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## Protection of Regulatory Data Relating to Medicinal Products for Human Use – Renewed Marketing Authorisations, Subsequent GMAs and Efficient Legal Protection

Since the marketing authorisation of a generic applicant depends on the completion of the reference medicinal products' data protection term, its starting point is crucial for a generic application. Whereas the starting points are certain in cases in which reference medicinal products were authorised in the decentralised procedure after full harmonisation, legal uncertainty arises in cases of preceding conditional and renewed fictitious marketing authorisations. The article addresses the capability of a non *aquis*-conform, conditional and renewed fictitious marketing authorisation to trigger the Regulatory Data

Protection Term of a reference medicinal product. This is accompanied by the question whether renewed marketing authorisations and subsequent *aquis*-conform marketing authorisations granted for the same medicinal product are captured by one global marketing authorisation. National courts confronted with these cases have specific obligations in proceedings brought before them by marketing authorisation holders of reference medicinal products, especially where legal remedies do not automatically suspend the generic marketing authorisations.

### I. Introduction

Data submitted for the initial marketing authorisation of a reference medicinal product in the EU is protected from referrals by generic competitors (regulatory data protection) for a general period of eight years. According to Art. 10(1) of Directive 2001/83/EC,<sup>1</sup> generic applicants may not be granted a marketing authorisation ("MA") in the decentralised procedure before completion of the regulatory data protection term.

In principle, the initial MA of a reference medicinal product triggers the protection term and pursuant to Art. 6(2) of Directive 2001/83/EC, subsequent MAs granted for any additional strengths, pharmaceutical forms, administration routes, presentations, as well as any variations and extensions are captured by the same global marketing authorisation ("GMA") as the initial MA and do not prolong the protection term.

Although the starting time of the protection term is easy to ascertain in most cases, a closer assessment is required where the medicinal product was authorised under a non *aquis*-conform, conditional and renewed fictitious MA ("Nachzulassung") under the German Medicinal Products Act during the transitional period of the harmonisation process in the EU.

To accelerate the delayed renewal process in Germany, the competent national authority, the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM) was authorised to grant MAs (renew fictitious MAs), which did not fulfil the EU data requirements, under the condition that the deficits are eliminated within a reasonable deadline.

However, these deficits may constitute ground for denial in the mutual recognition procedure under Art. 28 of Directive 2001/83/EC.

Under these circumstances, the holder of the renewed MA may subsequently apply for a new national MA (decentralised procedure) for the same medicinal product under submission of new data and according to German law, renounce his rights deriving from the renewed MA, thereby rendering the conditional, non *aquis*-conform MA void.

One has to wonder whether a conditional non *aquis*-conform renewed MA, which allowed the marketing authorisation holder ("MAH") to place a medicinal product on a national market until the authorisation was rendered

void, would have triggered the protection term. Which leads to the follow-up question, whether such renewed MAs – regardless of their in-/eligibility for Regulatory Data Protection (RDP) – and subsequent *aquis*-conform MAs granted for the same medicinal product were captured by one global marketing authorisation according to the Directive 2001/83/EC.

### II. Eligibility of a Conditional and Renewed Fictitious MA for RDP

According to Art. 10(1) of Directive 2001/83/EC and corresponding Sec. 24b(1) sent. 1 German Medicinal Products Act (AMG), RDP is granted to reference medicinal products which have been "authorised under Art. 6 for not less than eight years in a Member State or in the Community."

And for the purposes of Art. 10(1) of Directive 2001/83/EC "reference medicinal product" shall mean a medicinal product authorised under Art. 6, in accordance with the provisions of Art. 8".<sup>2</sup>

Therefore, for a medicinal product to be a reference medicinal product enjoying RDP it has to be authorised in compliance with Arts. 6 and 8 of Directive 2001/83/EC. Since fictitious marketing authorisations (MAs), which were granted until effectively renewed (transitional period) according to the Directive 2001/83/EC or 65/65/EEC,<sup>3</sup> may not be considered compliant with the Directives,<sup>4</sup> the assessment will focus on the eligibility of a renewed marketing authorisation ("Nachzulassung") for RDP under the Directives.

