MERZ v ALLERGAN

Promotion of Botox and alleged breach of undertaking

Merz Pharma complained about the promotion of Botox (botulinum toxin type A) by Allergan at the National Stroke Forum. Merz supplied Xeomin (also botulinum toxin type A). The exhibition panel at issue had been withdrawn.

Allergan's stand featured the claim 'No set dose ratio has been established between BoNT-A formulations' referenced to Benecke *et al* (2005), Roggenkamper *et al* (2006), Hunt and Clarke (2009), Dressler (2008) and Brown *et al* (2008). Merz alleged that the claim was misleading and could not be substantiated and was in breach of previous inter-company dialogue for the following reasons:

1 **Benecke *et al* and Roggenkamper *et al* both showed a successful change from Botox to Xeomin at a 1:1 clinical conversion ratio with no difference in efficacy.**

2 **Allergan had undertaken previously in inter-company dialogue, in June 2009, not to use Hunt and Clarke in any promotional material.**

3 **The PMCPA had ruled three times that the Hunt and Clarke data on three separate occasions did not reflect the clinical situation and was therefore misleading. Its use as a reference to justify a claim that 'no set ratio' had been established between Botox and Xeomin was contrary to the regulatory view and the evidence provided by several large clinical trials.**

4 **Dressler supported the view of the regulator and the large clinical trials that Xeomin and Botox were of equal potency and supported a set dose ratio of 1:1.**

5 **Brown *et al* suggested that the Xeomin was less potent than Botox, again using a pre-clinical mouse model. This was the same conclusion drawn by Hunt and Clarke and equally did not represent the clinical situation as recognised by the regulators and the Appeal Board.**

Merz alleged that as Allergan had not supported the claim with any references to Dysport (the third product on the market) the claim at issue was clearly a direct attack against Xeomin and the relative potency of Xeomin vs Botox

Xeomin had been compared to Botox in two large clinical trials at a 1:1 dose ratio and no difference had been detected between the products. This led the European Public Assessment Report (EPAR) for Xeomin to state:

> **'Taken altogether, the data from the non-clinical and clinical development program, which has been designed with support of Scientific Advice, provided sufficient evidence that a 1:1 dose ratio between XEOMIN and BOTOX with respect to efficacy and safety can be concluded and the adoption of the dosage which has been established for Botox is adequately justified. Against this background a further extensive dose-ranging program would not have been justifiable from an ethical point of view.'**

In addition to this, Bocouture (the same active ingredient as Xeomin) and Vistabel (the same active ingredient as Botox) were compared at a 1:1 dose ratio (Sattler *et al* 2010). This data in addition to the two other non-inferiority studies led to the SPC for Bocouture to state:

> **'Comparative clinical study results suggest that Bocouture and the comparator product containing conventional Botulinum toxin type A complex (900 kD) are of equal potency.'**

There was clearly no doubt that the regulators considered the two products to be equipotent and the dosing regimen for Xeomin was chosen explicitly to mirror that of Botox. In Merz's view this opinion was reinforced recently by the Appeal Board in Cases AUTH/2335/7/10 and AUTH/2346/8/10. During inter-company dialogue Merz asked Allergan to clarify this position with a statement that outlined the regulatory and Appeal Board position; however Allergan declined to do and stated that it did not believe that this statement reflected the available clinical evidence. Given that Allergan did not accept the very clear positions of the Appeal Board and the regulator and refused to accept the clinical evidence, Merz had no doubt that it intended to continue its campaign that Xeomin was less potent than Botox, of which this exhibition stand was just one part.

This claim, however, appeared to be a continuation of Allergan's position as set out in its letter of 20 October 2010 to the PMCPA in Case AUTH/2346/8/10 that 'Botox and Xeomin are not equivalent'.

The claim now in question was misleading as the dose conversion ratio had been clearly established in large clinical trials between Botox and Xeomin as 1:1. The claim clearly suggested that no dose ratio had been established between any of the botulinum type A products and was therefore misleading and could not be substantiated.
Merz was also extremely concerned that despite:

- the ruling in Case AUTH/2183/11/08 and its undertaking,

- the assurance in a letter to Merz of 24 June 2009 that the data would not be used in promotion following repeat usage

- assurances issued to Merz following inter-company dialogue on 21 October 2010

- the breaches of undertaking identified in Cases AUTH/2335/7/10 and AUTH/2346/8/10 and associated undertakings,

Allergan repeatedly used the Hunt and Clarke data to suggest that Xeomin and Botox had different potencies; the claim at the National Stroke Forum was no exception. Whilst Allergan had agreed to not use this reference for this particular claim, Merz considered that Allergan did not take its undertakings to either Merz or the PMCPA seriously and would continue to use this data to support the misleading assertion that there was a difference in potencies between the products.

