Reports of Cases

JUDGMENT OF THE COURT (Fourth Chamber)

27 March 2019*

(Appeal — Medicinal products for human use — Directive 2001/83/EC — Article 30(1) — Committee for Medicinal Products for Human Use — Referral of a matter to the committee subject to the absence of a previous national decision — Active substance estradiol — Decision of the European Commission ordering the Member States to revoke or vary marketing authorisations for medicinal products with 0.01% estradiol by weight for topical use)

In Case C-680/16 P,

APPEAL under Article 56 of the Statute of the Court of Justice of the European Union, brought on 23 December 2016,

Dr. August Wolff GmbH & Co. KG Arzneimittel, established in Bielefeld (Germany),

Remedia d.o.o., established in Zagreb (Croatia),

represented by P. Klappich and C. Schmidt, Rechtsanwälte,

appellants,

the other party to the proceedings being:

European Commission, represented by B.-R. Killmann and A. Sipos and by M. Šimerdová, acting as Agents,

defendant at first instance,

THE COURT (Fourth Chamber),

composed of T. von Danwitz, President of the Seventh Chamber, acting as President of the Fourth Chamber, K. Jürimäe, C. Lycourgos, E. Juhász (Rapporteur) and C. Vajda, Judges,

Advocate General: P. Mengozzi,

Registrar: A. Calot Escobar,

having regard to the written procedure,

after hearing the Opinion of the Advocate General at the sitting on 4 October 2018,

gives the following

* Language of the case: German.

Judgment

1 By their appeal, Dr. August Wolff GmbH & Co. KG Arzneimittel and Remedia d.o.o. ask the Court to set aside the judgment of the General Court of the European Union of 20 October 2016, *August Wolff and Remedia* v *Commission* (T-672/14, not published, 'the judgment under appeal', EU:T:2016:623) in so far as by that judgment the General Court dismissed their action for the annulment of Commission Implementing Decision C(2014) 6030 final of 19 August 2014 concerning the marketing authorisations for high concentration of estradiol containing human medicinal products for topical use in the framework of Article 31 of Directive 2001/83/EC of the European Parliament and of the Council ('the decision at issue'), in so far as that decision directs the Member States to comply with the requirements which it stipulated for the medicinal products with 0.01% estradiol by weight for topical use referenced and non-referenced in Annex I thereto, excluding the restriction that the medicinal products with 0.01% estradiol by weight for topical use referenced in that annex may still be used by vaginal application only.

Legal context

Directive 2001/83

2 The first paragraph of Article 31(1) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67), as amended by Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 (OJ 2010 L 348, p. 74) ('Directive 2001/83'), provides:

'The Member States, the Commission, the applicant or the marketing authorisation holder shall, in specific cases where the interests of the Union are involved, refer the matter to the Committee [for Medicinal Products for Human Use] for application of the procedure laid down in Articles 32, 33 and 34 before any decision is reached on an application for a marketing authorisation or on the suspension or revocation of a marketing authorisation, or on any other variation of the marketing authorisation which appears necessary.'

3 Article 32(1), (2) and (5) of that directive states:

'1. When reference is made to the procedure laid down in this Article, the Committee [for Medicinal Products for Human Use] shall consider the matter concerned and shall issue a reasoned opinion within 60 days of the date on which the matter was referred to it.

However, in cases submitted to the Committee in accordance with Articles 30 and 31, this period may be extended by the Committee for a further period of up to 90 days, taking into account the views of the applicants or the marketing authorisation holders concerned.

In an emergency, and on a proposal from its Chairman, the Committee may agree to a shorter deadline.

2. In order to consider the matter, the Committee shall appoint one of its members to act as rapporteur. The Committee may also appoint individual experts to advise it on specific questions. When appointing experts, the Committee shall define their tasks and specify the time-limit for the completion of these tasks.

…

5. Within 15 days after its adoption, the [European Medicines Agency (EMA)] shall forward the final opinion of the Committee to the Member States, to the Commission and to the applicant or the marketing authorisation holder, together with a report describing the assessment of the medicinal product and stating the reasons for its conclusions.

