	LEGAL OPINION
For:	Notre Bon Droit asbl
For the attention of:	Ms Isabelle Duchateau
From:	Peter Teerlinck, Raluca Gherghinaru and Alice Asselberghs
Purpose:	Analysis of the legality of the exemption clauses in the contracts with the manufacturers of COVID-19 vaccines made public by the European Commission
Date:	8 March 2021
Status:	**STRICTLY CONFIDENTIAL**

I. PURPOSE OF THE PRESENT LEGAL OPINION

1. The purpose of this legal opinion is to identify and analyse, in the light of Belgian law - which is the law governing the contracts - the "exemption" clauses, in the broad sense, contained in the advance purchase agreements entered into between the European Commission and the manufacturers of COVID-19 vaccines (i.e. AstraZeneca, CureVac and Sanofi) (the "**analysed agreements**"). More specifically, the purpose of this opinion is to answer the question of whether the manufacturers of COVID-19 vaccines can rely, against the Member States, on the exemption clauses provided for in the analysed agreements.

II. EXECUTIVE SUMMARY

2. Under Belgian contract law, the clauses under which manufacturers of COVID-19 vaccines do not guarantee nor bear responsibility for the efficacy and the safety of the vaccines should, *a priori*, be considered illegal. Indeed, according to their terms, these clauses are designed to exempt manufacturers from their essential obligation (i.e. the obligation to deliver and guarantee a product in compliance with the contract), but also - and above all - to deprive the contracts of their substance and any useful effect.

3. The clauses stating that the Member States (as buyers of the product) must commit to indemnify the manufacturers (as sellers of the product) against (almost) any harm that vaccines could cause to third parties (vaccinated people) are, at first glance, problematic. Given that the economic weight of civil liability towards third parties is ultimately borne (almost) entirely by the Member States, manufacturers no longer have any real incentive to deliver and guarantee effective and safe vaccines. As a result, there is no substance to the manufacturers' commitment.

4. Nevertheless, the trial judge may use his discretion to take into account the exceptional circumstances relating to the production of COVID-19 vaccines and the general economy of the contracts to 'mitigate' the apparent unlawfulness of these clauses. It is also possible that the judge declares the clauses valid if the manufacturers succeed to demonstrate that, at the time the COVID-19 vaccines were launched in the market, the state of scientific knowledge did not allow them to foresee the existence of serious adverse effects and/or the inefficacy of the vaccines.

III. ANALYSIS

A. Introductory remarks

5. In the context of the management of the COVID-19 pandemic, the European Commission concluded, on behalf of and for the account of the Member States, advance purchase agreements for vaccines through the Emergency Aid Instrument[1]. The objective of these advance purchase agreements was to allow Member States to purchase a defined number of doses of vaccine within a defined timeframe and at a pre-determined price, in return for Member States and the EU to finance part of the initial costs incurred by vaccine manufacturers[2].

6. To date, the Commission has concluded six advance purchase agreements for COVID-19 vaccines[3]. At the time of drafting the present legal opinion, only three of these agreements have been made public - in non-confidential versions - on the European Commission's website. These versions concern the agreements with AstraZeneca-Oxford[4] , CureVac and Sanofi-GSK[5].

7. These agreements are governed by the laws of Belgium and any disputes relating to the interpretation and execution of these agreements are subject to the exclusive jurisdiction of the courts of Brussels[6].

8. It is important to underline that the present analysis is based on the versions of the agreements as published on the European Commission's website, i.e. redacted versions. Our analysis of the "exemption" clauses cannot, therefore, be considered, at this stage, as exhaustive and definitive.

9. Furthermore, we note that the analysed agreements are not drafted in identical terms, reflecting the fact that each advance purchase agreement was negotiated individually with each of the manufacturers. Therefore, the analysis needs to be qualified, or even adapted, according to each agreement.

B. Exemption clauses in Belgian law

10. We have identified three main types of "exemption" clauses in the analysed agreements. These are ***(i)*** liability exemption clauses, ***(ii)*** warranty exemption clauses and ***(iii)*** indemnification clauses. After a brief presentation of the general legal regime applicable to these clauses under Belgian law, we will proceed to a concrete analysis of these clauses in the light of the applicable principles.

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1 See Council Regulation (EU) 2020/521 of 14 April 2020 activating emergency aid under Regulation (EU) 2016/369 and amending the provisions of that Regulation to take account of the spread of COVID-19.

2 See Communication from the European Commission "*EU Strategy on COVID-19 Vaccines*" of 17 June 2020, COM(2020), 245 final.

3 These are the following pharmaceutical companies/groups: AstraZeneca-Oxford, Pfizer-BioNtech, Moderna, Sanofi-GSK, Johnson&Johnson and CureVac.

4 Hereinafter referred to as "AstraZeneca".

5 Hereinafter referred to as "Sanofi".

6 Article 18.4 of the agreement with AstraZeneca; Article 1.21.1 of the agreements with CureVac; Article 1.11.1 of the agreement with Sanofi.

1. Definitions

11. As their name suggests, liability limitation or exemption clauses limit or eliminate the right of one party to obtain full indemnification for the damage it has actually suffered as a result of the other party's conduct.

12. Warranty limitation or exemption clauses are clauses which allow one party to limit or completely exempt itself from its warranty obligations. The most well-known are the warranty clauses that deal with latent defects in a sale contract.

13. Indemnification clauses[7] are not strictly speaking liability limitation or exemption clauses. They "shift" the economic burden of the liability of one of the contracting parties towards a third party onto the other contracting party. Indeed, by means of these clauses, one party assumes the final economic burden of the other party's civil liability and, more precisely, undertakes to indemnify the victim, in place of the offending party[8]. These clauses do not change the relationship between the victim, who is the claimant, and the offending party. Indeed, by virtue of the principle of privity of contracts, such a clause does not exempt the offending party from the liability it incurs towards a third party (the injured party or the victim)[9].

2. General considerations

14. Belgian law recognises the validity of the three types of clauses described above. However, this principle is subject to a number of exceptions and limitations.

15. Insofar as they deviate from the normal consequences of liability and warranty, clauses exempting or limiting liability or warranty should be interpreted strictly or even restrictively. This same principle also applies to indemnification clauses[10]. Since the judgment of 22 March 1979 of the Court of Cassation[11], it has also been established that, if there is any doubt as to the scope or the meaning of such clauses, they must be interpreted in a manner unfavorable to the party benefiting from them.

16. In any event, these clauses must be interpreted and enforced in the light of the principle of good faith. This principle prohibits a party from abusing the rights conferred on it by an agreement. Thus, a party may not exercise a contractual right in a manner which manifestly exceeds the limits of its normal exercise[12]. For example, case-law shows that there is an abuse of contractual rights when a liability exemption clause grants to one party a "*manifestly disproportionate*" advantage in view of the "*extremely serious consequences of the injuries suffered*" by the victim[13].

