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**Sent:** vendredi 20 mars 2020 15:32  
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**Subject:** URGENT: COVID19 MEDICINES PRODUCTION & SUPPLY  
**Attachments:** 20200320COVID19COM brief.docx; Medicines for Europe - regulatory flexibility COVID rev 2- 2020-03-20.docx; 20200317COVID19.pdf  
**Importance:** High

**TO THE KIND ATTENTION OF COMMISSIONERS STELLA KYRIAKIDES AND THIERRY BRETON**

Please find below an e-mail from Medicines for Europe [REDACTED], [REDACTED].

We remain at your disposal for any further information you may need.

Your sincerely,  
[REDACTED]

\*\*

*Dear Commissioners Kyriakides, Dear Commissioner Breton,*

*Please find enclosed the statement, in detail, that I raised on this morning's call.*

*I cannot overstate the urgency of the situation in Europe right now. Our industry is supplying the majority of essential medicines and the specific medicines used for Covid19 infected patients.*

*Our experience in Italy shows the complexity of managing demand surges in hospitals as Europe experiences unprecedented logistical problems and stocking (or sometimes hoarding) activities in different countries or settings.*

*Our association is now devoted entirely to keeping manufacturing running at full speed and getting medicines to patients. We need the full support of the EU to ensure we succeed.*

*Our team will work throughout the week end **and requests that key personnel in the institutions (Commission Santé, Grow, Transport, Home, Taxud/trade, EMA, ECDC) be available (see note)** to keep our medicines manufacturing running, our medicines moving and to respond to the anticipated demand surge.*

*Enclosed you will find:*

- Our briefing note for the call
- Our list of Regulatory flexibilities to be used
- Our letter already sent

I am available at any time [REDACTED]. We have a contact point to all manufacturers to contact them at any time and will share this with the EMA for the purpose of getting supplies to patients.

Yours respectfully,



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# Medicines for Europe update regarding medicines production and supply related to Covid-19

V2 17 March 2020

Our industry supplies 67% of prescription medicines and most of the critical medicines needed to treat infected patients. Our 400 factories/sites across Europe are operating at 100% capacity to maintain medicines supplies – both emergency and chronic – to all Europeans. At this time, there are no shortages of medicines in our sector related to the outbreak to our knowledge and our situation rooms are continuously monitoring stock levels and adapting production according to health needs. Our industry is ready to coordinate as closely as possible with the EU (and in parallel at national level) to keep the flow of medicines to all countries throughout the crisis. We thank our employees and our drivers/logistics for their tremendous efforts to continue working throughout this crisis.

We thank the Commission and the EU for rapidly establishing guidelines for member states to establish green lanes for the transport of medicines and related supplies for their manufacture and we hope this will be done quickly. This will facilitate our manufacturing and the flow of medicines to where they are needed. We are closely monitoring the situation and highlight the challenge regarding restrictions on the movement of truck drivers from Italy (requirement to quarantine) and is likely to be extended to Spanish drivers. As the outbreak spreads, more truck drivers of different nationalities could be subject to quarantine measures – which will mean that eventually we could run out of drivers allowed to cross borders. We strongly advise that precautionary safety measures would replace quarantines for truck drivers. Some countries have introduced such measures that could serve as guidelines. We will share information regarding the blockage of transit points with the services regularly. We would like to make the additional request that technicians needed to repair machinery in our factories should receive a dispensation to cross internal EU borders. As our factories are running at full capacity, the maintenance of critical production equipment becomes ever more critical.

We urge the Commission to continue its cooperation with other related industries that can supply much needed health related supplies (Cefic – chemicals, Euratex/plastics Europe – PPE, etc). It is vital that each industry can bring maximum production and efficiency to deliver the different needs based on its industrial specialisation. We would like to reiterate that our members are still facing challenges shipping PPE across internal EU borders to their production sites. Our factories cannot manufacture without this equipment.

There is a growing challenge with air freight into the EU which is important for the supply of materials for our production. We may need a coordination mechanism to get those supplies to different EU countries on a national or a regional basis. This is particularly challenging for smaller manufacturers to manage. We are consulting with our national associations on how this could be managed.

