

23 March 2007

Reference: BIWG 07007

BY COURRIER

Minister Rudy Demotte
Minister van Sociale zaken en Volksgezondheid
Kunstlaan, 7
1210 Brussel

Mr. Xavier de Cuyper
Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten
EUROSTATION II
8ste verdieping
Victor Hortaplein 40
1060 BRUSSEL

Dear Minister Demotte and Mr de Cuyper,

Subject: C.A.F.-D.C.F.'S announcement of its inability to supply immunoglobulin

PPTA represents the commercial manufacturers of plasma derived medicinal products, including immunoglobulin that are licensed and approved for distribution in Belgium. Details of our association and members can be found at: www.pptaglobal.org.

We are aware of a letter that was widely distributed during February 2007 by the C.A.F.-D.C.F. organization in which they announce, with immediate effect and without any warning that they are unable to meet orders for Multigam their immunoglobulin product. The same letter also acknowledges that C.A.F.-D.C.F. can give no guarantees about the supply situation in the future.

PPTA's members regret that C.A.F.-D.C.F. have taken this decision without anticipating the situation or providing appropriate warnings to help facilitate remedial actions. No adequate explanation of this inability to plan was provided and perversely C.A.F.-D.C.F. acknowledges that it has reduced its production of immunoglobulin and instructed the Red Cross to reduce their collection of plasma for fractionation.

C.A.F.-D.C.F.'s decision to reduce production is inexplicable as it is widely known that in recent years the demand for immunoglobulin has consistently grown both internationally, within Europe and in Belgium. PPTA members have consistently increased distribution each year for some years and have fulfilled their contractual commitments in Belgium.

Contrary to the C.A.F.-D.C.F. decision, in the last twelve months PPTA's members have increased plasma collections by more than 20% over the previous year.

The fact remains that demand for immunoglobulin has increased significantly and with distribution limited by the availability of plasma this has inevitably resulted in an increase in prices internationally.

The C.A.F.-D.C.F. letter puts its decision not to supply immunoglobulin in the context of Belgium's national self-sufficiency program. Recognizing that self-sufficiency in transfusion products is logistically necessary, PPTA believe that Belgian self-sufficiency in plasma derived medicinal products is NOT the panacea claimed by C.A.F.-D.C.F. PPTA members have experience in working with several European governments in the context of national

self-sufficiency through contract fractionation and other arrangements. It may be that this is the time for Belgium to reconsider its strategy towards implementing Belgian self-sufficiency. There are several other models that work well and help ensure a sufficient and sustained supply of plasma derived medicinal products are available to patients.

Access to state of the art manufacturing through contract fractionation should also bring self-sufficiency and patient benefits. For example if one manufacturer can only extract 2gms of immunoglobulin per litre of plasma it will take twice as much plasma to produce the same quantity of immunoglobulin compared to a manufacturing process that can extract 4gms per litre. Patients also know that there are differences between the various licensed immunoglobulin. Dependence on a single "self-sufficiency" product would obviously restrict choice and some patients will suffer.

Belgium's reimbursement policy will inevitably and regularly result in disrupted access to plasma derived medicinal products. This is because unlike chemical based pharmaceuticals for which the Belgian reimbursement system was developed, plasma derived medicinal products are limited by the quantity of plasma available. Inevitably, as demand increases so the price of plasma goes up. Belgium's system typically maintains prices at the same level and therefore becomes disconnected to global demand for IgG and price. This situation has been discussed and accepted at several occasions in the past. On this basis and in light of the current situation this needs to be discussed again urgently.

One other factor should not be ignored. As highlighted in our letter to Minister Demotte (dated 9 February 2007, reference: BIWG07001), legislation of 27 December 2006 imposing a tax on turnover contribution on many of the licensed and approved immunoglobulins and other plasma derived medicinal products provides a disincentive to PPTA members and makes distributing plasma derivatives in Belgium proportionately less attractive.

PPTA and its members are prepared to work constructively with relevant authorities and stakeholders to develop a long term solution to a challenge that has been caused by the C.A.F.-D.C.F. decision, without warning, not to deliver immunoglobulin that it had committed to supply.

In view of the C.A.F.-D.C.F decision to circulate their letter widely, a similar version of this letter is being made available to pharmacists and other stakeholders.

Yours sincerely



Charles Waller
Vice President PPTA Europe

Signed by PPTA in name of Charles Waller