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7 Indemnification clauses are commonly used in international agreements where they are called "*hold harmless agreements*". In Belgian law they are also known as "*pactes de garantie*".

8 P. VAN OMMESLAGHE , *Droit des obligations*, Tome deuxième-sources des obligations, Bruylant, 2013, p. 1736 et seq. ;, ; M. GOUDEN, "Chapitre 4. Les clauses réciproques d'abandon de recours et de "hold harmless"", *La rédaction des contrats internationaux*, Brussels, Bruylant, 2012, p. 77 et seq.

9 Cass., 7 septembre 1962, *Pas.*, I, p. 32 ; P. WERY, *Droit des obligations*, Volume 2, Larcier, 2016, p. 738 ; A. VAN OEVELEN, " Exoneratiebedingen en vrijwaringsbedingen", *Actuele ontwikkelingen inzake verbintenrecht*, Anvers, Intersentia, 2009, p. 33.

10 P. WERY, *ibidem*, p. 738; M. GOUDEN, *op. cit.*

11 Cass. 22 March 1979, *Pas.* 1979, I, p. 863, *R.C.J.B.* 1981, p. 189, note L. Cornelis.

12 The prohibition of abuse of rights is therefore also based on Article 1134 para. 3 of the Civil Code.19 September 1983, *Pas. Cass. 19 September 1983, Pas.* I, p. 52; Cass. 9 March 2009, *J.T.*, 2009, p. 392. See also P. WERY, *op. cit.* p. 146; T. DELAHAYE, "B. - L'abus de droit", *Le facteur temps dans le droit des contrats - Volume 1*, Brussels, Éditions Larcier, 2013, p. 241.

13 Trib. police de Namur (Div. Dinant), 25 March 2019 (see note by T. MALENGREAU "*L'illicéité de l'exonération contractuelle de la responsabilité d'une atteinte à l'intégrité physique*", *R.G.A.R.*, 2020/2, p. 15652).

17. It should also be stressed that, according to the principle of privity of contracts, only the parties to an agreement are bound by it. In other words, liability and warranty exemption or limitation clauses cannot produce effects (obligations) towards third parties. This also applies to indemnification clauses (see *below*).

18. With regard to the exceptions to the validity of these clauses in particular, the following exceptions should be highlighted, which apply generally to the three types of analysed clauses.

19. Firstly, such clauses are not valid and must be annulled if they are found to relate to essential obligations of the parties. As Professor Van Ommeslaghe points out, "*the traditional basis given for this rule is the same as one of the justifications for excluding waiver clauses in the case of fraud: the clause would have the effect of making the obligation purely potestative in that no liability would be incurred in the event of non-performance of the fundamental or essential element of the obligation*"[14]. What constitutes such an essential obligation has been the subject of numerous applications by legal doctrine and case-law. It emerges that these clauses are null and void when they have the effect of "*annihilating the obligation contracted by the debtor*"[15], when they make the subject-matter of the contract disappear[16], when they undermine "*the very essence of the contract*"[17], when they deprive the debtor's commitments of their substance, when they deprive the contract of all meaning, etc. [18].

20. Secondly, clauses exempting or limiting liability and warranty cannot have the object or the effect of exempting the party benefiting from them from criminal liability. Indeed, it is established that "*as criminal laws are of public order, any agreement which has the object or effect of modifying their scope, restricting their application, inducing someone to commit an offence or exonerating the perpetrator from the criminal liability he incurs, is without value*"[19]. This also applies to indemnification clauses. The doctrine considers that an indemnification clause could not relate to criminal fines or civil consequences of an offence, at least in cases where the offence involves an intentional element[20].

21. Thirdly, these clauses are not valid where it is shown that the party benefiting therefrom has committed an intentional misconduct[21], subject to the considerations below.

22. Fourthly, there are specific laws which, for reasons of public policy and general interest, explicitly prohibit liability and warranty exemption clauses[22].

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14 P. VAN OMMESLAGHE , *op. cit.* p. 1715.

15 Cass. 25 September 1959, *Pas,* 1960, I, p. 113, concl. av.-gén. P. Mahaux; Cass. 23 November 1987, *Pas*, 1988, I, p. 347; Cass. 27 September 1990, *Pas*, 1991, I, p. 821; Cass. 26 March 2004, *Pas*, 2004, p. 513.

16 B. TILLEMAN, "3. - Les clauses exonératoires", *La vente*, Brussels, Larcier, 2013, p.175.

17 S. STIJNS, " Contractualisation of sanctions in private law, in particular in the case of contractual breach of contract ", *R.W.*, 2001-2002, p. 1264 ; R. KRUITHOF, " Contractual liability schemes ", *T.P.R.*, 1984, p. 282, no 37. Voir également av.-gén. M. SOENENS, concl. préc. Gand, 28 février 1929, *B.J.*, 1929, col. 549.

18 B. DUBUISSON, "Les clauses limitatives ou exonératoires de responsabilité ou de garantie en droit belge", *Les clauses applicables en cas d'inexécution des obligations contractuelles*, under the coordination of P. Wéry, Brussels, La Charte, 2001, p. 64. See also M. GOUDEN, *op. cit.* , p. 85.

19 Cass. 6 September 2006, *R.D.P.*, 2007, n°77.

20 P. VAN OMMESLAGHE, *op. cit.*, p. 1738-1739. B. VAN BRUYSTEGEM, "Aanwetelen van beheersaansprakelijkheid", *R.W.* , 1980-1981, p. 976; M. GOUDEN, *op. cit.*, p. 87-88.

21 On the notion of fraud, see F. KUTY, "La notion de dol éventuel et son application à la tentative punissable", *J.T.*, 2018/17, n°6729, p. 369 et seq.

22 See in particular Article VI.83 of the Code of Economic Law and the Law of 25 February 1991 on liability for defective products, *M.B.*, 22 March 1991.

3. Special considerations

3.1. Regarding liability limitation or exemption clauses

23. As stated above, a party cannot escape the harmful consequences of its intentional misconduct[23]. By way of consequence, it cannot be exempted from the fraudulent conduct or intentional faults of its organs[24]. However, a party's liability can be exempted - and, *a fortiori,* limited - for the fraudulent conduct of its servants, agents or representatives. With regard to gross negligence[25], it is established that the parties can free themselves from the harmful consequences of their gross negligence, but also from the gross negligence of their agents, servants, representatives and organs[26].

3.2. Regarding warranty limitation or exemption clauses

24. Warranty limitation or exemption clauses are allowed and can cover different aspects such as the warranty period, defects (apparent or latent), etc.

25. As regards latent defects, it is established in Belgian law that the seller is liable for latent defects of the product sold which make it unfit for the use for which it was intended, or which diminish that use to such extent that the buyer would not have bought it, or would have bought it but at a lower price, if he had been aware of those defects[27]. However, and as underlined above, the legal provisions of the Belgian Civil Code on the warranty of defects in the product sold are suppletive and the parties may validly derogate from them contractually.