In the event of an opinion in favour of granting or maintaining an authorisation to place the medicinal product concerned on the market, the following documents shall be annexed to the opinion:

(a) a draft summary of the product characteristics, as referred to in Article 11;

(b) any conditions affecting the authorisation within the meaning of paragraph 4(c);

(c) details of any recommended conditions or restrictions with regard to the safe and effective use of the medicinal product;

(d) the proposed text of the labelling and leaflet.'

4 Article 33 of that directive provides:

'Within 15 days of the receipt of the opinion, the Commission shall prepare a draft of the decision to be taken in respect of the application, taking into account Community law.

In the event of a draft decision which envisages the granting of marketing authorisation, the documents referred to in Article 32(5), second subparagraph shall be annexed.

Where, exceptionally, the draft decision is not in accordance with the opinion of the [EMA], the Commission shall also annex a detailed explanation of the reasons for the differences.

The draft decision shall be forwarded to the Member States and the applicant or the marketing authorisation holder.'

5 Article 34(1) of the directive reads as follows:

'The Commission shall take a final decision in accordance with, and within 15 days after the end of, the procedure referred to in Article 121(3).'

Regulation No 726/2004

6 According to Article 56(1) of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ 2004 L 136, p. 1), as amended by Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 (OJ 2010 L 348, p. 1) ('Regulation No 726/2004'), the EMA is to be comprised of several committees including the Committee for Medicinal Products for Human Use ('the Committee'), which shall be responsible for preparing the opinion of the EMA on any question relating to the evaluation of medicinal products for human use.

7 The last sentence of Article 61(6) of Regulation No 726/2004 provides that the Member States are to refrain from giving committee members and experts any instruction which is incompatible with their own individual tasks or with the tasks and responsibilities of the EMA.

8 Article 62(1) of Regulation No 726/2004 provides:

'Where, in accordance with this Regulation, any of the Committees referred to in Article 56(1) is required to evaluate a medicinal product for human use, it shall appoint one of its members to act as rapporteur, taking into account existing expertise in the Member State. The Committee concerned may appoint a second member to act as co-rapporteur.

A rapporteur appointed for this purpose by the Pharmacovigilance Risk Assessment Committee shall closely collaborate with the rapporteur appointed by the [Committee] or the Reference Member State for the medicinal product for human use concerned.

When consulting the scientific advisory groups referred to in Article 56(2), the Committee shall forward to them the draft assessment report(s) drawn up by the rapporteur or the co-rapporteur. The opinion issued by the scientific advisory group shall be forwarded to the chairman of the relevant Committee in such a way as to ensure that the deadlines laid down in Article 6(3) and Article 31(3) are met.

The substance of the opinion shall be included in the assessment report published pursuant to Article 13(3) and Article 38(3).

If there is a request for re-examination of one of its opinions where this possibility is provided for in Union law, the Committee concerned shall appoint a different rapporteur and, where necessary, a different co-rapporteur from those appointed for the initial opinion. The re-examination procedure may deal only with the points of the opinion initially identified by the applicant and may be based only on the scientific data available when the Committee adopted the initial opinion. The applicant may request that the Committee consult a scientific advisory group in connection with the re-examination.'

The background to the dispute

9 The background to the dispute is set out in paragraphs 1 to 12 of the judgment under appeal as follows:

'1 Dr. August Wolff GmbH & Co. KG Arzneimittel ("the first appellant") holds marketing authorisations … issued by the competent national authorities of several Member States, namely the Federal Republic of Germany, the Republic of Bulgaria, Hungary, the Czech Republic, the Slovak Republic, the Republic of Lithuania, the Republic of Latvia and the Republic of Estonia, for the medicinal product Linoladiol N or Gel Linoladiol N 0.1 mg/g or Linoladiol N 0.1 mg/g vaginal cream ("Linoladiol N"). Linoladiol N is manufactured in Germany by Remedia d.o.o. ("the second appellant"), which holds the marketing authorisation for Linoladiol N in Croatia, where the medicinal product was marketed as Linoladiol N 0.01% krema za rodnicu. Linoladiol N is also sold in Austria.

2 Linoladiol N is a cream intended for treating menopausal women with vaginal and vulvar atrophy. Linoladiol N contains the hormone estradiol as its active substance in a concentration of 100 micrograms per gram.

