København, den 18. marts 2020

AFGØRELSE

Afgørelse vedr. KO-2020-0393 - reklamemateriale

Granskningsmandspanelet har dags dato truffet følgende afgørelse i klagesagen imellem parterne:

Klager: Boehringer Ingelheim Danmark A/S
Strødamvej 52
2100 København Ø

og

Indklagede: GlaxoSmithKline Pharma A/S
Nykær 68
Sektion for lægemidler
2605 Brøndby

Vedrørende: Reklamemateriale udarbejdet af indklagede.

Resumé:
GlaxoSmithKline Pharma A/S findes at have overtrådt reglerne i Reklamekodeksets § 4, stk. 2, og § 7, stk. 3.

Boehringer Ingelheim Danmark A/S gives delvist medhold i deres klagepunkter.

Baggrund:
Boehringer Ingelheim Danmark A/S (Boehringer) indsendte den 28. januar 2020 en klage over reklamemateriale udarbejdet af GlaxoSmithKline Pharma A/S (GSK), med henblik på en vurdering af, hvorvidt reklamen/arrangementet er i strid med Reklamekodekset.

Boehringer klager over fire hovedpunkter:

"Klage over reklame for Incruse Ellipta

Boehringer Ingelheim Danmark A/S (BI) indgiver hermed en klage over GSK, Nykær 68, 2605 Brøndby. Klagen er foranlediget af en 2-sidet reklame/direct mailing (Bilag A) for Incruse Ellipta (umeclidinium), som er sendt til sundheds-personer i januar 2020.

Reklamens hoved- og eneste budskab er et direkte angreb på Boehringer Ingelheim (BI)'s produkt Spiriva. Om denne form for sammenlignende reklame står der i ENLIs regler: "Det overordnede krav om saglige og fyldestgørende reklamer har central betydning i relation til sammenlignende reklamer, navnlig fordi denne reklameform udgør et væsentligt differentierings- og positioneringsværktøj".
BI mener ikke, at denne reklame er fyldestgørende eller for den sags skyld saglig.

Det er følgende forhold vi ønsker, at granskningsmandspanelet vurderer:

<u>1. Ubalanceret</u>
Når man sammenligner to produkter så direkte og aggresivt, er det vigtigt, at modtageren/lægen kan danne sig et overordnet indtryk af de to produkters fordele og ulemper. Det betyder, at man ikke kun må omtale de egenskaber, hvor ens eget produkt klarer sig bedst og udelade egenskaber, hvor konkurrenten har fordele. Det har GSK gjort ved f.eks. slet ikke at nævne evnen til at reducere risikoen for eksacerbationer - en meget vigtig effektparameter ved KOL-behandling. I de to produkters produktresuméer (se Bilag B) kan man se, at Spiriva har en signifikant effekt på eksacerbationer, modsat Incruse, hvor signifikans ikke er dokumenteret.

<u>2. "Bedre lungefunktion"</u>
På forsiden af reklamen står, at Incruse giver "Signifikant lungefunktionsforbed-ring" sammenlignet med Spiriva. Referencen henviser imidlertid til et 8-ugers sammenlignende studie med umeclidinium/vilanterol (produktnavn Anoro) og tiotropium/olodaterol (produktnavn Spiolto). Det kan hermed konkluderes, at reference 3 ikke underbygger udsagnet om bedre lungefunktion hos Incruse overfor Spiriva, da referencen omhandler to helt andre lægemidler.

<u>3. "Færre kritiske fejl"</u>
BI mener, det er unfair og ikke-fyldestgørende kommunikation, at der ikke forklares, hvad der menes med 'kritiske fejl'. Læseren af reklamen har ikke en chance for at afgøre betydningen af denne påstand.

Reference 2 henviser til et devicestudie, hvor Incruse-devicet Ellipta sammenlignes med bl.a. Spiriva-devicet HandiHaler. Studiet omhandler kun håndtering af device. Det vurderer ikke selve inhalationsteknikken, som er mindst lige så vigtig i forhold til at få medicinen ned i lungerne og dermed effekt af medicinen.

GSK påstår, at Incruse er 'enkel at betjene' og der refereres til reference 4, hvor Elliptapatienter er blevet spurgt, i hvilken grad de er enige i, at udsagnet 'Ease of use' passer på Ellipta. I referencen fremgår det imidlertid ikke, hvad HandiHaler-patienter har svaret på samme spørgsmål og derved er det en unfair påstand. Derudover mener BI ikke, at man ud fra dette studie kan påstå, at Ellipta er 'enkel at betjene'.

Ydermere insinueres det på den måde afsnittet "Færre kritiske fejl. Enkel at betjene" er skrevet, at man med Incruse oplever færre kritiske fejl (sammenlignet med Spiriva), fordi Ellipta er enklere at betjene. BI mener ikke, det er rimeligt eller korrekt at koble disse to påstande.

4. "Kan du spare tid?"
De anvendte referencer 5-7 henviser til produktresuméerne for hhv. Incruse, Anoro og Trelegy. Der er ikke forklaret, hvad der menes med 'step-up behandling' og der står ikke beskrevet i nogen af de anvendte referencer, at man kan spare tid ved ændring i den farmakologiske behandling ved sygdomsprogression. Påstanden er dermed udokumenteret.

Generelt
I alle de nævnte studier i reklamen mangler der generel information om f.eks. studiedesign, patientpopulation, antal inkluderede patienter og primært endepunkt - altsammen vigtige oplysninger som er nødvendige for, at en reklame anses som fyldestgørende.

Sammenfatning
Boehringer Ingelheim Danmark A/S anser på baggrund af ovenstående reklamen fra GSK som ikke-fyldestgørende og usaglig og indstiller derfor til, at den sanktioneres, gerne med krav om tilbagetrækning."

Sagen blev sendt i høring den 29. januar 2020 til GSK, jf. ENLI's Sagsbehandlingsregler § 9. I høringssvar af 11. februar 2020 havde GSK følgende bemærkninger;

*"**GSK context of the promotional material***

In 2002 the launch of Spiriva has made a strong impact on the treatment of COPD in Denmark. Spiriva has since then become the standard of care for patients receiving LAMA mono therapy, having a strong, market leader position in the market until this day. In 2016, Incruse was launched by GSK getting a new treatment alternative for HCPs in the LAMA Mono Class (GOLD group A, DLS Trin 1). Based on strong clinical data on Ellipta and Incruse, including a head to head comparison versus Spiriva, GSK decided to start actively inform HCPs of Incruse early 2020 – to offer a new treatment alternative in this class for physicians. Hence, this material was developed to offer exactly that alternative for therapeutic evaluation.

