board of the Canadian supply service, or a person delegated by such a member, may attend and is entitled to speak at the meetings of the governing board.

The same rule applies to a member of the haemovigilance committee established pursuant to this Act designated by the Minister.

14. The director general is responsible for the administration and direction of Héma-Québec within the scope of its by-laws and policies.

The function of director general must be exercised on a full-time basis.

15. The director general may not, on pain of forfeiture of office, have a direct or indirect interest in an enterprise causing the director general's personal interest to conflict with that of Héma-Québec. However, forfeiture of office is not incurred where the interest devolves to the director general by succession or gift, provided it is renounced or disposed of with dispatch.

Every other member of the governing board having such an interest must, on pain of forfeiture of office, disclose the interest in writing to the board and withdraw from meetings while any matter relating to the enterprise in which the interest is held is being discussed or voted upon.

16. The Government shall fix the remuneration, employment benefits and other conditions of employment of the director general.

The other members of the governing board shall receive no remuneration, except in such cases, on such conditions and to such extent as the Government may determine. They are entitled, however, to the reimbursement of the expenses they incur in the performance of their duties, on the conditions and to the extent determined by the Government.

17. The governing board may establish an executive committee composed of not fewer than five members of the board, including the chair and the director general, determine its functions and powers and fix the term of office of its members.

18. Héma-Québec may make by-laws concerning the exercise of its powers and its internal management.

The by-laws may, in particular, provide that absence from a specified number of meetings, in the cases and circumstances determined in the by-law, constitutes a vacancy.

19. The members of the personnel shall be appointed in accordance with the staffing plan and standards established by Héma-Québec by by-law. The by-law shall, in addition, determine the standards and scales governing the remuneration, employment benefits and conditions of employment of the personnel members.

The by-law shall be submitted to the Government for approval.

20. Héma-Québec may establish advisory committees to facilitate the execution of its mission, and determine the terms of reference of each committee and its rules of operation.

The members of such a committee shall receive no remuneration, except in such cases, on such conditions and to such extent as the Government may determine. They are entitled, however, to the reimbursement of the expenses they incur in the performance of their duties, on the conditions and to the extent determined by the Government.

The committees may hold their meetings at any place in Québec.

DIVISION IV

FINANCIAL PROVISIONS AND REPORTS

21. The fiscal year of Héma-Québec ends on 31 March.

22. Not later than 30 June each year, Héma-Québec must file its financial statements with the Minister together with a report of its operations for the preceding fiscal year.

The financial statements and the report of operations must contain all the information prescribed by the Minister.

23. The Minister shall table the financial statements and the report of operations in the National Assembly within 30 days of receiving them or, if the Assembly is not sitting, within 30 days of resumption.

24. The books and accounts of Héma-Québec shall be audited each year by the Auditor General, and whenever so ordered by the Government.

The report of the Auditor General must be submitted with Héma-Québec's financial statements.

25. The operations of Héma-Québec shall be financed out of the gifts, subsidies and other contributions it receives, out of the revenues deriving, in particular, from the supply of its products to health and social services institutions and other bodies, and, where applicable, out of the proceeds of the sale of its assets.

26. The Government may, on the terms and conditions it determines, guarantee the payment of the capital of and interest on any loan made by Héma-Québec and the performance of any of the obligations of Héma-Québec.

27. The Government may, on the terms and conditions it determines, authorize the Minister of Finance to advance to Héma-Québec any amount considered necessary for the pursuit of its mission.

28. The sums paid under section 26 or 27 shall be taken out of the consolidated revenue fund.

29. Héma-Québec must prepare three-year budgetary forecasts and forward them to the Minister annually on the date and in the form determined by the Minister.

30. Héma-Québec may not construct, acquire or dispose of an immovable except with the authorization of the Minister.

The same rule applies to any purchase of equipment for an amount exceeding the amount fixed by the Government, where the equipment is not required to ensure product safety.

31. Héma-Québec must provide any information required by the Minister concerning its operations within the time and in the form specified by the Minister.

DIVISION V

POWERS OF THE MINISTER

32. The Minister may assume the provisional administration of Héma-Québec in the following cases :

(1) if a permit that is necessary to the operations of Héma-Québec has been or is likely to be suspended or revoked, or has not been or is unlikely to be renewed;

(2) if the Minister considers that Héma-Québec is engaging in practices or is tolerating a situation that may compromise the safety, quality or quantity of the products it distributes;

(3) if the Minister considers that one or more of the members of the governing board have committed a gross fault such as malfeasance, breach of trust or other misconduct, or if the board has been seriously remiss in the performance of the obligations imposed on it by law.