26. Indeed, clauses limiting or exonerating the warranty are allowed, unless it can be shown that the seller was aware of the defect at the time of the sale[28]. However, there is an exception to this principle for manufacturers and specialist sellers[29]. According to the settled case-law of the Court of cassation, these sellers are presumed to have knowledge of the defects, including the latent ones, affecting the product they are selling, so that they cannot rely on warranty limitation or exemption clauses[30]. This presumption is based on the obligation of every seller to provide a product free of any defect and to take all necessary measures to detect all possible defects[31].

27. The presumption of knowledge can be rebutted by manufacturers or specialist sellers if they can demonstrate that they could not have known, under any circumstances, the existence of the defect or, according to the latest case-law, that the defect was absolutely undetectable[32]. The impossibility of detecting the defect must be established *in abstracto*. For certain defects, invincible

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23 Cass. 22 February 1990, *Pas*, 1900, I, p. 159.

24 Cass. 15 April 1977, *Pas*, 1977, I, p. 844.

25 Gross misconduct is defined as unintentional misconduct, but which is so excessive that it cannot be understood by a professional.

26 Cass. 28 June 1928, *Pas.* 1928, I, p. 211.

27 Article 1641 of the Civil Code.

28 Article 1643 of the Civil Code.

29 Initially, the case law used the term "professional seller". In recent decades, case law seems to have replaced this notion with the notion of "specialised seller", i.e. a seller who is not necessarily a professional but who has a high degree of specialisation or technical knowledge in his field.

30 Cass. 4 May 1939, *Pas*, 1939, I, p. 223; Cass. 27 June 1985, *J.T.*, 1986, p. 51; Cass. 15 June 1989, *Pas*, 1989, I, p. 1117; Cass. 7 December 1990, *R.W.*, 1992-1993, p. 431, note T. Vansweevelt; Pas. Vansweevelt; Pas, 1991, 1, p. 346.

31 B. DUBUISSON, *op. cit.* p. 88.

32 Cass. 6 May 1977, *Pas.* 1977, I, p. 907; *R.C.J.B.* 1979, p. 162, note by M. Fallon.

ignorance may be admitted in the case of the specialist seller, but not in the case of the manufacturer[33].

28. If manufacturers and specialist sellers succeed in overturning the presumption of knowledge, the warranty limitation or exemption clause becomes effective.

29. It is also important to stress that Belgian case-law, contrary to French case-law, applies the above principles even when the buyer is a professional buyer. Indeed, clauses exempting or limiting the warranty are not, in principle, valid - subject to the exceptions mentioned above - in sales concluded between professionals, even if they are active in the same field[34].

3.3. Regarding the indemnification clauses

30. Under Belgian law, the validity of indemnification clauses is subject to the same principles as those applicable to liability and warranty limitation or exemption clauses (see *above*), but with some adjustments and qualifications inherent to this type of clause.

31. Firstly, since indemnification clauses do not affect the principle of indemnification for damage, it is generally accepted that the validity of such clauses is not questionable, even where the liability at stake is based on public policy rules (ten-year liability of architects, liability for defective products, etc.).

32. Secondly, case-law and legal doctrine consider that it is, in principle, allowed to transfer the burden of indemnification of the victim from one party to the other, even in the case of gross negligence. On the contrary, indemnification clauses do not have any effect in the case of intentional misconduct attributable to the party itself or to its agents, servants and representatives[35].

33. Finally, contrary to French and Luxembourg law, Belgian law seems to allow indemnification clauses even when they concern indemnification for personal injury[36].

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[33] Civ. Liège, 2 October 2009, R.G.A.R., 2010/3, n° 14.623; Brussels, 8 February 2019, R.G.A.R.,2010/5, n° 14.645.

[34] Mons, 10 May 1988, *Pas* II, p. 202. See also P. VAN OMMESLAGHE, *op. cit.* p. 1717 and B. DUBUISSON, "Les clauses de garantie des vices cachés dans la vente entre professionnels", *D.A.O.R.*, 1986-1987, p. 231-240.

[35] T. VANSWEEVELT and B. WEYTS, *Handboek buitencontractueel aansprakelijkheidsrecht*, Intersentia, 2009, point 1442 et seq. DUBUISSON, "Les clauses limitatives ou exonératoires de responsabilité ou de garantie en droit belge", *op. cit.* p. 58.

[36] M. GOUDEN, *op. cit.* , p. 88.

C. Analysis of the validity of the exemption clauses provided for in the analysed agreements

1. Liability and warranty limitation or exemption clauses

34. The relevant provisions are :

- **Articles 15.1**[37] , **15.2**[38] and **15.3**[39] of the agreement with AstraZeneca and
- **Recital K**[40] and **Article I.1.14.3**[41] of the agreement with CureVac.

35. We have not identified a similar provision in the agreement with Sanofi.

36. In essence, the above articles provide that AstraZeneca and CureVac do not warrant or assume any liability arising out of or relating to lack of safety or efficacy of COVID-19 vaccines.

37. The agreement with AstraZeneca is the most explicit in this respect in that it provides that the Commission and the Member States "*waive and release any claim against AstraZeneca arising out of or relating to: (a) lack of safety or efficacy of the vaccine, subject to compliance by AstraZeneca with applicable EU regulatory requirements for a pandemic product, limited to manufacture by AstraZeneca of the vaccine in accordance with Good Manufacturing Practices; (b) use or administration of the Vaccine under pandemic conditions*" (Article 15.1)[42]. It follows from this provision that the Commission and the Member States waive any liability claims against AstraZeneca as long as AstraZeneca complies with the most basic and fundamental standards for the manufacture of medicinal products for human use[43].

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[37] "***15.1.*** *The Commission and each of the Participating Member States each within their respective competencies, on behalf of itself, waive and release any claim against AstraZeneca arising out of or relating to : (a) lack of safety or efficacy of the Vaccine, subject to compliance by AstraZeneca with applicable EU regulatory requirements for a pandemic product, limited to manufacture by AstraZeneca of the Vaccine in accordance with Good Manufacturing Practices; (b) use or administration of the Vaccine under pandemic conditions [...]* ". (Emphasis added).

[38] "***15.2.*** *Limitation of Liability for claims other than third party indemnification. The aggregate liability of AstraZeneca and its Affiliates in respect of claims made by the Commission or Participating Member States, or any affiliates acting on the Commission or Participating Member States' behalf (as distinguished from claims for third party indemnification), whether for breach of contract, another contractual-based claim, arising in tort (including negligence) or otherwise, arising out of, under or in connection with this Agreement* ". (Emphasis added).