3 Linoladiol N was first authorised in Germany in 1978. By decision of 26 September 2005, the German authorities refused to renew the authorisation for Linoladiol N. The first appellant initially lodged an action against that decision with the Verwaltungsgericht Köln (Administrative Court, Cologne, Germany), which dismissed its action by judgment of 27 October 2009. The first appellant then brought an appeal before the Oberverwaltungsgericht für das Land Nordrhein-Westfalen (Higher Administrative Court, North Rhine-Westphalia, Germany).

4 In a judgment of 13 March 2013 …, the Oberverwaltungsgericht für das Land Nordrhein-Westfalen (Higher Administrative Court, North Rhine-Westphalia) annulled the decision of 26 September 2005 and ordered the Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for Drugs and Medical Devices, Germany, 'the BfArM') to reconsider the first appellant's application for renewal of the authorisation for Linoladiol N in the light of its ruling.

5 By decision of 11 July 2013, the BfArM granted the renewed authorisation for Linoladiol N for applications of 35g, 50g, 100g and 250g, each with an applicator.

6 At the same time as proceedings were pending before the Oberverwaltungsgericht für das Land Nordrhein-Westfalen (Higher Administrative Court, North Rhine-Westphalia), the German authorities made a referral concerning Linoladiol N to the [Committee] under Article 31(1) of Directive [2001/83] on 24 May 2012.

7 On 19 December 2013, the [Committee] issued a provisional opinion …

8 By letter of 3 January 2014, the first appellant asked the [EMA] to re-examine its provisional opinion of 19 December 2013 in respect of Linoladiol N.

9 On 25 April 2014, the [Committee] issued its final opinion …

10 The [Committee] issued an assessment report on 2 May 2014 … under Article 32(5) [of Directive 2001/83], which provides the basis for the final opinion of 25 April 2014.

11 On 19 August 2014, the European Commission adopted the [decision at issue]. It is clear from the [decision at issue] that the national [marketing authorisations] for the medicinal products which are listed in Annex I to that decision must be varied by the Member States concerned in accordance with Annex III to the decision.

12 The [decision at issue] contains a "List of the names, pharmaceutical forms, strengths of the medicinal products, routes of administration and marketing authorisation holders in the Member States" in Annex I, a document under the heading "Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)" … in Annex II, a document under the heading "Amendments in the relevant sections of the summary of product characteristics and package leaflet" in Annex III and the "Terms of the marketing authorisation" in Annex IV.'

10 Annex IV to the decision at issue states that a course of treatment of Linoladiol N should be limited to a four-week period and that repeat use should be excluded.

The procedure before the General Court and the judgment under appeal

11 On 19 September 2014, the appellants brought an action before the General Court for the annulment of the decision at issue in so far as that decision directs the Member States to comply with the requirements which it stipulated for the medicinal products with 0.01% estradiol by weight for topical use referenced and non-referenced in Annex I thereto, excluding the restriction that the medicinal products with 0.01% estradiol by weight for topical use referenced in that annex may still be used by vaginal application only.

12 By separate document, lodged at the Registry of the General Court on 30 September 2014, the appellants made an application for interim measures, in which they submitted, in essence, that the President of the General Court should suspend the operation of the decision at issue. By order of 15 December 2014, the President of the General Court dismissed that application and reserved the costs.

13 In support of their action before the General Court, the appellants relied on three pleas of law based on infringement of Articles 31 and 32 of Directive 2001/83, on infringement of Article 116 of that directive, read in conjunction with Article 126 thereof, and on infringement of general principles of EU law, such as the principle of proportionality and the principle of equal treatment.

14 Having rejected those pleas, the General Court dismissed the action and ordered the appellants to pay the costs.

Forms of order sought

15 The appellants claim that the Court should:

– set aside the judgment under appeal and annul the decision at issue in so far as that decision directs the Member States to comply with the requirements which it stipulated for the medicinal products with 0.01% estradiol by weight for topical use referenced and non-referenced in Annex I thereto, excluding the restriction that the medicinal products with 0.01% estradiol by weight for topical use referenced in that annex may still be used by vaginal application only;

– in the alternative, set aside the judgment under appeal and refer the case back to the General Court;

– order the Commission to pay the costs.