The detailed response from Allergan is given below.

The Panel noted that the prominent claim 'Unit doses of botulinum toxins are not interchangeable from one product to another' appeared in a highlighted orange box at the top of the exhibition panel above the heading 'Botox is a homogeneous 900kDa botulinum toxin'. Beneath were 3 bullet points including: 'No set dose ratio has been established between BoNT-A formulations'; 'The SmPCs of all BoNT-A products carry the same statement "The unit doses of … are specific to the preparation and are not interchangeable with other preparations of botulinum toxin"'. The words 'No set dose' and 'not interchangeable' appeared in prominent orange font such that, in the Panel's view, they would be the take home message for delegates. The Panel noted that whilst the exhibition panel did not mention stroke, it was displayed at the National Stroke Forum and thus delegates would assume that the data therein were relevant to its use in stroke patients.

The Panel noted Merz's comments about the statement in the Bocouture SPC that comparative clinical study results suggested that Bocouture and the comparative product containing conventional Botulinum toxin type A complex (900KD) were of equal potency. This appeared beneath the general statement in the SPC that unit doses recommended for Bocouture were not interchangeable with those for other preparations of Botulinum toxin. The Panel noted that Bocouture was only indicated for the temporary improvement in the appearance of moderate to severe vertical lines between the eyebrows seen at frown (glabellar frown lines) in adults below 65 years when the severity of these lines had an important psychological impact for the patient. Xeomin and Botox had different indications.

The Panel noted the parties' submissions about the products' clinical conversion ratio and efficacy as evidenced by Benecke *et al* and Roggenkamper *et al*. The Panel noted the Xeomin EPAR stated that the non clinical and clinical development programme provided sufficient evidence that a 1:1 dose ratio between Xeomin and Botox with respect to efficacy and safety could be concluded. This was not included in the SPC. There was data showing non inferiority of the products in certain indications. However the Panel noted the differences between the Botox and Xeomin SPCs in relation to post-stroke spasticity, including the wording of the indication, the recommended muscles and dose ranges and the maximum total recommended doses (based on the clinical trials submitted to gain approval) as submitted by Allergan. The exact dose and the number and location of injection sites needed to be tailored to the individual patient. Each SPC stated that unit doses of botulinum toxins were not interchangeable from one product to another. The Panel considered that the claim 'No set dosing ratio has been established' was not an unreasonable reflection of the totality of the evidence; it was not misleading nor incapable of substantiation as alleged. No breach of the Code was ruled.

The Panel noted that an undertaking was an important document. It included an assurance that all possible steps would be taken to avoid similar breaches of the Code in future. It was very important for the reputation of the industry that companies complied with undertakings.

In relation to the reference to Hunt and Clarke (2009) and Allergan's alleged failure to implement an inter-company agreement with Merz, the Director noted that Allergan stated that it had reviewed all its current materials both manually and by audit of its electronic copy approval repository. No other promotional materials referred to Hunt and Clarke. The exhibition panel now at issue had been withdrawn. The Director considered that this aspect of the complaint had been resolved via inter-company dialogue and thus it was not referred to the Panel.

With regard to the alleged breach of undertakings in the previous cases, Cases AUTH/2183/11/08, AUTH/2335/7/10 and AUTH/2346/8/10 the Panel noted that Cases AUTH/2335/7/10 and AUTH/2346/8/10 related to claims about differences in potency between Xeomin and Botox based on Hunt and Clarke. The Appeal Board had ruled breaches of the undertaking given in Case AUTH/2183/11/08 due to the use of Hunt and Clarke to imply that Botox was more potent than Xeomin. The Panel considered that the material at issue in Case AUTH/2380/1/11 was sufficiently different for it not to be covered by the previous undertakings. The claim at issue did not refer to potency, nor did it imply an advantage for Botox. In addition the statement from the SPC was included on the poster. Another relevant factor was that the poster was used at the National Stroke Forum and there were differences between Xeomin and Botox

in relation to the indications and doses for post-stroke spasticity. The Panel ruled that the claim at issue was not in breach of the undertakings given in Cases AUTH/2335/7/10 and AUTH/2346/8/10. No breach of the Code was ruled.

