Bird & Bird & COVID-19 Market Access Q&A

Emergency legislation / Regulatory relaxation during COVID-19 pandemic

Contents

Introduction

Background

Due to the COVID-19 pandemic, many countries have enacted emergency legislation or new guidance removing or relaxing certain regulatory barriers, or to facilitate obtaining relevant marketing authorisations. The emergency provisions define the products that are exempted and also from which provisions they have been exempted. There may also be an expiry date stated for the emergency legislation. A differentiation has been made between products specifically for treatment or prevention of COVID-19 and medicinal products in general.

This overview is intended to summarise efforts in order to support our clients in their efforts to cope with the situation. This document does not constitute legal advice, if you require more information please feel free to reach out to the country contacts in this document.

Europe

The European Commission has taken several measures in order to address the issues created by the Coronavirus crisis in the manufacture and supply chain of medicinal products. Some of these measures are reserved for crucial medicines used for treating COVID-19 patients.

The EC published a Guidance Q&A on Regulatory expectations for medicinal products for human use during the Covid-19 pandemic ("Guidance"), which is constantly updated, so please check here for the final version. The summary below relates to the Guidance version of 17 April 2020.

The Guidance was agreed by EMA, the EC, the European medicines regulatory network and endorsed by the EU Executive Steering Group on Shortages of Medicines Caused by Major Events.

The Guidance explains regulatory expectations and flexibility during the COVID-19 pandemic to marketing authorisation holders of medicinal products for human use ("MAH"). The measures introduced cover different areas of the regulation of medicines such as marketing authorisations and regulatory procedures, manufacturing and importation of active pharmaceutical ingredients (APIs) and finished products, quality variations, and labelling and packaging requirements with flexibility to facilitate the movement of medicinal products within the EU. Most importantly:

- The coordination group established under Article 27 of Directive 2001/83/EC (CMDh) promotes the use of **zero-day mutual recognition procedure/repeat use procedure** to expand national marketing authorisations to new Member States who need these medicinal products;
- Member states may resort to **compassionate use**, or **authorisation of the distribution of an unauthorised medicinal product** in accordance with Article 5(2) of Directive 2001/83/EC if no relevant marketing authorisation exists. Applicants are requested to identify any such communication to the relevant NCA with the message "CONCERNS COVID-19";
- **Sunset clause exemption** may be applicable on public health grounds with reference to pandemic as a reason without the need for further justification at EC level;
- If there are severe problems of availability, certain **packaging requirements** may be waived.

Asia Pacific

The response to the COVID-19 pandemic has differed in each of the countries across the Asia-Pacific (APAC) region.

In relation to pharmaceutical products, every country in the region has their own regulatory framework, which provides for a diverse discussion on Market Access requirements.

For example, China has created a specific approval pathway for COVID-19 related medicinal products.

Hong Kong has not enacted any specific changes to its regulations and but has verbally committed to providing expedited review for any COVID-19 related pharmaceutical products. The Hong Kong regulations also allow for individual patient treatment with unregistered products.

Other countries, such as Australia and Singapore, also have provisions in their existing laws to allow supply of unregistered products for individual patients and have not enacted any specific changes to the regulation of medicines in response to COVID-19.

Despite a lack of specific changes to legal provisions, countries with formal regulatory systems have committed to expedited approval and access to any medicinal product to treat COVID-19 should they become available.

Australia

A. Emergency legislation for marketing authorisations non COVID-19 specific medicinal products.

1. Did national authorities issue guidance on "emergency provision" for marketing authorisations for non Covid-19 specific medicinal products (e.g. postponing of renewal applications, sunset clause applicability)?

Yes, given the business impacts caused by COVID-19, the Therapeutic Goods Administration (TGA) have established a temporary process for sponsors of listed, registered complementary and over the counter medicines to request consent from the TGA to supply products that do not comply with the new labelling requirements which will come into force on 1 September 2020, the Therapeutic Goods Order No. 92 - Standard for labels for non-prescription medicines. Any sponsor of listed, registered complementary and over the counter medicines are eligible to request this consent as long as they have been adversely impacted by COVID-19. The end date for the TGA to grant this consent to listed medicines is 6 March 2021. For OTC and registered complementary medicines, the end date to seek this consent is generally 6 March 2021 but longer time frames may be justified in extenuating and exceptional circumstances.