16 The Commission contends that the Court should dismiss the appeal and order the appellants to the pay the costs.

The appeal

17 In support of their appeal, the appellants rely on three grounds of appeal based on infringement of Articles 31 and 32 of Directive 2001/83, on infringement of Article 116 of that directive, read in conjunction with Article 126 of the directive, and on infringement of general principles of EU law, such as the principle of proportionality and the principle of equal treatment.

18 It is appropriate to consider, first of all, the second limb of the first ground of appeal by which the appellants allege that the General Court infringed the requirement for neutrality laid down in Article 32(2) of Directive 2001/83 and the principle of a diligent and impartial examination enshrined in Article 41(1) of the Charter of Fundamental Rights of the European Union ('the Charter').

Arguments of the parties

19 The appellants consider that, in paragraphs 94 to 104 of the judgment under appeal, the General Court applied erroneous criteria in assessing the principle of impartiality.

20 The appellants claim that, for there to be an infringement of that principle, it is not necessary for it to be established that there actually was a partial act, but suffices that external circumstances raise a reasonable suspicion that the facts were not examined neutrally and objectively.

21 In that regard, they rely on the fact that, in the present case, the chief rapporteur Ms W., appointed by the Committee to prepare the opinion of that committee, acted in a dual capacity, since she was also an employee of the BfArM, the national authority which initiated the procedure before the Committee. The appellants consider that that fact demonstrates an overlap in function and a conflict of interest giving rise to a legitimate doubt as to the impartiality of that procedure.

22 In addition, the appellants rely on evidence which, in their view, calls into question the subjective impartiality of Ms W., in particular the fact that she herself issued an unfavourable assessment of the risk-benefit balance of the medicinal product in question and recommended that marketing authorisation be revoked, whereas the Committee itself had adopted a more favourable approach.

23 The Commission challenges the argument that the appointment of Ms W. as rapporteur in a procedure before the Committee initiated by the national authority to which she belongs raised the suspicion, in the light of objective circumstances, that the facts had not been assessed neutrally and objectively. In that regard, the General Court has previously held that, in the absence of other elements, that fact is irrelevant. In addition, the Commission maintains that the application of the last sentence of Article 61(6) of Regulation No 726/2004 is capable of ensuring a neutral and objective examination. In any event, the Commission notes that Ms W. was only one of the four rapporteurs responsible for assessing Linoladiol N during the procedure before the Committee.

Findings of the Court

24 EU institutions and bodies are required to respect the fundamental rights of the European Union, which include the right to good administration enshrined in Article 41 of the Charter (see, to that effect, judgment of 11 July 2013, *Ziegler* v *Commission*, C-439/11 P, EU:C:2013:513, paragraph 154).

25 Article 41(1) of the Charter states, inter alia, that every person has the right to have his or her affairs handled impartially, fairly and within a reasonable time by the institutions and bodies of the Union.

26 In that regard, it should be made clear that the need for impartiality, required of institutions and bodies in carrying out their missions, is intended to guarantee equality of treatment, which is at the heart of the European Union. That requirement is intended, inter alia, to avoid a situation where there could be a conflict of interest on the part of officials or agents acting on behalf of those institutions and bodies. Having regard to the fundamental importance of ensuring the independence and probity of EU institutions and bodies as regards both their internal functioning and external reputation, the requirement of impartiality covers all circumstances in which an official or agent who is called upon to decide on an issue must reasonably consider that issue as being of such a nature as to be viewed by third parties as a possible source of impairment of his or her independence in that matter (see, to that effect, judgment of 25 October 2007, *Komninou and Others* v *Commission*, C-167/06 P, not published, EU:C:2007:633, paragraph 57).

27 Thus, it is incumbent upon those institutions and bodies to comply with both components of the requirement of impartiality, which are, on the one hand, subjective impartiality, by virtue of which no member of the institution concerned may show bias or personal prejudice and, on the other, objective impartiality, under which there must be sufficient guarantees to exclude any legitimate doubt as to possible bias on the part of the institution concerned (see, to that effect, judgment of 20 December 2017, *Spain* v *Council*, C-521/15, EU:C:2017:982, paragraph 91 and the case-law cited).