The other challenges we are seeing relate to employees working in factories. They are not systematically recognised as essential health workers and therefore do not benefit from national measures (like access to child day care services) to support, for example, hospital workers. In addition, there are some restrictions on the movement of cross border workers (Slovakia to Hungary) which is affecting our production. We will develop

proposals for guidelines for manufacturers if critical personnel (such as QPs) cannot work due to illness and will undertake the most appropriate efforts to maintain compliance to every extent possible.

Regarding the supply of medicines, we do not know of any declared shortages from our companies related to the crisis and we are producing with existing stocks of materials. Some supplies are arriving sporadically from China with logistics issues presenting the main challenge as well as a backlog of manufacturing due to the extended shut down. We are carefully monitoring supplies from India as the industry and the government are planning to upscale manufacturing for the crisis for local needs. Our company situation rooms are managing this situation and will establish a Single Point of Contact with the EMA to warn of any potential production bottlenecks and to offer their production support inasmuch as possible to any company or country facing a problem.

For the dialogue with the EU Executive Steering Group on shortages of medicines caused by major events (EU shortages group), we must understand that medicines supply in this crisis is not about static stock levels. The keys are to keep medicine production levels at maximum capacity and to move supplies for that production and medicines to wherever they are needed. We must also plan and manage potential demand surges at EU and national level related to Covid-19. For this we need the dialogue with the EU shortages groups and a parallel dialogue between national authorities and our industry associations at national level. to ensure supply meet demand in a sustainable and equitable way. Ensuring maximum European coordination is key. European solidarity is critical and positive to manage this crisis. The Commission and EMA are responsible for equitable access to medicines across Europe. Disproportionate measures by Member States affecting the availability of critical medicines and fragmenting the single market should not be allowed to disrupt our ability to deliver equitably across Europe.

We emphasize the need in each country to establish a regular structured dialogue between the national competent authority and industry stakeholders to assess the expected needs of hospitals to treat patients as the outbreak develops. This is currently being done in Italy on a nearly daily basis and it has been immensely helpful.

At national level, small changes such as extended prescription times (1-month to 3-months) can create panic in the retail distribution chain. This can be managed through rapid checks with our members and finding alternative solutions such as electronic prescribing where extended prescriptions would be disruptive to supply. As the crisis developments, more daily contacts will be required to manage supplies.

At EU level, we must plan for the specific needs of the outbreak to provide that supply and to maintain the supply of other essential and chronic medicines that are not required specifically for the outbreak but still necessary for healthcare (i.e. the management of chronic diseases). By helping chronic patients maintain their health, we can avoid that they would require an escalation of their care such as going to hospital. Medicines for Europe is reviewing available lists of critical medicines required for the crisis and would like to assess with you the volume requirements to ensure maximum efficiency in production and transport. For this, we will need some insights from the EU Supply Group on what will be done at national level and as much transparency as possible for our members to respond as efficiently as possible. This includes the possible production of medicines to be used experimentally for infected patients as well as the medicines required to treat patients in ICU. We reiterate that the dedication of production and supply for these purposes should also take account of the needs of patients that may currently be using these medicines for their chronic or other care. If necessary, this may include carefully managed switching from current treatment to equally effective alternative treatments.

We must also anticipate possible regulatory flexibilities to ensure maximum production levels as well as possible requests to shift production to address new needs. Our team would like to align with the EU on these measures now so that our members can plan for this possibility in a centrally coordinated manner. This would be the most efficient approach.

At international level, we believe that the global cooperation is essential to maximise production levels for all countries. We welcome the efforts to coordinate with the G7 countries. We also believe that there must be coordination with the major pharmaceutical volume producing regions which includes China (for chemicals), India (for medicines and API), Europe at large (EU-UK-Switzerland for medicines and API) and the US (for medicines) as well as any other major manufacturing country (i.e. Canada, Ukraine, Turkey, etc) that recognises the benefits of cooperation and supply chain efficiency to maximise production. The WHO could lead this dialogue involving volume manufacturers and industry/health ministries (EU should lead here for Europe).

We thank you again for your urgent action on these issues.