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<sup>1</sup> 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 L 311, 28.11.2001, p. 67-128.

<sup>2</sup> Art. 10(2)(a) of Directive 2001/83/EC.

<sup>3</sup> Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products, OJ 22, 9.2.1965, p. 369-373.

<sup>4</sup> Judgment of the CJEU of 18 June 2009, Case C-527/07 – *Generics (UK) Ltd v. Licensing Authority*; decision of the OVG NRW, 26 June 2008, 13 B 345/08, with annotations *Sträter*, PharmR 2008, 498.

Arts. 10 and 6 of Directive 2001/83/EC and the transposing German law (Sec. 24b AMG), which is to be interpreted according to the Directive and its *effet utile*, do not provide an explicit answer as to whether renewed fictitious MAs granted under conditions in an accelerated procedure such as Sec. 105(5 a) AMG enjoy RDP. Furthermore, due to a lack of indications in the wording of Arts. 10 and 6 of Directive 2001/83/EC and Sec. 24b AMG, the question has to be answered with reference to the object and purpose of RDP, the Directive's *effet utile* and the case-law of the CJEU in consideration of the transitional circumstances of the "Nachzulassung".

### 1. Object and Purpose of RDP

RDP "shelters research and development investments carried out by pharmaceutical companies",<sup>5</sup> by protecting the data of the reference medicinal product from referrals by generic competitors pursuant to Art. 10(1) of Directive 2001/83/EC. Thereby, pharmaceutical companies are given an incentive to place medicinal products on the European internal market in the regulatory expectation of additional investments into the research and development of medicinal products in the EU.

RDP granted to medicinal products authorised in the decentralised procedure is a result of thorough legislative evaluation. Ultimately, it is a compensation for the investments necessary to develop the medicinal products and in part for the investments necessary to provide the required data.

According to Art. 10(1) of Directive 2001/83/EC, merely MAHs who provide the necessary data shall be compensated by RDP.

It is up to the discretion of the legislator to strike the balance between investment protection and the public interest in preventing "repetitive tests on humans or animals"<sup>6</sup> and facilitating generic medicinal products – and indeed, the European legislator has balanced these interests in Art. 10(1) of Directive 2001/83/EC.<sup>7</sup>

Again, the object and purpose of the renewal procedure (Nachzulassung) have to correspond with this legislative choice.

### 2. Object and Purpose of the Renewal Procedure and the *Effet Utile* of Directive 2001/83/EC (Directive 65/65/EEC)

The object and purpose of the renewal procedure may be best described by the following recitals of Directive 2001/83/EC, which replaced Directive 65/65/EEC:

„(4) Trade in medicinal products within the Community is hindered by disparities between certain national provisions, in particular between provisions relating to medicinal products ... and such disparities directly affect the functioning of the internal market.

(5) Such hindrances must accordingly be removed; whereas this entails approximation of the relevant provisions.

(8) Standards and protocols for the performance of tests and trials on medicinal products are an effective means of control of these products and hence of protecting public health and can facilitate the movement of these products by laying down uniform rules applicable to tests and trials, the compilation of dossiers and the examination of applications.“

Due to the duty of cooperation and to achieve this approximation, the Member States were obliged (currently

under Art. 4(3) TEU) to transpose the Directives into national law and renew/re-registrate medicinal products placed on the respective national markets before the end of the transposition period of Directive 65/65/EEC.<sup>8</sup>

Renewed MAs of medicinal products shall, as a matter of principle, comply fully with the Directive's requirements. Advocate General *Ján Mazák* encapsulated the degree of necessary compliance to be achieved by the initial MA in his opinion in *Generics UK*:

“At the same time, it is clear that these articles [6(1), 8, 10(1) and 10(2)(a) of the Directive 2001/83/EC] cannot be interpreted in a manner which allows for a continuing form of authorisation of a reference medicinal product other than one which complies with Art. 6 and satisfies the requirements of Art. 8, not least that the full dossier of particulars and documents be provided.”<sup>9</sup>

Therefore, the option to renew a fictitious MA under conditions may not be introduced to undermine the approximation in the EU and the data requirements of Directive 2001/83/EC, unless, as Advocate General *Ján Mazák* pointed out, explicitly allowed for by binding Community law:

“Furthermore, neither the provisions at issue, the directive as a whole nor any other Community provision contain an exception which would justify following the procedure in Art. 6(1) otherwise than in full or would allow for alternative procedures, for instance in accordance with other Community provisions or with national law.”