While not as a result of COVID-19 but as a result of planned legislative change, from 1 July 2020, advertisers of medicines were no longer required to seek pre-approval from the TGA for advertisements of therapeutic goods in mainstream media, broadcast media, cinema and displays about goods. The TGA will continue to regulate the advertising of therapeutic goods and advertisers must continue to ensure they are fully compliant with the Therapeutic Goods Act 1989 and the Therapeutic Goods Advertising Code.

2. If yes, which ones and what are the requirements to fall within the scope of the emergency provisions?

Listed, registered complementary and over the counter medicines. This guidance can be found here.

3. What are the expiry dates, if any?

The end date for the TGA to grant this consent to listed medicines is 6 March 2021.

4. Under which competent authority(ies) do these emergency provisions fall in both English and the original language?

Therapeutic Goods Administration (TGA).

5. Are there specific procedures to be followed and what are those procedures?

The Sponsor must complete the form available for download here and pay a fee of $490 for the first entry plus $100 for each additional entry. The complete form and payment details should be emailed to accountsrec@health.gov.au

6. Do the emergency provisions outline what information (if any) must be provided to the relevant approval authority and if yes, what information?

See above.

7. Are there any additional requirements that must be met or other relevant information related to market access?

Not at this stage.

B. Emergency legislation/guidance for marketing authorisations for COVID-19 medicinal products.

1. Did national authorities issue other guidance on "emergency authorisation" for market authorisations specifically for Covid-19 medicinal products (e.g. lower threshold for obtaining marketing authorisation, waiving quality requirements)?

Yes, the Therapeutic Goods Administration (TGA) have implemented several temporary provisions in response to the COVID-19 pandemic in the form of guidelines, expedited processes as well as through legislation. These include:

1. The TGA have implemented an expedited processes for assessing the registrability of a therapeutic good and medical device as well as implemented exemptions from requirements for specific medical devices relating to COVID-19. The TGA is encouraging applicants to contact devices@tga.gov.au and immediately provide supporting technical files and data for assessment, once an application has been submitted.

2. Applications to supply COVID-19 tests are being prioritised. Legislation has also been passed which allows immediate supply of COVID-19 diagnostic tests to accredited pathology labs through the operation of the Therapeutic Goods (Medical Devices - Accredited Pathology Laboratories) (COVID-19 Emergency) Exemption 2020. This exemption will cease on 31 July 2020 after which time, the Therapeutic Goods (Medical Devices - Donor Screening) (COVID-19 Emergency) Exemption 2020 will be in place which has a more limited application but will allow accreditted pathology labs to continue to use the exempt COVID-19 test kits for the purpose of donor screening. This second exemption will have effect until 30 June 2021.

3. Under the Therapeutic Goods (Medical Devices—Ventilators) (COVID-19 Emergency) Exemption 2020, manufacturers can directly supply ventilators to hospitals without undertaking the rigorous testing and assessment procedures to register the ventilators on the ARTG. However, prior to the supply of such ventilators, the supplier must provide to the TGA the test procedure, test results and risk analysis undertaken by the relevant manufacturer in relation to the ventilator and declare that the ventilator has been manufactured in accordance with the minimum technical requirements. The TGA will assess the documents and will provide written permission for the supplier to supply the ventilator. This exemption will expire on 31 January 2021.

2. If yes, which ones and what are the requirements to fall within the scope of the emergency authorisation?

See above. The links to the legislation accord with the numbering above.
1. N/A
2. https://www.legislation.gov.au/Details/F2020N00032; https://www.legislation.gov.au/Details/F2020N00075
3. https://www.legislation.gov.au/Details/F2020N00046

3. What are the expiry dates, if any?

See above.

4. Under which competent authority(ies) do these emergency authorisations fall in both English and the original language?

The Therapeutic Goods Administration.

5. Are there specific procedures to be followed and what are those procedures?

See above at item A5.

6. Do the emergency provisions outline what information (if any) must be provided to the relevant approval authority and if yes, what information?

See above.

7. Are there any additional requirements that must be met?

N/A.

8. Does the emergency legislative provision for the products, or other legislation, provide "immunity" from, or any limitation on, liability and if yes, what are the provisions?

No.