In this annex, you will see some specific problems our companies are encountering:

1. Border closure is affecting the flow of trucks with API, finished product and all related material such as vials, packaging and devices. There are long lines and heavy administrative processes. A European communication of the green lanes and how to pass them fast could be helpful. Really “green” lanes for all pharmaceuticals (we are placing a sign on the truck). Another concern is that some European states keep their borders open for the goods but have personal restriction to the drivers. For example, this was the case at the border between Croatia & Austria.
2. Backlog to export & release finished products imported to countries not belonging to the Schengen zone. It would be helpful if the countries can give priority to pharmaceutical products and released them faster.
  - a. Germany to Latin America, Middle East & CIS
  - b. Austria to Balkan countries
3. Educational Establishments close even for children with their parents working in the pharmaceutical industry. This is slowing down the production of essential medicines. The pharmaceutical industry is a system relevant industry especially during a health crisis. There for employees in the pharmaceutical industry should be treated the same way as healthcare professionals, when it comes to emergency childcare. Parents in the pharmaceutical industry should receive childcare option, that they can continue to work for the patient’s safety. We have encountered the issue so far in the following countries:
  - a. Bulgaria
  - b. Germany
  - c. Austria
  - d. Belgium & Netherlands
  - e. Denmark
  - f. France
  - g. Italy
  - h. Portugal
  - i. Spain
4. Stock piling requirement from MOH, from hospitals and customers. This action is tightening supply as there are additional needs in all countries but would lead to only increasing unnecessary safety stock. there is no possibility to create safety stocks now If one country will receive a preferential treatment this could lead to a massive imbalance of the supply chain and endanger access to much needed medicines. The following countries have asked for safety stocks:
  - a. Czech Republic
  - b. Slovakia
  - c. Poland
  - d. Denmark
  - e. Germany
  - f. Italy
  - g. Portugal

5. Final customers (hospitals, wholesalers, distributors, pharmacies...) starting to hoard medicines. However, these shortages are already covered with a normal level of safety stock. We need to ensure that supply flow is smooth and regular to be able to react to real additional demands of countries with higher number of sick patients than to stockpile. A communication to calm down the network could be very appreciated.
6. Airborne delivery of products is endangered by the cancellation of most passenger flights to the EU. A significant cargo amount of air freight for medicines is delivered via spare loading capacities of passenger planes.

# 20 March 2020 Medicines for Europe meeting with COM. Kyriakides & Breton on Covid-19

20 March 2020

*Positive: Commission taking back control of the situation and able to manage this crisis – green lanes, removing internal EU trade restrictions on PPE (DE). Need to continue with leadership, action and rapid decision making. Europe is now at the centre of Covid-19 outbreak with heavy stress on hospital system. It is imperative to maintain production (and in some cases scale up) and to get our medicines to doctors to treat infected patients and to continue to supply existing patients with their medicines. We can do this with the support of the EU if we are jointly focused on solving problems as quickly as possible.*

*Medicines for Europe will work over the week end on these issues and needs contact points with the following officials over the week end*

- DG Santé: A contact at the medicinal products directorate over the week end
- ECDC: a contact to the modeler on expected hospitalisations and an epidemiologist on the list of products for infected patients
- EMA contact: so we can assess and contact companies regarding demand surges & so we can discuss regulatory measures that we will apply to get product to patients
- DG transport: a contact to address custom blockages inside EU
- DG Home: Same as above for movement of trucks.
- DG Trade/EEAS: address third country issues: neighbouring countries blockages.

## Key messages

- Maintaining medicines production open & logistics
  - Transport: Ask COM to deal with pressure points via services including 3<sup>rd</sup> country borders with ultra-high priority. We cannot allow shortages because trucks are stuck at borders. Please provide a list of Green Corridors and requirements. DG Trade/EEAS: address third country issues: neighbouring countries blockages
  - Air freight: We predictable flight schedules and priority for medicines and ingredients shipments in all flights from China, India, US.
  - Safety of workers: In case of outbreak, developing best practice to keep plant running. Industry needs to be on PPE priority list.
  - Cross-border workers: Ask COM to resolve blockage points where cross border workers needed specifically at DE/AT and CRO/SL borders →
- EU Medicines Supply group: need a group with clear focus on risk of shortages of chronic meds and of supply risks for Covid-19 critical medicines. Group needs clear authority to act urgently across EU (normal timelines do not apply anymore for regulatory issues) and to plan for supply to patients
- Plan for possible large-scale outbreak in different EU member states