GSK Response to the appropriate balance in the material

Lung function superiority against Spiriva is demonstrated in multicenter, randomized, blinded, double-dummy, parallel-group, non-inferiority, Head to Head study. Patients were enrolled in two arms based on the exact same inclusion and exclusion criteria and accordingly comparable base line values. The statistically significant superiority in lung function of Incruse versus Spiriva demonstrated in this clinical trial is important information for HCPs when guiding their choice of treatment for the mild COPD patients, who are not at risk of exacerbations and requiring a mono therapy (GOLD group A, DLS Trin 1).

GSK has chosen not to use a definitive or absolute term to guide the HCPs based on the proven superiority of Incruse vs Spiriva in this Head to Head trial. Instead, aligning to section 07.03 of the ENLI code, GSK is merely reminding HCPs that there is a treatment alternative to Spiriva by asking the HCP to reflect on their usual treatment choice, but ultimately form his own opinion of the therapeutic value of the medicinal product. GSK finds this a balanced, non-aggressive, manner of communicating the superiority of the data and accordingly does not agree with BI that the phrasing is either aggressive or an attack on Spiriva.

The ENLI code of practice Section 8.01 refers to a comparison of medicinal products. This advertisement does not give a direct, aggressive side-by-side comparison between the two products and the characteristics, the comparison on lung function comes from a multicenter, randomized, blinded, double-dummy, parallel-group, non-inferiority study including Incruse and Spiriva. This means that both products have been included and compared under equal circumstances. In the header of the material we have chosen to mention Spiriva, without directly comparing it in that statement. We have chosen to add Spiriva, because this product is currently standard of care. Therefore, to ensure the possibility to assess therapeutic choice from an objective point of view, without claiming any value judgment of the two products, we have chosen to mention Spiriva in this header. All text in the advertisement are aligned to Section 7.03, allowing the recipient to always form his own opinion of the therapeutic value of the medicinal product, and only making claims when it can be substantiated with relevant published data, as per Section 7.01 of the Promotional Code

In relation to the Bilag B, where the risk reduction of exacerbation is brought forward as an argument of unbalanced promotion, GSK refers to Section 7.03 of the ENLI Code of practice, stating that the information must be relevant for the physician to form an opinion on the therapeutic value. To ensure relevance, we´ve aligned to the COPD Guidelines of the Dansk Lungemedicinsk Selskab, which suggests the pharmacological choice of treatment with a mono LAMA component, such as Spiriva or Incruse, is prescribed for patients who are low symptomatic and have no exacerbations or hospitalizations. As a result of these guidelines, we therefore assess exacerbation data for the therapeutic evaluation not relevant and therefore not disturbing the balance of information in this advertisement.

Most critically in reference to the statement that GSK does not have significant risk reduction in exacerbations, GSK wants to stress that both labels show reduction in risk of exacerbations versus placebo. These are accepted in the label of the respective products, and therefore deemed relevant.

GSK Response to the significant lung function improvement

The unfortunate situation of incorrectly referencing the claim, although the correct reference is mentioned and referenced in the header, will be adjusted.

As already stated earlier in our response, we do however have the correct data to support the significant difference in lung function improvement, included in the material. Lung function improvement superiority against Spiriva is demonstrated in a Head to Head study, where patients were enrolled in the two arms based on the exact same inclusion and exclusion criteria and accordingly comparable base line values. The statistically significant superiority in lung function of Incruse versus Spiriva demonstrated in this Randomized Blinded Clinical trial is an important information for HCPs when guiding their choice of treatment for the mild COPD patients, not at risk of exacerbations and requiring a mono therapy. The difference has been quantified in the material to ensure we have no exaggeration of the claim, as per Section 07.01, and we ensure objectivity in the comparison in accordance with Section 08.01 of the code. BI is stating that the superiority claim of Incruse vs Spiriva isn't documented due to the reference to a Head to Head study showing superiority of Anoro versus Spiolto (GSKs Dual bronchodilator versus BIs dual bronchodilator) and not a Head to Head study comparing Incruse versus Spiriva.

Since the correct reference (Reference 1) is in fact is a Head to Head study of Incruse versus Spiriva showing significant superiority of Incruse, GSK assumes that BI would agree that the claim will be properly documented if the reference number is corrected.

GSK Response to the device & critical errors

BI is of the opinion that the Critical Error claim is unfair and inadequate, as it is unclear what is meant by a critical error. In the studies, to which the claim refers - a critical error is predefined as an error that was most likely to result in no or only minimal medication being inhaled, impacting treatment response. To support the consensus a recent publication in ugeskrift for læge, by Rune Fuglø-Mortensen, Peter Lange & Jann Mortensen states (https://ugeskriftet.dk/files/scientific_article_files/2019-08/v07180510_2.pdf):
"Kritiske fejl er ikke entydigt defineret, men der er konsensus om, at det er fejl, som giver behandlingssvigt"

GSK takes the position that this consensus, is accepted and known by the intended audience of this material.

The point on reference 2, where the device is being compared to several other devices, refers to a study that has done a review of 5 sub-studies where patients have been receiving the Patient Information Leaflet and had to use the device using only that information. In all 5 of these sub-studies, this publication clearly stated: all five substudies, after reading the PIL only, fewer patients had at least one critical error using the ELLIPTA inhaler compared with all five other inhalers.

The claim that the Ellipta device is "enkelt" to use is coming from the publication referred to. The claim is well substantiated as the reference has the mention of the term "easy to use". This claim is not insinuating or mentioning that Incruse is "easier" to use than Spiriva and is therefore not subject to section 8 in GSK´s interpretation of the rules. There are three publications to justify our claim, to be in line with Section 7.01:

The claim that Ellipta is easy to use is substantiated by
Reference 3. Feldman G.J. et al. Adv Ther 2017; 34: 2518-2533
Larger proportions of patients responded that the ELLIPTA inhaler was very easy to use with regard to the dose counter, learning how to use the inhaler, handling the inhaler, preparing the inhaler for use and holding the inhaler while using it, compared with the proportions responding similarly for DISKUS, MDI, Turbuhaler, Handihaler and Breezhaler (Supplementary Table 4)
Reference 4. Svedsater H et al. BMC Pulm Med 2013; 13(72):1-14.
Reference 1, Feldman G et al. International Journal of COPD 2016:11; 719-730.