Rewarding market authorisation holders with RDP in cases where the MA evidently does not fully comply with the Directive would run counter to the practical effect of Community law, by creating countervailing incentives regarding the compliance and enforcement of these requirements.

Accordingly, Germany authorised the BfArM (competent authority in Germany) to renew MAs under binding conditions in compliance with Sec. 105(5 a) AMG merely to accelerate the delayed renewal process in Germany and not to undermine Community standards.<sup>10</sup>

Besides, binding Directives take precedence over national provisions such as Sec.105(5 a) AMG, which allow for an accelerated authorisation under conditions, therefore, the national provision must be interpreted in accordance with the Directive.

### 3. Free Movement of Goods, Art. 34 TFEU

The level of necessary compliance is directly linked with Art. 34 TFEU, the free movement of goods and Art. 28 of Directive 2001/83/EC. As recital 4 and 5 of Directive 2001/83/EC state:

“Trade in medicinal products within the Community is hindered by disparities between certain national provisions, in particular between provisions relating to medicinal products (excluding substances or combinations

<sup>5</sup> Koenig/Ghazarian, *Stoffrecht* 2013, 173.

<sup>6</sup> Recital 10 of Directive 2001/83/EC.

<sup>7</sup> Koenig/Ghazarian, *Stoffrecht* 2013, 173.

<sup>8</sup> 15 years according to Art. 39(2) of the Second Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products, OJ L 147, 9.6.1975, p. 13-22.

<sup>9</sup> Opinion of Advocate General *Mazák* delivered on 26 March 2009, Case C-527/07, para. 28 – *Generics (UK) Ltd v. The Licensing Authority*.

<sup>10</sup> *Gaurich*, *Auswirkungen der 10. AMG-Novelle auf die Nachzulassung*, *PharmR* 2001, 170.



of substances which are foods, animal feeding-stuffs or toilet preparations), and such disparities directly affect the functioning of the internal market.

(5) Such hindrances must accordingly be removed; whereas this entails approximation of the relevant provisions.”

First, merely medicinal products that fulfil the harmonised requirements in safety and efficacy, as officially testified by the competent national authority in the MA, shall enter the market. Second, due to the compatibility testified by the aforementioned MA, other Member States may rely on the safety and efficacy and therefore, have no justification to deny the market entry of the medicinal product, hence, the free movement of goods is ensured.

A conditional renewed fictitious MA (Nachzulassung) does, due to the lack of accordance with the Directive,<sup>11</sup> not qualify for mutual recognition in another Member State under Art. 28 of Directive 2001/83/EC until the necessary data is submitted; which is comprehensive because a medicinal product is either in accordance with the Directive or it is not *aquis-conform*.

#### 4. Judgment of the CJEU in *Generics UK (C-527/07 – Nivalin)*

This line of interpretation is also supported by the case-law of the CJEU.<sup>12</sup> In *Generics UK*, the CJEU held that a medicinal product “which falls outside the scope of Regulation No. 726/2004, and the placing of which on the market in a Member State was not authorised in accordance with the applicable Community law, cannot be considered to be a reference medicinal product within the meaning of Art. 10(2)(a) of Directive 2001/83.”<sup>13</sup>

Even though the case differs in so far as the reference medicinal product was not at any time – not even under conditions (“Auflagen”) – authorised according to community standards (Directive 65/65/EEC or 2001/83/EC), nevertheless, the rationale is applicable to renewed MAs.