C. Emergency legislation/guidance on GMP, GDP, QP, changes in manufacturing, packaging and supply chain (please indicate if only applicable to COVID-19)

1. Is there emergency legislation/guidance on implementing changes in manufacturing or the supply chain and what are the key points?

Yes.

The TGA has suspended overseas GMP inspections and QMS audits due to the COVID-19 pandemic. As a result, the TGA developed a system involving remote GMP inspections of domestic manufacturers. From July 2020, remote GMP inspections will also be conducted for some overseas manufacturers.

The TGA will send a pre-inspection checklist to the overseas manufacturing site to be completed within 2 weeks of receipt of the document. This checklist will help the TGA to determine whether the site is ready for a remote inspection. Prior to the remote inspection, the manufacturer will be required to organise pre-recorded videos of the site and operations so that the inspectors can be presented with a virtual tour of GMP relevant areas. If the manufacturer has electronic systems for QMS databases such as complaints, deviations, OOS/OOT and other GMP relevant areas then it is requested to organise guest remote read only logins to the QMS' databases for the inspectors' use at the time of inspection.

The TGA have also implemented a temporary change to their documentation requirements for GMP Clearance applications submitted through the Compliance Verficiation (CV) pathway during the COVID-19 pandemic. Sponsors are now able to provide a recently expired inspection report from a recognised regulator and a GMP Clearance questionnaire as well as any additional documents identified during the completion of the questionnaire.

See this link for further information.

2. Is there emergency legislation/guidance to address difficulties in conducting on-site **GMP** inspections and what are the key points?

No, the TGA have only issued guidances for GMP and QMS audits and inspections.

3. Is there emergency legislation/guidance to address difficulties in conducting on-site **GDP** inspections and what are the key points?

No, the TGA have only issued guidances for GMP and QMS audits and inspections.

4. Is there emergency legislation/guidance on QP work and what does it entail (e.g. remote batch certification)?

No, the TGA have only issued guidances for GMP and QMS audits and inspections.

5. Is there emergency legislation/guidance on the packaging requirements, also including over-labelling?

Please refer to the answer to question A1.

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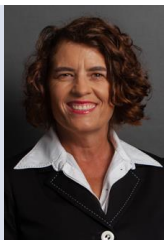

Belgium

A. Emergency legislation for marketing authorisations non COVID-19 specific medicinal products.

1. Did national authorities issue guidance on "emergency provision" for marketing authorisations for non Covid-19 specific medicinal products (e.g. postponing of renewal applications, sunset clause applicability)?

No.

However, the government promulgated a Royal Decree of 24 March 2020 concerning special measures to combat shortages of medicines in relation to SARS-CoV-2. The decree provides the possibility for the competent minister and the director of the Federal Agency for Medicines and Health Products (FAMHP) to take the measures specifically mentioned in the Decree, to prevent shortages of SARS-CoV-2 related medicines, provided that:

- the measures are necessary and proportional for combatting the spread of the SARS-CoV-2 virus and the consequences thereof, and
- the measures meet the actual needs of public health and are mainly focussed on adequate distribution and access to medicines.

In this regard, the FAMHP has been closely monitoring stocks of medicines. On the basis of aforementioned Decree the director of the FAMHP promulgated its own decree containing measures to prevent shortages in relation to medicines and raw materials that potentially can treat the SARS-CoV-2 Virus. However, the measures include also medicines and raw materials that do not have an antiviral effect, and that are used to provide the necessary (intensive) care to hospitalized COVID 19 patients and to treat any complications caused by the virus (such as antibiotics and curarisantia). In the annexes of the measures, the specific medicines and raw materials of which there is a danger of shortage are defined. For more information, *see below*.

B. Emergency legislation/guidance for marketing authorisations for COVID-19 medicinal products.

1. Did national authorities issue other guidance on "emergency authorisation" for market authorisations specifically for Covid-19 medicinal products (e.g. lower threshold for obtaining marketing authorisation, waiving quality requirements)?

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C. Emergency legislation/guidance on GMP, GDP, QP, changes in manufacturing, packaging and supply chain (please indicate if only applicable to COVID-19)

1. Is there emergency legislation/guidance on implementing changes in manufacturing or the supply chain and what are the key points?

