

# NEGOTIATING OUR HEALTH: THE EU PUBLIC POLICIES ON COVID-19 VACCINATION AND THE ASTRA ZENECA ADVANCE PURCHASE AGREEMENT

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## Abstract

*The ongoing covid-19 pandemic has taken us into uncharted territories in many a field: medical, legal, social and constitutional.*

*The EU has been actively pursuing, within its range of competencies, a broad policy to combat this unprecedented health crisis, which included negotiating and financing on behalf of its Member States the development of a viable vaccine by multiple pharmaceutical companies. These complex agreements and financing schemes have resulted in the purchase and distribution to the EU countries of vaccine doses according to a quota based on the size of the population. Given the novelty of the circumstances, the very short time in which these vaccines have been developed and tested, some vaccines have sparked public controversies, such as the one produced by Astra Zeneca.*

*This article endeavors to offer a brief analysis of the Advance Purchase Agreement signed with Astra Zeneca, recently made public by the EU Commission, with special reference to the clauses which, in our opinion, might have offered the private contracting company too much discretion in compliance with its contractual obligations.*

*The analysis will be preceded by an outline of the legal framework for the APA agreements concluded by the European Commission and some considerations on the legal formants – the complex interplay of the legal, political and economic interests which affect the management of the covid crisis on European and international level. The conclusions of this article will set forth the necessity of more transparency in negotiating this kind of agreements with massive impact on our health and the need of a more realistic approach to the policy of vaccination, based on the specificity of each country.*

**Keywords:** *EU public policies, Advance Purchase Agreement (APA), private company, pandemic, vaccination, legal formants, Astra Zeneca.*

## 1. Introductory considerations. Of Covid and law, of citizens and states.

A much quoted, apocryphal Chinese curse says “May you live in interesting times”<sup>1</sup>, though the actual proverb is equally compelling “Better to be a dog in times of tranquility than a human in times of chaos.” Both versions hold true today, when the whole planet grapples with the effects of the Covid pandemic, when governments scramble for economic solutions, employers for business, employees for employment, and everybody else for a semblance of normality, without sanitary masks, lockdowns and restrictions.

Since its beginning in the early 2020, the Covid pandemic has changed the paradigm of living and working in the Western world, exposing in the process the vulnerabilities of our healthcare systems, the shaky economic foundations of the post-industrial societies and the rigidity of the supposedly flexible legal framework when dealing with unexpected, disruptive factors. Many an adjustment have been made: the importance of artificial intelligence has increased exponentially, resulting in the famously infamous online school, for instance, or in longer working hours for the employees working from home during

successive lockdowns, which in turn prompted calls for the regulation of remote work in Europe<sup>2</sup> etc. There has been a domino effect on almost every aspect of our life as we know it, such as our ability to interact with friends, to dine at our favorite restaurant, to go to the local gym or to travel abroad or inland.

If at the economic level, the measures taken by the states were geared towards taming the adverse effects on businesses and employees, with various degrees of success, at the societal level the response has been less cohesive and exposed the ideological differences between, on one hand, the American and the European approach to handling the Covid crisis and, on the other hand, the differences between the various EU Member States regarding the policy mix of containment, incentives or restrictions to be implemented during the pandemics.

All these factors have heavily influenced the legislation at national and EU level since 2020, again with mixed results: at the beginning of the pandemics, a few EU states have taken measures which encroached severely on key constitutional rights, such as the freedom of movement, the freedom of association or the freedom of speech and many a piece of legislation – either primary or secondary – has been struck down

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<sup>1</sup> Knatchbull-Hugessen, Hughe, „Diplomat in Peace and War”, London, John Murray. 1940, p. ix.