[39] " ***15.3*** *Disclaimer of Warranties. The Parties acknowledge that they are not relying on any understanding, arrangement, statement, representation (including, any negligent misrepresentation but excluding any fraudulent misrepresentation), warranty, condition, term, customary practice, course of dealing or provision except for the warranties set out in this Agreement. All statements, representations, warranties, terms, conditions and provisions (including, any implied by statue or equivalent, case law or otherwise and any implied warranties and/or conditions as to merchantability, satisfactory quality, fitness for purpose and skill and care), other than fraudulent misrepresentations and the provisions set out in this Agreement, are hereby excluded to the maximum extent permissible by law*". (Emphasis added).

[40] "***K.*** *The Parties recognise that the accelerated development timelines to deliver the clinical trial and follow-up programme agreed with EMA means that the contractor under no circumstance can warrant, or assume any liability, at the time of entry into force of this APA that the Product will be ultimately available or will produce the desired results, i.e. shows sufficient efficacy to prevent a COVID-19 infection, or be without inacceptable side effects [...]* ". (Emphasis added)

[41] " ***I.1.14.3*** *Given the current status of the clinical development program and in light of the extraordinary circumstances of the execution and performance of this APA, the contractor, in particular, does not warrant that the Products will show sufficient efficacy to prevent a COVID-19 infection and/or be without inacceptable adverse event symptoms beyond what will be documented in the ongoing and planned clinical trials or what will be documented in the leaflet of the Product* ". (Emphasis added).

[42] Emphasis added.

[43] "Good Manufacturing Practice" means the practices established by the standards, rules, principles and guidelines set out in Directive 2001/83/EC on the Community code relating to medicinal products for human use, Directive 2003/94/EC laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use and EudraLex - Volume 4 of the Rules Governing Medicinal Products in the EU entitled "EU Guidelines on Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use".

38. These clauses should be qualified as *"liability and warranty exemption clauses*" under Belgian law. In principle, Belgian law allows such clauses.

39. However, several questions need to be raised regarding the scope and validity of these clauses.

1.1. Scope of liability and warranty exemption clauses

40. Firstly, it should be noted that Article 15.1 of the agreement concluded with AstraZeneca provides that the Commission and the Member States "*waive and release any claim against AstraZeneca [...]*[44].

41. As for the agreement with Curevac, its recital K provides that "*[CureVac] under no circumstance can warrant or assume any liability*[45].

42. It follows from the (very broad) wording of these clauses and, in general, from the will of the parties as reflected in other provisions of the agreements, that the vaccine manufacturers are exempted from liability towards the Commission and the Member States for facts which fall within the scope of both their contractual and extra-contractual liability. Indeed, at first sight, the above-mentioned clauses could be interpreted as meaning that, in the event that the vaccines are found to be ineffective and dangerous for the population, the Commission and the Member States will not be able to claim damages from the vaccine manufacturers, either on the basis of the purchase agreements or on the basis of Articles 1382 et seq. of the Belgian Civil Code.

43. In this respect, however, it should be recalled that the purpose or the effect of liability and warranty exemption clauses cannot be that of exempting the party benefiting from them from its criminal liability (see *above*). Under Belgian law, it is established that the manufacturing and the commercialisation of medicinal products which are dangerous to human health may engage the manufacturer's/distributor's criminal liability, most often on the basis of unintentional homicide or injuries. Indeed, if Covid-19 vaccines are found to be dangerous and produce (very) serious adverse effects, vaccine manufacturers will not be able to avoid criminal liability by invoking the above-mentioned exemption clauses.

1.2. Validity of liability and warranty exemption clauses

i. The liability and warranty exemption clauses in the agreements with AstraZeneca and CureVac are, prima facie, unlawful

44. In view of the very broad wording of the above-mentioned provisions, but also in view of the nature of the obligations from which vaccine manufacturers are exempted, it has to be examined whether this exemption does not deprive the manufacturers' commitments of (a large) part of their substance. As explained above, liability and warranty exemption clauses are not valid and must be declared null and void when they relate to the essential obligations of one of the parties.

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44 Emphasis added.

45 Emphasis added.

45. The Belgian courts have applied this principle in numerous ways[46]. In particular, judges verify to what extent a liability and warranty exemption clause affects the essential provisions of the contract - or, more generally, the fundamental content of the obligation in question - in order to refuse or accept it, depending on the circumstances. The examination of the essential character of the obligation falls within the discretion of the judge, who has a sovereign power of appreciation. Generally, judges are stricter when it comes to assessing the obligations of professionals.

46. Under Belgian law, the seller has two main obligations: to deliver and to guarantee the product he sells[47]. More specifically, the seller has, on the one hand, the obligation to deliver a "*product in conformity with the contract*"[48] and, on the other hand, the obligation to guarantee the product, in particular against latent defects[49].

47. In the case of a vaccine purchase agreement, the seller (*i.e.* the vaccine manufacturer) should, in principle, undertake to deliver a "*compliant*" vaccine and assume warranty obligations relating to vaccine compliance. These principles are reflected in the agreements with AstraZeneca and CureVac:

- *"AstraZeneca shall have the sole right and responsibility for all aspects relating to the research and development of the Vaccine with the goal of establishing a Vaccine that is safe and efficacious for manufacture and sale as contemplated by this Agreement*" (Article 4.1 of the agreement with AstraZeneca)"[50].

- *"The intention of the Commission, on behalf of the Member States, is to ensure that the population of the European Union will be able to access a vaccine in sufficient quantities and at a fair price, but also under safe conditions. The vaccine should only be available to the population once its safety and efficacy have been cleared by the competent regulatory bodies*" (recital F of the contract with CureVac)"[51].

48. In the light of the above principles, it seems clear to us that the provision of a safe and effective vaccine is an essential obligation of the seller (i.e. the vaccine manufacturer). Any clause which has the purpose or the effect of discharging the manufacturer of its obligation to provide a safe and effective vaccine would, in our view, relieve the manufacturer of one of its essential obligations, but also - and more importantly - render the contract meaningless and ineffective. As explained in detail below, this clause should be declared null and void.

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46 By way of illustration:

- An architect may not stipulate a clause exempting him from liability for any design defect in a building, since such a clause has the effect of emptying the agreement of its substance, since it relieves the architect of his obligations resulting from the design of the plans, i.e. of one of the essential obligations of his mission (Brussels, 21 September 1979, *J.T.*, 1981, p. 28).
- A depositary cannot exempt himself from his main obligation to keep and return the thing deposited (Civ. Liège, 29 June 1976, *Jur. Liège*, 1976-1977, p. 275).
- The clause aiming to exonerate the organiser of a soapbox race from any liability, including for serious bodily injury or death, empties the agreement of its substance (Trib. police de Namur (Div. Dinant), 25 March 2019, cited above).
- The general clauses of a press agency which provide that "*the publisher shall personally obtain all necessary authorisations for the reproduction of the works or persons appearing in the photographs*" without the press agency putting the publisher in a position to obtain such authorisation are null and void insofar as they have the consequence of annulling the obligation entered into (Brussels, 18 October 2001, *A.M.* , 2002, p. 168.).