- Focus on list of critical products for treatment of infected patients (experimental & on-label) with focus on getting flow of medicines to sick patients. Avoid massive stockpiling where not needed.
- Regulatory flexibility to avoid supply problems. The risk to global supply chains is worsened by air and logistics problems. The risk of export restrictions is very real. We need to plan for potential breakdowns while demand could surge. We can enable a flexible interpretation of regulation temporarily for member states (for example labels for safety stock like AIFA is doing in Italy – need to reduce production time in emergency – especially for hospital). We need to avoid bureaucratic discussions in an emergency.
- Maintain open cooperation with India/China/US (and foreign partners) – with diplomatic clear channel of communication on medicines supply (and supply chains) (India export ban)

Procurement: this won't work for our context and don't see any real value for us. We have products – we just need to get them where they need to go. Might need some guarantee for experimental or for emergency imports of medicines not registered in Europe.

#### For medicinal products

1. Are there any current shortages of medicinal products (e.g. paracetamol) due to the current COVID-19 epidemic since the last call? Are you able to increase production to cover the needs of EU patients?

No, there are no shortages and production continues for now but demand will surge for Covid19 critical products with a risk for further export restrictions/national stockpiles. Our biggest short term problem is travel & logistics. The closure of EU internal borders without green lanes for essential goods was a huge mistake.

Medicines for Europe is analysing how to increase supply for the list of Covid-19 critical medicines with the biggest volume manufacturers. This includes on and off-label medicines being used. For HIV medicines, we need to maintain supplies to HIV patients or work with authorities to manage a switch to other effective therapies. This must be managed. IV hospital products need to move across borders to get to red zones. Please help us get all medicines across borders.

Our primary concern is the health and safety of our associates and patients globally. We are however currently seeing some unusual patterns of behavior within the pharmaceutical market, including stock piling at both customer and wholesale level. We are currently evaluating the possible impact of this unusual market behavior on our stock levels and supply capacity. While we are actively encouraging our customers to act responsibly and to only maintain the level of stock necessary to meet patients' needs, should these behaviors continue, they may result in restricted supply. Our commitment to patients, health authorities and society is that we will be transparent about any shortages that we foresee are likely to occur as a result of the disruption triggered by the COVID-19 pandemic, and will notify potentially affected markets.

2. **Do you experience any disruptions in your supplies from outside the EU?**

For normal production, no. For products where we need to scale up production, export licencing procedures in India can be a delay even when large stock available.

We have a major problem with air freight; no space/prices increasing 10x/ need a coordinated response and will develop proposals over the week end.

3. The Commission has asked the Member States to mitigate the problem of transport of medicines due to the borders controls. Do you still have disruption of transport of medicines ?

Yes, we are regularly informing your services. We need the Commission to focus on blockage points inside the EU and contact the authorities in those member states to move our trucks through. We need alternative solutions to truck driver quarantines as we will soon run out of drivers as more countries go into crisis. We also have problems with external borders with Balkan countries, with Turkey (no more air travel possible), Ukraine, Russia. We cannot have trucks stuck for 4 days on these borders.

We also need to move some people across borders. Cross border workers for our factories and technicians that need to repair machinery in our factories running at full capacity.

For air freight, we need medicines and ingredients to be prioritised to limit impact on our production.

#### **For medical devices**

4. Are there any current shortages of non-in-vitro-diagnostic medical devices? Do you foresee a risk of future shortages?
5. Are there any current shortages related to in vitro diagnostic testing, including reagents, laboratory equipment, and consumables for laboratory use? Do you foresee a risk of future shortages?
6. What difficulties are you experiencing with regard to development and placing on the market of CE-marked diagnostic tests? With regard to development of research use only tests?

#### **For medicinal products and medical devices**

7. Could you please also give an update on the development of possible new treatments for COVID-19 such as remdesivir, chloroquine, Kaletra/interferon beta, tocilizumab, etc? What would be the scenario to increase the capacity and supply of the latter?