Abridged generic authorisation procedures allow for an exemption from the essential and costly regular data requirements of Art. 8 of Directive 2001/83/EC, which primarily safeguard the public health – i.e. the priority objective of Directive 2001/83/EC<sup>14</sup> – only by virtue of the specific regulatory safeguards to which the reference medicinal product mechanism is subjected under the Directive, ensuring the safety and efficacy of generic medicinal products.<sup>15</sup>

This relief is merely justifiable by the similarity of a generic medicinal product to the reference medicinal product, which, as proven by the submitted data, fulfils the community standards, thereby, securing the safety and efficacy of the medicinal product whilst preventing additional and – because the safety and efficacy is ensured – unnecessary “repetitive tests on humans or animals”.<sup>16</sup>

“... [T]he obligation on applicants seeking marketing authorisation for a medicinal product, to attach to the application the results of toxicological and pharmacological tests, and clinical trials, referred to in Art. 8(3) (i) of Directive 2001/83, is to provide proof of the safety and efficacy of a medicinal product ....

It should also be borne in mind that the abridged procedure established by Art. 10 of that directive – which relieves applicants seeking marketing authorisation for a generic of a reference medicinal product already authorised in accordance with that directive from having to provide the results of the aforementioned tests and trials – has, *inter alia*, as its objective,

as is apparent from recital 10 in the preamble to Directive 2001/83, to avoid the repetition of tests on humans or animals where not absolutely necessary ...”<sup>17</sup>

Otherwise, neither the reference medicinal product nor the generic product will meet the data requirements of Directive 2001/83/EC.

One might argue against the applicability of *Generics UK*<sup>18</sup> and the above line of argument, pointing out that RDP is not a matter of safeguarding public health but of investment protection, proposing a “divided interpretation” of Art. 10(1) of Directive 2001/83/EC.

However, neither the wording nor the regulatory context and coherency support this line of interpretation.

The regulatory purpose – which pervades the entire course of reasoning under the first and second question – was to harmonise the standards of medicinal products in the EU, thereby, removing obstacles for the free movement of medicinal products.<sup>19</sup> To achieve the approximation on a relatively high standard, applicants shall provide the required data according to Art. 8 of Directive 2001/83/EC. And as a compensation for the investments necessary to generate the data, MAHs are granted RDP and market exclusivity – due to the mutual recognition procedure – for the complete European internal market. This balanced system is conditional upon MAs being granted in accordance with the Directive. Any other approach leads to imbalance at some point, either in regard to safety and efficacy, prevention of unnecessary testing or investment protection.

In addition, it has to be borne in mind that the renewal and reregistration of fictitious MAs (Nachzulassung) was an exceptional and transitional process. MAs were issued under conditions to accelerate the process, thus, did not fulfil the requirements of the Directive, hence the conditions. Generic applicants may not rely on the data submitted for these MAs and these MAs do not qualify for mutual recognition under Art. 28 of Directive 2001/83/EC. Where national authorities and applicants tried to renew a fictitious MAs in accordance with Directive 2001/83/EC and failed because the data was insufficient, the authorisation procedure is to be considered failed and the MA not to be in accordance with Arts. 6 and 8 of the Directive 2001/83/EC. One undertaking might benefit more than the other from such a clear-cut approach, which, indeed, is a common side-effect of transitional regulation.

### III. Scope of GMA

Nevertheless, one might consider a conditional renewed fictitious MA – which was later declared void – and a

<sup>11</sup> Art. 28 para. 1 states: “1. With a view to the granting of a marketing authorisation for a medicinal product in more than one Member State, an applicant shall submit an application based on an identical dossier in these Member States. The dossier shall contain the information and documents referred to in Arts. 8, 10, 10a, 10b, 10c and 11. The documents submitted shall include a list of Member States concerned by the application”.

<sup>12</sup> Judgment of the CJEU of 18 June 2009, Case C-527/07 – *Generics (UK) Ltd v. Licensing Authority*.

<sup>13</sup> Judgment of the CJEU of 18 June 2009, Case C-527/07, para. 37 – *Generics (UK) Ltd v. Licensing Authority*.

<sup>14</sup> Recital 2 of Directive 2001/83/EC.

<sup>15</sup> Judgment of the Administrative Court Cologne of 30 October 2012, 7 K 2148/10, para. 58; Recital 10 of Directive 2001/83/EC.

<sup>16</sup> Preventing repetitive tests on humans or animals without over-riding cause is an aim of Directive 2001/83/EC as stated in Recital 10.

