

**CASE AUTH/0214/06/24**

## **KENVUE v CONSILIENT HEALTH**

### **Allegations regarding Cytisine claims**

#### **CASE SUMMARY**

**This case was in relation to the claims “quick to quit” and “fast” that Consilient Health made in connection with its smoking cessation product (Cytisine 1.5mg tablets).**

**The outcome under the 2021 Code was:**

<b>Breach of Clause 6.1(x2)</b>	<b>Making a misleading claim</b>
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**This summary is not intended to be read in isolation.  
For full details, please see the full case report below.**

#### **FULL CASE REPORT**

A complaint about Consilient Health was received from Kenvue.

#### **COMPLAINT**

The complaint wording is reproduced below with some typographical errors corrected:

“Kenvue has already expressed concerns to Consilient Health about the advertising of the smoking cessation product Cytisine 1.5 mg tablets. Following a period of productive intercompany dialogue, Consilient Health agreed to make a series of amendments which addressed Kenvue’s concerns for two of the three claims areas highlighted. However, for one area, resolution was not achieved. We therefore formally refer this aspect of our complaint to the PMCPA for consideration.

‘Quick to quit’ and ‘fast’

The Cytisine website [showed] the claims: ‘Quick to quit’ and ‘Fast’. Although, the website copy does not specify which of the product’s attributes can be considered fast, Kenvue believes that the reader would reasonably interpret “fast” in the context of “Quick to Quit” and expect that both speed claims pertain to the product’s licensed indication of smoking cessation. Intercompany dialogue confirmed that this was the intention of the claims. Hence, the reader would understand that use of Cytisine would result in the rapid attainment of smoking cessation. Kenvue is of the view that such a claim is illogical and misleading. Kenvue also believes that the claim implies that all users would achieve long lasting cessation and misrepresents the difficulty that smokers have in achieving sustained abstinence.

In Kenvue's opinion, it is not generally appropriate for claims of fast action to relate to a chronic condition, or to those conditions not requiring immediate relief. As tobacco dependency is a chronic, relapsing condition, speed claims for quitting are inappropriate and misleading.

The terms 'quick' and 'fast', by definition, relate to something happening during the passage of a short amount of time. In this case, it would be the amount of time that passes to the point that the smoker stops for good, and this is open to interpretation. There is no single definition of the point at which smoking abstinence can be considered achieved and this is evidenced by the fact that clinical studies for smoking cessation therapies use differing definitions for the endpoint of smoking abstinence. This is the true for both time elapsed from the last cigarette (e.g. 24 hours, 1 week, 1 month, 3 months, 6 months, 1 year) and the approach to measurement (e.g. continuous abstinence measuring a sustained quit attempt, versus point prevalence over a defined period such as no cigarettes in the past week). In the absence of an accepted definition of the point at which abstinence can be considered to occur, it is impossible to ascertain whether any quit attempt can be viewed as quick.

In its response, Consilient Health argues that the terms 'quick' and 'fast' are acceptable as regards smoking cessation with Cytisine due to the product's defined 25-day treatment course. It is suggested that this is shorter than for other smoking cessation treatments. However, it should be noted that most Nicorette products e.g. Nicorette Quickmist, Nicorette Inhalator, Nicorette Gum and Nicorette Lozenge do not have a defined treatment period and users are instructed to stop using the product as soon as they are able. Moreover, in the study used on the Consilient website to compare NRT and Cytisine (Why use Cytisine? Cytisine vs nicotine replacement therapy (NRT)), the authors consider the quit date as being sooner for NRT than for Cytisine tablets i.e. from the same day as starting NRT but from day 5 after starting Cytisine.

Regardless of considerations about comparative treatment durations, the point at which a course of treatment with a given smoking cessation therapy is concluded, is not synonymous with the establishment of a confirmed quit attempt. Therefore, the duration of therapy should not be used as the basis for a speed claim relating to smoking cessation. Additionally, there is no mention of the duration of the Cytisine treatment course in the advertising to give context to the claim and even if one were to accept that cessation is achieved within 25 days, it is hard to see how this can be considered 'quick'.

It was also mentioned during intercompany dialogue that the label instruction to stop smoking no later than the 5th day of Cytisine treatment provided further support for the "quick to quit" and "fast" claims. However, Kenvue would argue the opposite as this means that a proportion of smokers taking the product would continue to smoke until day 5. Unfortunately, many of these would inevitably fail to continue beyond this point and revert to cigarettes, whilst others would relapse to smoking either prior to the end of the 25-day treatment course, or later. Given that a proportion of smokers, having started treatment with Cytisine, will continue to smoke until day 5 or relapse thereafter, Kenvue maintains that a claim pertaining to rapid smoking cessation is not appropriate and of no health benefit if patients then quickly relapse back to smoking. In one of the main references used on the Consilient Health website (Why use Cytisine? Cytisine vs placebo), the primary outcome measurement used by West et al was 12 months of

abstinence after the end of treatment (i.e. quit was measured from week 4 of the study). Subjects were allowed no more than 5 cigarettes from week 4, or any cigarettes in the week prior to the follow up visit, otherwise they were considered to have relapsed. Secondary endpoints included quit rate 6 months after treatment had ended. At 6 months, quit rates were 10% vs 3.5% and at 12-months quit rates were 8.4% vs 2.4% in the Cytisine vs placebo groups respectively. In other words, at 6 months, although significantly more subjects had quit compared with placebo and the benefit of Cytisine is clear, 9 out of 10 had relapsed back to smoking. This further illustrates that the speed to the point of 'quit' is not important if the cessation attempt is not sustained.