<sup>2</sup> Rolf, Pamela, Birnbaum, Michael, „While covid-19 continues to force remote work, Europe looks to enforce a right to disconnect”, September, the 7th, 2020, Washington Post online, available at: [https://www.washingtonpost.com/world/europe/coronavirus-remote-work-europe/2020/09/04/6e4a19c6-e23e-11ea-82d8-5e55d47e90ca\\_story.html](https://www.washingtonpost.com/world/europe/coronavirus-remote-work-europe/2020/09/04/6e4a19c6-e23e-11ea-82d8-5e55d47e90ca_story.html).

by the respective national ordinary<sup>3</sup> or Constitutional Courts<sup>4</sup>.

The prolonged restrictions have taken a heavy toll on the EU citizens, confronted with a dramatic change in their lifestyles and expectations. It could be argued that the culture of rights in Europe – some critics might label it as a culture of entitlement – has significantly crippled the pragmatic efforts made by the governments to fight the pandemic. A weary population, naturally inclined to question the legitimacy and opportunity of the decisions made by those in power, even if democratically elected, have now additional reasons to criticize the political forces, in the context of the vaccination program now in full swing in the EU.

Given the extent of the crisis, the EU response to it has been adequate and varied, fully circumscribed within its range of competencies<sup>5</sup>. It included, *inter alia*, negotiating and financing on behalf of its Member States the development of a viable vaccine by multiple pharmaceutical companies, all of whom were, sadly, non-EU. These complex agreements and financing schemes have resulted in the purchase and distribution to the EU countries of vaccine doses according to a quota based on the size of the population.

Taking into account the very short time in which these vaccines have been developed and tested, and some deaths of inoculated persons which occurred after their vaccination with certain types of vaccines, there is no wonder that so many public controversies have surrounded the respective vaccines and the whole vaccination program. An ongoing controversy relates to the vaccine produced by Astra Zeneca. It gained such magnitude, that the EU Commission felt compelled to disclose at the end of January this year<sup>6</sup> the (edited) contract signed with the developing company, which did very little to quell the alarmed European public opinion.

The centralized, state-controlled way the vaccination program is run and the prominent role played by the European Commission have brought into the spotlight the EU institutions and the entire decision making process at European level.

We share the belief that it is necessary to combine both the black-letter approach – reflected in our brief analysis of the Advance Purchase Agreement signed with Astra Zeneca with special emphasis on the clauses

pertaining to contractual liability, with the broader outline of the legal framework for the APA agreements at EU level. The complex interplay of the legal, political and economic interests which affect the management of the Covid crisis on European and international level will also be taken into account to formulate conclusions and recommendations in the final section of this paper.

## 2. Brief outline of the general legal framework for the Advance Purchase Agreements in the EU

The AP agreements negotiated by the EU Commission on behalf of EU Member States for the development, production and distribution of viable vaccines are based primarily on the so-called *ISI Regulation*, namely the Council Regulation (EU) 2016/369 of 15 March 2016 on the provision of emergency support within the Union, as amended by Council Regulation (EU) 2020/521 of 14 April 2020 activating the emergency support under Regulation (EU) 2016/369, and amending its provisions taking into account the COVID-19 outbreak. The amended ISI Regulation states at Article 4, paragraph 5, point (b) that<sup>7</sup>:

*“Emergency support under this Regulation may be granted in any of the following forms:(...)”*

*(b) procurement by the Commission on behalf of Member States based on an agreement between the Commission and Member States.”*

The procurement procedure is subject to the rules laid down in the same Article, paragraph 6, as follows:

*“6. In the event of a procurement procedure as referred to in point (b) of paragraph 5, the ensuing contracts shall be concluded by either of the following:*

*(a) the Commission, whereby the services or goods are to be rendered or delivered to Member States or to partner organisations selected by the Commission;*

*(b) the participant Member States whereby they are to directly acquire, rent or lease the capacities procured for them by the Commission.*

*7. In the event of procurement procedures as referred to in points (b) and (c) of paragraph 5, the*

<sup>3</sup> A recent example (March 31, 2020) comes from Belgium, where an ordinary court (*le tribunal de première instance de Bruxelles*) has ordered the government either to lift all restrictions pertaining the coronavirus situation or to translate them into proper primary legislation. See „Court orders Belgium to reframe virus restrictions as laws”, available online at: <https://apnews.com/article/travel-pandemics-coronavirus-pandemic-covid-19-pandemic-belgium-51dfbf0fd7bec97323f0b8d43480ce2>. French source: <https://www.lesoir.be/363910/article/2021-03-31/info-le-soir-letat-condamne-par-le-tribunal-de-bruxelles-qui-juge-les-mesures>.