<sup>17</sup> Judgment of the CJEU of 18 June 2009, Case C-527/07, para. 30 – *Generics (UK) Ltd v. Licensing Authority*.

<sup>18</sup> Judgment of the CJEU of 18 June 2009, Case C-527/07 – *Generics (UK) Ltd v. Licensing Authority*.

<sup>19</sup> Recital 14 of Directive 2001/83/EC.

subsequent MA of the same medicinal product to be captured by the same GMA according to Art. 6(2) of Directive 2001/83/EC and, thereby, deny the new data of the subsequent MA a full protection term.

The concept of GMA subsumes various authorised developments of one medicinal product under one and the same GMA<sup>20</sup> and was implemented into the EU regulatory framework of RDP in 2004 under Art. 6(2) of Directive 2001/83/EC.<sup>21</sup>

In Germany, the concept of GMA has been implemented in Sec. 25(9) AMG for medicinal products authorised after 6 September 2005 (Sec. 141(9) AMG).<sup>22</sup>

Sec. 25(9) sent. 3 AMG is a transposition of Art. 6(2) of Directive 2001/83/EC, therefore, has to be interpreted closely in light of Art. 6(2) of Directive 2001/83/EC to ensure that amongst several possible interpretations the one will prevail which best guarantees the practical effect of existing Community law.

### 1. Directive 2001/83/EC

To determine the scope of the GMA pursuant to Directive 2001/83/EC, the concept has to be construed according to the object and purpose of RDP while likewise balancing between the conflicting interests, i.e. investment protection and public interests.<sup>23</sup>

The legal foundation of the GMA is Art. 6(2) sent. 2 of Directive 2001/83/EC:

“When a medicinal product has been granted an initial marketing authorisation in accordance with the first subparagraph, any additional strengths, pharmaceutical forms, administration routes, presentations, as well as any variations and extensions shall also be granted an authorisation in accordance with the first subparagraph or be included in the initial marketing authorisation. All these marketing authorisations shall be considered as belonging to the same global marketing authorisation, in particular for the purpose of the application of Art. 10(1).”

Pursuant to the wording of Art. 6(2) sent. 2 of Directive 2001/83/EC, the following constituent elements of a GMA may be deduced:

First, the initial MA must have been granted in accordance with Art. 6(1) (and therefore Art. 8(1)) of Directive 2001/83/EC. Second, one or more variations and/or extensions of the medicinal product have been authorised either by a new MA or inclusion in the initial MA.

Also the object and purpose of the GMA do not indicate a broader interpretation of “accordance with the directive”.

The GMA was implemented into the regulatory framework to prevent the undue prolonging of RDP. In absence of a GMA, the initial MAH may prolong the protection term by applying for new MAs for variations and extensions of the medicinal product at staggered intervals.

Hence, for the object and purpose of the GMA to apply, the MA must have been granted in accordance with EU law and enjoy RDP in the first place, otherwise, there is no risk of prolongation and the purpose of GMA not concerned.

### 2. Prolonged Data Protection Term

One might state to the contrary that a MAH, who placed a medicinal product on the market authorised by a renewed non *aquis*-conform MA, has *de facto* been able to

recoup (partly) his investments until the MA was rendered void.

The protection periods of 8 (data protection) and 10 years (market exclusivity) under Art. 10(1) of Directive 2001/83 are the result of a balancing act between sufficient investment protection and incentive on the one hand and public interests on the other. Data protection and market exclusivity according to Art. 10(1) of Directive 2001/83 protect the investments of MAHs and create an incentive for further investments into the research and development of medicinal products.

If a MA is rendered or declared completely void before the end of the general protection term, it ceases to exist or to authorise the MAH either *ex tunc* or *ex nunc*. In those cases, the MAH is not authorised and allowed placement of the medicinal product during the full protection term and therefore unable to recoup the initial investments to the extent intended by the Directive.

If the protection term started with a MA, which is subsequently rendered or declared completely void, the MAH would neither be able to realise the value of his property (the data) nor regularly be able to generate additional data and to apply for a new MA in time to enjoy the rest of the protection term.