GSK Response to pharmacological treatment at disease progression

Step-up treatment is a term where there is consensus in the national and international medical societies. You can for example find on the sundhedsstyrelsen website a section around Guide til KOL-step-up og -step-down https://www.sst.dk/da/udgivelser/2017/rationel-farmakoterapi-7-2017/medicinsk-behandling-af-kol-%E2%80%93-stabil-fase-og-eksacerbationer

Similarly can this be found in the international GOLD guidelines for COPD treatment - https://goldcopd.org/wp-content/uploads/2018/02/WMS-GOLD-2018-Feb-Final-to-print-v2.pdf

GSK does not make a statement but poses a question for reflection for the HCP. Step up and Step down is common, as can be read in the references above, and spending time on device handling and training is part of this procedure. We are not making a claim (påstand) and therefore the statement of BI insinuating that this is an undocumented claim is not of relevance, as we only ask the HCP to reflect on their choices in a frequently occurring dynamic, namely treatment of COPD patients.

GSK Response to the general commentary on study information

The material´s intention is to ensure the HCP can make a well-informed assessment of the therapeutic treatment. GSK has purposely chosen studies that included, within the same study design, both the medicine or inhalator. This means that in the comparison made, all claims are based on identical criteria, which are part of the respectively referred studies. For example, reference 1 compares Incruse and Spiriva in a Head to Head Randomized Blinded Clinical trial, reference 2 has frequently used inhalators pooled in the study comparing the Ellipta against those other inhalers and reference 3 is a randomized, two-period crossover open-label study in symptomatic patients with COPD comparing Anoro and Spiolto. Due to the selection of quality studies directly comparing the medicine or inhalator within the same design, we deem the information provided in this material relevant and sufficient.

Summary

GSK Pharma A/S takes a position that this material is giving the HCP the possibility to make a therapeutic evaluation of treatment, for each individual patient. The material has been aligned to the code, providing relevant information to the patient profile for LAMA Mono treatment (GOLD & DLS) and only makes a direct comparison when there is sufficient data to substantiate the comparison. GSK therefore takes the position that this material was adequate, relevant and substantiated with strong evidence to give the HCP a chance to make a therapeutic evaluation."

Sagen blev sendt i supplerende høring den 13. februar 2020 til Boehringer, jf. ENLI's Sagsbehandlingsregler § 9. I høringssvar af 19. februar 2020 havde Boehringer følgende bemærkninger;

*"**1. Ubalanceret***

Først og fremmest er BI ikke enig med GKS i, at reklamen ikke er en direkte sammenligning mellem de to produkter. Reklamen opfordrer netop lægen til at sammenligne de to produkter ('Kunne du tænke Incruse næste gang du tænker Spiriva') og der bruges ord som 'bedre' og 'færre', hvilket er direkte sammenlignende. Det sammenlignende element er så fremtrædende, at alle udsagn i reklamen læses i kontekst af en sammenligning og dermed bør de kunne dokumenteres og være fair og balanceret.

BI er desuden uenig i GSKs påstand om, at reklamen er 'without claiming any value judgment of the two products'. Reklamen indeholder som sagt påstande som 'Bedre lungefunktion'og 'Færre kritiske fejl'.

GSK skriver, at reklamen for Incruse er lavet med det formål at gøre læger opmærk-somme på, at der er et alternativ til Spiriva. Det har BI forståelse for, men når man sammenligner to

produkter så direkte, skal det ske på en fair og balanceret måde, så lægen (som GSK selv skriver) kan danne sin egen mening. Det mener BI fortsat ikke er tilfældet i reklamen blandt andet fordi:

***a)** Eksacerbationsdata er yderst vigtige i forhold til den farmakologiske behandling af KOL patienter, hvilket fremgår af nedenstående:*

Den internationale sammenslutning Global Initiative for Chronic Obstructive Lung Disease (GOLD) skriver i deres seneste rapport følgende om behandlingsmål for stabil KOL 'The main treatment goals are reduction of symptoms and future risk of exacerbations.' (Ref. 1 p. 78).

Dansk Selskab for Almen Praksis (DSAM) skriver følgende i deres KOL vejledning: 'Mål for behandling er at sikre det bedst mulige funktionsniveau, livskvalitet og tryghed og færrest mulige eksacerbationer samt at minimere lungefunktions-tab og progression af sygdommen.' (Ref 2, Behandling).

DSAM beskriver i deres behandlingsvejledning til KOL patienter at LAMA (f.eks. Spiriva eller Incruse) anbefales som monoterapi til KOL patienter med eksacerbationer og få symptomer (Ref 2, Tabel 2).

I Danmark anvendes GOLD bla. til scoring af KOL patienter udfra deres eksacerbationshistorik og symptomer i en matrix, også kaldet GOLD A-D (Ref 1, Figur 4.2 p. 84). LAMA (f.eks. Spiriva eller Incruse) er indiceret som farmakologisk førstevalg til GOLD B, C og D. Selv i GOLD B, skal man have 0-1 moderate eksacerbationer og i GOLD C og D skal man have ≥2 moderate eksacerbationer eller ≥1 eksacerbation, der fører til indlæggelse. Til GOLD A patienter anbefales blot en bronkodilatator, hvilket også kan betyde en kortidsvirkende bronkodilatator og ikke nødvendigvis en LAMA, som anført af GSK.

Derfor mener BI modsat GSK, at eksacerbationsdata er yderst relevant i forhold til behandlingen af KOL patienter.

GSK fremfører at have signifikant reduktion af eksacerbationer for Incruse. Dette er i modstrid med produktresuméet. Studiet, som GSK henviser til i produktresuméet, var ikke specifikt designet til at evaluere effekten af behandlingen af KOL-eksacerbationer og statistisk signifikans blev ikke opnået i studiet.

***b)** BI mener ikke, at effekt på FEV1 alene kan udgøre en behandlingsfordel. I studiet (ref 1) kommer Incruse og Spiriva lige godt ud med hensyn til dyspnø (målt ved Transition Dyspnea Index TDI), helbredsrelateret livskvalitet (målt ved St. George Respiratory Questionnaire, SGRQ) og symptomer målt ved CAT score. Dette er en vigtig pointe, at selvom der er observeret statistisk signifikant forskel på FEV1 mellem Incruse og Spiriva i studiet, så bliver dette ikke overført til en klinisk relevant effekt på hverken dyspnø, helbredsrelateret livskvalitet eller symptomer. Myndigheder som Det Europæiske Lægemiddel-agentur (EMA) skriver i deres Guideline on Clinical Investigation of Medicinal Products in the Treatment of Chronic Obstructive Pulmonary Disease 'Measurement of lung function parameters alone is considered to be insufficient in the assessment of therapeutic effect. If lung function is selected as a primary endpoint (FEV1 would be the parameter of choice), additional evidence of efficacy must be demonstrated through the use of a co-primary endpoint, which should either be a symptom-based endpoint or a patient-related endpoint.' (Ref. 3 sektion 4.3.2).*

BI mener derfor, at det er illoyalt kun at fremføre et enkelt positivt resultat (FEV1) fra studiet uden at have de andre delresultater med.