Merz Pharma UK Ltd complained about the promotion of Botox (botulinum toxin type A) by Allergan Limited at the National Stroke Forum which took place in Glasgow between 30 November and 2 December 2010. Merz Pharma supplied Xeomin (also botulinum toxin type A). Inter-company dialogue had resolved some but not all matters at issue. The exhibition panel at issue had been withdrawn.

COMPLAINT

Merz stated that Allergan's promotional stand at the meeting in question featured the claim 'No set dose ratio has been established between BoNT-A formulations' referenced to Benecke *et al* (2005), Roggenkamper *et al* (2006), Hunt and Clarke (2009), Dressler (2008) and Brown *et al* (2008). Merz alleged that the claim was misleading and could not be substantiated and was in breach of previous inter-company dialogue for the following reasons:

1 Benecke *et al* and Roggenkamper *et al* both showed a successful change from Botox to Xeomin at a 1:1 clinical conversion ratio with no difference in efficacy.

2 Allergan had undertaken previously in inter-company dialogue, in a letter of 24 June 2009, not to use Hunt and Clarke 'Specifically, the study by Hunt *et al* will not be used in any promotional material ...'. This was clearly using this data in a promotional setting and Merz required Allergan to abide by its previous undertaking.

3 The PMCPA had ruled three times that the Hunt and Clarke data on three separate occasions did not to reflect the clinical situation and was therefore misleading. Its use as a reference to justify a claim that 'no set ratio' had been established between Botox and Xeomin was contrary to the regulatory view and the evidence provided by several large clinical trials.

4 Dressler supported the view of the regulator and the large clinical trials that Xeomin and Botox were of equal potency and supported a set dose ratio of 1:1.

5 Brown *et al* suggested that the Xeomin was less potent than Botox, again using a pre-clinical mouse model. This was the same conclusion drawn by Hunt and Clarke and equally did not represent the clinical situation as recognised by the regulators and the Appeal Board.

Merz alleged that as Allergan had not supported the claim with any references to Dysport, the claim at issue was clearly a direct attack against Xeomin and the relative potency of Xeomin vs Botox.

It remained the case that Xeomin had been compared to Botox in two large clinical trials at a 1:1 dose ratio and no difference had been detected between the products. This led the European Public Assessment Report (EPAR) for Xeomin to state:

> 'Taken altogether, the data from the non-clinical and clinical development program, which has been designed with support of Scientific Advice, provided sufficient evidence that a 1:1 dose ratio between XEOMIN and BOTOX with respect to efficacy and safety can be concluded and the adoption of the dosage which has been established for Botox is adequately justified. Against this background a further extensive dose-ranging program would not have been justifiable from an ethical point of view.'

In addition to this, Bocouture (the same active ingredient as Xeomin) and Vistabel (the same active ingredient as Botox) were compared at a 1:1 dose ratio (Sattler *et al* 2010). This data in addition to the two other non-inferiority studies led to the SPC for Bocouture to state:

> 'Comparative clinical study results suggest that Bocouture and the comparator product containing conventional Botulinum toxin type A complex (900 kD) are of equal potency.'

There was clearly no doubt that the regulators considered the two products to be equipotent and the dosing regimen for Xeomin was chosen explicitly to mirror that of Botox. In Merz's view this opinion was reinforced recently by the Appeal Board in Cases AUTH/2335/7/10 and AUTH/2346/8/10. During inter-company dialogue Merz asked Allergan to clarify this position with a statement that outlined the regulatory and Appeal Board position; however Allergan declined to do and stated that it did not believe that this statement reflected the available clinical evidence. Allergan repeatedly refused to accept the conclusions of the clinical data, the regulator and now the Appeal Board without providing any argument or evidence to support its position. Given that Allergan did not accept the very clear positions of the Appeal Board and the regulator and refused to accept the clinical evidence, Merz had no doubt that it intended to continue its campaign that Xeomin was less potent than Botox, of which this exhibition stand was just one part.

This claim, however, appeared to be a continuation of the statement contained in Allergan's letter of 20 October 2010 to the PMCPA in response to Merz's appeal in Case AUTH/2346/8/10. Wherein Allergan made it clear that its position was that 'Botox and Xeomin are not equivalent'.

