

## PHARMACEUTICAL INFORMATION: DOES THE DIRECTIVE 2001/83/EC PROTECT SUCH A RIGHT FOR THE END-USER?

Andrea Faeh\*

### Introduction

Information is an important asset for the consumer to decide whether to buy, rent, use or consume a specific good. This is certainly true for consumers of pharmaceuticals, as they want to know the characteristics of the medicinal products they purchase and use in order to exercise their right to self-determination. Patients consuming prescription-only pharmaceuticals do not actually decide on which product they should use to improve their medical condition. The prescribing doctor is the main decision maker and has the duty to inform the patient about the prescribed or administered medicine. If the doctor does not adequately inform the patient or withholds factual or technical information, despite knowing the decisive facts on the use of that product, the doctor can be held legally responsible for the possible consequences stemming from not disclosing such information.<sup>1</sup> Then again, a different situation arises when the doctor does not obtain the decisive information or could not possibly be aware of the side effects emerging from the use of the product.

The Directive on the Community code relating to medicinal products for human use (Directive 2001/83/EC)<sup>2</sup> entails the rules on pharmaceutical product information. This article will scrutinise the level of legal protection granted to the end-users of pharmaceutical products, in situations of which the producer or the competent authority of a Member State violates the applicable rules. The main goal of the article shall be a systematic analysis of the legal effect that a Directive has and should have on the consumer's right to information. In this respect the focus will be directed on the conditions needed for the correct implementation of the provisions within national law and the consequences thereof if the implementations were to fail. Attention will also be given to the provision that might be deployed by the Directive when addressing such concerns.<sup>3</sup>

### I. Interest of the Patient on Information

In order for the patients to exercise their right to self-determination and to consent to therapy, they require sufficient information to make informed

---

\* Andrea Faeh has recently defended her Doctoral Dissertation at the School of Law, University of Fribourg (Switzerland). She is a Postdoctoral Research at the Faculty of Law, University of Copenhagen (Denmark) and conducts research in the area of European pharmaceutical legislation.

<sup>1</sup> See, for example: E. Deutsch & A. Spickhoff, *Medizinrecht: Arztrecht, Arzneimittelrecht, Medizinprodukterecht und Transfusionsrecht*, Berlin: Springer-Verlag 2008, para. 201.

<sup>2</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 311/2001, p. 67-128 as last amended by OJ L 242/2009, p. 3 (in the following referred to as "Directive 2001/83/EC" or "pharmaceutical Directive").

<sup>3</sup> This contribution reflects a condensed version of one selected problem of a more in-depth analysis of the legal position of the consumer of pharmaceuticals in the European Union that the author has carried out in her PhD Dissertation; see: F. Andrea, *Die Rechte des Verbrauchers im Arzneimittelmarkt der Europäischen Union*, Bern: Schulthess (forthcoming), the relevant literature is therefore not entirely reproduced.

decisions on the consumption of pharmaceutical products.<sup>4</sup> Ultimately patients decide whether they want to forgo the consumption of the drug regardless of their disorder or whether they should consume a drug that has the potential of having adverse effects. The concerned person can only make a decision if the necessary information is available. Availability of information is not the only criterion that must be satisfied. The information must also, in general, be useful, utilisable, in addition to being used.<sup>5</sup> In the pharmaceutical context this means, first, that the information provided must be pertinent (in a quantitative and qualitative way) and effectively facilitate the decision making process. Second, the presentation of the information must fulfil some basic quality requirements. Thirdly, the consumer must read and understand the information.<sup>6</sup> The last condition in the decision making process is left to the consumer, but can only occur when the first two conditions are met. Consequently, the product information for the end-user of pharmaceuticals has to be available, correct and complete, as well as understandable, readable and clear.

## II. Scope of the Rules on Information

The Directive 2001/83/EC regulates the information and the form in which the product has to be presented to the patient. The Member States have the discretion to change the given rules in selected and explicitly named aspects only.<sup>7</sup>

The rules on packaging and labelling (Title V) in the Directive 2001/83/EC are equally applicable to pharmaceuticals which are subject to the centralised authorisation procedure according to Regulation (EC) No 726/2004.<sup>8</sup> In this event it is not the national authority but the European Medicines Agency (EMA) which checks and validates whether the conditions for an authorisation are met in accordance to the Directive.<sup>9</sup>

### II.1 Labelling

The Directive regulates which information must be printed on the packaging (i.e. on the outer packaging or, if missing, on the immediate packaging<sup>10</sup>) in a detailed manner.<sup>11</sup> If the immediate packaging (such as a blister pack) is in an outer packaging, some selected information will equally have to be presented on the former.<sup>12</sup> In addition, the Directive regulates which information is necessary if the immediate packaging is too small.<sup>13</sup>

Besides the exact quantity of information that has to be included on the labelling, the Directive specifies that the label has to be easily legible, clearly

---

<sup>4</sup> For general information on the importance of information as a patient's right, see: H.J.J. Leenen, J.K.M. Gevers & G. Pinet, *The Rights of Patients in Europe: A Comparative Study*, Deventer: Kluwer Law and Taxation 1993, pp. 31 *et seq.*

<sup>5</sup> See: S. Vigneron-Maggio-Aprile, 'L'information des consommateurs en droit européen et en droit suisse de la consommation', Geneva: Schulthess 2006, p. 449: "l'information doit répondre à trois critères: elle doit être utile, utilisable et utilisée".

