----- Original Message -----
From: Jan Larsson
To: entr-pharmaceuticals@ec.europa.eu
Sent: Monday, March 22, 2010 7:52 PM
Subject: Regarding the Commission decision 27 May 2009 about safety actions for “methylphenidate” products (in Sweden mainly Ritalin and Concerta) and the actions of the Swedish Medical Products Agency (MPA)

Dear Pharmaceuticals Unit,

On 2 February I got the question below from you. I answered by copying the earlier communications from the Unit in the matter (below). Since then I have heard no more about this specific matter.

I must say I am still puzzled about this matter. Why did the Unit question me about what the Unit earlier had written? Why wasn't the question about changing the prescription rules directed to the Medical Products Agency in Sweden, getting the Agency to confirm that Sweden is not to follow what is put up in the SPC text?

So I hope you can clarify this thing for me. Has the Unit changed its mind in this matter, is the text in the SPC no longer legally binding for member states and isn't compliance expected in the matter I took up?

Yours sincerely,

Janne Larsson

----- Original Message -----
From: entr-pharmaceuticals@ec.europa.eu
To: jan.olov.larsson@telia.com
Sent: Tuesday, February 02, 2010 2:57 PM
Subject: RE: Regarding the Commission decision 27 May 2009 about safety actions for “methylphenidate” products (in Sweden mainly Ritalin and Concerta) and the actions of the Swedish Medical Products Agency (MPA)

Dear Mr Larsson,

In your letter below you have adduced the short answer from the Commission dated 25th October. As your query raises issues requiring an in-depth examination, can you send us a copy of this answer?

Yours faithfully,

Pharmaceuticals Unit

----- Original Message -----
From: Jan Larsson
To: entr-pharmaceuticals@ec.europa.eu
Sent: Tuesday, February 02, 2010 6:10 PM
Subject: Regarding the Commission decision 27 May 2009 about safety actions for “methylphenidate” products (in Sweden mainly Ritalin and Concerta) and the actions of the Swedish Medical Products Agency (MPA)

Dear Pharmaceuticals Unit,

Thank you for your answer. I have below pasted the answer from the Commission that you asked for.

Yours sincerely,

Janne Larsson

----- Original Message -----
From: Stefan.FUEHRING@ec.europa.eu
To: jan.olov.larsson@telia.com
Sent: Sunday, October 25, 2009 12:56 PM
Subject: RE: Final Question about the Commission decision 27.5.2009 regarding medicinal products for human use which contain the active substance "methylphenidate"

Dear Mr. Larsson,
It means compliance, not just recommendation.
Best regards,
Stefan Führing

Unit F2 - Pharmaceuticals
Enterprise and Industry Directorate-General
European Commission
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Website: http://ec.europa.eu/enterprise/pharmaceuticals/index_en.htm
Disclaimer: The above text cannot be regarded as an official position of the European Commission; any views expressed are exclusively those of the author. It is intended solely for the person to whom it is addressed and may contain confidential information. If you received this e-mail in error, please notify us immediately by e-mail or telephone and delete the e-mail without copying or disclosing its contents to any other person.

From: Jan Larsson [mailto:jan.olov.larsson@telia.com]
Sent: Sunday, October 11, 2009 10:32 PM
To: FUEHRING Stefan (ENTR)
Subject: Final Question about the Commission decision 27.5.2009 regarding medicinal products for human use which contain the active substance "methylphenidate"
Dear Mr.Stefan Führing,

Excuse me for having to ask for a final clarification in this matter.

I have come to understand that the point I took up in my earlier mail *("Treatment must be initiated under the supervision of a specialist in childhood and/or adolescent behavioural disorders"),* despite you clarifying that the decision text is legally binding on Member States, have been interpreted to just have the status of "recommendation", meaning one can choose to follow it or not.

In order to get this point clarified I would very much appreciate to get an answer also on this: Does implementation of the SPC requirements mean compliance also to this rule or is this part just a recommendation?

Janne Larssson

END OF MAIL

----- Original Message -----
From: entr-pharmaceuticals@ec.europa.eu
To: jan.olov.larsson@telia.com
Sent: Tuesday, February 02, 2010 2:57 PM
Subject: RE: Regarding the Commission decision 27 May 2009 about safety actions for “methylphenidate” products (in Sweden mainly Ritalin and Concerta) and the actions of the Swedish Medical Products Agency (MPA)
Dear Mr Larsson,

In your letter below you have adduced the short answer from the Commission dated 25th October. As your query raises issues requiring an in-depth examination, can you send us a copy of this answer?