The claim in question as presented at the National Stroke Forum was misleading as the dose conversion ratio had been clearly established in large clinical trials between Botox and Xeomin as 1:1. The inclusion of a reference to Dysport SPC would detract from the fact that a dose ratio had been determined between Botox and Xeomin. The

claim clearly suggested that no dose ratio had been established between any of the botulinum type A products and was therefore misleading and could not be substantiated. Merz alleged breaches of Clauses 7.2 and 7.4.

Merz was also extremely concerned that despite:

- the ruling in Case AUTH/2183/11/08 and its undertaking,
- the assurance in a letter to Merz of 24 June 2009 that the data would not be used in promotion following repeat usage
- assurances issued to Merz following inter-company dialogue on 21 October 2010
- the breaches of undertaking identified in Cases AUTH/2335/7/10 and AUTH/2346/8/10 and associated undertakings

Allergan repeatedly used the Hunt and Clarke data to suggest that Xeomin and Botox had different potencies; the claim at the National Stroke Forum was no exception. Whilst Allergan had agreed to not use this reference for this particular claim, Merz considered that Allergan did not take its undertakings to either Merz or the PMCPA seriously and would continue to use this data to support the misleading assertion that there was a difference in potencies between the products.

When writing to Allergan, the Authority asked it to respond in relation to Clauses 2, 9.1 and 25 of the 2008 Code in addition to the clauses cited by Merz.

RESPONSE

Allergan stated that it did not consider that the claim, 'No set dose ratio has been established between BoNT-A formulations', was misleading or incapable of substantiation. The claim was clearly supported by the heading, 'Unit doses of botulinum toxins are not interchangeable from one product to another' and the subsequent bullet point, 'The SmPCs of all BoNT-A products carry the same statement: "The unit doses of … are specific to the preparation and are not interchangeable with other preparations of botulinum toxin"'.

As was established by the Appeal Board in Case AUTH/2270/10/09, both Allergan and Merz agreed that Benecke *et al* and Roggenkamper *et al* were non-inferiority studies which showed Xeomin was no worse than Botox by a pre-specified margin (delta) that was clinically acceptable. The Appeal Board noted Merz's submission that it had no data upon which to make the claim that Xeomin was equivalent to Botox. Therefore, Benecke *et al* and Roggenkamper *et al* did not support a '… 1:1 clinical conversion ratio with no difference in efficacy' as submitted by Merz. Clearly a 1:1 dosing ratio was chosen in these two studies in cervical dystonia and blepharospasm but this was not 'a set dose ratio' across all indications.

The claim regarding 'no set dose ratio' was contextualised as discussed above and the heading and bullet point referenced the SPCs for Botox, Xeomin and Dysport.

The recommended SPC dosing for Botox, Dysport and Xeomin clearly indicated that the starting and maximum doses were different across indications and that there was no set dose ratio between the products. Importantly all three also had different licensed indications.

More specifically, there were very clear differences in the SPCs for Botox and Xeomin with respect to post stroke spasticity, the most relevant indication for clinicians attending the National Stroke Forum. These differences were outlined in the table provided but included differences in the wording of the indication, the recommended muscles and dose ranges and the maximum total recommended doses (based on the clinical trials submitted to gain licence approval). When comparing the Botox and Xeomin SPCs with the SPC for Dysport, across all indications, including post stroke spasticity, these differences were even more apparent. However, what was clear across all the SPCs and the various indications was that the exact dose and the number and location of injections sites needed to be tailored to the individual patient and titrated to effect.

As stated in section 4.2 of the Xeomin SPC:

> 'The optimum dosage and number of injection sites in the treated muscle should be determined by the physician individually for each patient. A titration of the dose should be performed.'
>
> 'The exact dosage and number of injection sites should be tailored to the individual patient based on the size, number and location of muscles involved, the severity of spasticity, and the presence of local muscle weakness.'

These were a selection of the statements made on this theme, many similar statements could be found in the Botox and Dysport SPCs.

When considering these statements, in addition to the clear statement in all three SPCs that unit doses of botulinum toxins were not interchangeable from one product to another, Merz's assertion that there was a set dose ratio between Botox and Xeomin was incorrect and not in line with the SPCs.