2. "Bedre lungefunktion"

GSK erkender, at de har brugt en forkert reference til deres påstand om bedre lungefunktion. Hvis den korrekte reference havde været brugt (ref 1), er BI enige i, at de oplyste data

(154 ml vs 95 ml) er korrekte, men at påstanden er mangelfuld og illoyal, se også argumentation ved punkt b ovenfor. Derudover mangler læseren nogle vigtige oplysninger om studiedesign mv (se også punktet 'Generelt').

3. "Færre kritiske fejl"
GSK anfører, at det er almindeligt kendt, hvad der menes med 'kritiske fejl'. Det er BI ikke enig i, da dette begreb defineres forskelligt i forskellige studier. Derfor mener BI, at det er vigtigt, at læseren af Incruse reklamen nemt kan se, hvad definitionen af kritiske fejl er i netop dette studie. Det er ikke nok, som GSK skriver, at dette er beskrevet i referencen.

Standpunktet 'GSK takes the position that this consensus is accepted and known by the intended audience of this material' finder BI ikke dokumenteret alene ved den nævnte reference. Det må påligge GSK at påvise dette udsagn yderligere.

Med hensyn til udsagnet 'Enkel at betjene' mener BI fortsat ikke, at reference 4 er fair at benytte. I referencen fremgår nemlig ikke, hvad Handihaler-brugerne svarede på spørgsmålet om, hvorvidt devicet var nemt at bruge.

4. "Kan du spare tid?"
BI er ikke enige med GSK i, at de ikke påstår noget i dette afsnit. Ved at stille spørgsmålet 'Kan du spare tid?' og lige derefter gøre opmærksom på at forskellige behandlinger er tilgængelige i samme inhalator, insinueres, at der er en fordel her. Denne fordel er ikke dokumenteret i de tre angivne referencer (produktresuméerne).

Med hensyn til om 'step-up behandling' er et alment kendt begreb, er BI ikke enige med GSK. Begrebet er ikke medtaget i nationale KOL behandlingsvejledninger, hverken fra DSAM eller Dansk Lungemedicinsk Selskab (DLS, Ref 4), hvorfor BI ikke mener, det er et alment kendt begreb.

Generelt
BI anfægter ikke, at de nævnte studier kan bruges. Det vi klager over er, at reklamen ikke indeholder nogen form for studiebeskrivelse (design, patientpopulation, antal patienter, primært endepunkt etc.) og derved har læseren ingen forudsætninger for at vurdere de påstande, reklamen indeholder.

Sammenfatning
Boehringer Ingelheim Danmark A/S anser på baggrund af ovenstående fortsat reklamen fra GSK som ikke-fyldestgørende samt illoyal og indstiller derfor til, at den sanktioneres gerne med krav om tilbagetrækning."

Sagen blev sendt i anden høring den 20. februar 2020 til GSK, jf. ENLI's Sagsbehandlingsregler § 9. I høringssvar af 5. marts 2020 havde GSK følgende bemærkninger;

"GSK context of the promotional material

In 2002 the launch of Spiriva has made a strong impact on the treatment of COPD in Denmark. Spiriva has since then become the standard of care for patients receiving LAMA mono therapy, having a strong, market leader position in the market until this day. In 2016, Incruse was launched by GSK getting a new treatment alternative for HCPs in the LAMA Mono Class. Based on strong clinical data on Ellipta and Incruse, including a head to

head comparison versus Spiriva, GSK decided to start actively informing HCPs of Incruse early 2020 – to offer a new treatment alternative in this class for physicians. Hence, this material was developed to offer exactly that alternative for therapeutic evaluation.

1. GSK Response to second BI letter on the appropriate balance in the material

There are several categories around the balance in the material to which BI responded in their letter. With the aim to simplify the response – GSK has aimed to categorize the response accordingly.

1.1 Direct comparison between the two medicines
1.2 Inclusion of exacerbation data in the material
1.3 Exacerbation reduction in the product label
1.4 FEV1 as a treatment benefit
1.5 Patient reported outcome

1.1 Direct Comparison between the two medicines

GSK has not made a direct comparison, or value judgment, between the two medicines except when comparing on product characteristics where evidence is documenting the claim with reference to a legal source (peer reviewed publication on Head to Head study). §7.1 was followed.

The intent of the title, to which BI writes their first remark, was to ensure the HCP would acquire knowledge about an alternative to Spiriva as LAMA mono treatment for their COPD patients. Hence the careful words, "Can you think about Incruse when you think about Spiriva?", over e.g. "Can you choose" or "You can choose". BI responded to have understanding for our objective, to make the HCP aware of an alternative treatment.

Consequently, BI refers to words used such as "bedre" and "færre". GSK has chosen to only use these words, when they can be justified based on data from a legal reference. In line with §7.1 of the ENLI code, emphasis on ***special product benefits****, it states that if a company chooses those wordings comparatively, it should be documented in the reference. In the examples mentioned, GSK has ensured the data was relevant and adequate to support the claim, basing it on Head to Head studies from peer reviewed publications. E.g. when GSK states superiority versus Spiriva "Bedre Lungefunktion – Signifikant lungefunktionsforbedring versus Spiriva – (154 mL vs 95 mL)" the data is based on Head to Head study from the peer reviewed publication, Feldman G et al, International Journal of COPD, 2016: 11; 719-730 - reference 1. Furthermore, GSK ensured relevance to the guidelines for Bronchodilation in COPD treatment, using both latest national (DLS, 2017) and international (GOLD, 2020) COPD guidelines.*
Therefore, GSK does not agree to the complaint by BI related to fairness and balance of documentation of our claims.

1.2 Inclusion of exacerbation data in the material

GSK has aligned all information in the promotional material to guidelines, to ensure relevance of the information for the HCP. BI brought forward that exacerbation data is relevant for HCPs prescribing a LAMA, bronchodilation therapy. GSK has the following arguments to support relevance of the current information of the material:

Firstly, BI refers to page 78 of the GOLD Guidelines for COPD treatment (Reference 1), referring to the sentence: "the main treatment goals are reduction of symptoms and future risk of exacerbations". Although GSK fully supports the importance of both treatment goals for management of the disease, the relevance of this reference for this complaint is inadequate. The material in question is a specific class of medication within COPD.