<sup>4</sup> For instance, in May 2020, the Romanian Constitutional Court struck down the Government Emergency Ordinance (OUG) no. 34/2020 regarding the amendment of OUG nr. 1/1999 concerning the state of emergency and the state of siege, as unconstitutional, on the grounds that it is the Parliament and not the President which has the competency to instate - by primary legislation only - restrictions on the basic freedoms and rights of the citizens. See CCR Decision no. 152/6.05.2020, [http://www.ccr.ro/wp-content/uploads/2020/06/Decizie\\_152\\_2020.pdf](http://www.ccr.ro/wp-content/uploads/2020/06/Decizie_152_2020.pdf).

<sup>5</sup> For an in-depth analysis on this subject, see Salomia, Oana-Mihaela, Dumitraşcu Augustina, “Eficacitatea măsurilor adoptate de Uniunea Europeană pentru sprijinirea statelor membre în perioada pandemiei de covid-19” (*The effectiveness of the measures taken by the EU to support Member States during the covid-19 pandemic*), *Revista “Analele Universității din București”, seria Drept*, 2020, Ed. C.H. Beck.

<sup>6</sup> „Covid: EU-AstraZeneca disputed vaccine contract made public”, 29 January 2021, <https://www.bbc.com/news/world-europe-55852698>.

<sup>7</sup> Regulation (EU) 2016/369 of 15 March 2016, available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02016R0369-20200201>.

*Commission shall follow the rules set out in Regulation (EU, Euratom) 2018/1046 for its own procurement.”*

In addition to these general legal provisions, the EU Commission has adopted the Decision C(2020) 4192 final of 18 June 2020 approving the agreement with Member States on procuring covid-19 vaccines on behalf of the Member States and related procedure<sup>8</sup>.

The complexity of the EU legislation regarding the public procurement, the involvement of both the EU Council and the Commission<sup>9</sup>, the manifold aspects concerning the delegated powers, the shared or exclusive regulatory competencies have lead, in practice, to implementation problems related to the very structure of the split decision making process in the EU. It is beyond the scope of this paper to dwell on the technicalities of the public procurement in the EU, aspects which have been analysed at length by the academic doctrine<sup>10</sup>.

Complexities notwithstanding, this legal structure enabled the EU Member States to act cohesively and to mitigate the humanitarian consequences of the Covid crisis, benefiting both in terms of priority and of choice of vaccines, as opposed to negotiating individual agreements with the pharmaceutical companies. EU has concluded AP agreements with a number of private companies, but to date only Pfizer, BioNTech, Moderna, Astra Zeneca and Johnson & Johnson have produced and delivered tested vaccines, while the Sanofi-GSK and CureVac vaccines are still in development stage.

But what do these advance purchase agreements mean and which role do they play in dealing with the Covid crisis?