Allergan thus did not believe the claim was in breach of either Clauses 7.2 or 7.4.
Whilst Allergan did not believe the claim was misleading or incapable of substantiation it acknowledged that the claim referenced Hunt and Clarke which was not in accordance with the inter-company dialogue agreement. Allergan acknowledged this error in its letter to Merz of 20 December 2010, and it had withdrawn the stand panel at issue. Allergan took this error in referencing very seriously, it had reviewed all of its promotional materials and no other promotional materials referred to Hunt and Clarke or Brown *et al*.

Allergan submitted that this was human error not a 'direct attack' against Xeomin and the relative potency of Xeomin vs Botox. Regarding the assertion that Allergan had deliberately excluded reference to Dysport, this was clearly not so as it had twice referenced the Dysport SPC on the exhibition panel.

Allergan believed the claim 'No set dose ratio has been established between BoNT-A formulations' was supported by reference to the product SPCs, as outlined above. Allergan could not agree that these were 'irrelevant' references for the reasons outlined above.

Merz incorrectly stated that a dose ratio had been clearly established between Botox and Xeomin of 1:1. In support of this argument it cited Benecke *et al* and Roggenkamper *et al*, non-inferiority studies which showed Xeomin was no worse than Botox by a pre-specified margin (delta) that was clinically acceptable. As discussed, earlier, a 1:1 dosing ratio was chosen in both studies but this did not mean there was 'a set dose ratio' of 1:1 for Botox and Xeomin across all indications.

In further support of its argument of a set dose ratio between Botox and Xeomin, Merz cited the Bocouture SPC. The statement in the Bocouture SPC that: 'Comparative clinical study results suggest that Bocouture and the comparator product containing conventional Botulinum toxin type A complex (900kD) are of equal potency' reflected the results of the Merz non-inferiority study conducted to gain approval of Merz's botulinum toxin for glabellar lines. A similar statement regarding the European therapeutic non-inferiority studies in cervical dystonia and blepharospasm (Benecke *et al*; Roggenkamper *et al*) was not contained in the Xeomin SPC. Therefore, Allergan failed to see how this statement for Bocouture supported a set dose ratio for Xeomin.

Allergan noted that the Bocouture SPC stated:

> 'Unit doses recommended for Bocouture are not interchangeable with those for other preparations of Botulinum toxin.'

In addition, there were differences in the recommended dosing schedules for Bocouture and Vistabel (Allergan's botulinum toxin type A licensed for management of glabellar lines), in that the Bocouture SPC suggested an increase to 30 units, if required. This statement was not in the Vistabel SPC.

> ***Bocouture SPC:*** 'After reconstitution of Bocouture (50 units/1.25ml) the recommended injection volume of 0.1ml (4 units) is injected into each of the 5 injection sites: two injections in each corrugator muscle and one injection in the procerus muscle, which corresponds to a standard dose of 20 units. The dose may be increased by the physician to up to 30 units if required by the individual needs of the patients, with at least '3-months' interval between treatments.'
>
> ***Vistabel SPC:*** 'Reconstituted VISTABEL (50 U/1.25ml) is injected using a sterile 30 gauge needle. 0.1ml (4 U) is administered in each of the 5 injection sites: 2 injections in each corrugator muscle and 1 injection in the procerus muscle for a total dose of 20 U.'

In summary, as stated earlier, the exhibition panel and claim at issue, had been withdrawn from use. Allergan confirmed that if the claim, or a similar, was used in the future, it would directly reference all the SPCs for all the relevant botulinum toxin type A formulations. As the claim and the item at issue were not in use, Allergan considered inter-company dialogue on this matter was concluded.

The incorrect citation of Hunt and Clarke and Brown *et al* was simply human error, not part of a 'direct attack' on Xeomin.

However, as discussed above, the assertion by Merz that there was a set dose ratio between Botox and Xeomin was incorrect and not in line with the product SPCs.

Therefore, Allergan did not believe the claim was in breach of either Clauses 7.2 or 7.4.

Allergan strongly denied the allegation that it had breached the undertaking given in Case AUTH/2183/11/08.

As discussed earlier, the claim at issue 'No set dose ratio has been established between BoNT-A formulations' was an accurate reflection of the SPCs for the botulinum toxin type A products on the market. There was no suggestion or statement relating to differences in potencies between Botox and Xeomin.