The FAMHP issued a decree containing binding measures to prevent shortages in relation to medicines that potentially can treat the SARS-CoV-2 Virus, but also in relation to medicines that do not have an antiviral effect, but that are used to provide the necessary (intensive) care to hospitalized COVID 19 patients and to treat any complications caused by the virus, such as antibiotics, curarisantia. The raw materials used to compose such medicines are also subject to these measures. In the annexes of the decree, the specific medicines and raw materials of which there is a danger of shortage are defined.

The measures allow the FAMHP to closely monitor the named medicines and raw materials. To prevent shortages or unequal distribution, the FAMHP can impose specific instructions and distribution keys on hospitals, wholesalers and persons authorized to deliver medicines to the public.

The measures also impose a sale restriction to wholesalers of the medicines and raw materials mentioned in the annexes. The restriction comes down to the amount of medicines or raw materials sold last year during the same period, increased with a coefficient of maximum 50%. The delivery of the defined medicines and raw materials can exceed the set limitation, provided that the delivery will not adversely affect the supply to other wholesalers-distributors, hospitals and persons authorized to deliver medicines to the public (pharmacies). Such derogation can take place upon prior notice to the FAMHP.

The medicines and raw materials cannot be delivered to others than hospitals, wholesalers and other persons authorized to deliver medicines to the public, unless the medicines and raw materials are delivered to the federal public service for public health, safety of the food chain and environment, in order to strategically stockpile the medicines.

Upon prior notice to the FAMHP, medicines and raw materials named in the annex can be exported to (legal) persons established in a member state of the EEA, provided that only hospitals, authorized persons and wholesalers will receive the exported goods. Notifications will be sent to coronashortages@fagg-afmps.be.

First, the FAMHP had issued a ban on export of medicines to countries outside the EEA. In order to prevent these countries from suffering unnecessary drug shortages, the ban on exports outside the EEA has been replaced by a notification requirement. Upon prior notice to the FAMHP, medicines and raw materials can be exported to (legal) persons outside the EEA. The FAMHP can still file an opposition, within three working days, if this is in the interest of Belgian patients, in which case the medicinal products cannot be exported. Notifications will be sent to coronashortages@fagg-afmps.be.

Hospitals and persons authorized to deliver medicines to the public who possess a stock of the named medicines exceeding their sales volume of one month (calculated on the basis of the sales of last year during the same period increased with a coefficient of maximum 50%) are under an obligation to notify the FAMHP of their stock in view of redistribution. The same obligation exists for stocks of raw materials exceeding the necessary stock for one month for the preparation and the sale of officinal or medicinal preparations.

Due to massive purchasing of paracetamol at the beginning of the crisis, measures were imposed to limit further extreme purchasing. However, the sale of paracetamol has now normalized and the restrictions have been lifted. Nevertheless, intravenous infusion of paracetamol is regulated by abovementioned measures to prevent medicine shortages during the crisis.

The measures are in force since their promulgation and will last during a renewable period of one month. Up until now, the director of the FAMHP renewed the duration of the measures until 1 June 2020.

2. Is there emergency legislation/guidance to address difficulties in conducting on-site **GMP** inspections and what are the key points?

No.

3. Is there emergency legislation/guidance to address difficulties in conducting on-site **GDP** inspections and what are the key points?
No
4. Is there emergency legislation/guidance on QP work and what does it entail (e.g. remote batch certification)?
No
5. Is there emergency legislation/guidance on the packaging requirements, also including over-labelling?
No

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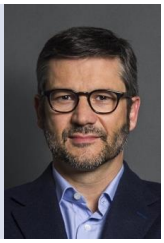

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China & Hong Kong

Mainland China

A. Emergency legislation for marketing authorisations non COVID-19 specific medicinal products.

1. Did national authorities issue guidance on "emergency provision" for marketing authorisations for non Covid-19 specific medicinal products (e.g. postponing of renewal applications, sunset clause applicability)?

No.

B. Emergency legislation/guidance for marketing authorisations for COVID-19 medicinal products.

1. Did national authorities issue other guidance on "emergency authorisation" for market authorisations specifically for Covid-19 medicinal products (e.g. lower threshold for obtaining marketing authorisation, waiving quality requirements)?