In June 2020, the European Commission has issued the Communication on EU Strategy for COVID-19 vaccines, COM (2020) 245 final, stating its goals and strategy related to this stringent issue. Recognising that the development of a viable vaccine usually takes more than 10 years, the Commission sets forth its strategy on Covid-vaccine development and production within a timeframe of 12-18 months, based on 2 principles:

“ - *Securing sufficient production of vaccines in the EU and thereby sufficient supplies for its Member States through Advance Purchase Agreements (APAs) with vaccine producers via the Emergency Support Instrument (ESI 2 ). (...)*

- *Adapting the EU’s regulatory framework to the current urgency and making use of existing regulatory*

*flexibility to accelerate the development, authorisation and availability of vaccines while maintaining the standards for vaccine quality, safety and efficacy.”<sup>11</sup>*

The purpose served by the advance purchase agreements is explained clearly in Section 2.2., Paragraph 1:

*“In order to support companies in the swift development and production of a vaccine, the Commission will enter into agreements with individual vaccine producers on behalf of Member States. In return for the right to buy a specified number of vaccine doses in a given timeframe and at a given price, part of the upfront costs faced by vaccines producers will be financed from the ESI. This will be done in the form of advance purchase agreements (APAs).”*

This upfront part-financing scheme has already yielded results, as mentioned above, EU being able to secure an adequate share of vaccines at a given price, though – it is important to note – none of the working vaccines were developed in Europe. This mechanism seemed to work flawlessly until delays in delivery of Astra Zeneca vaccines angered the public opinion in Europe. The pressure on the EU Commission mounted, culminating in the disclosure of the significantly edited procurement agreement signed with Astra Zeneca.

### **3. The Astra Zeneca Advance Purchase Agreement – a case for limited liability?**

What are the controversial clauses? What triggered so much resentment, what prompted so many headlines in online media?

The answer is not clear-cut and it involves, as stated in the introductory section, more than the legalistic analysis of the actual contract. Caving in to public pressure, the Commission has published not only the APA with Astra Zeneca, but also the edited agreements signed with Moderna and Pfizer, while the Johnson & Johnson contract is - to date - not available<sup>12</sup>.

The headlines in the media focused initially on the delays in delivery of the vaccine doses, Astra Zeneca invoking production issues at the Belgium manufacturing plant. Instead of (presumably) 80 million vaccines, as initially scheduled, at the beginning of the year the company had delivered only

<sup>8</sup> Decision C(2020) 4192 final of 18 June 2020, available at [https://ec.europa.eu/info/sites/info/files/decision\\_approving\\_the\\_agreement\\_with\\_member\\_states\\_on\\_procuring\\_covid-19\\_vaccines\\_on\\_behalf\\_of\\_the\\_member\\_states\\_and\\_related\\_procedures.pdf](https://ec.europa.eu/info/sites/info/files/decision_approving_the_agreement_with_member_states_on_procuring_covid-19_vaccines_on_behalf_of_the_member_states_and_related_procedures.pdf).

<sup>9</sup> For an interesting perspective on the complex role played by the EU Council and the Commission in relation to the EU Member States, see Bantaş, Dragoş-Adrian, “Considerations relating to the role of the Council in the institutional union of the European Union”, p. 448-451, CKS 2019, Public Law Section, available online at: <http://cks.univnt.ro/articles/14.html>.

<sup>10</sup> Salomia, Oana-Mihaela, Bantaş, Dragoş-Adrian, “Aspecte generale privind competența Uniunii Europene în domeniul achizițiilor publice”, (*General considerations on the EU competencies regarding the public procurement*), in Revista „Achizițiile publice. Idei noi, practici vechi”, Ed. Universitară, 2020, p. 230-233.

<sup>11</sup> COM (2020) 245 final, available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020DC0245>.

<sup>12</sup> See [https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/public-health/eu-vaccines-strategy\\_en#authorised-vaccines](https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/public-health/eu-vaccines-strategy_en#authorised-vaccines), for the published redacted contract; consulted at 8<sup>th</sup> of April, 2021.

a quarter of the amount specified by the contract<sup>13</sup>. The questions that were starting to pop up concerned the contractual commitments undertaken by Astra, the extent of its liability and the means – if any – available to the Commission as signatory party on behalf of the EU Member States to enforce the contract and impose penalties for delays in delivery.