28 As regards, more particularly, the second component of the principle of impartiality, it should be made clear that, where a number of EU institutions or bodies are given separate responsibilities of their own in the context of a procedure that is liable to result in a decision adversely affecting a party, each of those institutions and bodies is required, in respect of its own activities, to comply with the requirement of objective impartiality. Consequently, even where only one of them has breached that

requirement, such a breach is liable to render the decision adopted by the other at the end of the procedure at issue unlawful (see, to that effect, judgment of 20 December 2017, *Spain* v *Council*, C-521/15, EU:C:2017:982, paragraph 94).

29 It must therefore be determined whether the appointment of Ms W. as chief rapporteur of the Committee in the procedure relating to the application to renew the marketing authorisation for Linoladiol N complied with the requirements resulting from such a principle in the light of the fact that she was an employee of the national authority which referred the matter to the Committee, that that authority had previously rejected the application to renew the marketing authorisation for that medicinal product and that, at the time of Ms W.'s appointment as rapporteur, the first appellant was involved in pending court proceedings against that authority in relation to the latter's rejection of the former's application.

30 As the appellants have submitted, the objective impartiality of the Committee may be jeopardised where one of its members could have a conflict of interest as the result of an overlap in function, irrespective of that member's actual conduct.

31 In the first place, it must be considered in the present case that the procedure before the national authority under which the matter was referred to the Committee and the procedure before the Committee under Article 32 of Directive 2001/83 aim to fulfil the same substantive purpose, namely to decide on the quality, safety and efficacy of medicinal products for the purposes of issuing a decision on whether to grant marketing authorisation.

32 In the second place, in the light of the common purpose of both procedures, the findings to be made in those procedures must also be regarded as of the same nature.

33 In the third place, in accordance with the first paragraph of Article 62(1) of Regulation No 726/2004, where the Committee is required to evaluate a medicinal product for human use, it is to appoint one of its members to act as rapporteur and may appoint a second member to act as co-rapporteur. The role of rapporteur entails taking on an important role in preparing the opinion which the Committee is called upon to issue.

34 It follows that a rapporteur appointed by the Committee has responsibilities of his own in that procedure for issuing an opinion.

35 In that regard, it must also be noted that, in accordance with the third paragraph of Article 33 of Directive 2001/83, only exceptional circumstances may justify the Commission in not following such an opinion.

36 The fact that, as the Commission maintains and is laid down in the first paragraph of Article 62(1) of Regulation No 726/2004, the Committee may appoint a second member to act as co-rapporteur cannot call into question that conclusion, which equally applies to the fact, also relied on by the Commission, that, in the present case, two other members of the Committee were appointed at the re-examination stage as chief rapporteur principal and second rapporteur.

37 Indeed, in that regard and in any event, in order to show that the organisation of an administrative procedure does not ensure sufficient guarantees to exclude any legitimate doubt as to possible bias, it is not necessary to prove lack of impartiality due to the specific characteristics of the role of rapporteur in the procedures conducted before the Committee. It is sufficient for a legitimate doubt to arise which cannot be dispelled.

38 It is therefore for the Committee, in view of the rapporteur's own responsibilities, to be particularly vigilant in attributing that role in order to avoid giving rise to any legitimate doubt as to possible bias. In the present case, it was, more particularly, for the Committee to take account of the fact, of which

the Federal Republic of Germany had notified it, as is clear from the request for an opinion lodged by that Member State, that the BfArM had refused to renew the marketing authorisation for Linoladiol N and that an action before the German courts in respect of that refusal was pending at the time the matter was referred to the Committee.

39 It is common ground that Ms W. is employed by the national authority which took the decision not to renew the marketing authorisation for Linoladiol N and which, as the defendant in the action brought against that decision, defended that decision before the national courts and, then, referred the matter to the Committee for the Committee to issue an opinion relating to that medicinal product. In those circumstances, third party observers could legitimately consider that that authority, by referring the matter to the Committee, was continuing to pursue its own national level interests and that persons employed by that authority who are involved in the procedure before the Committee may not act impartially.