Yours faithfully,

Pharmaceuticals Unit

From: Jan Larsson [mailto:jan.olov.larsson@telia.com]
Sent: Friday, January 29, 2010 5:06 PM
To: ENTR /F/2 PHARMACEUTICALS
Cc: Lars-Erik.Holm@socialstyrelsen.se; registrator@social.ministry.se; christina.akerman@mpa.se; FUEHRING Stefan (ENTR)
Subject: Regarding the Commission decision 27 May 2009 about safety actions for "methylphenidate" products (in Sweden mainly Ritalin and Concerta) and the actions of the Swedish Medical Products Agency (MPA)

Regarding the Commission decision 27 May 2009 about safety actions for "methylphenidate" products (in Sweden mainly Ritalin and Concerta) and the actions of the Swedish Medical Products Agency (MPA)

29 January 2010

In the beginning of July 2009 I wrote to the Commission about the scientific conclusions (p. 34 in the attached document), where it was stated about methylphenidate: "It is an amphetamine-like drug that has controlled drug status, which imposes restrictions on prescribing and handling." In the SPC text (page 43) it was stated in bold letters: "**Treatment must be initiated under the supervision of a specialist in childhood and/or adolescent behavioural disorders."**

What I understood one of the purposes with the Commission decision was to achieve harmonisation of the prescription rules and texts for the countries concerned. The prescription rules, as stated in the new SPC text were very clear and my question to the Commission was: Does the text about prescription rules in the Commission decision (as the bold text above) supersede earlier nationally formulated prescription rules?

I also wrote that I assumed that this text was ***legally binding*** for the the member states concerned (like Sweden). I assumed that different member states could not make their own decisions on the point above (that treatment must be initiated in the way described) and that member states could not widen this rule to mean something else (so that treatment could be initiated by a wider sphere of doctors).

On 25 July I got the answer from the Commission:
"The decision is legally binding on Member States. Thus, Member States have to base their national marketing authorisations on the amendments of the summary of the product characteristics and the package leaflet set out in Annex III. They can not go beyond these requirements."

Based on this clear answer I asked the Swedish Medical Products Agency how they looked upon this decision, as the nationally formulated prescription rules by the Agency clearly was in conflict with the Commission text.

It took a very long time to get an answer but 28 September the judicial department of the MPA answered (Nordback). He stated:
"The question about which specialist competence a treating doctor must have or should have is not among the things that an SPC should contain. If it still does it must rather be seen as a kind of recommendation."

In other words, the new SPC text was not at all legally binding on the above mentioned part, as an SPC should not contain data about prescription restrictions.

I then took the matter to the Commission again, asking:
“I have come to understand that the point I took up in my earlier mail *(”Treatment must be initiated under the supervision of a specialist in childhood and/or adolescent behavioural disorders”),* despite you clarifying that the decision text is legally binding on Member States, have been interpreted to just have the status of ”recommendation”, meaning one can choose to follow it or not.

In order to get this point clarified I would very much appreciate to get an answer also on this: Does implementation of the SPC requirements mean compliance also to this rule or is this part just a recommendation?”

I got a short an clear answer on this from the Commission 25 October:
“It means compliance, not just recommendation.”

I then took this new clarification to the MPA asking about the nationally issued directive LVFS 2002:7 (changed and reprinted through **LVFS 2008:11**), which states that methylphenidate can be prescribed (and the treatment started) by **“doctors with specialist competence in child and adolescent psychiatry, psychiatry, forensic psychiatry, or child and adolescent neurology with rehabilitation”,** and that it was possible to also after special approval **“admit that doctors with other specialist competence but with certain knowledge within the field could be given the right to prescribe [methylphenidate].”** (Attached, in Swedish.)

I asked the simple question if this directive now was superseded by the Commission text, that Sweden had ascertained compliance to.

On this it was 13 November answered (Lindström):
“An acknowledgement that LVFS 2008:11 has ceased to be valid due to the statement from the Commission cannot be given. The Directive is valid until it is cancelled by the Medical Products Agency.”

As I thought this answer was very strange – considering the clarifications made earlier by the Commission – I stated:
“The Commission text, which Sweden should be ‘in compliance with’, must be legally valid. Even if the Medical Products Agency *not yet officially* has cancelled LVFS 2008:11, that text, as being in conflict with the EC text, must at this time have no legal validity.”

On this I got the simple answer:
”I stand by my earlier answer.”

I then took the matter to the Foreign Ministry, having responsibility for the affairs with other European countries. On 7 January 2010 I got an answer from the Prime Minister’s Office (Heina), where it was stated (translation):
“In general the EC decisions are binding for the one/ones that the decision is directed towards…The EC judicial acts have precedence over national law and that principle is also valid for the Commission decisions. That means that a regulation in national law, for example in a Swedish decree cannot be applied if it violates, in this case, a regulation in the Commission decision.”

I was directed to the Ministry of Health and Social Affairs for further questions about this matter.

In its answer to my question the Ministry of Health and Social Affairs (Lindberg), 20 January, stated that they could only agree with the analysis above. However they could not say anything further about the special case with the SPC text. On a

questing *who could* I got the answer that the proper authority in this case would be a competent court.

That's the development of this affair so far.

I had thought from the beginning that the Swedish authorities concerned would be quite happy to know about the safety restrictions they may have missed, and that the response would be that they immediately would take action to implement the vital decisions taken by the Commission 27 May 2009. I had no expectations that this would develop into an affair where strong judicial resources were called upon to prove why Sweden *must not* implement the actions decided by the Commission.

I had also expected that the senior authorities – like the Ministry of Health and Social Affairs, would be interested in taking action to get the safety actions implemented.

As seen above I was wrong.

Janne Larsson
Reporter
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Sweden