

# HEALTHCARE JOURNALIST v NOVARTIS

## Galvus press release

A journalist from a pharmaceutical trade magazine complained about a Galvus (vildagliptin) press release from Novartis Pharma AG which detailed the approval in the EU of Galvus for type 2 diabetes patients with moderate or severe renal impairment with limited treatment options.

The complainant noted the claim 'Controlling blood sugar levels in patients with type 2 diabetes and renal impairment can be complex as many oral anti-diabetic medicines are not recommended for use, are contraindicated or should be used with caution. As a result, physicians have few treatment options for these high-risk patients' and alleged that the whole press release was tailored to meet the view that there were 'few treatment options' for type 2 diabetics with renal impairment, which was not so. There were already two other medicines with licences for this indication and whilst the complainant did not expect Novartis to name its competitors, to imply they did not exist was not correct.

The complainant further alleged that Cavanaugh (2007), cited in the press release, which stated that there were indeed few treatment options for this patient population was no longer correct; an out-of-date study had been used to back up a false assertion.

The detailed response from Novartis is given below.

The Panel noted the submission from Novartis UK that it had had no part in the creation, review or distribution of the press release which was issued by Novartis Pharma AG based in Switzerland. The circulation list provided, however, showed that the press release was sent mainly to UK-based publishers including a number of UK-specific publications such as the BMJ.

The supplementary information to the Code required that activities carried out and materials used by a pharmaceutical company located in a European country must comply with the national code of that European country as well as the national code of the country in which the activities took place or the materials were used. The press release was issued by a company based in Switzerland but inasmuch as it was sent to specific UK publications, the Panel considered that that aspect of its use came within the scope of the Code.

The press release was entitled 'Novartis drug Galvus approved in EU for type 2 diabetes patients with moderate or severe renal impairment with limited treatment options'. Underneath the title were two bullet points; the first referred to the percentage of patients with type 2 diabetes affected by renal impairment (25%) and the second stated 'Majority of currently available medications are not

recommended, contraindicated or have to be taken with caution in this population'. The press release went on to state that the approval of Galvus for use in this patient population 'expands treatment options for patients with moderate or severe renal impairment'. A Novartis employee from the global company was quoted as stating that the approval provided physicians with a '...much-needed new treatment to control blood sugar in a vulnerable patient population...'

The Panel noted Novartis's submission that of 19 medicines available to treat type 2 diabetes (not including insulin), only three were indicated without the need for caution in both moderate or severe renal impairment. Two products were mentioned by the complainant. Onglyza could only be used at a lower dose and in severe renal impairment with an additional advisory caution. Trajenta could be used without caution or dose adjustment in severe renal failure. Galvus required a dose adjustment in moderate or severe renal impairment or with end stage renal disease when the recommended dose was 50mg once daily.

The Panel noted the statement quoted by the complainant from the press release 'Controlling blood sugar levels in patients with type 2 diabetes and renal impairment can be complex as many oral anti-diabetic medicines are not recommended for use, are contraindicated or should be used with caution'. Given that the title of the press release referred to '...limited treatment options', the text referred to 'few treatment options' and 'expanding treatment options', the Panel did not consider that the press release conveyed that Galvus had 'plugged a gap in the market' as alleged. It was clear from the press release that there were already 'a few' treatment options available and that Galvus had added to these. No breach of the Code was ruled.

The Panel noted that since Cavanaugh had been published, at least two medicines (Onglyza and Trajenta) and Galvus had been approved for use in type 2 diabetes with renal impairment. It might be argued that this was not the impression given by the use of a 2007 reference. On balance, however, the Panel considered that it was still the case that treatment options were limited as stated in the paper. No breaches of the Code were ruled including no breach of Clause 2.

A healthcare journalist with a pharmaceutical trade magazine complained about a press release about Galvus (vildagliptin) which he had received by email from Novartis Pharma AG. Galvus was indicated for the treatment of type 2 diabetes mellitus as dual oral therapy in combination with metformin, a sulphonylurea or a thiazolidinedione. The press

release was about the approval in the EU of Galvus for type 2 diabetes patients with moderate or severe renal impairment with limited treatment options.

## COMPLAINT

The complainant noted the claim 'Controlling blood sugar levels in patients with type 2 diabetes and renal impairment can be complex as many oral anti-diabetic medicines are not recommended for use, are contraindicated or should be used with caution. As a result, physicians have few treatment options for these high-risk patients' and stated that the whole press release was tailored to meet the view that there were 'few treatment options' for type 2 diabetics with renal impairment which was not so. Several months ago the European Medicines Agency (EMA) approved Boehringer Ingelheim's Trajenta (linagliptin) for this indication and AstraZeneca/Bristol-Myers-Squibb's Onglyza (saxagliptin) gained an extended European licence for this indication in March.