47 Article 1603 of the Civil Code.

48 Article 1604 of the Civil Code.

49 Articles 1641 et seq. of the Civil Code.

50 Emphasis added.

51 Emphasis added.

49. The same conclusion as to the illegality of the clause should be reached if the rules and principles described above regarding the warranty against latent defects were applied. Indeed, as explained above, professional sellers (such as AstraZeneca and CureVac) are presumed to have knowledge of their products' defects, including the latent ones. This presumption applies even in cases where they conclude contracts with professional buyers, such as the Member States and the European Commission[52]. This conclusion is all the more necessary since, as regards the purchase of vaccines, within the framework of and on the grounds of public health (as in the present case), the standards applicable to the manufacturers' obligation to guarantee the vaccine are even higher than usual.

50. By exempting themselves from all liability and warranty obligations in the event of serious and unacceptable adverse reactions and ineffectiveness of the COVID-19 vaccines, AstraZeneca and CureVac are in fact exempting themselves from any latent defects in these vaccines. This exemption is illegal unless the manufacturers can demonstrate that, at the time of the conclusion of the contract, they could not have known, under any circumstances, the existence of these defects or that these defects were completely undetectable (see *below*).

51. Finally, it is interesting to note that Article VI.91/5.6° of the Code of Economic Law ("CEL") explicitly provides that clauses in contracts between undertakings which have as their object "*to discharge the undertaking from its liability as a result of its intentional fault, gross negligence or that of its employees or, except in cases of force majeure, as a result of any failure to perform the essential obligations forming the subject-matter of the contract*[53]", are presumed to be unfair, in the absence of proof to the contrary, and are to be regarded as null and void.

52. Although this provision and, more generally, the legislation on abusive clauses in contracts between undertakings, do not, *prima facie*, apply to the analysed agreements[54], they can, in our opinion, be used, by analogy, to demonstrate the unlawfulness of the liability and warranty exemption clauses contained in the contracts with AstraZeneca and CureVac.

ii. Mitigation of the unlawful nature of the liability and warranty exemption clauses in the contracts with AstraZeneca and CureVac

53. There are several references in the analysed agreements to the *"exceptional circumstances"* of the COVID-19 pandemic and, in particular, to the need to develop new vaccines at an unprecedented rate to enable mass immunisation and to the high financial risks taken by vaccine manufacturers in developing and marketing COVID-19 vaccines[55].

54. It is therefore likely that the manufacturers will rely on the exceptional circumstances surrounding the manufacturing of the COVID-19 vaccine to demonstrate the legality of the clauses exempting the manufacturers from their liability and warranty obligations, including against latent defects.

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[52] Although they are not professional purchasers as such, the Member States and the European Commission can be assimilated to professional purchasers because it is clear from the various public documents that they were able to obtain advice, in the context of the negotiation of the analysed agreements, from their own experts.

[53] Emphasis added.

[54] Article VI.91/1 §2 of the CEL provides that Title 3/1 of Book VI of the CEL on unfair terms in agreements between undertakings does not apply to public tender agreements. We conclude that this title does not apply to public tender agreements which are governed by the Belgian public procurement regulations. Although it is not excluded that title 3/1 may apply to the analysed agreements insofar as they are not governed by Belgian public procurement regulations, this application seems to us to be risky.

[55] See for example Article I.1.14.3 and I.1.23.2 of the agreement with CureVac and Article 1.9 of the agreement with AstraZeneca.

55. In this respect, a parallel can be drawn with the Law of 25 February 1991 on liability for defective products[56]. This law is often invoked by persons injured by a defective product (including defective medicines or vaccines) to engage the liability of the manufacturer[57]. Indeed, the Law of 25 February 1991 has the advantage of providing for a no-fault liability regime. Consequently, the victim will only have to prove the defect in the product, the damage and the causal link between the damage and the defect in the product, irrespective of whether the manufacturer in question has committed a fault or not. However, the manufacturer will not have to incur liability and indemnify the victim in certain cases explicitly provided for by the law. In this respect, Article 8(e) provides that the manufacturer is not liable under the Law of 25 February 1991 if he demonstrates that "*the state of scientific and technical knowledge at the time when the product was put into circulation did not allow the existence of the defect to be detected*"[58].

56. We conclude that, if the legislator allows manufacturers of defective vaccines to exempt themselves from liability towards consumers when the state of scientific knowledge at the time the defective vaccine was placed on the market did not make it possible to detect the existence of the defect, the same conclusion should, *a fortiori,* apply in the case of an agreement for the purchase of vaccines concluded with professional purchasers such as the Member States and the European Commission.

57. It is therefore not excluded that, in the context of assessing the validity of the liability and warranty exemption clauses provided for in the agreements with AstraZeneca and CureVac, the Belgian courts may declare these clauses valid if the manufacturers succeed to demonstrate that, at the time the COVID-19 vaccines were launched, the state of scientific knowledge did not allow them to detect the existence of unacceptable side effects and/or the ineffectiveness of the vaccines.

58. In this respect, it is also very likely that vaccine manufacturers will invoke the fact that they have received a (conditional) marketing authorisation from the European Medicines Agency, so that their vaccines should be presumed to be safe enough to be commercialized and administered to the population. To our knowledge, the merits of such a defence have not yet been judged in Belgium. However, it seems to be clear from the recent case-law of the European Court of Human Rights and of the French courts that the fact that the marketing of a medicinal product has been authorised by the competent authority does not necessarily exclude the possibility that a medicinal product could be qualified as "defective" and that the victim would be entitled to indemnification[59].

59. Finally, we are of the opinion that the trial judge, in the context of his sovereign power of appreciation, will also have to take into account the fact that the exemption affects the essential obligations of the manufacturers and the very substance of the agreements, so that if the exemption clauses were to apply, the agreements would be deprived of part of their purpose and of any useful effect. Still within the framework of its sovereign power of appreciation, it seems also important that

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[56] This law could not be invoked by the Member States against vaccine manufacturers because they do not fall into the category of "injured persons" which includes "*all natural persons who, as a result of a defective product, suffer damage that can be made good within the meaning of the law, and it does not matter whether or not there is a direct contractual relationship with the actual, apparent or presumed producer*" (C. DELFORGE, "Le consommateur et la responsabilité du fait des produits de santé", *D.C.C.R.*, 2013/3-4, n°100, p. 47).

[57] Indeed, the victim of a defective product may choose to engage the extra-contractual liability of the manufacturer on the basis of Articles 1382 and 1383 of the Civil Code or to rely on the *sui generis* liability regime provided for by the Law of 25 February 1991, provided that the conditions for the application of these two liability regimes are simultaneously met.

[58] Emphasis added.