Medicines for Europe has set up a group to plan for demand surges for experimental medicines with the biggest suppliers. The EMA should give guidance on what works/doesn't based on experience in Italy/China. We need accurate estimates of future demand. Massive (entire population) requests for stockpiles is neither possible nor sensible. We can develop scenarios and work with manufacturers to allocate the medicines to where they are needed. We need to have access to and study the data from Italy (collected partially by AIFA). Our manufacturers will do everything possible to produce as much as is needed. We call for more EU leadership and coordination to manage this so we can avoid a scenario of export restrictions and requisitioning at national level.

8. Could you please also give an update on the development of possible new devices?
9. Did you experience any issues related to the specific regulatory context of clinical trials ?
10. The Commission has now launched joint procurement for protective equipment, masks and respirators. Have you consider the interest of joint procurements for other products ?

From a practical perspective, a joint procurement of medicines won't work for our sector. The surge in demand depends on the number of cases and the development of severe conditions. We also don't know for sure that experimental medicines work. An alternative for consideration would be for the EU to provide manufacturers with a *guarantee* to build up some buffer stock for medicines that may or may not be needed. For example, chloroquine stocks would not serve any purpose other than for Covid-19 (no malaria in EU). Similarly, if we import products without an EU licence for the crisis and if they are not used, we would not be able to sell them. Some guarantees that we could sell these products post-crisis or that the EU would buy them for say donations to charities that provide medicines to crisis zones (refugee camps, etc.)

Another consideration could be to organise air freight to key destination: China, India, US to facilitate the flow of essential ingredients for our production. This is what India has done.

#### 11. Can you supply the necessary PPEs for your workers?

We have had many problems even shipping our own PPE across borders. Not clear our industry is on the priority list although we need this for production.

#### 12. How do quarantine measures impact your employees' availability? Do you foresee any disruption in your production for labour reasons?

We have developed a guidance to our members to minimise this risk as we need to keep production going 100%. Our short term risks are for truck drivers (we cannot run out) and for cross border essential workers.

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#### Keep manufacturing and logistics moving in EU

- Remove cross border restrictions for workers to keep our critical manufacturing operating at full capacity.
- Ensure that green lanes are fully operational for the movement of goods across borders and work to remove export restrictions – including in places like India.
- consider an EU plan to airlift key supplies from India/China like the Indian government has done for its industry. Air freight is very challenging for our industry right now but critical for production

#### Support our industry to plan for Covid-19 medicines

- Establish channels of communication with India/China/US to keep international logistics moving.
- To build buffer stocks of experimental medicines for Covid-19 (HIV/Malaria medicines, or temporary imports from US or other regulated markets) provide financial guarantees to our industry if it is not needed. If it is unsold, it can be donated by EU to developing countries (for malaria/HIV) or to refugee centres.

#### Plan for Covid-19 medicines surge:

- we are dealing with real medicines surges in Italy and Spain for Covid-19 infected patients. We can further expand production output to meet the demand. What we need is flexibility by national authorities on labelling languages, packaging sizes and aggregation demands (Germany). This will facilitate our ability to supply as much as Europe needs.

- for some experimental drugs, we can work with you to build up supplies with guarantees but we also need to protect patients currently on treatment (HIV patients) so they continue to receive treatment or receive another good treatment for their disease.

the flexibility should be granted to countries to find solutions with countries and the Commission should grant especially smaller countries that possibility so we can move quickly and efficiently to serve patients. A specific high level regulatory be created between EMA, key national regulators and ourselves to discuss extraordinary regulatory flexibility measures on a temporary basis

REV 2- 20.03.2020

## **Regulatory flexibility needed for COVID 19 situation (non- exhaustive list)**

Each MS's individual actions to facilitate regulatory processes in these exceptional circumstances are very helpful. However, it is most important to have an agreement at the European level (the EC in cooperation with the HMA/ EMA/ EU Executive Steering Group on shortages of medicines caused by major events) on temporary flexible regulatory measures allowed in this exceptional situation in all MSs.