Whilst Allergan did not believe the claim was misleading or incapable of substantiation it acknowledged that the claim referenced Hunt and Clarke which was not in accordance with the inter-company agreement. Allergan acknowledged this error in its letter to Merz dated 20 December 2010, and it had withdrawn the exhibition panel at issue. Allergan took this error in referencing very seriously. It had thoroughly reviewed all of its current promotional materials using both a manual check and an audit of its electronic copy approval repository (Zinc). Allergan submitted that no other promotional materials referred to Hunt and Clarke or Brown *et al*. Allergan believed it had maintained high standards by acting swiftly in this matter. Allergan had made all best efforts to resolve this matter via inter-company dialogue.

Allergan believed it had maintained high standards and had complied with its undertaking with respect to Case AUTH/2183/11/08. Allergan denied breaches of Clauses 2, 9.1 or 25.

PANEL RULING

The Panel noted that the prominent claim 'Unit doses of botulinum toxins are not interchangeable from one product to another' appeared in a highlighted orange box at the top of the exhibition panel above the heading 'Botox is a homogeneous 900kDa botulinum toxin'. Beneath were 3 bullet points including: '**No set dose** ratio has been established between BoNT-A formulations'; 'The SmPCs of all BoNT-A products carry the same statement "The unit doses of … are specific to the preparation and are **not interchangeable** with other preparations of botulinum toxin"'. The words 'No set dose' and 'not interchangeable' appeared in prominent orange font such that, in the Panel's view, they would be the take home message for delegates. The Panel noted that whilst the exhibition panel did not mention stroke, it was displayed at the National Stroke Forum and thus delegates would assume that the data therein were relevant to its use in stroke patients.

The Panel noted Merz's comments about the statement in the Bocouture SPC that comparative clinical study results suggested that Bocouture and the comparative product containing conventional Botulinum toxin type A complex (900KD) were of equal potency. This appeared beneath the general statement in the SPC that unit doses recommended for Bocouture were not interchangeable with those for other preparations of Botulinum toxin. The Panel noted that Bocouture was only indicated for the temporary improvement in the appearance of moderate to severe vertical lines between the eyebrows seen at frown (glabellar frown lines) in adults below 65 years when the severity of these lines had an important psychological impact for the patient. Xeomin and Botox had different indications.

The Panel noted the parties' submissions about the products' clinical conversion ratio and efficacy as evidenced by Benecke *et al* and Roggenkamper *et al*. The Panel noted the Xeomin EPAR stated that the non clinical and clinical development programme provided sufficient evidence that a 1:1 dose ratio between Xeomin and Botox with respect to efficacy and safety could be concluded. This was not included in the SPC. There was data showing non inferiority of the products in certain indications. However the Panel noted the differences between the Botox and Xeomin SPCs in relation to post-stroke spasticity, including the wording of the indication, the recommended muscles and dose ranges and the maximum total recommended doses (based on the clinical trials submitted to gain approval) as submitted by Allergan. The exact dose and the number and location of injection sites needed to be tailored to the individual patient. Each SPC stated that unit doses of botulinum toxins were not interchangeable from one product to another. The Panel considered that the claim 'No set dosing ratio has been established' was not an unreasonable reflection of the totality of the evidence; it was not misleading nor incapable of substantiation as alleged. No breach of Clauses 7.2 and 7.4 was ruled.

The Panel noted that an undertaking was an important document. It included an assurance that all possible steps would be taken to avoid similar breaches of the Code in future. It was very important for the reputation of the industry that companies complied with undertakings.

With regard to the alleged breach of undertakings in the previous cases, Cases AUTH/2183/11/08, AUTH/2335/7/10 and AUTH/2346/8/10 the Panel noted that Cases AUTH/2335/7/10 and AUTH/2346/8/10 related to claims about differences in potency between Xeomin and Botox based on Hunt and Clarke. The Appeal Board had ruled breaches of the undertaking given in Case AUTH/2183/11/08 due to the use of Hunt and Clarke to imply that Botox was more potent than Xeomin. The Panel considered that the material at issue in Case AUTH/2380/1/11 was sufficiently different for it not to be covered by the previous undertakings. The claim at issue did not refer to potency, nor did it imply an advantage for Botox. In addition the statement from the SPC was included on the poster. Another relevant factor was that the poster was used at the National Stroke Forum and there were differences between Xeomin and Botox in relation to the indications and doses for post-stroke spasticity. The Panel ruled that the claim at issue was not in breach of the undertakings given in Cases AUTH/2335/7/10 and AUTH/2346/8/10. No breaches of Clauses 2, 9.1 and 25 were ruled.

Complaint received **4 January 2011**

Case completed **10 May 2011**