[59] ECHR judgment of 13 February 2020, Sanofi Pasteur v. France; French Court of Cassation judgment of 27 November 2019, n°18-16.537.

the trial judge assesses the extent of the risks actually incurred by the manufacturers of COVID-19 vaccines - and, therefore, the need for exemption - given that the advance purchase agreements "*de-risk the necessary investments related to both vaccine development and clinical trials, and the preparation of the at-scale production capacity along the entire vaccine production chain* "[60].

60. In any case, if it is established that the manufacturer knew or could have detected the serious adverse effects and/or ineffectiveness of the vaccine at the time the vaccines were launched, the exemption clauses should be declared invalid. The same conclusion should, in our view, be reached if the vaccine manufacturers were found to have committed intentional misconduct or violated "good manufacturing practices".

2. Indemnification clause

61. The relevant provisions are :

- **Article 14.1** [61]of the Agreement with AstraZeneca
- **Article I.1.23.3** to **I.1.23.5**[62] of the Agreement with CureVac
- **Articles II.6.4** and **II.6.5**[63] of the Agreement with Sanofi

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[60] See Communication from the European Commission "*EU Strategy on COVID-19 Vaccines*" of 17 June 2020, COM(2020), 245 final, cited above.

[61] " ***14.1***. *Member States. Each Participating Member State shall indemnify and hold harmless AstraZeneca, its Affiliates, subcontractors, licensors, and sub-licensees, and officers, directors, employees and other agents and representatives of each (collectively, the "Indemnified Persons") from and against any and all damages and liabilities, including settlements for which the Indemnifying party has given its consent pursuant to Section 14.2, and necessary legal costs relating to, resulting from or associated with claims for death, physical, mental, or emotional injury, illness, disability, or condition, fear of the foregoing, property loss or damage, and business interruption of the injured party or a Related Person of such injured person (together, "Losses") relating to or arising from the use or administration of the Vaccine shipped or allocated to its jurisdiction. Such indemnification will be available regardless of where the Vaccine is administered, where the claim is brought, and whether the claim investigation, manufacture, labelling, formulation, packaging, donation, dispensing, prescribing or licensing of the Vaccine in its jurisdiction. Such indemnification will not be available to Indemnified Persons [confidential]. Indemnification under this Section 14.1 will be available for Losses arising from the use and administration of vaccines supplied under this Agreement, regardless of when or where vaccination occurred and regardless of when or where the injury leading to the Losses occurs or is reported* ". (Emphasis added).

[62] " ***1.23.3*** *[...] Each participating Member State shall indemnify and hold harmless the contractor, its Affiliates, sub-contractors and sub-licensees, including contract partners involved in the research, development (including pre-clinical and clinical testing), manufacturing and/or delivery; and officers, directors, employees and other agents, representatives and service providers of each (together, the "Indemnified Persons") for liability incurred and normally borne by them relating to harm, damages and losses (together, the "Losses") as further specified in Article I.23.5 arising from the use and deployment of the Products supplied to the participating Member State (or another entity appointed by that participating Member State) under this APA, irrespective of the time when the Losses occur.*

1.23.4. *Such indemnification will not be available to the Indemnified Persons to the extent that [confidential].*

1.23.5. *Indemnification pursuant to Article 1.23.3 will only be available for Losses that consist of: (i) liability towards the injured Party [confidential] for death, physical, mental or emotional injury, illness, disability, cost of care, property loss or damage, loss of earnings, and business interruption; and (ii) all reasonable and necessary costs related to such Losses including legal fees, expert fees and other litigation or settlement expenses. [...]*». (Emphasis added).

[63] « ***II.6.4***. *Each Participating Member State shell, directly or through any of its agencies and/or existing indemnification funds indemnify and hold harmless each Sanofi Pasteur and GSK and their respective Affiliates (the "Sanofi Pasteur Indemnified Entities" and the "GSK Indemnified Entities", respectively) for any and all liability, and reasonable direct external legal costs necessary to the defense in Third Party Claims. (i.e. law firm's fees, external experts fees) incurred and normally borne by them relating to harm, damages and losses (together, the "Losses") associated with the death, physical, mental or emotional injury, illness, disability, property loss or damage or business interruption of a party injured as result ("the Injury") of the use or deployment of the Adjuvanted Pandemic Vaccine in the jurisdiction of the Participating Member State in question.*

Such indemnification will be available to the Sanofi Pasteur Indemnified Entities and the GSK Indemnified Entities for the Losses arising from the use and administration of any Adjuvanted Pandemic Vaccine doses sold during the initial duration of the Down Payment and Advance Purchase Agreement which term will be of [confidential] months (the "Covered Doses") (even if delivered and/or used after) and will apply to Losses arising from vaccination with such Covered Doses regardless of when the Injury leading to the Losses occurs or is reported.

2.1. *Scope of the indemnification clauses in the agreements concluded with AstraZeneca, CureVac and Sanofi*

62. These provisions require Member States to *indemnify and hold harmless* AstraZeneca, CureVac and Sanofi for any damages suffered by third parties as a result of the use or administration of the COVID-19 vaccines. The agreement with CureVac goes even further as it provides for the possibility for the manufacturer to request the Member States to assume (with their own counsels and at their own expenses) exclusive control of the defence against claims of third parties or regarding settlement with the latter, under certain conditions[64].

63. The above-mentioned clauses qualify as indemnification clauses under Belgian law (see *above*).

64. The general scope of these provisions is remarkable. Indeed, the notion of "loss" that Member States undertake to indemnify is very broad and covers all damages related to death, physical, mental or emotional injury, illness, disability, cost of care, property damage, loss of earnings and business interruption, but also all reasonable and necessary costs related to such loss and damage, including legal fees, expert fees and other litigation or settlement costs.

65. The indemnification clause is also broad in that it provides for indemnification of not only the manufacturers, but also their affiliates, subcontractors and sublicensees, including contractual partners involved in research, development, manufacturing and/or delivery, as well as the officers, directors, employees and other agents, representatives and service providers of each of them.

66. The agreements seem to provide for some exceptions to the application of this general indemnification obligation by Member States. However, the relevant provisions have been redacted in the versions of the agreements published on the European Commission's website, so that we cannot take them into account in this analysis.

2.2. *Validity of the indemnification clauses in the agreements with AstraZeneca, CureVac and Sanofi*

67. As mentioned above, indemnification clauses are allowed under Belgian law, with some exceptions.

68. First, it is appropriate to question the legality of these clauses in that they provide for compensation for damage such as death or injury to physical integrity. As indicated above, Belgian law allows the parties to contractually provide that one of the parties will bear compensation for bodily injury suffered by a third party as a result of the wrongful conduct of the other party[65].

In the event the Parties mutually agree to extend the Advance Purchase Agreement after its initial duration and then mutually agree to supply additional doses of the Adjuvanted Pandemic Vaccine under such extended agreement, the Parties will discuss in good faith whether any amendment to the above indemnification provisions is warranted ».