<sup>6</sup> For general information on the requirements of information for the consumer, see *idem*, p. 449.

<sup>7</sup> The Member States can for example legislate that additional information has to be given on the labelling, such as the price, reimbursement conditions, etc.

<sup>8</sup> Art. 9 para. 1 lit. c and Art. 9 para. 4 lit. d Regulation (EC) No 726/2004.

<sup>9</sup> In this contribution the effect of a centrally authorised medicinal product (according to Reg. (EC) No 726/2004) shall not be assessed.

<sup>10</sup> This is the part of the packaging that comes in contact with the pharmaceutical itself, see definition in Art. 1 lit. 23 Directive 2001/83/EC.

<sup>11</sup> Art. 54 lit. a-n Directive 2001/83/EC.

<sup>12</sup> Art. 55 para. 2 Directive 2001/83/EC.

<sup>13</sup> Art. 55 Abs. 3 Directive 2001/83/EC.

comprehensible and indelible.<sup>14</sup> The name of the pharmaceutical has to be added on the packaging in Braille format.<sup>15</sup> Lastly, the particulars on the labelling have to be given in the official language(s) of the Member State, that is, where the product is being placed on the market. If more than one language is used on the labelling the information must be identical in each language.<sup>16</sup>

## II.2 Package Leaflet

All packaging containing a pharmaceutical must include a package leaflet that covers all of the particulars enlisted in Article 59 of the Directive 2001/83/EC, in addition to having a summary listing the characteristics of the product. An additional package leaflet is not necessary if all required information is entailed on the outer or immediate packaging.<sup>17</sup>

In order for the end-user to understand and act accordingly, possibly with the support of a health professional, the package leaflet has to be clear, legible and written in the official language(s) of the Member State in which it is being marketed.<sup>18</sup>

## II.3 Joint Rules

The applicant has to provide models of the outer packaging, the immediate packaging and a draft of the package leaflet, as well as the results of the assessment of patient opinions on the documents (under Article 59 para. 3 Directive 2001/83/EG), when applying for a market approval of a pharmaceutical.<sup>19</sup> The market approval would be denied if the requirements on package labelling and package leaflets are not fulfilled.<sup>20</sup> Additionally, all changes made to these documents that have no connection with the product characteristics must first be approved by the competent authority.<sup>21</sup> Information on the outer packaging or in the package leaflet can be accompanied by symbols or pictograms in order to clarify certain information.<sup>22</sup> If a pharmaceutical is not directly administered to the patients, the competent authorities can grant exemptions for certain information that should normally appear on the packaging or the package leaflets.<sup>23</sup>

When the provisions under this title are not met, the competent authority can suspend the marketing authorisation, until the requirements have been satisfied. This only occurs in the case when an applicant, upon having been given notice by the competent authority, does not react accordingly.<sup>24</sup>

## III. Rights Derived from a Directive

Since the well-known *Van Gend en Loos*-Case, the protection of individual rights has been an ongoing discussion among EU scholars<sup>25</sup>. The following

---

<sup>14</sup> Art. 56 RL Directive 2001/83/EC.

<sup>15</sup> Art. 56a Directive 2001/83/EC.

<sup>16</sup> Art. 63 para. 1 Directive 2001/83/EC.

<sup>17</sup> Art. 58 Directive 2001/83/EC.

<sup>18</sup> Art. 63 para. 2 Directive 2001/83/EC.

<sup>19</sup> Art. 61 para. 1 Directive 2001/83/EC.

<sup>20</sup> Art. 61 para. 2 Directive 2001/83/EC.

<sup>21</sup> Art. 61 para. 3 Directive 2001/83/EC.

<sup>22</sup> Art. 62 Directive 2001/83/EC.

<sup>23</sup> Art. 63 para. 3 Directive 2001/83/EC.

<sup>24</sup> Art. 64 Directive 2001/83/EC.

