

# ETHICS webinar

2 June 2020



## ETHICS WEBINAR 3 Covid-19: Public Procurement in times of crisis & other practical cases

ethics



# Webinar objective

- ⌚ This webinar is the third edition of a series of webinar organised by ETHICS.
- ⌚ The objective of this webinar is to allow healthcare compliance officers to share and discuss challenges brought about by the COVID-19 crisis. It addresses the impact of COVID-19 on public procurement.
- ⌚ Note: only personal opinions are expressed during this session



# Agenda

<b>Intro and welcome</b>	Roeland Van Aelst, ETHICS President
<b>Public procurement in times of crisis</b>	Steffen Amelung, Counsel Clifford Chance Germany
<b>Discussion on "Exceptional Price Increases, EU Anti-Trust Exemptions and Are We Still In An Emergency Situation?" by John McLoughlin, Lawyer and ETHICS Editor</b>	John McLoughlin, Lawyer and ETHICS Editor
<b>Practical Case</b>	Anne-Sophie Bricca, Deputy General Counsel TERUMO BCT
<b>Considerations on TPIs being investigated for price gouging</b>	Roeland Van Aelst, ETHICS President and EMEA Lead Third Party Intermediary Ethics & Compliance, Johnson & Johnson
<b>Questions and answers</b>	Session moderated by Arthur Muratyan, ETHICS General Secretary

**C L I F F O R D  
C H A N C E**



**PUBLIC PROCUREMENT  
IN THE CONTEXT OF COVID 19**

STEFFEN AMELUNG, CLIFFORD CHANCE DEUTSCHLAND LLP  
ETHICS WEBINAR  
2 JUNE 2020



## **AGENDA**

- I. Legal background**
- II. Urgent procurement due to COVID-19**
- III. COVID-19 impact on existing public contracts**
- IV. Examples on national level**
- V. Summary**

# I. LEGAL BACKGROUND



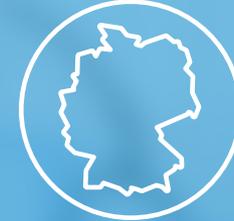
## 1. EU Directive 2014/24/EU ("Public Procurement Directive" – "PPD")

- Principles of procurement, Art. 18 PPD
- Choice of procedures, Art. 26 et seq. PPD
- In particular: negotiated procedure without prior publication
- Time limits



## 2. Guidance from the European Commission on using the public procurement framework in the emergency situation related to the COVID-19 crisis (2020/C 108 I/01)

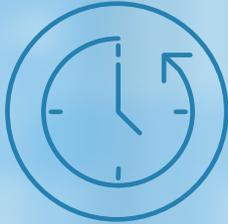
- In particular: options and flexibilities for the purchase of supplies and services



## 3. National public procurement law

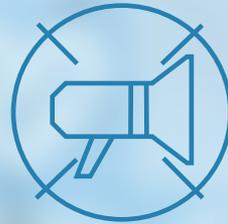
- Above EU thresholds:  
in general, PPD has been  
transposed literally  
into national law
- Below EU thresholds:  
only national law applies

## II. URGENT PROCUREMENT DUE TO COVID-19



### 1. Reducing deadlines to accelerate open/restricted procedure

- Admissible in case of **urgency**: reduction of the deadline to submit an offer from 35/30 to 15/10 days



### 2. Negotiated procedure without publication, Art. 32 PPD

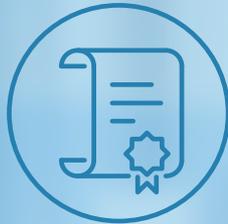
- Admissible in case of **extreme urgency**, (+) if
  - reg. specific needs of hospitals (personal protection/technical equipment/intensive care)
  - compliance with general deadlines impossible
  - only used in order to cover the gap until more stable solutions can be found



### 3. Direct award to a preselected company

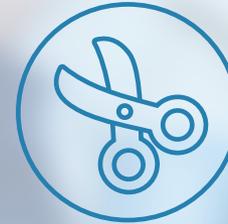
- Only admissible in case of extreme urgency **and** if only one company is able to deliver within the technical and time constraints imposed by the extreme urgency

### III. COVID-19 IMPACT ON EXISTING PUBLIC CONTRACTS



#### 1. Contract modifications reg. service enhancements / increasing quantities (Art. 72 PPD)

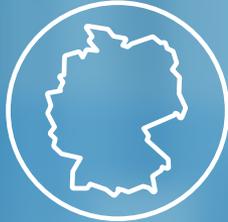
- Obligation to re-tender in case of substantial modifications
- No re-tender reg. modifications
  - that have been provided for in the initial procurement documents / original contract
  - due to unforeseeable circumstances (COVID-19), **but**: modifications must not alter the nature of the contract **and** increase in price does not exceed 50% of original contract value