Incruse and Spiriva are LAMA mono-bronchodilators. Therefore, one should focus on the Key Points on Bronchodilator treatment in COPD. On page 43 under this section, GOLD states: "Bronchodilator medications in COPD are most often given on a regular basis to prevent or reduce symptoms".
If one focuses more on management of stable COPD and bronchodilation, GOLD writes on page 47: "Inhaled bronchodilators in COPD are central to symptom management and commonly given on a regular basis to prevent or reduce symptoms".

Following the argument on GOLD Guidelines, BI refers to the DSAM guidelines (Reference 2, 2017). Most importantly, GSK would like to point out that the referred DSAM guidelines have been written in 2008 and been revised in 2017 based on ***older versions*** *of the DLS guidelines (2012), GOLD Guidelines (2015) and Sundhedsstyrelsen (2015), so GSK questions whether this adequately reflects the latest, relevant science from GOLD (2020) and DLS (2017 - based on GOLD 2017).*

In relation to DSAM, BI refers to the patient criteria for choosing a LAMA monotherapy. They state that the LAMA treatment is recommended for group C patients. BI did not mention that in the guidance on the table referred to (Table 2), DSAM mentions that the first two criteria for the first-choice treatment are price and how long the medicine has been on the market.
Additionally, DSAM states the following on bronchodilation therapy: "SABA tages ved behov (ikke fast) i GOLD A, B, C og D. Korttidsvirkende bronkodilatator kan bruges som eneste behandling til enkelte patienter med KOL uden daglige symptomer, fx åndenød i forbindelse med større anstrengelse. Ellers er fast LABA og/eller LAMA den farmakologiske grundbehandling."

In their response, BI unfortunately did not mention the DLS (Reference 4, Dansk Lungemedicinsk Selskab) view on LAMA treatment in their guidelines. GSK wants to re-iterate that, to ensure relevance, GSK has aligned to the COPD Guidelines of the Dansk Lungemedicinsk Selskab, which suggests the pharmacological choice of treatment with a mono LAMA component, such as Spiriva or Incruse, is prescribed for patients who are low symptomatic and have no exacerbations or hospitalizations. As a result of these guidelines, GSK therefore assesses exacerbation data for the therapeutic evaluation not relevant and therefore not disturbing the balance of information in this advertisement.

Lastly, BI refers to the GOLD identification of patients and the ABCD assessment tool for pharmacological therapy. GSK does not see the relevance to this promotional material. GOLD Guidelines clearly separate criteria of patient identification from the objective of different pharmacological choices. Since the promotional material focuses only on the pharmacological option, not how patients are classified, GSK does not see the relevance of the argument in relation to the complaint. Nevertheless, to ensure GSK covers the complaint properly, we reiterate that GOLD states the following on the pharmacological treatment:

- *GOLD writes: "Bronchodilator medications in COPD are most often given on a regular basis to prevent or reduce symptoms" (Page 43)*
- *In addition to BI´s point on stable COPD management, GOLD writes: "Inhaled bronchodilators in COPD are central to symptom management and commonly given on a regular basis to prevent or reduce symptoms" (Page 47)*

To conclude, GOLD Guidelines, DSAM and DLS guidelines are aligned that the primary objective of the pharmacological choice of a bronchodilation treatment is symptom control. Therefore, GSK stands by the position that focusing on FEV1 is relevant, balanced, and moreover, strongly documented through a multicenter, randomized, blinded, double-dummy, parallel-group, non-inferiority, Head to Head study which means the claim made is strongly substantiated.

Based on the additional and original justification GSK does not agree to the complaint of BI on the balance of data in the material.

1.3 Exacerbation reduction in the product label

BI incorrectly accuses GSK of claiming a significant reduction of exacerbations, which goes in against the product resume. We want to stress that GSK has not claimed significance of the reduction in exacerbations in the response. Additionally, BI says GSK did not reach significance, which is an incorrect assumption:

The p value for exacerbations for Incruse was p = 0,035 as stated in the SmPC. However due to step wise reduction, patients were pulled out of the study should an exacerbation occur (to ensure patients could be treated ethically outside the study with a sufficient combination therapy if mandated) , significance could not be "deduced" ("udledes"), which is very different from not being "reached". Accordingly, it is not correct to state that statistical significance was not "reached". The SmPC for Incruse states that Incruse reduced exacerbation.

Based on the additional and original justification, GSK does not agree to the complaint of BI on exacerbation data in label.

1.4 FEV1 as a treatment benefit

In the second response, BI assumes that FEV1 as stand alone is not providing a treatment advantage. GSK does not agree to this point on the following basis

BI is referring to the EMA Guideline for Clinical Investigation of Medicinal Products (Reference 3), which is a guideline on the requirement for studies, their designs and criteria. The study to which GSK bases the FEV1 claim on has been performed completely in line with these criteria EMA has set under the chapter 4.3.2 – Confirmatory Trials.

When it comes to BI´s conclusion of unloyalty to this guidance, this is an incorrect interpretation of the reference. These guidelines are written for the design of the study GSK is referring to, not the outcome.

Although GSK finds the BI conclusion incorrect based on the argumentation, GSK does want to point out that in the same EMA guidance FEV1 is mentioned as the primary parameter of adoption COPD strategies.

- *"FEV1 is the most extensively used parameter for adopting treatment strategies in COPD. FEV1 is one of the most repeatable lung function parameters and in COPD is a measure of the obstructive element of the disease."*

1.5 patient reported outcome

BI also argues, that there was no statistical difference between different patient reported outcomes including health related quality of life in the Head to Head study between Incruse and Spiriva, and that these data should have been included in the material.