<sup>25</sup> ECJ, Case 26/62, *Van Gend en Loos*, [1963] ECR 1.

section will not discuss why and on which grounds the provisions from the primary legislation might directly be applicable on individuals. Instead, the subject of this contribution shall focus on the secondary legislation, in particular Directives, which might have an effect on individuals, so as to scrutinise the consequences this entails for the consumer of pharmaceutical products and their interest in having access to information on the product.

### III.1 Characteristics of a Directive

Individuals can directly rely on the provisions stipulated in the primary legislation, if the provisions are unconditional and sufficiently precise.<sup>26</sup> This is equally possible for the provisions in a Regulation, granted that the provisions meet the two named requirements (direct effect), as specified in Article 288 para. 2 of the Treaty on the Functioning of the European Union (TFEU). Hence, the provisions of a Regulation have immediate effect in national law and can be the source of rights for individuals.<sup>27</sup> This, nonetheless, does not exclude some provisions from further being substantiated in the legislation at the national level.<sup>28</sup> The characteristics of a Directive are different, since a Directive requires an implementation of its rules in the national legal order (Article 288 para. 3 TFEU). Only after its implementation would the national rule be directly applied. Thus, the first issue that has to be discussed is the correct implementation into national law. Closely linked to this is the issue of whether the individual right to action has to be guaranteed in national law on the basis of the Directive. The legal consequences for the individual due to an incorrect implementation will also need to be addressed. This is the pathological case, whereby a provision of a Directive can have direct effect for individuals.

### III.2 Individual Rights through Implementation: Requirements

The European Court of Justice (ECJ) had to rule in a number of cases, especially in environmental matters, on the implementation of provisions of Directives and their requirement to create rights for individuals.<sup>29</sup> In all of these cases, the ECJ ruled that under a Directive "those concerned should be able to rely on mandatory rules in order to enforce their rights", provided that the Directive states in its recital that it, *inter alia*, aims at protecting public health.<sup>30</sup> Essentially, Directives which have a specific purpose that aims to protect individual interests have to be implemented by the Member States, so that the affected individuals can rely on the national provisions in order to have their rights protected.

An individual right to action is borne (through the implementation) upon the fulfilment of two conditions. First, the concerned Directive has to protect *individual interests*, so that a person is directly covered by the protected goal and could actually or potentially be encumbered when the danger occurs.<sup>31</sup> Such a goal is not only limited to the protection of public health, but might also cover less 'vital' interests, so as to allow the creation of a

---

<sup>26</sup> ECJ, Case 26/62, Van Gend en Loos, [1963] ECR 1.p. 25.

<sup>27</sup> ECJ, Case 106/77, Amministrazione delle finanze dello Stato vs. Simmenthal [1978] ECR 629, paras. 14/16.

<sup>28</sup> ECJ, Case 230/78, Eridania [1979] ECR 2749, para. 34.

<sup>29</sup> ECJ, Case C-131/88, Commission vs. Germany [1991] ECR I-825; ECJ, Case C-361/88, Commission vs. Germany [1991] ECR I-2567; ECJ, Case C-59/89 [1991] I-2607; ECJ Case-Commission vs. Germany [1991] I-4983; ECJ, Case C-298/95 [1996] I-6755.

<sup>30</sup> ECJ, Case C-58/89, Commission vs. Germany [1991] ECR I-4983, para. 14.

<sup>31</sup> B.W. Wegener, Rechte des Einzelnen: Interessenklage im europäischen Umweltrecht, Baden-Baden: Nomos 1998, p. 181 et seq.

right of action in national law.<sup>32</sup> Second, the provision which protects personal interests can only be relied upon in national law by a person who is *actually affected*.<sup>33</sup> Despite the protection of an individual interest provided by a Directive, the ECJ in the *Enichem Base* case denied an individual such protection, since a connection to a violation of an individual right was not established.<sup>34</sup> What is important is not the number of persons that are affected, but whether they can individually prove their concerns.<sup>35</sup>

The ECJ has given a similar reasoning in the Case *Janecek* (preliminary ruling), where a provision places a Member State under an obligation to act<sup>36</sup> in order to protect the interests of the individuals (as mentioned in the Directive's recital).<sup>37</sup> Therefore, individuals who are actually prone to a risk that the provision is aimed at anticipating must have the possibility to rely on this compulsory provision.

In conclusion, a Directive with the aim of protecting individual interests, *inter alia*, has to be implemented into national law, so that the aggrieved party can rely on the compulsory provisions set forth in the national legislation and, consequently, file an action in front of the national court.<sup>38</sup>

The pharmaceutical Directive entails in its recital No. 2 a very similar goal: "The essential aim of any rules governing the production, distribution and use of medicinal products *must be to safeguard public health*".<sup>39</sup> For this reason, similar to the different Directives covering matters in environmental law, it would follow that this reference should equally be transposed into national law, so as to ensure that individuals can rely on compulsory provisions and protect their right to information.