Yes, it has been reported by third party media platforms that the Center for Drug Evaluation ("CDE") of National Medical Products Administration ("NMPA") has prepared the Special Review Program for Anti-Novel Coronavirus Drugs ("CDE Program"), together with 4 technical guidance and 2 procedural guidance such as the "Key Points of Application Materials for Special Review and Approval of Anti-Novel Coronavirus (2019-nCoV) Drugs (for trial implementation).

However, these documents are only available to the relevant applicants.

This fast track review for covid-19 prevention and treatment drugs/vaccines is likely based on the Drug Special Review Procedure issued by the State Food and Drug Supervision Administration (now NMPA) in 2005. This sets out the review procedures for applications for market authorization ("MA") during a "public health emergency".

In addition, the new PRC Drug Administration Law ("DAL") 2019, current Drug Registration Rules ("DRR 2007") and new Drug Registration Rules (that take effect on 1 July 2020) ("DRR 2020") also provide other routes by which to expedite review for MA.

Some clinical trial and MA approval for anti covid-19 related drugs have been granted by NMPA via these routes of expedited review.

2. If yes, which ones and what are the requirements to fall within the scope of the emergency authorisation?

There are four ways to expedite a MA as set out below. These can be used for anti covid-19 drugs:-

1 **Special approval procedure**: Article 3(2) of the 2005 Drug Special Review Procedure and Article 72 of the DRR 2020 allows this pathway to be used when emergency treatment procedures for public health emergencies are started according to law.

In January 2020, 31 provinces in China initiated a first-level response to a public health emergency against the covid-19 pandemic, relying on the authority in the PRC Emergency Response Law, National Emergency Plan for Public Health Emergencies and corresponding provincial emergency plan. This response satisfied the threshold to allow applications via the special approval procedure.

1 **Conditional approval procedure**: Article 26 of DAL and Article 63 of DRR 2020 provides that

a Drugs for treatment of serious life-threatening diseases with no comparable treatment options,

b Drugs urgently needed for public health,

Vaccines urgently needed for major public health emergencies, or other vaccines that are confirmed by the National

Health Commission to be urgently needed and evaluated to have benefit greater than risk. .

Both (i) and (ii) require the efficacy and expected clinical value to be confirmed by ongoing drug clinical trials.

(Zhejiang Hisun Pharmaceutical Co., Ltd obtained conditional approval for MA in Feb 2020 on its favipiravir tablets with authorized indication to treat certain flu. They also obtained clinical trial approval to treat Covid-19 by applying for the following third pathway.)

1 **Priority review and approval procedure**: Article 96 of the DAL and Article 68 of the DRR 2020 provides that

   a drugs urgently needed clinically, and innovative drugs and improved new drugs that are used to prevent and treat major infectious diseases and rare diseases;

   b new varieties, dosage forms and specifications of the paediatric drugs that cater to children's physiology;

   c vaccines and innovative vaccines that are urgently needed for disease control and prevention;

   d drugs that are satisfactory for the breakthrough therapeutic drug procedure;

   e drugs that are approved conditionally;

   f other situations stipulated by the NMPA where the priority evaluation and approval can be applied

2 **Breakthrough therapeutic drug procedure:** Article 59 of DRR 2020 provides that this pathway is for innovative drugs or improved new drugs that can prevent and treat the diseases that severely threaten life or affect quality of life, with no comparable treatment options, or that is demonstrated with sufficient evidence to have the significant clinical advantages in comparison to the existing treatment approaches.

3. What are the expiry dates, if any?

No expiry dates have been provided in the above laws and regulations in terms of the four fast track procedures.

However, the application for breakthrough therapeutic drug procedure or conditional approval procedure should be submitted during the clinical trial stage. Alternatively, the priority review and approval procedure could apply if the application has not been submitted until the MA application stage.

4. Under which competent authority(s) do these emergency authorisations fall in both English and the original language?

NMPA

5. Are there specific procedures to be followed and what are those procedures?

For each of the fast track procedures that may be applicable to a MA application for anti covid-19 drugs, the procedures are set out below:-

1 **Special approval procedure**: after the clinical trial is completed, the MA application can be submitted and NMPA shall organize technical review within 24 hours after receiving the application documents.

   NMPA will notify their provincial counterpart MPA, at the applicant's location, to conduct on-site verification of the drug production status and conditions, and organize sampling and testing of trial samples.