Firstly, the patient reported measures referred to by BI are all secondary endpoints and accordingly not conclusive. Whereas secondary endpoints in promotional material always mandates inclusion of primary endpoints and study design to respect the evidence hierarchy, this does not apply for the reverse situation, meaning that primary endpoints do not require inclusion of secondary endpoints according to ENLI rules.
Secondly, GSK would like to draw the attention to the important fact that Quality of life related endpoints requested to be included in the material by BI simply are not allowed in promotional materials according to "ENLI guide vedr. Informationsmateriale og Dokumentation". In the Q and A section from this guide the following is stated:

"Kan man bruge oplysninger om forbedret livskvalitet i en reklame?
***Svar:** Nej, ikke umiddelbart. Som det fremgår af EU-dommen 249/09, kan man ud over oplysninger fra SPC alene anvende oplysninger fra videnskabelige studier, der bekræfter eller præciserer de oplysninger, der fremgår af SPC. Om end livskvalitet kan være relevant, må det som udgangspunkt siges at ligge for langt væk fra lægemidlets indikationsområde til, at det kan siges at bekræfte eller præcisere oplysningerne i SPC'et."*

In summary GSK has:

- *used the relevant endpoint (Lung function/FEV1) for this sub group of COPD patients*
- *used primary endpoints*
- *used Head to Head data*
- *not been fishing data or excluded any data which could have changed the balance*

On the contrary GSK experience BI is fishing for data when insinuating, that GSKs product didn't reach significance for a less relevant parameter although this in fact in not the case, when reading the SmPC correctly.

Based on the additional and original justification, GSK will amend the incorrect reference, but does not agree to the complaint of BI.

2. GSK Response to second BI letter on the device & critical errors

There are two sub-topics under the complaint of BI:

2.1 Consensus on critical errors

2.2 Simple to use device

2.1 Consensus on Critical Errors

BI disagrees to GSKs position that there is consensus on the term critical errors. Unfortunately, in the response, BI does not specify what the different definitions are, nor does BI respond to the fact that GSK assumes consensus on the outcome of critical errors, which is treatment failure.

GSK has brought forward a reference by three Danish pulmonologists Rune Fuglø-Mortensen, Peter Lange & Jann Mortensen to support the consensus on critical errors. https://ugeskriftet.dk/files/scientific_article_files/2019-08/v07180510_2.pdf. They base this position of consensus on three additional references in the article.

- *Chrystyn H, van der Palen J, Sharma R et al. Device errors in asthma and COPD: systematic literature review and meta-analysis. NPJ Prim Care Respir Med 2017;27:22.*
- *Chrystyn H, Price D. Not all asthma inhalers are the same: factors to consider when prescribing an inhaler. Prim Care Respir J 2009;18:243- 9.*
- *Melani AS, Bonavia M, Cilenti V et al. Inhaler mishandling remains common in real life and is associated with reduced disease control. Respir Med 2011;105:930-8.*

BI raises a disagreement without any evidence to concur GSK´s argumentation. GSK based the position on Danish pulmonologists´ view, substantially referenced in the source mentioned.

Based on the additional and original justification, GSK does not agree to the complaint of BI on consensus on critical errors.

2.2 Simple to use device

BI claims that the "enkel at betjene", is not referenced fairly by Reference 4 in the promotional material, as they are not asking the patients on the Handihaler. The reference has interviewed patients on the Ellipta device vs. the currently used inhaler. This includes the Spiriva treatment. The table below, provides the answers the sample has provided from the Svedsater et al. publication comparing the Ellipta based treatment vs. current Spiriva treatment. In this section of the study, there has been opportunity for the patient to express that their Spiriva treatment was indeed simpler to use, in the open ended questions asked.

B – HandiHaler (N = 20)		
Simple mode of action / Fewer steps (17)	Simpler / not complex (11)	"Takes a lot less time to use"
		"This is much simpler because I have arthritis in my hands"
	Fewer steps / less time (8)	"I reach in my bag, grab the new device, open it, breathe and put it back; it's much less time"
		"Just takes less time"
	Difficulties managing Handihaler (4)	"Spiriva is more difficult, many more steps to manage and more messy"
Fewer components (7)	No capsules (5)	"Capsules are a pain in the butt"
		"Because there is no pill there is no complication"
	No blister pack (3)	"I don't need a scissors to open the package that has the pill inside, which is good because I have arthritis"
Reliable (6)	More assured getting medicine (4)	"I wonder if I'm getting all the medication out of the capsule, and here I don't have to worry."
	Less chance for error (4)	"Less chance for mistakes—this is fool-proof"
		"Much less chance of a mistake"

*GSK is aware of the ENLI requirement to be able to substantiate any claim made regarding product benefit including claims like "Enkelt at betjene": GSK is also very aware of several ENLI cases where companies concluded their products to be either "simple and flexible" (**AN-2018-2631)** or be able to provide "freedom", make the patient "more comfortable" and "increase confidence" **(R-2018-3088)** all based on a subjective assessment of their product's characteristics However, GSK is making the claim "Enkelt at betjene" with direct reference to a legal peer reviewed publication - Svedsater H et al, BMC Pulm Med, 2013 (72) . This reference substantiates the claim without GSK adding any interpretation of the outcome in accordance with the requirement for substantiating product benefit claims.*

Based on the additional and original justification, GSK does not agree to the complaint of BI around balance of device simplicity in the study.

3. GSK Response to second BI letter on the reflection on time saving

BI takes the position that the "Can you save time?" is a claim. GSK does not indicate that our devices indicate time-saving, but we give the HCP their opportunity to evaluate whether having the same inhalator throughout disease progression can mean anything for a physician. DLS guidelines states that the device choice should be made whilst keeping in mind an as simple as possible treatment regime in respect to e.g. number of inhalators.

- *"Man bør tilsigte et så simpelt og ensartet behandlingsregime som muligt med hensyn til antallet af inhalatorer, sug og formuleringer (spray, pulver, kapsler etc.)."*

It is therefore, that GSK deems this question relevant in this material – and justifiable to be asked, without interpreting it for the HCP.

Based on the additional and original justification, GSK does not agree to the complaint of BI around claiming time saving.

4. GSK Response to second BI letter on the definition of step-up behandling

Unfortunately, BI has not responded to GSK´s provided references to Sundhedsstyrelsen and GOLD international guidelines from the first response letter. GSK stays at the position that step-up behandling is generally known, providing 3 sources – Danish and international to back up this argument.

BI refers to DLS (Reference 4), claiming they do not mention step up treatment. However, in the guidelines there is coverage of "optrapning" & "nedtrapning" i.e. step-up and step-down, under the section Farmacologisk Behandling.

- *"Ved manglende effekt kan yderligere optrapning (til middel- eller højdosis) overvejes/forsøges."*
- *"Patienter med stabil KOL (uden eksacerbationer eller indlæggelser på grund af KOL gennem mindst et år) kan overvejes ned- og/eller udtrappet i henhold til nedenstående og figur 2."*

Based on the additional and original justification, GSK does not agree to the complaint of BI around the definition of step up behandling.