### III.3 Individual Rights through Direct Effect of a Directive

In due time, the Member States are obliged to implement a Directive into their national legal system and can choose the appropriate form and method when so doing. However, instances can occur, especially given the multiplicity of those enacted Directives to be implemented, that the implementation is made either incorrectly or not on time. A non-implementation or a wrongful transposition can lead to discrepancies in the application of EU law amongst Member States. In its jurisprudence, the ECJ developed a set of criteria which has led to the direct effect of certain provisions of a Directive to offset these inconsistencies, after the transition period has elapsed. The criteria are set out as follows: (a) the provision is not correctly implemented or not implemented at all; (b) the implementation period has expired, and; (c) the provision in question is unconditional and

<sup>32</sup> *Idem*, p. 186; M. Gellermann, *Natura 2000: Europäisches Habitatschutzrecht und seine Durchführung in der Bundesrepublik Deutschland*, Berlin: Blackwell 2001, p. 258; G. Winter, 'Individualrechtsschutz im deutschen Umweltrecht unter dem Einfluss des Gemeinschaftsrechts', *Neue Zeitschrift für Verwaltungsrecht* 1999-18, p. 474; A. Epiney & K. Sollberger, *Verwaltungsrechtlicher Rechtsschutz in Umweltangelegenheiten*, Bern: Stämpfli 2003, p. 155.

<sup>33</sup> Gellermann 2000, *supra* note 32, p. 262; Winter 1999, *supra* note 32, p. 474; A. Epiney, 'Primär- und Sekundärrechtsschutz im Öffentlichen Recht', *Veröffentlichungen der Vereinigung der Deutschen Staatsrechtslehrer* 2002-61, p. 405.

<sup>34</sup> ECJ, Case 308/87, *Enichem Base* [1989], 2491, paras. 22 *et seq.*

<sup>35</sup> Epiney 2002, *supra* note 33, pp. 406 *et seq.* (with examples).

<sup>36</sup> I.e. put together an action plan when there is a risk to the 'limit values' and in the case where the 'alert thresholds' have been exceeded.

<sup>37</sup> ECJ, Case C-237/07, *Janecek vs. Freistaat Bayern* [2008] ECR I-6221, para. 35.

<sup>38</sup> See for a detailed analysis of the condition for concession of individual rights in this context: Epiney 2002, *supra* note 33, pp. 396 *et seq.*

<sup>39</sup> Emphasis added by the author; this goal has been confirmed by the CFI, Cases T-74/00, T-76/00, T-83/00 to T-85/00, T-137/00 and T-141/00, *Artegoda* [2002] ECR II-4945, paras. 173 and 175.

sufficiently precise.<sup>40</sup> The problematic issue with the direct effect of Directives is the persistent denial by the ECJ for horizontal direct effect (i.e. that of a private party). Therefore, a provision in a Directive cannot, or can only be indirectly relied upon if the counterpart of the action is another private party.<sup>41</sup> The ongoing discussion on the direct effect of Directives will not be reproduced in detail here, but rather, attention will be focused on the implications that the jurisprudence of the ECJ has on the individual who is (negatively) affected by the different (unpredictable) interpretation techniques used by the Courts.<sup>42</sup>

### III.3.1 Mechanisms to bypass the horizontal direct effect

Directives can have a direct effect, if the aforementioned requirements are fulfilled and the person who relies on the provision does so, either against the state or as an emanation of the state (direct vertical effect).<sup>43</sup> The state cannot, however, rely on such a provision in itself and, consequently, create an obligation for a private individual.<sup>44</sup>

The Court developed several mechanisms within the doctrine of direct effect to achieve the objective of a uniform application of Union law, regardless of the failed transposition of the Directive and without accepting the horizontal direct effect.<sup>45</sup> The latter is primarily denied in reference to the wording of Article 288 para. 3 of the TFEU and the legal nature of the Directive, in the sense that they are directed at Member States only and can therefore only create obligations for them. Moreover, the difference between a Regulation and a Directive would vanish, if they could have a parallel effect.<sup>46</sup>

The ECJ accepts an adverse repercussion on the right of third parties (individuals) in cases where an individual relies on a provision in a Directive against the State and, through the application of the Union rule, a third party suffers negative effects in their legal position.<sup>47</sup> Even if an individual relies on a Directive in the proceedings against another private party (horizontally) the Court accepts the direct application of the provision, granted that the provision in question obliges the Member State to take action. Because the Member State fails to do so, the national rule is not applicable and negative effects on another private party can occur.<sup>48</sup> Other mechanisms established by the Court are the extension of the term

---

<sup>40</sup> ECJ, Case 8/81, *Becker* [1982] ECR 53, para. 25; see for a historical summary of the development of this doctrine: S. Prechal, *Directive in EC Law (2nd ed.)*, Oxford: Oxford University Press 2005, pp. 216 *et seq.*

<sup>41</sup> Since ECJ, Case 152/84 *Marshall vs. Southampton and South-West Hampshire Area Health Authority* [1986] ECR 723, para. 48.