As the situation is very dynamic and a fast reaction is needed, there is no time for the MAH to check the interpretation/ acceptance of flexibility level in each of the 27 MSs

In general, there is a need to create an extended grace period for some regulatory processes, such as waiving or deferring upcoming renewals, allowing QP discretion for variations for changes without the potential to impact the quality of a product to be waived. These are really simple, practical steps to allow the QP to continue to release goods that could otherwise be blocked for "formal" reasons. Flexibility to allow the easing of movement of goods to allow foreign packs to be used without a translation and the labelling approval step etc.. The need for the MAH to provide wet signatures, original copies of documents etc. should cease. We must also ensure flexibility in regulatory processes to ensure maximum production levels and the continued release of goods as well as possible requests to shift production to address new needs. Our team would like to align with the EU on these measures now so that our members can plan for this possibility in a centrally coordinated manner. This would be the most efficient approach.

Some situations to be tackled are listed below (the list of issues is not exhaustive as well as suggestions of possible solutions).

1. Moving a medicinal product from one market to another depending on patients' needs/ available stock in the EU
  - Flexibility on language/ leaflet/ packaging/ pack size/ authorisation (zero-day RUP MRP)
  - To ship products between countries without the need to repackage.
    - i. Could companies exceptionally post the package leaflet electronically on their website if product is not repacked?
  - Exemption from mandatory serialisation in case of moving product X from one country to another
  - Acceptance of products with valid MA from other countries
2. Flexibility on accepting another manufacturing site/ API source/ new player in the supply chain as long as quality standards are met (within the EU or other regions with a comparable level of EU requirements)
  - More discretion on the part of the MAH holder in assessment of quality standards
    - i. Allow "notifications" instead of formal variations to be used for all supply chain changes, including new API sources (with a previously EU assessed DMF, or an EDQM certificate of suitability) and production sites (if satisfactory inspection history from any of /EU/ MHRA/USFDA/Australia/Canada/Japan)

- i. Allowing copies of documents, no need for legally authorised documents or certificates etc. The need for the MAH to provide wet signatures, original copies of documents etc. should be stopped.
  - ii. Relaxed execution of the conditions/ documentation to be provided for each variation (to allow emergency variations to ensure supply of critical medicines)
  - iii. No need to submit QP statement for variations/new application for a certain period if MAH/QP can prove GMP conditions (e.g. via valid GMP certificate in the EudraGMDP database, audit report published by other international competent authority (ICH or PCIS member) audit report availability from a site but related to a different API
  - iv. Flexibility on accepting QP declaration including desktop instead of physical audit and commitment to conduct physical audit when situation is cleared.
- Manufacturing capacities:
  - i. In critical situations when products are urgently needed: to use non-EU based manufacturing capacity (if still free) to produce for EU needs e.g. to add a non-EU manufacturing site
  - ii. Redeployment of existing manufacturing facilities/resources by relying on appropriate cleaning and process “verification” rather than extensive “validation”
  - iii. Relaxation of conventional expectations of equipment qualification and validation for equipment being brought in for a critical situation.
  - iv. Prioritisation and redeployment of resources for IPC and Release Testing rather than ongoing stability testing.
- 
- 3. Impact of travel restrictions on auditing capabilities as this may end up, sooner or later, generating complicated non-compliance in GMP, GVP and GCP:
  - Flexibility to accommodate changes in the planned auditing GXP auditing calendars
  - Flexibility on validity of a GMP certificate which is about to expire- no consequences until the situation is back to normal plus possible exchange between EU authorities and increasingly simplified co-operational work for extension of GMP certificates
  - Inspections - whilst it is important that these are pushed out for routine inspections, inspections for new sites, product categories etc. are critical and the regulators need to find a way to do these remotely if necessary, e.g. documentation and/or skype interviews in as efficient a way as possible.
- 4. QP / testing
  - Possibility to release the products which may not be 100% regulatory compliant from the formal perspective
  - QP release - HPRA has written to primary QPs to say they can release remotely now (previously HPRA policy was QP release must be physically on approved site).
  - To find an alternative solution if QP is sick (small companies have 1 or 2 QPs; they need a possibility to release the products)
  - QP release - there need to be ways e.g. fast-track addition of QPs to MIAs. Experienced QPs should have the ability to train quickly as they have core knowledge (may be formulation specific e.g. sterile, non-sterile etc.) and fast-track training on local processes should be adequate - we need consensus on this amongst regulators. Can QPS be added in advance to MIAs with a training plan rather than be already trained? Then once an MIA has a QP need, the training plan (a few days training perhaps max) should kick in prior to release.