5. GSK Response to second BI letter on the general context

*GSK understands and agrees with the need for including study design for all **indirect** study comparisons where results from different studies are compared, or if mandated by evidence hierarchy where claims are related to secondary endpoints. However, this does not apply to the GSK material, where comparison was based on a Head to Head study and the primary endpoints of these studies. GSK refers to the ENLI promotional code, §7.2 Endepunkter og studiedesign, stating: "I en reklame,der anprises direkte på de primære endepunkterfra fase 3-studiet, der ligger til grund for den godkendte indikation, er der umiddelbart ikke et stort behov for supplerende oplysninger om studiedesign mv. for at reklamen kan anses for at være fyldestgørende."*

Prior to the approval of the material, GSK has also reviewed related ENLI cases to ensure compliance to the code.

*In case **KO-2018-2712**, an inclusion of study design was mandatory, due to the evidence hierarchy, where claims were related to secondary endpoints. In the GSK material, statements are based on primary endpoints. Therefore, according to the code and this case, GSK is not mandated to include study design information.*

*In case **AN-2018-3964,** study design should have been included because comparison was based on different studies (indirect comparison). However, in the GSK material at hand the comparison is made in Head to Head studies with both medicines included based on same in- and exclusion criteria and baseline values. Therefore, according to the code and this case, GSK is not mandated to include study design information.*

Based on the additional and original justification, GSK does not agree to the complaint of BI on study information requirements.

6. GSK Summary

GSK Pharma A/S stands by the position that this material is giving the HCP the possibility to make a therapeutic evaluation of treatment, for each individual patient. With this secondary supplement of information, ENLI case reviews, additional sources and argumentation GSK has been able to further justify why this material is adequate, relevant and substantiated with strong evidence for the claims made."

Granskningsmandspanelet tog herefter sagen op til afgørelse.

Granskningsmandspanelets vurdering og afgørelse:
I forhold til de fire klagepunkter, har Granskningsmandspanelet vurderet klagepunkterne ud fra Reklamekodeksets § 4, stk. 2, samt § 7, stk. 3, der lyder således:

Reklamekodeksets § 4, stk. 2: "*Reklame for et lægemiddel skal være fyldestgørende og saglig, og den må ikke være vildledende eller overdrive lægemidlets egenskaber. Oplysninger i reklamen skal være i overensstemmelse med lægemidlets godkendte produktresumé."*

Reklamekodeksets § 7, stk. 3: "*Alle oplysninger […], skal være fyldestgørende, saglige, nøjagtige, aktuelle, kontrollerbare og tilstrækkeligt udførlige til, at modtageren kan danne sig en personlig mening om lægemidlets behandlingsmæssige værdi."*

Ad punkt 1 – (Ubalanceret):
Boehringer mener, at reklamen er ubalanceret, og nævner specifikt at Spiriva – modsat Incruse – har en signifikant evne til at nedsætte risikoen for eksacerbationer, hvilket ikke fremgår af reklamen. Til dette svarer GSK, at begge produkter ifølge COPD Guidelines fra Dansk Lungemedicinsk Selskab er indiceret til patienter som har få symptomer og ingen eksacerbationer eller hospitalsindlæggelser, og derfor har man ikke lagt vægt på at nævne eksacerbationer i reklamen, dvs. at man ikke direkte kan sammenligne de to produkter. Herudover anføres det, at GSK's produkt Incruse faktisk nedsætter antal eksacerbationer ift. placebo (dokumenteres i SPC'et).

Boehringer anfører i deres supplerende høringssvar**,** at reklamen netop opfordrer lægen til at sammenligne de to produkter med udsagnet "*Kunne du tænke Incruse næste gang du tænker Spiriva?*". Herudover mener Boehringer fortsat, at det er yderst relevant, når de to produkter sammenlignes, at der medtages eksacerbationsdata, og at det er illoyalt kun at fremføre data på FEV1 ("*Bedre lungefunktion*", klagepunkt 2).

I GSK's supplerende høringssvar fastholder GSK i en lang række punkter (og guidelines), at FEV1 er den primære og bedste effektmarkør til at vurdere bronkodilatation: "*To conclude, GOLD Guidelines, DSAM and DLS guidelines are aligned that the primary objective of the pharmacological choice of a bronchodilation treatment is symptom control. Therefore, GSK stands by the position that focusing on FEV1 is relevant, balanced, and moreover, strongly documented through a multicenter, randomized, blinded, double-dummy, parallel-group, non-inferiority, Head to Head study which means the claim made is strongly substantiated*".

Granskningsmandpanelets vurdering af klagepunkt 1:
Boehringers gives medhold i, at udsagnet "*Bedre lungefunktion*" (se også klagepunkt 2) er ubalanceret, men primært fordi det ikke her er tydeliggjort, at med lungefunktionen menes bedring i FEV1. Dette forhold skulle have været tydeliggjort. Det er således Granskningsmandspanelets vurdering, at udsagnet ikke er fyldestgørende, og dermed udgør en overtrædelse af Reklamekodeksets § 4, stk. 2.

Granskningsmandspanelet giver dog ikke Boehringer medhold i, at alle sekundære endepunkter som f.eks. eksacerbationsdata nødvendigvis skal indgå i den reklamebærende del. Se yderligere under klagepunkt 2.

Ad punkt 2 – (bedre lungefundktion):
Klagepunktet vedrører udsagnet: "*Bedre lungefunktion (ref. 3)* | *Signifikant lungefunktionsbedring vs. Spiriva (154 mL vs 95 mL)"*

GSK indrømmer i deres første høringssvar, at de har angivet en forkert reference – det skulle have været ref. 1 i stedet for ref. 3 – men de fastholder, at konklusionen i ref. 1 (Head-to-Head studie af Feldman fra 2016) er, at lungefunktionen bliver signifikant bedre med Incruse end med Spiriva (FEV1 bedres med 59 ml ved brug af Incruse).

I Boehringers supplerende høringssvar accepterer Boehringer, at Feldman 2016 viser en bedring i det primære endepunkt FEV1, men anfører, at man også bør medtage de sekundære endepunkter fra artiklen i udsagnet (fx et dyspnø endepunkt).

I supplerende høringssvar fra GSK fastholdes det, at de troværdigt har gengivet resultaterne af det pågældende Head-to-Head studies primære effektmål ("154 mL vs. 95 mL").

Granskningsmandpanelets vurdering af klagepunkt 2:
Boehringer gives medhold i, at der er angivet en forkert reference. Det betyder, at udsagnet "*Bedre lungefunktion*" ikke er fyldestgørende og kontrollerbart, jf. Reklamekodeksets § 7, stk. 3.