<sup>42</sup> A. Ward, *Judicial Review and the Rights of Private Parties in EU Law*, Oxford: Oxford University Press 2007, p. 72.

<sup>43</sup> ECJ, Case 148/78, *Ratti* [1979] ECR 1629, para. 22; ECJ, Case 8/81, *Becker* [1982] ECR 53, paras. 22-24.

<sup>44</sup> ECJ, Case 152/84 *Marshall vs. Southampton and South-West Hampshire Area Health Authority* [1986] ECR 723, para. 48; ECJ, Case 80/86, *Kolpinghuis Nijmegen* [1987] ECR 3969, paras 9 *et seq.*; ECJ, Cases C-387/02, C-391/02 and C-403/02, *Berlusconi and others* [2005] ECR I-3624, para.74.

<sup>45</sup> These mechanisms shall only be listed, whereas a general discussion of the effect of the single mechanisms will not follow.

<sup>46</sup> See for example: ECJ, Case C- 91/92, *Faccini Dori* [1994] ECR I-3325, paras. 22 *et seq.*

<sup>47</sup> See: ECJ, Cases C-152/07 to 154/07, *Arcor and others* [2008] ECR I-5959, paras. 36 *et seq.*; ECJ, Case C-201/02, *Wells* [2004] ECR I-723, paras. 56 *et seq.*; ECJ, Case 103/88, *Fratelli Costanzo* [1989] ECR I-1839, paras. 28 *et seq.*

<sup>48</sup> ECJ, Case C-194/94, *CIA Security International SA vs. Signalson and Securitel* [1996] ECR I-2201, paras. 44 *et seq.*; ECJ, Case C-443/98, *Unilever* [2000] ECR I-7535, paras. 49 *et seq.*; also know as incidental horizontal effect, see for example: C. Hilson & T. Downes, 'Making Sense of Rights: Community Rights in EC Law', *European Law Review*, 1999-24, p. 125; ECJ, Case C-555/07, *Küçükdeveci*, not yet in the ECR, paras. 50 *et seq.*

"emanation of the state"<sup>49</sup>, that is, the interpretation of national law by national courts that goes 'as far as possible' in order to comply with goals pursued by the Directive,<sup>50</sup> as well as the possibility of state liability to recuperate a loss of a private party that is caused by the non-implementation of a Directive.<sup>51</sup>

### **III.3.2 Application of a Directive: Obligation vs. other negative effects**

The various mechanisms of the ECJ to assist in the extensive application of EU rules might provide the individual with certain insecurities about the actual effect an unimplemented provision of a Directive might have on them. This is especially problematic for the person who has to accept the negative effects, which might come as more of a surprise, leaving them with similar legal or financial consequences as would a horizontal direct effect.

This becomes apparent in the different ECJ rulings, such as the acceptance of adverse repercussions, the incidental horizontal effect, the broad term of the definition of the state and the extensive interpretation of Union rules. In all of these cases the person who has to bear the burden of the unimplemented provision of the Directive has little chance in predicting its actual application via the national or the Union courts and, thus, simply has to accept the negative effects.<sup>52</sup> For them it does not matter that the Court labels this effect as a negative repercussion, since it impinges upon them just as an obligation would.<sup>53</sup> In order to enhance the predictability and transparency of the legal rules which originate in EU law, it would, for all intensive purposes, serve the people to have the deficient national law step aside so as to allow the provisions of the Directive to take direct effectiveness until the national law complies with the EU rules. Legal certainty and the principle of the Union rules endorses the horizontal direct effect of Directives.

## **IV. Protection of Individuals' Interests and Possible Rights**

The Directive 2001/83/EC contains, as mentioned above, very detailed rules on information and does not leave the Member States much room for the actual implementation with regards to the content. The question arises whether the Directive protects the interests of the consumer to available, correct, thorough, understandable, readable and clear information, even if there is only little scope for the implementation of these provisions. Additionally, it determines the position of the consumer in the event that the implementation is sought out (in)correctly.

<sup>49</sup> ECJ, Case 152/84 Marshall vs. Southampton and South-West Hampshire Area Health Authority [1986] ECR 723, para. 51; ECJ, Case-222/84, Johnston [1986] ECR 1651, para. 56; ECJ, Case C-188/89, Foster vs. British Gas [1990] ECR I-3313, para. 20.