   The provincial counterpart MPA should report the on-site verification and relevant opinions to NMPA within 5 days. The GMP inspection can be carried out together with the review on MA application if needed.

   The drug inspection institutions shall conduct immediate testing for the drug samples and submit the inspection report to NMPA within 2 days after the inspection is completed.

   NMPA will then conduct technical review and complete within around 20 days with possible extension for certain conditions and then conduct the administrative review and complete within 3 days. The NMPA will then issue approval or rejection to the MA application. (Articles 23-27 of the Drug Special Approval Procedure)

2 **Conditional approval procedure**: The applicant is required to file the MA application after confirming the requirements for conditional approval and the post-market surveillance through communication with the CDE.

   The drug registration certificate should state the validity period of conditional approval, the post-market

surveillance and the time limit for completing the surveillance and other relevant requirements.

The MAH shall take the appropriate post-market risk management measures, complete the required drug clinical trials within the stipulated time limit, and file a post-market application.

If the MAH fails to complete the required research within the stipulated time limit or prove that benefits outweigh risks, the NMPA can, amongst other things, revoke the conditional approval or even deregister the drug registration certificate. (Articles 64, 66-67 of DRR 2020)

3 **Priority review and approval procedure**: The applicant is required to communicate with the CDE and upon confirmation apply to the CDE for the priority evaluation and approval at the same time of filing the MA application.

If the application is successful, the CDE shall publish the application in accordance with the procedure before applying the priority review and approval procedures.

The applicant can enjoy certain priorities including

a the time limit for review of MA application is 130 days;

b the time limit for review of drugs that are urgently needed for rare diseases and have been marketed outside of China but not marketed in China is 70 days;

c inspection, test and approval of the generic names of drugs should be in priority; and

d the applicant can submit supplemental technical materials after communication and confirmation with CDE. (Articles 69-70 of DRR 2020)

4 **Breakthrough therapeutic drug procedure**: The applicant has to file an application with the CDE. If the application is successful, the CDE shall publish the application in accordance with the standard procedure before applying the breakthrough therapeutic drug procedure.

The applicant can enjoy certain policy support including

a request to communicate with the CDE during the key stage of drug clinical trials, and the CDE shall arrange evaluators for communication; and

b provide the CDE with the research materials for the current stage of the clinical studies, and the CDE shall give advice, suggestions & feedback on the research plan for the next stage on the basis of available research data. (Articles 60-61 of DRR 2020)

6. Do the emergency provisions outline what information (if any) must be provided to the relevant approval authority and if yes, what information?

No

7. Are there any additional requirements that must be met?

No

8. Does the emergency legislative provision for the products, or other legislation, provide "immunity" from, or any limitation on, liability and if yes, what are the provisions?

No

C. Emergency legislation/guidance on GMP, GDP, QP, changes in manufacturing, packaging and supply chain (please indicate if only applicable to COVID-19)

1. Is there emergency legislation/guidance on implementing changes in manufacturing or the supply chain and what are the key points?

No

2. Is there emergency legislation/guidance to address difficulties in conducting on-site **GMP** inspections and what are the key points?
No
3. Is there emergency legislation/guidance to address difficulties in conducting on-site **GDP** inspections and what are the key points?
No
4. Is there emergency legislation/guidance on QP work and what does it entail (e.g. remote batch certification)?
No
5. Is there emergency legislation/guidance on the packaging requirements, also including over-labelling?
No

Hong Kong

A. Emergency legislation for marketing authorisations non COVID-19 specific medicinal products.
1. Did national authorities issue guidance on "emergency provision" for marketing authorisations for non Covid-19 specific medicinal products (e.g. postponing of renewal applications, sunset clause applicability)?
No. The HK Drug Office (DO), the body responsible for review, approval and recertification of drug products has not issued any specific COVID-19 related guidelines or announcements concerning non-COVID-19 related drugs.
B. Emergency legislation/guidance for marketing authorisations for COVID-19 medicinal products.
1. Did national authorities issue other guidance on "emergency authorisation" for market authorisations specifically for Covid-19 medicinal products (e.g. lower threshold for obtaining marketing authorisation, waiving quality requirements)?
No. The HK Government and the HK DO office have not issued any specific guidance on COVID-19 drug products. The DO has confirmed that they will expedite the review of clinical trial applications or MA applications for any products that treat COVID-19 but this requires prior discussion/approval with the DO.
C. Emergency legislation/guidance on GMP, GDP, QP, changes in manufacturing, packaging and supply chain (please indicate if only applicable to COVID-19)
1. Is there emergency legislation/guidance on implementing changes in manufacturing or the supply chain and what are the key points?
No. There has been no specific legislation or guidance issued by the HK Government or DO on manufacturing and supply chain. The HK HA monitor the drug stock situation of the HA pharmacies and keep buffer stock for drug products in the HA Formulary.