Boehringer gives dog ikke medhold i, at alle de sekundære endepunkter burde være nævnt i reklamen. Det er Granskningsmandspanelets vurdering, at det er tilstrækkeligt, at det primære endepunkt fra et studie, der direkte sammenligner FEV1'er, nævnes. GSK burde dog specifikt have angivet i det anprisende udsagn, at det var FEV1 der var tale om ("154 mL vs. 95 mL").

Ad punkt 3 – (Færre kritiske fejl):
Klagepunktet vedrører udsagnet: "Færre kritiske fejl (ref. 2) | Enkel (ref. 4) at betjene – en inhalation, en gang dagligt (ref. 5)"

GSK giver i deres første høringssvar Boehringer medhold i, at udsagnet "færre kritiske fejl" er unfair og ikke fyldestgørende, fordi udsagnet ikke forklares nærmere. GSK mener derimod, at udsagnet klart er defineret i den refererede artikel (reference 2 af van der Palen fra 2016), og henviser herudover til en aktuel

artikel fra UFL i 2019, hvor definitionen på "kritiske fejl" gennemgås, således at danske læger (målgruppen for reklamen) gøres bekendt med begrebet. Granskningsmandspanelet bemærker, at UFL-artiklen er ikke angivet i reklamen.

Hvad angår udsagnet "enkel at betjene…" anfører GSK, at de er uenige med Boehringer. GSK mener, at udsagnet er objektivt og dokumenteres i de angivne referencer (2, 4 og 5). I Boehringers supplerende høringssvar, anfører Boehringer, at man ikke er enig i at det er almindeligt kendt hvad der menes med "kritiske fejl", og Boehringer mener, at udsagnet skal underbygges og defineres. Boehringer mener heller ikke, at udsagnet "enkel at betjene" er dokumenteret af den pågældende reference 5. Til dette svarer GSK i deres supplerende høringssvar fortsat, at begrebet "kritiske fejl" er dokumenteret ved reference 2, og "enkel at betjene" dokumenteret i reference 4. GSK henholder sig til det kvalitative peer-reviewede studie: "Svedsater et al. BMC Pulmonary Medicine 2013, 13: 72", hvor patienter med KOL elle astma blev spurgt om brugstilfredsheden ved at anvende forskellige inhalatorer, inklusiv Incruse Ellipta fra GSK og Spiriva HandiHaler fra Boehringer. Tabel 5 (sektion B) i dette studie godtgør ifølge GSK, at anvendelsen af Incruse Ellipta er enklere at anvende end HandiHaler fra Boehringer.

Granskningsmandpanelets vurdering af klagepunkt 3:
Boehringer gives medhold i, at udsagnet "Færre kritiske fejl" er så bredt, at det bør forklares og defineres mere detaljeret i den reklamebærende del. Granskningsmandpanelet mener ikke, at begrebet er alment kendt af læserne af reklamen, uagtet at det måtte være dokumenteret i reference 2 (van der Palen 2016). Her er der igen tale om et udsagn, der ikke forklarer læseren tydeligt nok, hvad der ligger bag udsagnet. Granskningsmandspanelet finder således, at det udgør et ikke fyldestgørende udsagn, hvilket er en overtrædelse af Reklamekodeksets § 4, stk. 2.

Boehringer gives dog ikke medhold i, at begrebet "enkel at betjene" ikke er troværdigt dokumenteret fra den angivne reference (Svedsater 2013).

<u>Ad punkt 4 – (Kan du spare tid?):</u>
Klagepunktet vedrører udsagnet: "Kan du spare tid?"

GSK anfører i deres første høringssvar, at udtrykket "Kan du spare tid?" ikke er et anprisende udsagn, men et objektivt spørgsmål til sundhedspersonerne. De mener endvidere, at "Step-up behandling…" er et velkendt udtryk for reklamens målgruppe af læger, og henviser bl.a. til Sundhedsstyrelsens udgivelse Rationel Farmakoterapi og artiklen "Medicinsk behandling af KOL". Granskningsmandspanelet bemærker, at der ikke er henvist til denne artikel i reklamen.

Boehringer anfører i deres supplerende høringssvar, at når man umiddelbart efter udsagnet "Kan du spare tid?" gøres opmærksom på behandlingsmuligheder (med Incruse), er det en anprisning af produktet. Herudover anfører Boehringer, at udtrykket "Step-up behandling…" ikke er et alment kendt begreb, og nævner eksempler på guidelines, hvor udtrykket ikke figurerer.

I GSK's supplerende høringssvar fastholder GSK, at meningen med spørgsmålet "Kan du spare tid?" ikke er at indikere en tidsbesparende effekt af Incruse ift. Spiriva, men at udtrykket skal få sundhedspersonen til at reflektere over, om man i et helt sygdomsforløb skal anvende samme device. Vedrørende udsagnet

”Step-up behandling…” anfører GSK, at Boehringer i deres høringssvar ikke har kommenteret de af GSK anførte kilder, der efter GSK's mening godtgør, at udtrykket skulle være alment kendt. GSK fastholder således deres argumentation fra første høringssvar.

Granskningsmandpanelets vurdering af klagepunkt 4:
Boehringer gives medhold i, at udtrykket ”Kan du spare tid?” er vildledende og usobert med et skjult anprisende formål. Herudover finder Granskningsmandspanelet, at udtrykket ”Step-up behandling…” ikke er alment kendt, og at udtrykket burde være forklaret nærmere i den reklamebærende del.

Det er således Granskningsmandspanelets vurdering, at de påklagede punkter under klagepunkt 4 begge udgør en overtrædelse af Reklamekodeksets § 4, stk. 2. Det findes særligt usagligt og vildledende med udtrykket ”Kan du spare tid?” i den sammenhæng det præsenteres i, i den pågældende reklame.

Afgørelse:
GlaxoSmithKline Pharma A/S findes således at have overtrådt Reklamekodeksets § 4, stk. 2 samt § 7, stk. 3, og pålægges som følge heraf følgende sanktioner:

Sanktion:

- GlaxoSmithKline Pharma A/S pålægges at ophøre med at anvende reklamen i dens foreliggende form.
- GlaxoSmithKline Pharma A/S pålægges endvidere en bøde på 50.000 kr. + moms i henhold til ENLI's Sanktions- og gebyrregulativ § 4, stk. 1, litra e).

Kopi af nærværende skrivelse sendes til klager hhv. indklagede og til Lægemiddelstyrelsen til orientering, når sagen er endelig.

Med venlig hilsen

Kim Dalhoff
Lægefaglig granskningsmand