« ***II.6.5****: There shall be no obligation to indemnify and hold Sanofi Pasteur Indemnifies Entities and GSK Indemnified Entities harmless where it is demonstrated that [confidential]* ".

64 " ***1.23.11.*** *Alternatively, the contractor may request, to the extent possible under the applicable rules of procedure, the participating Member State to assume (with its own counsel and at its own costs) sole control of the defence or settlement of the Third Party Claim; provided that: (i) the participating Member State shall reasonably take the contractors interests into consideration and shall not settle such Third Party Claim without the prior written consent of the contractor (such consent not to be unreasonably conditioned, withheld or delayed); and (ii) the contractor shall have the right, but not the obligation, to participate in the defence or settlement of the Third Party Claim and to retain its own counsel in connection with such Third Party Claim at its own expense. [confidential]* ".

65 M. GOUDEN, *op. cit.* , p. 88

However, as a general rule, conduct resulting in the death or physical injury of a person is covered by criminal law.

69. In this respect, the lawfulness of an indemnification clause applicable to the civil consequences of a criminal offence is not yet clearly established by the case-law. The majority of the doctrine is of the opinion that this type of clause should be considered unlawful, all the more so if the offence involves an intentional element[66]. Similarly, the indemnification clause cannot be interpreted as relating to possible criminal fines that the offending party (in this case, the manufacturer) will have to pay[67].

70. Secondly, we are also of the opinion that, given the very broad wording of the indemnification clause, which provides for the indemnification of the manufacturers for (almost) all kinds of damage that the vaccines may cause, the (essential) obligation of the manufacturers to deliver and guarantee effective and safe vaccines is, in reality, a purely potestative obligation. In particular, the trial judge will, in our view, have to verify whether, as a result of the application of the indemnification clause, the manufacturers actually continue to bear financial risks and whether they still have an incentive to fulfil their contractual obligations.

71. In this respect, it is interesting to quote Article VI.91/5.3° of the CEL, which provides that clauses in agreements between undertakings which have as their object "*to place the economic risk on one party without consideration, whereas this risk normally lies with the other party*"[68] are presumed to be unfair, unless proven otherwise. Although this article is not applicable as such for the reasons described above, it remains relevant to demonstrate the problematic nature of this type of clause which completely disrupts the economic balance of an agreement.

72. Thirdly, it is also clear to us that the indemnification clause cannot be effective if the manufacturers and/or their agents, servants or representatives are found to have committed an intentional fault or to have violated "*good manufacturing practices*".

73. Finally, in assessing the validity of this clause, the trial judge will also have to take into account the exceptional circumstances relating to the production of COVID-19 vaccines (see *above*).

3. Sanctions applicable to unlawful clauses

74. Since several of the analysed clauses above are problematic and may be declared unlawful, we will analyse below the sanctions applicable by the Courts in the event of the unlawfulness of a clause.

3.1. Applicable principles

75. In theory, the law of obligations provides that '*an agreement which is affected by a defect in its conclusion is vitiated by a cause of nullity*'[69]. Article 1172 of the Civil Code provides that '*any condition of a thing which is impossible, or contrary to morality, or prohibited by law, is null and void and renders the agreement dependent on it null and void*'. Nullity is a residual sanction

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66 See in particular P. VAN OMMESLAGHE, *op. cit.* p. 1738.

67 Cass. 6 September 2006, R.G. n°P. 06.0492.F, www.cass.be; *Rev. Dr. Pén.* 2007, p. 77.

68 Emphasis added.

69 P. WERY, "Titre 3 - Les sanctions des défauts dans la formation du contrat et des fautes précontractuelles", *Droit des obligations*, Volume 1, Brussels, Larcier, 2021, p. 337.

applicable in the absence of a specific sanction provided by the legislator[70]. However, the parties may insert a severability clause in their agreement '*specifying that the nullity of one of the contractual provisions shall not entail the nullity of the entire agreement*'[71]. In this case, only the illegal clause will be declared null and void by the judge. There are, however, two exceptions which limit the scope of a severability clause and lead to the annulment of the entire agreement, namely if:

1) the contractual term in question constitutes one of the essential conditions for the validity of the agreement. If the clause was the impulsive and determining cause for the conclusion of the agreement, the agreement must be considered indivisible and the agreement must be cancelled in its entirety[72].

2) the clause in question is decisive for the will of the parties. In particular, the judge could decide that, notwithstanding the existence of a severability clause, the unlawful clause is inseparable from the rest of the agreement in the minds of the parties[73].

76. A judge who annuls an unlawful clause cannot, in principle, replace that clause with "*a different clause which is not [a clause provided for by use] or which is not based on the will of the parties*"[74]. However, attention should be paid to the recent case-law of the Court of Cassation. The rulings of 23 January 2015 and 25 June 2015 of the Court of Cassation confirmed that the nullity can only affect a part of the contractual clause, without jeopardising the validity of the rest of the clause or, *a fortiori,* the validity of the rest of the agreement. Partial nullity of a clause may result from a legislative text or from certain contractual provisions. It may also be pronounced by the judge even in the absence of a legal text or an express clause[75]. The Court of Cassation has thus ruled that a competition clause that violates a provision of public policy may be declared partially null and void. The judge may thus "*limit the nullity, unless prohibited by law, to the part of the agreement or clause that is contrary to this provision [of public policy], provided that the continued existence of the partially nullified agreement or clause corresponds to the will of the parties*"[76].

77. Case-law[77] has identified three conditions for the partial nullity of an unlawful clause to be considered by the judge:

1) It is first required that such a sanction be possible, and, more precisely, that the unlawful part of the clause can be separated from the rest of the clause.

2) It is then required that the partially annulled clause corresponds to the common intention of the parties at the time of the conclusion of the agreement.

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[70] R. JAFFERALI, "A. - En deçà du contrat: nullité partielle, réduction et conversion", *La rétroactivité dans le contrat*, Brussels, Bruylant, 2014, p. 726.

[71] P. WERY, "Titre 3 - Les sanctions des défauts dans la formation du contrat et des fautes précontractuelles ", *op. cit.* , p. 357.

[72] R. JAFFERALI, *op cit.* , p. 714.

[73] R. JAFFERALI, *ibidem*, p. 714.

[74] P. WÉRY, "Titre 3 - Les sanctions des défauts dans la formation du contrat et des fautes précontractuelles", *op cit*, p. 359; Cass. 23 March 2006, *R.C.J.B.*, 2007, p. 422-427.

[75] P. WÉRY, *ibidem*, p. 369.

[76] Cass. 23 January 2015, R.G. n° C.13.0579/N/1, available at www.juridat.be.