There are countless ways in which a company could benefit from the wording of a contract, ranging from the definitions of the terms used, to the warranties, rights and obligations and the choice of applicable substantial or procedural law. Some key points on the Astra Zeneca APA: the choice of law is Belgian law, pertaining to the civil law tradition, hence the interpretation of contract is made according to the principles of interpretation that stem from the tradition of the Napoleonic code, which emphasizes the contextual, systematic interpretation of the contract. Like the Romanian law, the Belgium law recognises the difference between an obligation of means (endeavours clause) and an obligation of result, a difference which reflects directly in the way the liability and the burden of proof are distributed in case of breach of contract.

The wording of the contract clearly states that the company is under an obligation of means, and not of result, with respect to the manufacturing and supply of the initial doses allocated to Europe, as per Article 5.1:

“5.1. Initial Europe Doses. AstraZeneca shall use its Best Reasonable Efforts to manufacture the Initial Europe Doses within the EU for distribution, and to deliver to the Distribution Hubs, following the EU marketing authorisation, as set forth more fully in Section 7.1, approximately [edited], Q 1 2021, and (iii) the remainder of the Initial Europe Doses by the end of [edited]”.

Though familiar to the Anglo-Saxon lawyers, the “Best Reasonable Efforts” is by no means a very clear concept that could be separated by the extensive case law in US or UK courts and, in our opinion, does not have an equally extensive case law equivalent in the civil legal systems. The endeavour clauses (*Best efforts/endeavours, Reasonable efforts, Best reasonable efforts* etc.) express various degrees of commitment and efforts required from the party undertaking an obligation of means<sup>14</sup>. In case of the Astra Zeneca contract, the term used implies a heightened - but not a maximal, nor unmitigated - obligation and is defined in Article 1.9 as follows:

1.9. “Best Reasonable Efforts” means

(a) in the case of AstraZeneca, the activities and degree of effort that a company of similar size with a similarly-sized infrastructure and similar resources as AstraZeneca would undertake or use in the

development and manufacture of a Vaccine at the relevant stage of development or commercialization having regard to the urgent need for a Vaccine to end a global pandemic which is resulting in serious public health issues, restrictions on personal freedoms and economic impact, across the world but taking into account efficacy and safety; and

(b) in the case of the Commission and the Participating Member States, the activities and degree of effort that governments would undertake or use in supporting their contractor in the development of the Vaccine having regard to the urgent need for a Vaccine to end a global pandemic which is resulting in serious public health issues, restrictions on personal freedoms and economic impact, across the world.”<sup>15</sup>

The Commission alleged that the delays in the supply of the Initial EU Doses were caused, *inter alia*, by the parallel commitments undertaken by Astra Zeneca to deliver vaccines to other countries, mainly to the UK. Following the statements made by Pascal Sariat, the chief executive of the company, during an interview for the Italian newspaper La Repubblica<sup>16</sup>, that the pharmaceutical company was under an obligation to make its best reasonable efforts to deliver and not under an obligation to actually deliver the vaccines, the Commission accused the British-Swedish company that it was not making its best reasonable efforts to compensate the shortages in the manufacturing site in Belgium, by using the capabilities of the UK manufacturing sites, assimilated as per Article 5.4 (“Manufacturing Sites”) to the manufacturing sites located within the EU. It also invoked the warranty made by Astra Zeneca in Article 13.1. (e) that “it is not under any obligation, contractual or otherwise, to any Person or third party in respect of the Initial Europe Doses or that conflicts with or is inconsistent in any material respect with the terms of this Agreement or that would impede the complete fulfilment of its obligations under this Agreement”. The means available to the Commission in case of breach of contract by the company are set out in Article 12.3. (“Termination for cause”), with a strong emphasis on pre-termination measures and negotiation.

The company undertook the necessary steps to remedy the shortages in production. The manufacturing and delivery of Astra Zeneca vaccines continue, despite new controversies which appeared, this time, in relation to the safety and efficiency of the vaccine itself.