#### 2. Shortening of contract period / reduction of supplies and services / contract cancellations

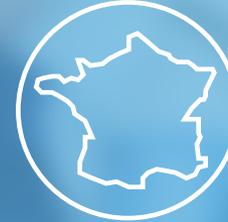
- No public procurement law but national law applies
- In principle, the wording of the contract is decisive
- In addition, national administrative or private/contract law may apply (2 examples see next slide)

## IV. EXAMPLES ON NATIONAL LEVEL (SHORTENING CONTRACT PERIOD /CANCELLATION OF CONTRACT)



### 1. Germany

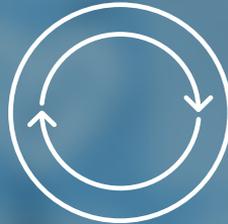
- *Pacta sunt servanda* – contracts must be observed
- In exceptional cases, the basis of the contract may cease to exist
  - e.g. if it would be unreasonable for at least one party to adhere to the contract



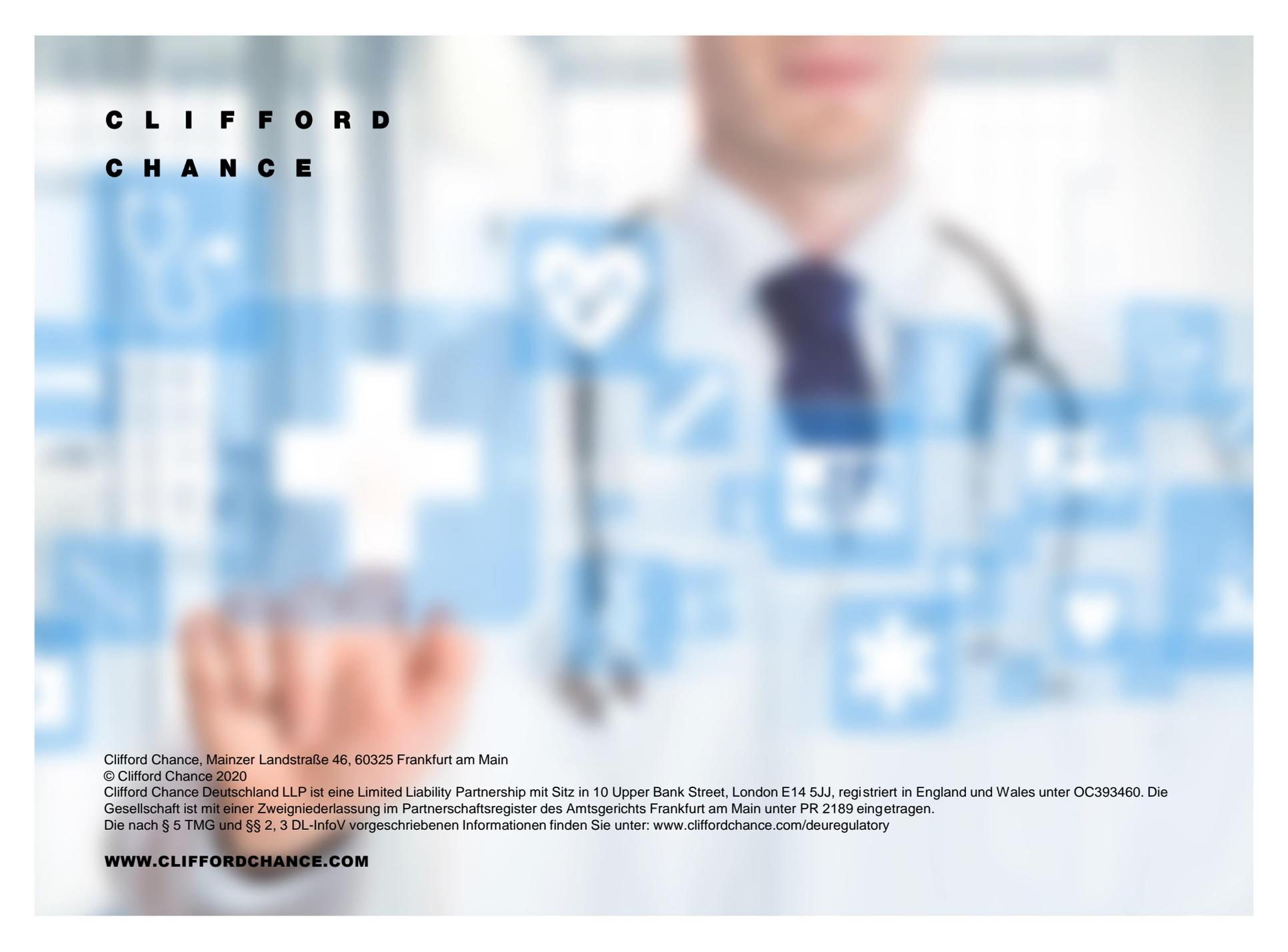
### 2. France

- Art. L6 of French Ordinance N 2018-1074:
  - Allows French contracting authorities to unilaterally modify or terminate public contracts
  - However, the contractor may claim indemnification for the losses actually incurred