Where the Minister assumes the provisional administration of Héma-Québec, the powers of the members of the governing board are suspended, and the Minister shall exercise all the powers of the governing board.

33. After assuming the provisional administration of Héma-Québec, the Minister must file a preliminary report containing observations and recommendations with the Government as soon as possible.

Before filing the report, the Minister must give Héma-Québec an opportunity to present observations, and the Minister must append a summary of the observations to the report.

34. After receiving the Minister's preliminary report, the Government may request that the Minister continue the provisional administration of Héma-Québec for a period not exceeding three months, or that the Minister terminate the provisional administration within the time it indicates.

Where the Government requests that the Minister continue the provisional administration, it shall indicate whether all or any of the powers normally exercised by the governing board will be suspended and exercised by the Minister.

35. The Minister shall file a report with the Government as soon as the Minister finds that the situation referred to in section 32 has been corrected, or that it cannot be corrected before the end of the provisional administration.

After receiving a report from the Minister, the Government may take either of the steps provided for in section 34.

36. No person who assumes the provisional administration of Héma-Québec under the authority of the Minister may be prosecuted for anything done in good faith in exercising the person's functions.

37. On the advice of the haemovigilance committee, the Minister may require that Héma-Québec take certain specific steps to ensure the quality and safety of the products it distributes.

In the same manner, the Minister may, for the same reasons, require that Héma-Québec withdraw certain products and notify any persons to whom such products have been distributed of the risk of contamination they present.

DIVISION VI

DETERMINATION OF THE CONDITIONS GOVERNING THE SUPPLY OF PRODUCTS

38. The Minister may designate a body to manage joint supplies to institutions and require Héma-Québec to reach an agreement with that body concerning the conditions governing the supply of its products to health and social services institutions in Québec.

The Minister may subject all or only certain of the products supplied by Héma-Québec to such a procedure.

The Minister may in addition require that the conditions governing the supply of a product be the same for all health and social services institutions, whatever the conditions governing, in particular, the delivery of the product or the quantity of product supplied.

39. If, one month before the date fixed for the forwarding of the budgetary forecasts of Héma-Québec to the Minister, Héma-Québec and the designated body have not reached agreement, they must appoint a mediator to assist them in settling their dispute.

If, on the date fixed for the forwarding of the budgetary forecasts, the parties have not agreed on a mediator, or if they have not settled their dispute three months after that date, the Minister may require the parties to submit their dispute to arbitration.

The arbitration proceedings shall commence on the date of the Minister's decision.

40. Each party must appoint an arbitrator within ten days after the Minister's decision, and such arbitrators must appoint a third arbitrator within ten days after their appointment. Failing the making of such appointments by the parties or the arbitrators within the time limits stipulated, the Minister may apply to a judge of the Court of Québec to make the appointments, and the judge's decision may not be appealed.

41. Articles 944.1 to 945.8 of the Code of Civil Procedure (R.S.Q., chapter C-25) apply to the arbitration, with the necessary modifications.

The arbitration award must be rendered within two months after the appointment of the third arbitrator.

42. All the conditions governing the supply of products, including the price of the products, must be fair and reasonable.

Where a dispute pertains to the price of a product, the arbitrators must have regard in particular to

- (1) the expenditure which they consider necessary to pay the costs of production, in particular costs relating to the recruitment of donors, product collection, analysis, processing, storage and distribution and an allowance for the depreciation of the equipment and capital property used;

- (2) the undepreciated research and development expenditures;

- (3) the fact that the objects of Héma-Québec do not include the making of a profit and that it must finance its operations in accordance with section 25.

43. The arbitration award may not be appealed, and Héma-Québec cannot impose different conditions on the health and social services institutions for the acquisition of its products.

CHAPTER II

HAEMOVIGILANCE COMMITTEE

44. A haemovigilance committee is hereby established under the name “Comité d’hémovigilance”.

45. The function of the haemovigilance committee is to advise the Minister, as considered necessary by the Minister and not less than once yearly, on current risks relating to the use of blood, blood products and blood components and the use of substitute products.

The mandate of the haemovigilance committee shall include examining any matter submitted to it by the Minister in connection with the blood supply system and giving the Minister its opinion within the time indicated by the Minister.

The Minister may assign the haemovigilance committee similar functions with regard to bone marrow or any other human tissue.