The public interest and alarm, fuelled by the acrimonious statements on both the European and the British side, led to an intense pressure on the Commission to disclose the Advance Purchase Agreement and raised the question of where the balance

<sup>13</sup> Tensions rise as AstraZeneca, EU spar over vaccine delays”, by Raf Casert, Samuel Petrequin and Danica Kirka, January 28, 2021, available at: <https://apnews.com/article/europe-europe-coronavirus-pandemic-coronavirus-vaccine-ba107e05dec2653f91555ff88033ade9>

<sup>14</sup> For an analysis of the way the US courts are likely to interpret these terms, see Kenneth A. Adams “Understanding *Best Efforts* And Its Variants (Including Drafting Recommendations)”, available at: <https://adamsdrafting.com/downloads/Best-Efforts-Practical-Lawyer.pdf>.

<sup>15</sup> The edited Astra Zeneca APA is available at: [https://ec.europa.eu/info/files/redacted-advance-purchase-agreement-astrazeneca\\_en](https://ec.europa.eu/info/files/redacted-advance-purchase-agreement-astrazeneca_en).

<sup>16</sup> Antonello Guerrera, Stefanie Bolzen, Rafa de Miguel, *Pascal Sariat: ‘There are a lot of emotions on vaccines in EU. But it’s complicated’*, 26.01.2021, at: [https://www.repubblica.it/cronaca/2021/01/26/news/interview\\_pascal\\_sariat\\_ceo\\_astrazeneca\\_coronavirus\\_covid\\_vaccines-284349628/](https://www.repubblica.it/cronaca/2021/01/26/news/interview_pascal_sariat_ceo_astrazeneca_coronavirus_covid_vaccines-284349628/).

of contractual power actually lies. As mentioned at the beginning of this section, the Commission also disclosed the edited versions of the APAs signed with Pfizer and with Moderna. How different are these two contracts from the Astra Zeneca agreement?

The contract signed with Moderna, a company incorporated in Switzerland, is not illuminating in any respect, given the fact that the section referring to the company's liability has been edited, so was the section setting out the applicable law and the dispute resolution (section I.11.2.) or the section detailing the schedule for the delivery of the vaccines<sup>17</sup>. Moreover, Article 1.2 of the contract also uses the term of *Best reasonable efforts* to circumscribe the obligation of the company "to establish sufficient manufacturing capacities to enable the manufacturing and supply of the contractually agreed volumes of the Product".

The APA signed with Pfizer and BioNTech (an American-German joint venture) is disclosed on the site of the Commission along the same lines<sup>18</sup>. Article 1.2 ("Definitions") has the definition of *Best Reasonable Efforts* edited in full, and that of what constitutes *Force Majeure* almost in full. Other sensitive clauses, of legitimate interest for the public opinion, such as the product supply mechanism, the schedule, indemnification are extensively or fully edited. The agreement is governed by the Belgium law, as in the case of Astra Zeneca.

Even when analysing the heavily edited versions of the contracts, it can be easily ascertained that all the disclosed APAs contain similar clauses, that all of them place the manufacturing companies under an enhanced obligation of best reasonable efforts and not under an obligation of result, and that the wording of the contracts reflects the style of contractual drafting specific to common law lawyers, in spite of the Belgium law chosen as governing law of the agreements.

This brief presentation purported to show that the legalistic approach to the Astra Zeneca contract is not sufficient by itself when attempting to analyse the possible implications of the agreement on the EU management of the pandemic and the future decisions regarding our health.

#### 4. Vaccination today: beyond the medical side-effects

Are there any other factors to affect the EU vaccination policy, besides the somewhat too liberal wording of the contracts concluded with the pharmaceutical companies?

Borrowing loosely from the field of comparative law the concept of legal formants, defined as "the

different components that concur to build any given legal system"<sup>19</sup>, I will endeavour to show how the EU health policies and health related regulations are shaped by the complex interplay of the legal, political and economic interests on European and international level. I would like to put forth the idea that vaccines have citizenships just as people do and that they are not ideological-neutral.