- QP declarations needed for renewals and some types of variations are becoming an issue due to postponed audits, or difficulties to get them signed (if QP is working remotely). So flexibility is needed so that those are accepted without a wet signature, and/or without having most recent GMP audit reports available. (some countries already do this)
  - For imported products requiring EU testing (from India for example) EU testing labs have lost capacity and so re-testing (repeating in full all tests already done at the non-EU manufacturing site) is not possible (in a timely manner). Hence QP discretion to do EU batch release without re-testing in the EU if needed would help. UK have said they would need batch-specific variations for this, which imposes a high regulatory burden, although in principle accept it is reasonable in the circumstances.
  - There are also cases where testing in EU labs to realise products for the EU (for products manufactured outside the EU e.g. in India) is not possible because the labs are closed and people work from home. We need a solution to be able to release those medicines (i.e. acceptance of the lab certificate from country where the production was done? )
  - Risk based approach to QC sampling, allowing air freighted samples and the rest of the batch shipped in a different way e.g. by sea, so that QC testing can be conducted in parallel to shipping to expedite release
5. To speed up all on-going MA procedures with critical antiviral APIs ( e.g chloroquine, HIV (combination) products)
  6. For narcotic products linked to ventilator use (opioid IVs)- temporary relaxation of the import/export permit system for the next few months as the procedures are very long.
    - to get paper work arranged at both sides of the shipment - any assistance with that can shave 2-4 weeks off delivery time. **At the moment, it takes overall 4 to 7 weeks**
  7. To speed up any COVID -19 related regulatory process and make it very visible for Regulatory Authorities (see the example of labelling from Poland)
  8. Impact on non-COVID related procedures
    - The full engagement of Authorities in COVID management creates pressure on non-COVID related procedures. We observe some delays in variations which we can handle, but others might lead to stock-out situations. It is important to find a way how to communicate if variations are really going to limit stock or not.
    - To temporarily allow use i.e. of old leaflet (when a batch is waiting for a text change approval and it is not a major amendment to the leaflet, of unapproved text or of old text.
  9. PhV / Clinical trial inspections
    - Stop routine GMDP, pharmacovigilance and GCP inspections – with the inspectorate moving into supportive mode
    - Taking into account that most of the PV personnel (if not all) is working from home, it is possible/expected that there will be problems with internet connections and access to Eudravigilance, therefore some delays might occur with regard to reporting obligations, e.g. reporting of ICSRs and article 57 database updates. Therefore, there should be some leniency towards companies in the event of such delays.
  10. PHV
    - Cessation/Postponement of certain non-critical PhV activities (e.g. brand reviews etc) as staff prioritise critical activities such as spontaneous ADRs and med info and are possibly redeployed into other critical regulatory activities (and/or staff are absent due to sickness). Many of these, such as literature searches, can be conducted at a later date for the period deferred.
    - Cessation of need to conduct PV activities for non-marketed MA with a commitment to do so if and when these products are marketed in the future (MHRA already has a pragmatic approach on this for all non-marketed MAs, HPRA allow this for Risk Management plans & DHCP letters



only but this should be extended to a full scope of non-marketed MAs and consistent across MSs)

- Limit Safety variations to PRAC only and for marketed products only during this period. Also, consideration by PRAC of timelines for PRAC in the light of benefit risk to supply of changes in artwork.
- Postponement of PSURs

#### 11. GDP/WDA(h)

- Fast track of additional new storage sites, product categories and/or RPs
- Provision to increase delegation of RP activities e.g. sign off returns, new customers, suppliers, products
- Relaxation of 48 hour rule on medicines being out of licensed supply chain during distribution which prevents weekend deliveries i.e. leave site on Friday and can arrive on Monday at the hospital. Currently, we cannot ship on a Friday unless it arrives within 48 hours.
- Possible relaxation on a risk based approach of 10 day rule on returns, including serialisation aspects as otherwise such products must be destroyed
- Extension of “use & learn” period or equivalent on serialisation - including the case of Ireland ceasing the Pilot for primary wholesalers scanning on receipt from manufacturers or designated wholesalers