46. The haemovigilance committee shall be composed of the following persons, appointed by the Minister :

(1) one person from the public health laboratory known as Laboratoire de santé publique du Québec ;

(2) two persons working in the public health departments of the regional boards established pursuant to section 371 of the Act respecting health services and social services (R.S.Q., chapter S-4.2) ;

(3) one medical epidemiologist ;

(4) one ethicist ;

(5) four medical haematologists practising in a health and social services institution ;

(6) three users of the health and social services system having an interest in the blood supply system.

The Minister may also appoint two other members to the committee where the Minister considers that their expertise would advance the work of the committee.

47. One person designated by Héma-Québec and two persons designated by the Deputy Minister of Health and Social Services shall attend the meetings of the haemovigilance committee and shall be entitled to speak at the meetings.

48. The members of the haemovigilance committee shall be appointed for a term not exceeding two years.

At the end of their term, the members of the haemovigilance committee shall remain in office until reappointed or replaced.

49. The Minister shall designate a chair and a vice-chair of the haemovigilance committee from among the members; the vice-chair shall chair the haemovigilance committee when the chair is absent or unable to act.

One of the persons designated by the Deputy Minister of Health and Social Services to attend the meetings of the committee shall act as the secretary of the committee.

50. The quorum at meetings of the haemovigilance committee is a majority of its members, including the chair or, where applicable, the vice-chair.

In the case of a tie-vote, the chair has the casting vote.

51. The haemovigilance committee may make by-laws concerning its internal management.

52. The fees and allowances of the members of the haemovigilance committee shall be fixed by the Government, as shall the fees of the consultants and experts consulted by the haemovigilance committee.

53. The Ministère de la Santé et des Services Sociaux shall pay the fees and allowances referred to in section 52. It shall also, within the scope of its resources, pay for the administrative support needed by the haemovigilance committee to carry out its work.

54. The haemovigilance committee shall provide the Minister with any information required by the Minister concerning its operations, within the time and in the form indicated by the Minister.

CHAPTER III

MISCELLANEOUS AND FINAL PROVISIONS

55. Except after obtaining the authorization of the Minister of Health and Social Services, no health and social services institution may use any blood, blood products or blood components, including fractionated products, except those supplied by Héma-Québec. However, the Minister may, in respect of the products determined by the Minister, grant such an exclusivity to another supplier.

The same rule may apply to substitute products or to any other product supplied by Héma-Québec, where so decided by the Minister.

56. The Minister of Health and Social Services is responsible for the administration of this Act.

57. The members of the governing board of Héma-Québec in office on *(insert here the date of coming into force of section 1 of this Act)* shall remain in office until the date determined by the Government.

58. The operations of Héma-Québec relating to product collection, processing and distribution shall begin on the day fixed in the agreement to be entered into with the Canadian Red Cross Society, or on any other day determined by the Government.

59. If, on the day fixed for Héma-Québec to begin its operations referred to in section 58, an effective invoicing of the products distributed to health and social services institutions proves impossible, the Minister may temporarily, with the authorization of the Conseil du trésor, pay the cost of the products to Héma-Québec directly on the terms and conditions determined by the latter.

If, on that same day, the conditions governing the supply of products to which a decision of the Minister under section 38 applies have not been fixed in the manner set out in Division VI, those conditions shall be determined by an agreement entered into by Héma-Québec and the Minister; the agreement must be approved by the Conseil du trésor or, where no agreement is reached, by the Government. In both cases, the conditions governing the supply of products are valid for a period not exceeding two years.

60. The Government may expropriate any property of the Canadian Red Cross Society which it considers necessary in the pursuit of the mission of Héma-Québec.

After such an expropriation, the Government may transfer ownership of the expropriated property to Héma-Québec on the conditions it determines. The Government may also retain ownership of the immovables and lease them or otherwise entrust their use to Héma-Québec, or transfer ownership of the immovables to the Corporation d'hébergement du Québec for the purpose of leasing them or otherwise entrusting their use to Héma-Québec.

61. Section 111.0.16 of the Labour Code (R.S.Q., chapter C-27) is amended by replacing “the Canadian Red Cross Association” in the fourth and fifth lines of paragraph 7 by “Héma-Québec”.

62. Schedule C to the Act respecting the process of negotiation of the collective agreements in the public and parapublic sectors (R.S.Q., chapter

R-8.2), amended by section 120 of chapter 63 of the statutes of 1997, is again amended by inserting the expression “Héma-Québec”, which is to be ordered alphabetically.

63. The provisions of this Act come into force on the date or dates to be fixed by the Government.