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**A MESSAGE FROM ANNE-SOPHIE BRICCA CO-CHAIR OF
THE ETHICS STRATEGIC COMMITTEE**

Dear ETHICS members – Welcome to Special Edition N°4 of ETHICS In Action. This edition focuses on ethics and compliance considerations relating to supply chain disruptions, product shortages and the risks of unjustified excess pricing and fraud arising out of the current COVID 19 crisis. Follow-up Special Editions will review from a compliance perspective the European Commission’s Temporary Antitrust Framework and the Communication from the European Commission on Public Procurement during the COVID 19 emergency.



Anne-Sophie Bricca

Do not miss our upcoming ETHICS COVID 19 WEBINARS which will address many of the above topics. Clarisse Aillet will be sending out information on the next webinar shortly.

**SUPPLY CHAIN DISRUPTIONS, PRODUCT SHORTAGES,
UNJUSTIFIED EXCESS PRICING AND FRAUD IN THE CONTEXT OF
COVID 19**

The current COVID 19 emergency has forced healthcare companies to take exceptional measures in order to deal rapidly with urgent customer requirements. Companies are finding that prices of certain raw materials have increased dramatically. In addition, many supply chains have been overwhelmed due to exceptional demand resulting in product shortages. The situation has also attracted bad actors who are trying to profit from the crisis.

During the past several weeks the press has been reporting that many public hospitals, health authorities and even governments are having great difficulty in obtaining sufficient quantities of pharmaceutical products and medical devices as well as personal protection equipment for their healthcare professionals. As a result, certain purchasers have turned to unknown intermediaries who promise rapid deliveries. In some cases these sales have turned out to be scams. Either the items purchased were not delivered or if they were they did not conform to specifications or were defective. Frequently, in these situations the prices charged are exorbitant.

Pharmaceutical and medical technology companies are at risk of falling victim to these same illicit channels by inadvertently aiding and abetting bad actors in carrying out their unethical and sometimes illegal schemes. For example, an unknown intermediary may have convinced a public hospital or health authority which is desperate for a particular type of medical device or drug which it cannot obtain through its normal source of supply that the intermediary can

deliver the product quickly but at a very high price. The public hospital or health authority agrees to make the purchase. In fact, the intermediary does not have the product in stock. Instead, it contacts a healthcare company which produces the products in question, negotiates a purchase price at or above the healthcare company's normal list price and then resells the goods to the public hospital or health authority at a huge markup. Much later, the scheme is uncovered and the national authorities start an investigation for unjustified excess pricing. Of course, by that time the intermediary has disappeared and the healthcare company ends up facing scrutiny regarding its perceived involvement in the scheme.

Set out below is a short summary of some of the steps that four European countries and the EU Commission have taken to date regarding supply chain disruptions, product shortages, unjustified excessive pricing and fraud:

France – On March 3 the French government issued a decree requisitioning all inventories of high protection (FFP2) and basic anti-projection facial masks held by any company or legal entity in France. On March 23, prices for hand gels and similar disinfecting solutions were fixed by Decree. On May 1, the Ministry of Economy and Finance announced price restrictions on facial masks and instructed the French economic police (DGCCRF) to conduct an investigation regarding on-line and other channels selling masks in France, often at highly inflated prices and of poor quality.

Spain – In April, the Spanish Agency for Medication and Health Products issued a warning to the public not to purchase so-called “coronavirus drugs” on the internet since the drugs being offered for sale are fraudulent. The authorities pointed out that there is no known effective self-treatment for coronavirus and, in any event, only medication prescribed by a doctor should be taken.

Italy – The Italian Consumer Protection and Competition Authority (AGCM) is currently investigating misleading claims and excessive price increases relating to various personal protection items. Also, an investigation regarding fraudulent products have been initiated. In April the Italian police seized over 900 fake coronavirus testing kits which were found in a lab in Calabria.

UK – On March 20 The UK Competition and Markets Authority (CMA) sent an open letter to the pharmaceutical industry saying “...(We) have received reports that a minority of firms in your sector are seeking to capitalize on the current situation by charging unjustifiably high prices for essential goods ... If appropriate, the CMA has recourse to a range of competition powers to tackle bad behavior.”

EU Commission – On March 23, the European Competition Network (ECN), which represents national regulators in the 27 member states, issued a joint statement saying that they will not “actively intervene” when companies must cooperate “in order to ensure the supply and fair distribution of scarce products to all consumers” during the current COVID 19 crisis. However, the joint statement goes on to say that “it is of utmost importance to ensure that products considered essential to protect the health of consumers in the current situation ...remain available at competitive prices. The ECN will therefore not hesitate to take action against companies taking advantage of the current situation”.

It should be noted that it is possible for pharmaceutical and medical technology companies to justify sudden and even major product price increases if they are the result of supply problems.

For example, it has been widely reported that the market price of certain raw materials and compounds have increased dramatically. Also, supply chains have in certain countries suffered disruptions which require alternative arrangements that significantly increase costs. In such situations, price increases can be justified if properly documented. The UK Competition and Markets Authority (CMA) in its open letter to the pharmaceutical industry wrote “We understand that some price rises may result from constraints further up the supply chain. For example, if an individual firm raises its prices as a result of passing on increased prices from wholesalers or suppliers, then this may be unavoidable.” However, the CMA then goes on to say “However, where this is happening, we would like to hear from you about any information relating to such price increases by wholesalers or suppliers, so that we can investigate these issues further up the supply chain.”

Clearly, the EU Commission and the authorities in most European countries are looking closely at practices by companies in the healthcare sector in order to prevent and, in some cases, prosecute unethical and illegal behavior during the COVID 19 crisis.

Points to consider:

1. Does my company have systems in place to identify supply chain issues that may result in increased sales prices to customers above pre-COVID 19 levels?
2. Are those supply chain issues being properly documented?
3. Are customers being informed about the reasons for significant price increases?
4. Where appropriate or required are procedures in place to inform my company’s trade association of supply chain problems that will significantly push up the sales price of our products so that the association can notify the appropriate authorities (for example, the UK’s CMA)? As a precaution, should my company notify the authorities directly regarding the reasons behind exceptional price increases?
5. What procedures are in place in my company to avoid falling into ethical or legal traps when dealing with previously unknown suppliers or customers? Have we identified the possible risks involved? Have expedited vetting procedures been put into place to minimize these risks? Should my company only add new customers that are Healthcare Organizations rather than intermediaries during the COVID 19 crisis? Do our SOPs cover these types of situations?
6. Should my company issue a press release explaining exceptional price increases due to the COVID 19 crisis?

If you have ideas, experiences or compelling stories which could help your colleagues and that you would like to share with other ETHICS members relating to the impact of COVID 19 on ethics and compliance, please let us know by contacting the ETHICS In Action editor, John McLoughlin, at john.mcloughlin.ethics@gmail.com