The complainant alleged that essentially, Novartis wanted to convey that it had plugged a gap in a market, but it had simply added to two already available medicines in Europe for the licence it had gained. Novartis had been deliberately underhand. The complainant did not expect Novartis to name its competitors but to imply they did not exist was not correct.

The complainant also questioned a reference in the press release as a point of corroboration. The third reference cited (Cavanaugh 2007) stated that there were indeed few treatment options for this patient population but this was no longer correct. The complainant alleged that Novartis had deliberately used an out-of-date study to back up its false assertion.

The complainant submitted that so underhand was it that a competitor magazine had printed the story as fact and stated that there were few other treatments and went with the angle that Galvus had plugged a gap in the market.

When writing to Novartis, the Authority asked it to respond in relation to the requirements of Clauses 7.2, 22.2 and 2 of the Code.

## RESPONSE

Novartis stated that the press release was created, reviewed and distributed by its global colleagues at Novartis Pharma AG based in Basel, Switzerland. As Novartis UK had no part in the creation, review or distribution of it, it had not been approved under the UK Code as this was not applicable.

After approval by the global compliance team, the press release was sent by its medical media agency to a list of international medical publications which it compiled as directed by the global Novartis organization. A copy of the circulation list was provided. Novartis submitted that this demonstrated that this was a general listing for European and international publications.

During the course of discussions with other reporters in the publishing house regarding this press release, it was recommended to the medical media agency that a particular individual would be the appropriate contact and thus the press release was emailed directly to him by the medical media agency. Subscriptions for the trade magazine were available via the online site.

The Authority specifically raised the question of amendments to the press release by Novartis to include reference to existing treatments and asked for information on this matter. The complainant's related statement was slightly ambiguous, and therefore Novartis answered the Authority's specific question: Novartis UK's global colleagues confirmed that no amended press release was issued. However, it appeared to Novartis UK that the complainant had referred to the coverage by a competitor publication, and that this publication took it upon itself to subsequently amend its story to include existing treatments within the same class.

Novartis noted that the complaint related to the following statement:

'Controlling blood sugar levels in patients with type 2 diabetes and renal impairment can be complex as many oral anti-diabetic medicines are not recommended for use, are contraindicated or should be used with caution. As a result, physicians have few treatment options for these high-risk patients.'

The complainant alleged that this statement and Cavanaugh to which it referred were used to endorse the view that treatment options were 'limited' which could not be substantiated.

Cavanaugh was a comprehensive review of the issues for diabetes management in patients with chronic kidney disease and reviewed the treatment options available. It considered which medicines could be used with no dose adjustment, where dose adjustment was required or whether the medicine was to be used with caution and finally whether it was contraindicated in this patient population and so should be avoided. Novartis believed that despite the article being published in 2007 treatment options for patients with chronic kidney disease had not materially changed.

Novartis noted that the complainant had submitted that the availability of two newer gliptins (Onglyza and Trajenta; the former with a licence amendment in 2011 and the latter newly launched in 2011), made the claim incapable of substantiation as it was therefore not balanced or based on an up-to-date evaluation of all the evidence.

Novartis noted that the Electronic Medicines Compendium website ([www.medicines.org.uk](http://www.medicines.org.uk)) listed 19 medicines available in the UK (either as single agent therapy or combination therapy) for the treatment of type 2 diabetes; only three were indicated without the need for caution in both moderate or severe renal impairment in the diabetic

patient population which the press release specifically addressed. All the others were either contraindicated, not recommended or to be used with caution (this list did not include insulin preparations). Even the licence details of the two gliptins mentioned by the complainant were such that Onglyza could be used at the lower dose in moderate renal impairment but for patients with severe renal impairment at a lower dose with an advisory caution, whilst Trajenta could be used without caution or dose adjustment.

Therefore the statement that the majority of currently available medications were either not recommended, contraindicated or had to be taken with caution in this population remained true, even when including the two gliptins noted by the complainant.

With regard to Clauses 22.2 and 2 Novartis submitted that, as demonstrated by the circulation list the press release was issued to the healthcare industry press. The target audience was journalists familiar with this type of press release and/or health professional experts in the therapy area who would be familiar with the treatment options in renally impaired diabetics.