## V. SUMMARY



1. Public procurement (PPD) law also applies in the context of COVID-19
2. Guidance from the EU Commission (2020/C 108 I/01) helps to apply/interpret the PPD
3. According to Art. 32 PPD, services and supplies reg. specific needs in the hospital/healthcare sector may be awarded by way of the negotiated procedure or even by way of a direct award using very short deadlines
4. Contract modifications reg. service enhancements or increasing quantities are governed by public procurement law; may be justified without an obligation to re-tender, Art. 72 PPD
5. Contract modifications reg. reduction of supplies and services / contract cancellations are governed by national law



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**COVID 19**  
**Exceptional Price Increases**  
**Cooperation Between Competitors**  
**Are We Still in An Emergency Situation?**

**Ethical, Compliance & Legal Considerations**

**John McLoughlin**  
**Editor – ETHICS In Action**



# EXCEPTIONAL PRICE INCREASES

- Price increases for certain medical products have been dramatic during the past several months.
- European countries and the EU Commission have taken steps to prevent, investigate and in some cases prosecute unjustified excessive pricing.
- Action taken in France and Italy.
- March 20 The UK Competition and Markets Authority (CMA) Open Letter to the pharmaceutical industry.
  - Some firms are seeking to capitalize on the current situation by charging unjustifiably high prices for essential goods
  - The CMA Open Letter points out that it has recourse to a range of competition powers to tackle bad behavior



However, not all exceptional price increases are the result of abusive practices. Many have occurred due to supply chain disruptions or shortages.

It is critical for pharmaceutical and medical technology companies to properly document the reasons behind sudden significant product price increases in order to clearly demonstrate that the increases were due to market conditions and, therefore, were not abusive.



# EU ANTI-TRUST EXEMPTIONS - JOINT STATEMENT

On March 23, the European Competition Network (ECN), which represents national anti-trust regulators in the 27 European member states, issued a Joint Statement on the COVID 19 emergency regarding cooperation between competitors and the exchange of confidential information between them.

- The Joint Statement provides that the current COVID 19 crisis is an “extraordinary situation” which may trigger the need for companies to cooperate in order to ensure the supply and fair distribution of scarce products to all consumers.
- The ECN “will not actively intervene against **necessary** and **temporary** measures put in place in order to avoid a shortage of supply”.
- Exchange of information between companies is permitted for a limited period of time only during this extraordinary situation.



**HOWEVER, VIOLATIONS MAY BE PROSECUTED**

**COMPANY FILES REGARDING COOPERATION WITH**

**OTHER HEALTHCARE COMPANIES MUST BE**

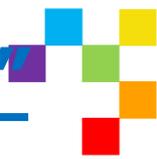
**DOCUMENTED AND SHOULD DESCRIBE AND JUSTIFY**

**THE NATURE AND EXTENT OF THE COOPERATION,**

**THE INFORMATION EXCHANGED AND THE TIME**

**LIMITS INVOLVED**

# ARE WE STILL IN AN “EXTRAORDINARY” “EXTREME” OR “EMERGENCY” SITUATION?



- Different terms are used by the authorities to describe the current emergency situation.
- Are we still in an emergency?
- It can be argued that given the significant drop in new COVID 19 cases in most areas of Europe, the emergency phase of the crisis in Europe has come to an end, although there may be local regional exceptions.
- Are the procurement exceptions set out in the European Commission’s April 1, 2020 Public Procurement Guidance Document and the March 23, 2020 ECN Anti-Trust Joint Statement still applicable or have they expired?



- Shortages of medical equipment and drugs still exist in some areas
- There may be a second wave of COVID 19
- Hospitals and public authorities are "stocking up"
- There may be other pandemics or natural disasters in the future
- However, it is clear that both for public procurement and the anti-trust exemptions the EU authorities envisaged only immediate, short term measures and not long-term exceptions.

COMPANIES MUST OBTAIN WRITTEN CONFIRMATION FROM PURCHASING HOSPITALS AND PUBLIC AUTHORITIES THAT THE EXCEPTIONS SET OUT IN THE PUBLIC PROCUREMENT GUIDANCE DOCUMENT APPLY

# What About New Vaccines, Drugs and Medical Equipment?



- Competing companies are working together to develop and manufacture new vaccines and drugs to treat COVID 19 as well as antibody testing machines and other equipment.
- These projects could take a year or more.
- The March 23 ECN Joint Statement on Cooperation Between Competitors refers to:
  - A limited time only,
  - Where there is a shortage of supply.



**COMPETITORS SHOULD SEEK A SPECIFIC COOPERATION EXEMPTION FROM EU AND LOCAL AUTHORITIES WHEN WORKING ON LONG-TERM VACCINE, DRUG & OTHER PROJECTS**

**ALL FORMS OF COOPERATION WITH COMPETITORS WHETHER PAST PRESENT OR FUTURE NEED TO BE JUSTIFIED AND DOCUMENTED BY THE COMPANIES CONCERNED.**



**THANKS FOR YOUR ATTENTION**

**STAY SAFE AND ETHICAL**