<sup>50</sup> ECJ, Case 14/83, von Colson and Kamann [1948] ECR 1891, para. 26; ECJ, Case C-106/89, Marleasing [1990] ECR I-4135, para. 8; ECJ, Cases C-397/01 to C-403/01, Pfeiffer and others [2004] ECR I-8835, para. 113.

<sup>51</sup> ECJ, Case C-6/90, Francovich and Bonifaci vs. Italien [1991] ECR I-5357.

<sup>52</sup> Equally critical to certain or all aspects of the denial of the horizontal direct effect, see: H. Jarass & S. Beljin, 'Grenzen der Privatbelastung durch unmittelbar wirkende Richtlinien', *Europarecht* 2004-39, pp. 728, 732; A. Dashwood, 'From Van Duyn to Mangold via Marshall: Reducing Direct Effect to Absurdity', *The Cambridge Yearbook of Legal Studies* 2006-2007-9, pp. 93, 99; W. van Gerven, 'The Horizontal Effect of Directives Provisions Revisited: The Reality of Catchwords', in: D. Curtin & T. Heukels (eds.) *Institutional Dynamics of European Integration: Essays in Honour of Henry G. Schermers*, Dordrecht: Martinus Nijhoff Publishers 1994, pp. 343 *et seq.*, 347.

<sup>53</sup> N. Reich, 'Economic Law, Consumer Interests and EU Integration', in: H.W. Micklitz, N. Reich & P. Rott (eds.), *Understanding EU Consumer Law*, Anwerpen et al.: Intersentia 2009, p. 42.

#### **IV.1 Obligation to Obtain a Permit for Pharmaceutical Information**

The very detailed provisions on pharmaceutical information lay down, *inter alia*, two specific obligations that the Member States have to fulfil. First, the market authorisation may not be denied or impeded on the ground of the package leaflet or the labelling, if the provisions in this title are complied with<sup>54</sup>. In contrast, the Member States are obliged to prohibit market approval if the product information is not in line with the summary of the product characteristics.<sup>55</sup> From these two provisions it can be deduced that the product information in the Directive form the minimum requirements. Consequently, additional information can be provided, which will not prohibit the obtainment of market authorisation. Moreover, different national rules are to be accepted, so long as they fulfil the requirements of this title.

The national competent authority examines in the procedure for granting a market authorisation, whether the applicant provides all necessary information for the product by checking the models of the outer packaging, the immediate packaging and the draft of the package leaflet.<sup>56</sup>

##### **IV.1.1 Requirements for the Implementation of the Obligation**

The duty of the competent authority to examine the compliance with the information rules is a compulsory provision<sup>57</sup>. Moreover, this duty aims at protecting the consumer's health, by requiring all product information of the respective pharmaceutical to be available and understandable to the consumer in order for them to be able to make an informed decision on whether to consume the pharmaceutical or not.<sup>58</sup> The official assessment ensures that the information provided by the applicant matches the product and the requirements of the pharmaceutical Directive. If the duty of assessing is not properly conducted, there might be an infringement on the personal, legally protected interests of the consumer and thus, have an affect on that person. Since this provision is compulsory a person who is effectively affected by the non-compliance of the provision must be able to depend on that provision in front of a national court, so as to receive adequate judicial protection. Hence, the provision must be implemented into national law in a manner to allow the affected individual to rely on the national rule so they can enforce their right if the rule is not complied with.

Should a person suffer damages due to insufficient or wrong information, the holder of the marketing authorisation can be held liable if the Directive 2001/83/EC is implemented as outlined above, since the person can directly rely upon the correctly implemented national provision.<sup>59</sup> There is no possibility for state liability if the holder of the marketing authorisation becomes insolvent, since there is no violation of any Union rules.

##### **IV.1.2 None or Insufficient Implementation of the Obligation**

It is possible for a concerned individual to directly rely on the provision of the Directive (vertical direct effect) if a Member State does not implement or assess the information, because the provision is unconditional and

---

<sup>54</sup> Art. 60 Directive 2001/83/EC.

<sup>55</sup> Art. 61 para. 2 Directive 2001/83/EC.

<sup>56</sup> Art. 61 para. 1 Directive 2001/83/EC.

<sup>57</sup> Art. 19 para. 1 Directive 2001/83/EC.

<sup>58</sup> See also: recital No 40 Directive 2001/83/EC.

<sup>59</sup> *Nota bene*: a correct implementation implicates that all information that are legally required by the Directive are available for the patient, which means that the right to information is correctly implemented and hence not violated nor can it lead to a state liability.

sufficiently precise (and the deadline for the implementation has elapsed). This would prevail regardless of Article 61 para. 4 of the Directive 2001/83/EC, which states that there is no change to the general legal liability of the producer or the marketing authorisation holder, if the competent authority does not refuse a marketing authorisation pursuant to para. 2 or 3 of the provision.