One might reject these concerns as mere arguments of fairness.

Nevertheless, one purpose of RDP is exactly to guarantee (a full) protection term and a regulatory framework investors may rely on before their investment decision, thereby providing a comprehensive regulatory system.

As already stated above, one undertaking might benefit more than the other, which, indeed, is a common side-effect of transitional periods such as the “Nachzulassung”.

Several medicinal products were placed on the market merely authorised under fictitious MAs and generated profits, while the renewal process took years in many Member States. That does not justify “infecting” the harmonised authorisation system, *inter alia*, the registers, by allowing MAs not compliant with the Directive 2001/83/EC to be captured by a GMA and, thereby, allowing (pre-) clinical data (possibly below Directive 2001/83/EC standards) to be indirectly referred to by generic competitors, who must merely prove the bioequivalence to the originator product.

### IV. Practical Effect of Regulatory Data Protection ensured by Effective Legal Protection

To ensure the practical effect (*effet utile*) of Art. 10(1) of Directive 2001/83/EC<sup>24</sup> in the decentralised procedure, the innovator also has to be able to rely on comprehensive legal protection before national courts.

Considering the procedural autonomy of the Member States, the following shall give an overview of the extent to which the Member State courts are required to provide efficient legal remedies in national court proceedings for MAHs enjoying regulatory data protection against referrals by generic applicants.

<sup>20</sup> Koenig/Ghazarian, Stoffrecht 2013, 173.

<sup>21</sup> Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004, OJ L 136, 30.4.2004, p. 34.

<sup>22</sup> In accordance with Directive 2004/27/EC.

<sup>23</sup> Koenig/Ghazarian, Stoffrecht 2013, 173.

<sup>24</sup> See note 2.



## 1. Balance Between Procedural Autonomy and *Effet Utile*

“It is the Court’s settled case-law that, in the absence of European Union rules governing the matter, it is for the domestic legal system of each Member State, in accordance with the principle of the procedural autonomy of the Member States, to designate the courts and tribunals having jurisdiction and to lay down the detailed procedural rules governing actions for safeguarding rights which individuals derive from European Union law, the Member States having none the less responsibility for ensuring that those rights are effectively protected in each case.”<sup>25</sup>

In addition, Art. 47 of the Charter of Fundamental Rights of the EU, which has the same value as the primary law according to Art. 6(1) TEU and which the Member States are bound by, requires the EU and the Member States to provide individuals with efficient legal remedies *ratione personae, materiae et temporis*.

It follows from the foregoing that the Member States enjoy procedural autonomy up to the threshold of effective (*effet utile*) enforcement of individual rights deriving from European Union law such as Directive 2001/83/EC.

### a) Art. 10(1) of Directive 2001/83/EC provides Individual Rights

RDP is introduced into the regulatory framework to protect the (intellectual) property value of the (pre-) clinical data required for the initial MA.<sup>26</sup> It is a common European constitutional principle – and also pursuant Art. 17 of the Charter of Fundamental Rights of the EU – that the material and precise definition of the ambit of constitutional property rights under primary law is submitted to secondary law, i.e. Art. 10(1) of Directive 2001/83/EC.<sup>27</sup>

“Art. 17, Right to Property

1. Everyone has the right to own, use, dispose of and bequeath his or her lawfully acquired possessions. No one may be deprived of his or her possessions, except in the public interest and in the cases and under the conditions provided for by law, subject to fair compensation being paid in good time for their loss. The use of property may be regulated by law in so far as is necessary for the general interest.

2. Intellectual property shall be protected.”

Through RDP, pharmaceutical companies are given a further incentive to invest into the development of medicinal products and their placement on the European internal market by protecting an innovator’s data from referrals by generic competitors.

Indeed, it is already implied in the *effet utile* of the incentive provided for by RDP under Art. 10(1) of Directive 2001/83/EC that RDP grants individual protection to the reference MAH (i.e. the property holder).

Without the individual right of the MAH to invoke the administrative and judicial enforcement, the intended RDP would be rendered vastly ineffective.