12. Pause the N-nitrosamine investigations – freeing up laboratory capacity for batch release QC testing and to extend the deadline of 26 March for submission of risk assessment
13. The rules for “grouping” of variations to be relaxed for supply chain changes so that only 1 application is needed, which can be submitted up to 12 months after implementation
14. The once a year Product Quality Review (PQR) to be used by companies as the way of documenting Coronavirus supply changes per product. No regulatory variations or submissions now. The PQR would be available for review at the next routine inspection.
15. In urgent cases, Mutual Recognition of MAs granted in any of MHRA/EU/USFDA/Australia/Canada/Japan
16. Postpone the start of execution of Medical Device Regulation, e.g. until Jan 2021. Prolongation of the MDD product certificates which are becoming invalid in the next few months e.g. by 6 months. The certification procedure will not be possible during the Corona crisis. MDD audits not possible, but notified body has to supervise. How this should happen?.



**Annex:****GOOD PRACTICES AT NATIONAL LEVEL TO FOLLOW:****1. Message to the QPs**

Dear Qualified Person,

In Ireland there is a legislative requirement for the QP to be present at the authorised site when performing batch certification. The relevant legislation permits use of alternative premises, from time to time, if approved in writing by the HPRA.

Taking into account the extenuating circumstances presented by the Covid-19 pandemic, the HPRA can approve of a proposal made in writing by an MIA holder for a QP listed on its authorisation, to perform batch certification remotely.

Any such proposal should be addressed to [compliance@hpra.ie](mailto:compliance@hpra.ie) with the subject line of *Request for Remote QP Certification*

Approval would be conditional on the following arrangements and confirmation of these aspects should be provided with the proposal:

- The certifying QP would need to have access to all information necessary to enable them to perform the batch certification steps;
- The address where batch certification takes place will be recorded as part of the certification documentation;
- Any batches certified under this process would be documented within the non-conformance / deviation management system if the relevant SOPs have not been updated to reflect this change;
- The recording of the batch certification in the register (or equivalent document) would be contemporaneous. The following provisions should be defined;
  - o If the register remains at the site, responsibility for keeping it up to date when the QP has remotely certified a batch
  - o If the register stays with the QP, the arrangements for returning it to the site

We will endeavor to respond to requests within two working days.

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**Special label for communication with agency on issues COVID related** (from POLAND)

Should it be applicable to any regulatory process related to the COVID? (e.g. urgent variations, notification etc)

Warsaw, 17-03-2020

**MESSAGE FROM  
THE PRESIDENT OF THE AUTHORITY FOR REGISTRATION OF MEDICINAL PRODUCTS, MEDICAL  
PRODUCTS AND BIOCIDAL PRODUCTS**

**of 17 March 2020**

on the method of marking the submitted documentation on SARS-CoV-2 coronavirus to  
the Office for Registration of Medicinal Products, Medical Devices and Biocidal  
Products

In connection with the pandemic caused by SARS-CoV-2 coronavirus causing COVID-19 disease and epidemiological threat in the Republic of Poland, please, in the case of submitting documentation regarding SARS-CoV-2 coronavirus to the Registration Office for Medicinal Products, Medical Devices and Biocidal Products mark it at the top of the first page by adding an expression "**Concerns the SARS-CoV-2 coronavirus**".

Additional marking of documentation in the above manner will help the Office's employees in giving priority to matters related to the SARS-CoV-2 coronavirus.

The above request applies to all areas of the Office's activities.

#### **QP declarations**

**QP declarations** needed for renewals and some types of variations are becoming an issue due to postponed audits, or difficulties to get them signed (if QP is working remotely).

So flexibility is needed so that these are accepted without a wet signature, and/or without having the most recent GMP audit reports available.

Some authorities have already indicated that they will be flexible here - otherwise, we would lose a lot of marketed registrations with an invalid renewal submission in the next couple of months ! (note: only pure Gx procedures can follow the shortened renewal procedure, while all others need the full documentation sent with the submission!)

Several authorities (IT, EL) now accept submissions without **originally signed paper documents**, but those papers might need to be sent "later on". The issue is that these documents can no longer be distributed to the responsible RA manager when all RA staff work from home. PL and BG authorities are not yet fully at this point, unfortunately, but hope they will introduce this flexibility as well.