Novartis considered that the press release presented newsworthy information for the additional European licence approval for Galvus. The content of the press release was not an unqualified claim for Galvus as the only treatment in this patient group but highlighted that it was an additional choice where treatment choices were limited.

In keeping with the requirements of Clause 22.2 Novartis therefore considered this press release was factual and presented in a balanced way. Novartis did not consider it raised unfounded hopes of a treatment in this patient population or that it was misleading with respect to the safety of the product.

Novartis submitted that, furthermore, the press release did not contain statements which would encourage members of the public to ask their health professional to prescribe a specific prescription only medicine. Therefore, Novartis did not consider that the press release warranted breaches of Clauses 7.2 and 22.2 or that Novartis had failed to maintain high standards or brought discredit to, or reduced confidence in, the pharmaceutical industry warranting a breach of Clause 2.

## PANEL RULING

The Panel noted the submission from Novartis that it had had no part in the creation, review or distribution of the press release in question, and that it was issued by Novartis Pharma AG based in Basel, Switzerland. The Panel noted from Novartis's submission that the press release was sent to 'international medical publications'. According to the circulation list provided, however, the press release was sent mainly to publishers based in the UK including a number of UK-specific publications such as The Pharmaceutical Journal, BMJ and the on-line BBC Health News.

The supplementary information to Clause 1.8, Applicability of Codes, required that activities carried out and materials used by a pharmaceutical company located in a European country must comply with the national code of that European country as well as the national code of the country in which the activities took place or the materials were used. The press release in question was issued from a company based in Switzerland but inasmuch as it was sent to specific UK publications, the Panel considered that that aspect of its use came within the scope of the Code. The Panel noted the advice in the supplementary information to Clause 14.3, Examination of Other Material, that material which related to medicines but which was not intended as promotional material for those medicines *per se*, including, *inter alia*, press releases etc should be examined to ensure that it did not contravene the Code.

The Panel noted that the press release was entitled 'Novartis drug Galvus approved in EU for type 2 diabetes patients with moderate or severe renal impairment with limited treatment options'. Underneath the title were two bullet points; the first referred to the percentage of patients with type 2 diabetes affected by renal impairment (25%) and the second stated 'Majority of currently available medications are not recommended, contraindicated or have to be taken with caution in this population'. The press release went on to state that the approval of Galvus for use in this patient population 'expands treatment options for patient with moderate or severe renal impairment'. It also quoted a Novartis employee from the global company stating that the approval provided physicians with a '...much-needed new treatment to control blood sugar in a vulnerable patient population...'.

The Panel noted Novartis's submission that of 19 medicines available to treat type 2 diabetes (not including insulin), only three were indicated without the need for caution in both moderate or severe renal impairment. Two products were mentioned by the complainant. Onglyza could only be used at a lower dose and in severe renal impairment with an additional advisory caution. Trajenta could be used without caution or dose adjustment in severe renal failure. The Galvus summary of product characteristics (SPC) gave a recommended daily dose of 100mg when used in dual combination (which metformin or a thiazolidinedione) and 50mg once daily when used in dual combination with a sulphonylurea. There was a dose adjustment in moderate or severe renal impairment or with end stage renal disease when the recommended dose was 50mg once daily.

The Panel noted the statement quoted by the complainant from the press release 'Controlling blood sugar levels in patients with type 2 diabetes and renal impairment can be complex as many oral anti-diabetic medicines are not recommended for use, are contraindicated or should be used with caution'. Given that the title of the press release referred to '...limited treatment options', the text referred to 'few treatment options' and 'expanding treatment options', the Panel did not consider that

the press release conveyed that Galvus had 'plugged a gap in the market' as alleged. It was clear from the press release that there were already 'a few' treatment options available and that Galvus had added to these. No breach of Clause 7.2 was ruled.

The Panel noted the complainant's comment that the Cavanaugh article was out-of-date. This reference was cited in support of the claim that there were few treatment options available in type 2 diabetics with renal impairment. The Panel noted that since this paper had been published, at least two medicines (Onglyza and Trajenta) and Galvus had been approved for use in this patient population. It might be argued that this was not the impression given by the use of a 2007 reference. On balance, however, the Panel considered that it was still the case that

treatment options were limited. No breach of Clause 7.2 was ruled.

The Panel noted its rulings of no breach of Clause 7.2 and thus considered that in this regard the content of press release had not failed to meet the requirements of Clause 22.2. Thus no breach of that clause was ruled.

The Panel noted its rulings above and ruled no breach of Clause 2.

**Complaint received**                      **7 December 2011**

**Case completed**                              **3 February 2012**

---