This aspect has been openly acknowledged by some British commentators<sup>20</sup> when considering the patchwork picture of the Astra Zeneca vaccine rollout in Europe: problems with the supply, fears about the link between the vaccine and some thrombosis-caused deaths, the briefly considered, but not enforced ban by the EU on vaccine exports to the UK etc. The view from across the Channel regarding the EU agreement with Astra Zeneca is that the EU has been outsmarted by the countries with faster vaccine authorisation procedures and more flexible decision making structures and that all the legal skirmishes are actually side effects of the post-Brexit EU-UK trade relations.

Under the terms of the EU scheme for vaccine strategy, as set out by Article 7 of the Decision C (2020) 4192 final of 18 June 2020 (mentioned in the previous section), the EU Member States are allowed to conclude separate deals with vaccine producers which have not signed agreements with the EU. The implications of this apparently neutral legal provision are all but neutral: the development by Russia and China of alternative vaccines and the aggressive marketing conducted at state-level in support to their respective national vaccines divided Europe along ideological lines: Poland and Romania, for example, refused even to consider the possibility of importing these vaccines, while countries such as Hungary, Slovakia already bought the Sputnik V vaccine developed by the Russian company Gamaleya. At the end of March, Germany and France started to show more receptiveness about these vaccines, in spite of the ongoing tense relations with Russia over its treatment of political dissidents and involvement in regional conflicts or the disagreements with China over its human rights track record.

In contrast to the European policies, the US measures regarding the vaccine development have been less hampered by bureaucracy, the previous administration pursuing an aggressive policy of 'America first' in securing the supply of vaccine doses for its population through public acquisitions – a significant departure from the practice of letting private companies to procure and distribute vaccines for individuals. A faster authorisation process gave the US a competitive advantage over EU in this matter, even if the legal instruments were similar – the use of advance

<sup>17</sup> The APA signed with Moderna is available at: [https://ec.europa.eu/info/files/redacted-advance-purchase-agreement-moderna\\_en](https://ec.europa.eu/info/files/redacted-advance-purchase-agreement-moderna_en).

<sup>18</sup> The APA signed with Pfizer BioNTech is available at: [https://ec.europa.eu/info/files/redacted-purchase-agreement-biontech-pfizer\\_en](https://ec.europa.eu/info/files/redacted-purchase-agreement-biontech-pfizer_en).

<sup>19</sup> Gardella Tedeschi B. (2019) "Legal Formants" in: Marciano A., Ramello G. (eds) *Encyclopedia of Law and Economics*. Springer, New York, NY. [https://doi.org/10.1007/978-1-4614-7883-6\\_708-1](https://doi.org/10.1007/978-1-4614-7883-6_708-1).

<sup>20</sup> Simon Jack, "AstraZeneca vaccine - was it really worth it?", 30 March 2021, <https://www.bbc.com/news/business-56570364>; see also "Covid: What's the problem with the EU vaccine rollout?", 8 April 2021, <https://www.bbc.com/news/explainers-52380823>.

purchase agreements largely, but not exclusively, funded by the government.

Last, but not least, there are sheer economic considerations at play. Can the pharmaceutical companies (some of which are ranked as “Big Pharma”) reign in their drive for profit maximisation and prioritize considerations such as the global solidarity in face of an extraordinary health crisis? From the very beginning of the pandemics, governments and private donors poured huge amount of money in the development of viable vaccines. Some companies, like Astra Zeneca or Johnson & Johnson, announced they intended to sell their vaccines at a price that just covers their manufacturing costs.<sup>21</sup> Given the current EU official trend for redacted contracts, it is not easy to ascertain in practice if their resolution came true with respect to the advance purchase agreements signed with the EU Commission.

All these factors - ideology, politics and economics - are legal formants, in the sense that they do shape the health policies at both national and European level.