Out of the above mentioned reasons, the consumer must be able to oblige the competent authority to carry out the assessment of the information and do this in a manner consistent with the *Janecek* case<sup>60</sup>. Non-conformity with the Directive is similarly given, when the insufficient implementation of certain particulars do not form a part of the assessment. Accordingly, national law requires only the control of certain selected particulars, (some particulars do not need to be provided at all) despite the pharmaceutical Directive actually demanding for the information.

The consumer must have the possibility to directly rely on the provisions of the Directive 2001/83/EC when such deficits in the implementation occurs, in order to invoke their right to complete access to product information as stipulated in the Directive.

#### **IV.2 Violation of the Information Rules by the Producer**

In the event that an insufficient implementation leads to discrepancies between the information rules in the Directive and the applicable rules in national law the individual can be affected because of a lack of information. This would not allow the consumer to exercise their right to self-determination as they do not possess the minimum particulars that the Directive demands. The producer can provide the particulars on the packaging and the package leaflet as they are required in the pharmaceutical Directive regardless of the conflicting national law. The problematic issue with information is that the consumer, due to the lack of expert knowledge, can rarely detect whether the information is complete, missing or wrongful. Easier to spot are the apparent mistakes such as typing errors. An additional component on gathering information about a product is the perceivability, readability and the clarity of the available information.<sup>61</sup>

When a consumer obtains the missing or wrongful information from another source (e.g. physician, pharmacist), the person cannot claim that the necessary information was missing, as the essential particulars given in the Directive are known. Consequently, as the person disposes of the minimum set of information, they do not have standing to invoke their right to information.

In the following it is to be investigated which legal remedies individuals have, when they lack of important information which is missing on the package leaflet or on the packaging as a consequence of the wrongful implementation of the Directive, while at the same time they cannot obtain the information by other means (through the physician, producer etc.). In principle, the preconditions for direct effect of a Directive are met (implementation limit has expired, wrongful implementation, provision is unconditional and sufficiently precise) and the concrete situation for the individual is not to examine.

---

<sup>60</sup> ECJ, Case. C-237/07, *Janecek vs. Freistaat Bayern* [2008] ECR I-6221.

<sup>61</sup> Art. 56 and 56a Directive 2001/83/EC.

#### **IV.2.1 Action against the Member State (vertical effect)**

The consumer can invoke an action against the Member State and directly rely on the provision in the Directive that has been violated under reference to their right of complete product information and unlawful approval of the marketing authorisation due to the violation of the Directive. The Member State has to revoke the market authorisation until the lawful status (as enacted in the Directive) is re-established.

A private person (marketing authorisation holder) will suffer adverse repercussions on their own rights pursuant to such action, since no additional obligations on the private party are created through the action. The marketing authorisation holder could claim that the annulment of the market authorisation is contrary to the principle of legal certainty because the procedure for the authorisation was already terminated.<sup>62</sup> That being said, consideration should also be given to whether the consumer did not have an opportunity to intervene at an earlier stage before the authorisation procedure was actually terminated (as occurred in the *Wells* case) as the consumer does not enjoy participation rights in the authorisation procedure. In the *Fratelli Costanzo* case a competitor equally lost his award due to the reflex impact of a directly effective provision of a Directive.<sup>63</sup> When information is incomplete, wrong or missing, the consumer is exposed to considerable risks which justify the marketing authorisation to be temporary revoked so as to adequately protect the consumers at risk.

The Member State cannot directly assure that the marketing authorisation holder will publish the additional information, since the state would then transfer its own obligation (i.e. to correctly carry out the assessment of the product information) onto the producer.<sup>64</sup> The action of the concerned person is fruitless in respect to the actual lack of information about the product.

#### **IV.2.2 Action against the Producer (horizontal effect)**

Should the consumer decide to bring an action against the producer and induce their right to information, they are confronted with the problem of the denial of the horizontal direct effect of Directives.<sup>65</sup> Since an obligation to obtain a permit for the product information exists, it is not an exclusive two party action.<sup>66</sup> It can be assumed that this is a case of an incidental repercussion of a private party, as the *Unilever* case indicates.<sup>67</sup> Therefore, it can be argued that the reasoning of this case can be applied similarly. The wrongful assessment of the information is contrary to the Directive which is why the national provision cannot be applied.<sup>68</sup> In *Unilever*, a duty to notify was violated and led to the inapplicability of the national rule. The present case does not refer to a duty to notify, but a duty to inspect on the side of the Member State. The non-compliance of Article 54 *et seq.*, in conjunction with Article 61 para. 2 of the Directive 2001/83/EC, amounts to an essential procedural error which should equally lead to the non-application of the

---

<sup>62</sup> Unlike the ECJ, Case C-201/02, *Wells* [2004] ECR I-723, para. 60.