[77] Cass. 23 January 2015, R.G. n° C.13.0579/N/1, available at www.juridat.be; Cass. 25 June 2015, *J.T.* , 2015, p. 717. See also S. STIJNS, 'Het aankomend verbintenissenrecht in de recente rechtspraak van het Hof van Cassatie', *R.G.D.C.*, 2018/8, p. 421.

3) Finally, partial nullity must be permitted by law. It is, *a contrario,* excluded when the law sanctions the unlawfulness of a clause with full nullity[78].

78. Finally, the parties may agree to attach to their severability clauses an obligation to renegotiate the cancelled clause. This is known as a review clause. The review clause contains an undertaking by the parties, in the event of annulment, "*to enter into negotiations in good faith with a view to replacing the unlawful clause by a lawful clause fulfilling, as far as possible, an equivalent economic function*"[79]. However, the modification of the agreement must be in accordance with the law and the will of the legislator[80].

3.2. Application of the aforementioned principles in the present case

79. The three analysed agreements contain specific severability clauses[81].

80. In essence, these severability clauses provide that each provision of the agreement is severable and distinct from the others. If a provision is or becomes illegal, invalid or unenforceable, in whole or in part, it must be separated from the rest of the agreement. However, this shall not affect the legality, validity or enforceability of the remaining provisions of the agreement which shall remain in full force and effect. The illegal, invalid or unenforceable provision shall be replaced by a legal, valid and enforceable provision that corresponds as closely as possible to the original intention of the parties at the time the agreement was concluded[82].

81. The trial judge should verify whether these severability clauses can be applied, as the liability and warranty exemption clauses and indemnification clauses seem to have been determinant of the parties' intentions. Indeed, the pharmaceutical companies would not have entered into the agreement without such clauses. This can be inferred, in particular, from recital K of the CureVac agreement: "*[t]he Parties recognise that the accelerated development timelines to deliver the clinical trial and follow-up programme agreed with EMA means that the contractor under no circumstance can warrant, or assume any liability, at the time of entry into force of this APA that*

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78 This is the case, for example, of Articles 65, §2, 86 and 104 of the Law on Employment Contracts of 3 July 1978. F. PERAER, 'Het Hof van Cassatie erkent en bevestigt de mogelijkheid tot reductie van nietige concurrentiebedingen in het gemene recht', note under Cass. 23 January 2015 and 25 June 2015, *R.G.D.C.*, 2016/4, p. 194 - 195.

79 R. JAFFERALI, *op cit.* , p. 723.

80 R. JAFFERALI, *ibidem*, p. 724.

81 Agreement with AstraZeneca: " ***18.10***. *Severability. If any provision of this Agreement is held to be void or otherwise unenforceable by a court of competent jurisdiction from whose judgment no appeal is made within the applicable time limit then the provision shall be omitted and the remaining provisions of this Agreement shall continue in full force and effect* ".

Agreement with CureVac: " ***II.1.*** *Each provision of this APA is severable and distinct from the others. If a provision is or becomes illegal, invalid or unenforceable to any extent, it must be severed from the remainder of the APA. This does not affect the legality, validity or enforceability of any other provisions of the APA, which continue in full force and effect. The illegal, invalid or unenforceable provision must be replaced by a legal, valid and enforceable substitute provision which corresponds as closely as possible with the actual intent of the Parties under the illegal, invalid or unenforceable provision. The APA must be interpreted as if it had contained the substitute provision as from its entry into force". "**I.23.13** The Parties acknowledge and agree that the provisions of this indemnification clause are reasonable and necessary to protect the legitimate interest of the Indemnified Persons. However, if any provision in this clause were to be held to be illegal, invalid or unenforceable, in whole or in part, then such provision shall not be nullified but the Parties, including the participating Member States, shall be deemed to have agreed to such provision that conforms with the limitations imposed by applicable law and that is as close as possible to the original intention of the Parties and has the same or as similar as possible economic effect, and such provision shall be automatically reformed accordingly* ".

Agreement with Sanofi: " ***II.3.*** *Each provision of this APA is severable and distinct from the others. If a provision is or becomes illegal, invalid or unenforceable to any extent, it must be severed from the remainder of the APA. This does not affect the legality, validity or enforceability of any other provisions of the APA, which continue in full force and effect. The illegal, invalid or unenforceable provision must be replaced by a legal, valid and enforceable substitute provision which corresponds as closely as possible with the actual intent of the Parties under the illegal, invalid or unenforceable provision. The APA must be interpreted as if it had contained the substitute provision as from its entry into force* ".

82 The latter part is, however, not foreseen in the agreement with AstraZeneca (see *below*).

the Product will be ultimately available or will produce the desired results, i.e. shows sufficient efficacy to prevent a COVID-19 infection, or be without inacceptable side effects. The participating Member States are willing to share those risks, which includes an obligation of the participating Member States to indemnify the contractor and its CMOs in case of liability incurred, settlements paid and certain costs relating to third party claims with respect to those risks under the conditions set out in this APA. The Commission and participating Member States acknowledge that the use of Products will happen under epidemic conditions requiring such use, and that the administration of the Product will therefore be conducted under the sole responsibility of the participating Member States[83].

82. It is therefore not excluded that the unlawfulness of the indemnification and liability and warranty exemption clauses leads to the nullity of the entire agreement. However, we are of the opinion that, in the present case, a partial nullity (which concerns only the unlawful clauses) seems to be more appropriate and more judicious than a total nullity of the agreements.

83. In this respect, we recall in particular the very recent case-law of the Court of Cassation according to which the judge has the power not to consider a public procurement agreement as being null and void (even in cases where the conclusion of such agreement is affected by a cause of absolute nullity such as the absence of organisation of a prior call for competition) if it is established that compelling reasons of general interest (such as reasons of public health) require that the effects of the public procurement agreement be maintained[84]. In the present case, it seems to us that the supply of vaccines in the context of a pandemic such as that relating to COVID-19[85] could constitute a compelling reason of general interest likely to justify the maintenance of the effects of the agreements for the purchase of vaccines against COVID-19, and this despite the nullity of the exemption clauses described above.

84. In this case, however, it should be borne in mind that "*in the event of the annulment of a liability waiver clause [...], it would be directly contrary to the will of the legislator to allow the co-contractor to renegotiate a price increase in order to fully compensate for the impossibility of relying on the clause which is null and void*"[86]. The pharmaceutical companies could not, therefore, modify the agreements and provide that the price of the vaccines will be increased following the nullification of the indemnification and the liability and warranty exemption clauses.

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[83] Emphasis added.

[84] Cass. , 22 janvier 2021, *Proximus c Interkabel Vlaanderen and Others*, C.19.0303.N.

[85] The conclusions of Advocate General Ria Mortier presented before the delivery of the above-mentioned judgment of the Court of Cassation of 22 January 2021 explicitly mention the provision of vaccines as a "*compelling reason of general interest*".

[86] R. JAFFERALI, *op cit.* , p. 724.