### b) Requirements for “effective Protection” by Member States

Since RDP is granted in regard to third parties, i.e. generic competitors applying for the abridged procedure of Art. 10(1) of Directive 2001/83/EC, the legal protection of the individual rights must extend to the following:

First, the MAH may seek the enforcement of RDP by the competent authority in every Member State where a ge-

neric competitor has applied for a MA under Art. 10(1) of Directive 2001/83/EC, corresponding with pursuant rights in administrative and judicial proceedings.

Second, the MAH must be able to intervene in administrative and judicial proceedings between the generic applicant and the competent authority of the Member State to prevent the issuance of a MA under Art. 10(1) of Directive 2001/83/EC. Therefore, national (procedural) laws of the Member States are required to provide for an *effective judicial locus standi* of MAHs as third parties in proceedings between the generic applicant and the authority.

Third, interim measures must be permitted and ordered if necessary, to ensure the effective enforcement of the RDP,<sup>28</sup> corresponding with pursuant rights in administrative and judicial proceedings.

Fourth, the *effet utile* of RDP requires a suspensory effect invoked upon legal remedies before national courts in order to defend individual RDP rights of MAHs provided for under Directive 2001/83/EC, if measures issued by the competent authority of the respective Member State risk to violate such individual RDP rights without a suspensory effect provided for by national (procedural) law against the measures under judicial review.<sup>29</sup>

## V. Conclusion

As compensation, inter alia, for the investments necessary to generate the required data, MAHs are granted RDP and market exclusivity – due to the mutual recognition procedure – for the complete European internal market. To achieve the approximation in the EU and, therefore, ensure the free movement of goods, this balanced system is conditional upon MAs being granted in accordance with the Directive.

Therefore, evidently non *aquis*-conform conditional MAs – which do not qualify for mutual recognition in other EU Member States and were rendered/declared void before completion of the full protection term – do not enjoy RDP and may not trigger the regulatory data protection term.

Such a conditional renewed MA, which obviously did not fulfil the requirements at any point, and a subsequent *aquis*-conform MA of the same medicinal product are not captured by one GMA.

Regulatory data protection and market exclusivity are granted for a certain period of time. Every issuance of a generic MA or placement of a medicinal product on the internal market before completion of the RDP term devalues the property of the reference MAH permanently.

Unlawful referrals and medicinal product placements (not resolved for years of litigation) may be prevented by interim measures or the order of a suspensory effect, in case

<sup>25</sup> Judgment of the CJEU of 27 June 2013, Case C-93/12, para. 35 – *ET Agroconsulting-04-Velko Stoyanov v. Izpalnitelen direktor na Darzhaven fond ‘Zemedelie’ – Razplashatelna agentsia*.

<sup>26</sup> Judgment of the Administrative Court Cologne of 30 October 2012, 7 K 2148/10, para. 31.

<sup>27</sup> E.g. Art. 14(1) sent. 2 of the German Federal Constitution (“Inhaltsbestimmung des Eigentums durch einfaches Gesetz”).

<sup>28</sup> Judgment of the CJEU of 13 March 2007, C-432/05, para. 67 – *Unibet*.

<sup>29</sup> Art. 278 TFEU (no automatic suspensory effect) does merely apply to legal remedies before the Court of Justice of the European Union to ensure the uniform application of European Union law in all Member States. To the contrary, in order to safeguard rights, which individuals derive from European Union law, a suspensory effect of legal actions before national courts, in order to defend such rights (against national measures), may further the uniform application of the respective (primary or secondary) Union law providing for these individual rights.

legal remedies do not automatically suspend the generic MA.<sup>30</sup>

Otherwise, the initial MAH would neither be able to prevent the issuance of a generic MA in breach of the RDP nor prevent placement of the generic medicinal product on the market. Depriving a MAH, whose submitted data enjoys RDP, from effective judicial review would infringe on the

right to an effective remedy according to Art. 47 of the Charter of Fundamental Rights of the EU.

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<sup>30</sup> Sec. 80(1) of the German Code of Administrative Procedure (Verwaltungsgerichtsordnung, VwGO) states that legal actions seeking the annulment of an administrative act ("Anfechtungsklage"), have an automatic suspensory effect.