Consilient Health has pointed out that the advertising has been vetted by MHRA. However, Kenvue is aware that the PMCPA judges material in relation to the requirements of the ABPI Code of Practice and there are examples of where complaints concerning vetted materials have been upheld under the Code (AUTH/3137/12/18 - ViiV Healthcare v Gilead Sciences (pmcpa.org.uk)).

In summary, Kenvue does not agree that claims that the use of Cytisine leads to a 'quick' / 'fast' quit are supported. Kenvue maintains that the claims 'quick' and 'fast' as relates to the achievement of smoking cessation are misleading and in breach of Clause 6.1 of the ABPI Code of Practice (Information, claims and comparisons must be accurate, balanced, fair, objective and unambiguous and must be based on an up-to-date evaluation of all the evidence and reflect that evidence clearly. They must not mislead either directly or by implication, by distortion, exaggeration or undue emphasis. Material must be sufficiently complete to enable recipients to form their own opinion of the therapeutic value of the medicine).

When writing to Consilient Health, the PMCPA asked it to consider the requirements of Clause 6.1 of the 2021 Code.

## **CONSILIENT HEALTH'S RESPONSE**

The response from Consilient Health is reproduced below:

"Consilient Health abides by the PMCPA Code of Practice as a non-member company.

Cytisine was launched by Consilient Health in the UK in the week of 22nd January 2024 following a distribution deal signed with the manufacturer and the granting of a product license by MHRA in October 2023.

The licensed indication for Cytisine is:

Smoking cessation and reduction of nicotine cravings in smokers who are willing to stop smoking. The treatment goal of Cytisine is the permanent cessation of the nicotine containing products use.

Possibly due to the short launch timelines the MHRA requested 'pre-vetting' of our marketing materials on 29th January 2024, as is standard practice; but in this case, after we had launched the product, which they acknowledged. We received no comments from them by the end of the timeframe in which they had indicated that they would respond to us (approximately 7th March).

Kenvue contacted us on 12th March and the correspondence and meeting minutes have been included faithfully in their letter to you. As described, we had a period of productive intercompany dialogue with resolution achieved for two of the three claims areas at issue. The website has subsequently been updated in line with our agreement with Kenvue. The final claims which are the subject of the current complaint concern the use of 'Quick to quit' and 'Fast'.

After the closure of intercompany dialogue and about four months after submitting our materials to MHRA we received a response from them on 6th June 2024. MHRA raised a number of points which included the use of the terms 'Quick to quit' and 'Fast', though from the perspective of supporting with relevant sections from the SPC. We responded to them on 17th June agreeing to update affected materials by end July 2024. We await a response.

The product has now been on the market for nearly 6 months and in this time we have also had feedback from customers, therefore we have decided to update our marketing campaign. This being the case, while we still stand by the claims 'Quick to quit' and 'Fast', we accept the breach of Clause 6.1, commit to stop using these claims, and will be revising our materials accordingly."

## PANEL RULING

This case was an intercompany dispute about Consilient Health's claims ("*quick to quit*" and "*fast*") in relation to its smoking cessation product; Cytisine 1.5mg tablets.

The claims appeared on the homepage for Cytisine and the words "*QUICK TO QUIT*" appeared in the largest text on the page, with an image of a plume of smoke, a cigarette and a woman. The next largest text stated "*Cytisine*" and underneath that in smaller font was the wording "*Consilient Health. Nicotine free. Fast. Effective. Available*". Underneath that, in much smaller font, was the licensed indication: "*CYTISINE is indicated for smoking cessation and reduction of nicotine cravings in smokers who are willing to stop smoking. The treatment goal of Cytisine is the permanent cessation of the nicotine-containing products use.*"

The complaint by Kenvue was essentially that the claims "*quick to quit*" and "*fast*" implied rapid smoking cessation and were therefore misleading given the chronic nature of tobacco dependency and the lack of a clear definition for sustained abstinence.

Consilient Health's initial response in the intercompany dialogue was that these claims could be justified, given its 25 day treatment course was shorter than e.g. nicotine replacement therapy. However, in its later response to the PMCPA regarding this complaint, Consilient Health accepted that these claims amounted to a breach of Clause 6.1 and confirmed that it will no longer use these claims.

Although Consilient Health's response confusingly accepted a breach of Clause 6.1, whilst also stating that "*we still stand by the claims*", the Panel based its decision on the full inter-company exchange, in addition to the correspondence between Consilient Health and the MHRA. The

Panel noted that Consilient Health confirmed it accepted that the record of this inter-company exchange had been “*included [by Kenvue] faithfully in their letter to you [the PMCPA].*”

The Panel noted the requirements of Clause 6.1, in particular that claims must be “*accurate, balanced, fair, objective and unambiguous*”. The Panel concluded that the two claims in question were ambiguous and therefore misleading because:

1. It was unclear whether these claims related to the pharmacological mechanism of action or the overall clinical result.
2. The full indication for Cytisine included important qualifications which were not referenced in the claims:
  - a. it was for smokers who are “*willing to stop smoking*”, and
  - b. permanent cessation of nicotine products was the “*treatment goal*” of Cytisine but not necessarily the outcome in every case.
3. The word “*quit*” was used without qualification or explanation of when that would be achieved. For example, the treatment course is for a defined duration of 25 days, but that is not necessarily how long it would take to quit.

For all of these reasons, the Panel ruled a **breach of Clause 6.1** in relation to each of the claims, as acknowledged by Consilient Health.

**Complaint received**      **13 June 2024**

**Case completed**        **25 April 2025**