## 5. Conclusions

Aware of the glitches in its health policies and strategies to combat the covid pandemics, the EU Commission has launched on the 31<sup>st</sup> of March an online public consultation on the Health Emergency Preparedness and Response Authority (HERA),

addressing questions on topics such as: “the EU's framework to develop, manufacture and deploy medical countermeasures; anticipatory threat and risk assessments; market dynamics and supply chain intelligence; the development and financing of new countermeasures in times of crisis; the impact, role, scope and coordination of a future HERA”<sup>22</sup>. It remains to be seen if yet another European body will indeed make all the difference in the management of the future crises or if the problems are of a different nature.

In the short run, measures such as streamlining the authorisation procedures for vaccines and increasing the manufacturing capacities of the EU based companies should, in our opinion, take precedence. Based on the divergent decisions adopted by the individual governments with respect to the alternative vaccines purchased in addition to those negotiated on their behalf by the Commission, it may well be that, in the future, the EU Member States will exercise more discretion in opting for certain vaccines, to the expense of the principle of solidarity within the Union. It becomes necessary to adopt a common stance – a Europe who speaks with one voice – which, in turn, will strengthen the principle of solidarity which underlines the whole European legal order.

Unwittingly, the row over the Astra Zeneca advance purchase agreement might have been the impulse for a more pragmatic approach to the all important issues and future decisions regarding our health.

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## Online resources:

- The ASTRA ZENECA Advance Purchase Agreement (APA), redacted form, available online at: [https://ec.europa.eu/info/files/redacted-advance-purchase-agreement-astrazeneca\\_en](https://ec.europa.eu/info/files/redacted-advance-purchase-agreement-astrazeneca_en);
- The MODERNA Advance Purchase Agreement (APA), redacted form, available online at: [https://ec.europa.eu/info/files/redacted-advance-purchase-agreement-moderna\\_en](https://ec.europa.eu/info/files/redacted-advance-purchase-agreement-moderna_en);
- The PFIZER-BIONTECH Advance Purchase Agreement (APA), redacted form, available online at: [https://ec.europa.eu/info/files/redacted-purchase-agreement-biontech-pfizer\\_en](https://ec.europa.eu/info/files/redacted-purchase-agreement-biontech-pfizer_en);
- Regulation (EU) 2016/369 of 15 March 2016, available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02016R0369-20200201>;
- CCR Decision no. 152/6.05.2020, available online at: [http://www.ccr.ro/wp-content/uploads/2020/06/Decizie\\_152\\_2020.pdf](http://www.ccr.ro/wp-content/uploads/2020/06/Decizie_152_2020.pdf);

<sup>21</sup> Lucy Hooker, Daniele Palumbo: “Covid vaccines: Will drug companies make bumper profits?”, 18 December 2020, available at: <https://www.bbc.com/news/business-55170756>.

<sup>22</sup> [https://ec.europa.eu/commission/presscorner/detail/en/IP\\_21\\_1522](https://ec.europa.eu/commission/presscorner/detail/en/IP_21_1522).

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- Rolf, Pamela, Birnbaum, Michael, “While covid-19 continues to force remote work, Europe looks to enforce a right to disconnect”, September, the 7th, 2020, Washington Post online, available at: [https://www.washingtonpost.com/world/europe/coronavirus-remote-work-europe/2020/09/04/6e4a19c6-e23e-11ea-82d8-5e55d47e90ca\\_story.html](https://www.washingtonpost.com/world/europe/coronavirus-remote-work-europe/2020/09/04/6e4a19c6-e23e-11ea-82d8-5e55d47e90ca_story.html);
  - „Court orders Belgium to reframe virus restrictions as laws”, March 31, 2020, available online at: <https://apnews.com/article/travel-pandemics-coronavirus-pandemic-covid-19-pandemic-belgium-51dfbf0fd7becc97323f0b8d43480ce2>;
  - [https://ec.europa.eu/info/index\\_en](https://ec.europa.eu/info/index_en).