40 In that context, the sole fact that the last sentence of Article 61(6) of Regulation No 726/2004 requires the Member States to refrain from giving committee members and experts any instruction which is incompatible with their own individual tasks or with the tasks and responsibilities of the EMA cannot dispel the legitimate doubts set out in the previous paragraph.

41 Therefore, without it being necessary to examine the appellants' line of argument relating to the requirement of subjective impartiality, it follows from the foregoing that the General Court erred in law by holding, in paragraph 104 of the judgment under appeal, that the Committee had ensured the existence of sufficient guarantees to exclude any legitimate doubt as to compliance with the obligation of impartiality enshrined in Article 41 of the Charter.

42 The second limb of the first ground of appeal must therefore be upheld.

43 In those circumstances, the Court sets aside the judgment under appeal without it being necessary to examine the other grounds of appeal.

The action before the General Court

44 In accordance with the first paragraph of Article 61 of the Statute of the Court of Justice of the European Union, if the appeal is well founded, the Court is to quash the decision of the General Court. It may then itself give final judgment in the matter, where the state of the proceedings so permits.

45 In the present case, the Court has the necessary information to give final judgment on the action for annulment of the decision at issue brought by the appellants before the General Court.

46 In the third limb of the first plea in law at first instance, the appellants criticised the Commission inter alia for having disregarded the principle of a diligent and impartial examination enshrined in Article 41 of the Charter. It follows from the grounds set out in paragraphs 24 to 41 above that such criticism is well founded.

47 The third limb of the appellants' first plea in law in the action before the General Court must therefore be upheld and the contested decision annulled to the following extent.

48 Although the appellants have asked the Court to set aside the decision at issue not only in so far as it concerns them, but also in so far as its concerns the other marketing authorisation holders listed in Annex I thereto, they have not established, or even alleged, that they have standing to bring the action on behalf of the other marketing authorisation holders. Accordingly, the annulment must be limited to the marketing authorisations held by the appellants.

49 The Court therefore annuls the decision at issue in so far as that decision directs the Member States to comply with the requirements which it stipulated for the medicinal products, for which the appellants hold the marketing authorisation, with 0.01% estradiol by weight for topical use referenced and non-referenced in Annex I thereto, excluding the restriction that the medicinal products with 0.01% estradiol by weight for topical use referenced in that annex may still be used by vaginal application only.

Costs

50 Under Article 184(2) of the Rules of Procedure of the Court of Justice, where the appeal is unfounded or where the appeal is well founded and the Court itself gives final judgment in the case, the Court is to make a decision as to costs.

51 Under Article 138(1) of those rules, applicable to appeal proceedings by virtue of Article 184(1) thereof, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings.

52 Since the Commission has been unsuccessful in the appeal, the contested decision has been annulled and the appellants have applied for the Commission to be ordered to pay the costs, the Commission must be ordered to pay, in addition to its own costs, the costs incurred by the appellants, relating both to the proceedings at first instance and on appeal.

53 As far as concerns the costs of the proceedings for interim measures, since the appellants have been unsuccessful in those proceedings before the General Court, the appellants must be ordered to pay their own costs in those proceedings.

On those grounds, the Court (Fourth Chamber) hereby:

1. **Sets aside the judgment of the General Court of the European Union of 20 October 2016, *August Wolff and Remedia* v *Commission* (T-672/14, not published, EU:T:2016:623).**

2. **Annuls Commission Implementing Decision C(2014) 6030 final of 19 August 2014 concerning the marketing authorisations for high concentration of estradiol containing human medicinal products for topical use in the framework of Article 31 of Directive 2001/83/EC of the European Parliament and of the Council in so far as that decision directs the Member States to comply with the requirements which it stipulated for the medicinal products, for which Dr. August Wolff GmbH & Co. KG Arzneimittel and Remedia d.o.o. hold marketing authorisation, with 0.01% estradiol by weight for topical use referenced and non-referenced in Annex I thereto, excluding the restriction that the medicinal products with 0.01% estradiol by weight for topical use referenced in that annex may still be used by vaginal application only.**

3. **Orders the European Commission to pay the costs of the proceedings at first instance and on appeal, with the exception of the proceedings for interim measures, which are to be borne by Dr. August Wolff GmbH & Co. KG Arzneimittel and Remedia d.o.o.**

[Signatures]