<sup>63</sup> ECJ, Case 103/88, *Fratelli Costanzo* [1989] ECR 1839, para. 32.

<sup>64</sup> ECJ, Case C-201/02, *Wells* [2004] ECR I-723, para. 56.

<sup>65</sup> Since ECJ, Case 152/84 *Marshall vs. Southampton and South-West Hampshire Area Health Authority* [1986] ECR 723, para. 48.

<sup>66</sup> ECJ, Cases C-397/01 to 401/01, *Pfeiffer and others* [2004] ECR I- 8835, para. 109.

<sup>67</sup> ECJ, Case C-443/98, *Unilever* [2000] ECR I-7535, paras. 50 *et seq.*

<sup>68</sup> Analogue line of argument in ECJ, Case C-443/98, *Unilever* [2000] ECR I-7535, paras. 30 *et seq.*

national rule.<sup>69</sup> The ECJ protects the party who acts in compliance with the provision of the Directive.<sup>70</sup> Thus, the consumer – who complies with the Directive – has to be protected and the necessary information must be provided ex-post. The defendant will certainly be opposed to this argument and claim that these other cases cannot be compared to the present case. Currently, it is difficult to predict which line of argument the ECJ would follow. The consumer might not be successful and will have to accept this legal uncertainty.

Though, it is doubtful whether the pharmaceutical company would not rather issue the information needed to avoid a trial. The potential risk for other consumers is still not settled if the authorisation holder does not react immediately by exchanging the packaging and the package leaflet which will certainly lead to extra expenses for them.

#### **IV.2.3 Assumption of a horizontal direct effect**

The situation could be solved if the consumer has the possibility to directly rely on the provision in the pharmaceutical Directive, requiring the producer to correct the wrongful information. Such an effect would have a number of advantages for the plaintiff and other potential consumers. First, the consumer could be sure that they will actually succeed with the claim (legal certainty). Second, they would immediately receive the missing or wrongful information. Finally, the national provision would be replaced by the provision of the Directive setting a situation in which all producers would act in compliance with EU law and thus, prevent other patients from being at risk. The Member State does not forgo its right to implement the provision of the Directive as they would just need to replace the 'old' provision with a new one that is in line with the requirements in the Directive. The legal situation for the producer would also be more predictable and they would not have to fear indirect negative repercussions of any kind as long as they comply with the obligations in the Directive.

#### **Conclusion**

The consumer is in a rather unsatisfying and legally insecure situation in respect to one of their most vital rights. It is very probable that the consumer could possibly obtain the information from another source (such as physician, pharmacist, and producer). However, this does not eliminate the problem that different standards can exist among the Member States which should have been eliminated through the Directive.

The goal of the Directive is to protect the health of the consumer and to provide them with adequate information so that they can make an informed and autonomous decision. In order to exercise this right the consumer must have an explicit right to claim at the national legal level. This would then allow the consumer to obtain the correct information. Since all other consumers are still at risk, the protection of the individual right is not enough and would need to be accompanied by the consequence, that if the claim is accepted, the marketing authorisation is nullified until the defendant complies with the rules. This could also entail that products must be withdrawn from the market.

---

<sup>69</sup> Similar to ECJ, Case C-443/98, Unilever [2000] ECR I-7535, para. 50.

<sup>70</sup> ECJ, Case C-194/94, CIA Security [1996] ECR I-2201; ECJ, Case C-443/98, Unilver [2000] ECR I-7353.

In the event of a correct implementation, that is that the individual has a right to claim information under national law if there is a violation of a provision, the individual receives appropriate protection. Problems will certainly arise if the implementation fails. Even though there is, to a certain extent, a direct effect of the mentioned provisions, the consumer faces legal insecurity when they try to directly induce proceedings against another private party. The situation could be simplified by the acceptance of a horizontal direct effect of these provisions.<sup>71</sup>

This conclusion would also be in line with the current tendency of the Commission to give the consumer access to more information in order to make an informed decision.<sup>72</sup> It is, however, important that the patient does not necessarily have access to more information, but that they are able to obtain the information that they are already legally entitled to through adequate legal remedies.

---

*-The Amsterdam Law Forum is an open access initiative supported by the VU University Library-*

---

<sup>71</sup> Same opinion in respect to Directives in Consumer protection law, see: S. Weatherill, 'Consumer Policy', in: P. Craig & G. de Búrca (eds.) *The Evolution of EU Law*, Oxford: Oxford University Press 1999, pp. 717 *et seq.*

<sup>72</sup> Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - Safe, Innovative and Accessible Medicines: a Renewed Vision for the Pharmaceutical Sector, COM (2008)666 final, S. 10.