In addition, the HK DO maintains a list of "core drugs" (found in the Annex to Guidance Notes on Drug Shortage Notification). Aside from vaccines and anti-TB drugs, the only other core drugs are the anti-viral drugs – Amantadine, Oseltamivir and Zanamivir.

Certificate holders of the core drugs (including vaccines) are responsible to notify/report to the Department of Health (DH) on the drug shortage.

The certificate holder must notify the DH if supply continuity cannot be guaranteed as per expected consumption in next 2 months because of:-

- Unusual upsurge in demand;
- Low Stock level, and the expected arrival time of the next shipment is unclear;
- Temporary interruption of production.

The certificate holder should notify DH immediately and no later than 72 hours upon the confirmation of the above (i) and (ii).

2. Is there emergency legislation/guidance to address difficulties in conducting on-site **GMP** inspections and what are the key points?

No. There has been no specific legislation or guidance issued by the HK Government or DO in relation to GMP inspections. The HK DO is a member of the PIC/S scheme for GMP inspections. The DO GMP inspectors are able to conduct GMP inspections at local or overseas sites. In general, due to the limited resources, certificate holders should submit the application for review at least 32 weeks before the product registration expires.

3. Is there emergency legislation/guidance to address difficulties in conducting on-site **GDP** inspections and what are the key points?

No. There has been no specific legislation or guidance issued by the HK Government or DO in relation to GDP inspections.

The HK DO does not appear to perform these inspections.

4. Is there emergency legislation/guidance on QP work and what does it entail (e.g. remote batch certification)?

No. There has been no specific legislation or guidance issued by the HK Government or DO in relation to QP certifications.

As most drug products are imported into HK, the "Code of Practice for Holder of Wholesale Dealer Licence" (issued by the Pharmacy and Poisons Board 2015) outlines incoming product checks under s3.5.

For wholesalers who import drug products into HK, the normal practice is for each incoming delivery of drug product to be physically checked upon receipt for tampering and damage. Label description, type and quantity of the incoming products shall be verified against the relevant purchase order. All drug products shall be accompanied by batch release certificates or certificates of analysis issued by the manufacturers and these certificates shall be checked to ensure the quality of the products delivered. The checking and verification conducted shall be supported by documentary records.

5. Is there emergency legislation/guidance on the packaging requirements, also including over-labelling?

No. There has been no specific legislation or guidance issued by the HK Government or DO in relation to drug packaging requirements.

General labelling requirements for drug products in HK are set in the DO's "Guidelines on the Labelling of Drug Products". Basic requirements are:

1 Name of the product.

2 Name and quantity of each active ingredient.

3 Name and address of the manufacturer.

4 Hong Kong registration number of the product.

5 Batch Number.

6 Expiry date.

7 Specific storage conditions, if any.

There are extra requirements specifically outlined for certain drugs or classes of products.

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A. Emergency legislation for marketing authorisations non COVID-19 specific medicinal products.

1. Did national authorities issue guidance on "emergency provision" for marketing authorisations for non Covid-19 specific medicinal products (e.g. postponing of renewal applications, sunset clause applicability)?

No general guidelines have been published. As a response to COVID-19 pandemic, State Institute for Drug Control ("**SUKL**") has released number of individual statements that are described below.

SUKL has released Q&A on their website that is addressing the situations when subjects are not able to submit necessary documentation for already commenced authorization procedure (available here in Czech). In one of the answers, SUKL announced that the request for extension of deadline has to be submitted 5 working days prior to the deadline. This applies on requests for amendments of the application for registration, extensions of registration, variations or transfers of the registration ("**Request**"). SUKL noted that electronic submissions are preferred, although, personal delivery or delivery by post will be accepted.

As a response to COVID-19 Pandemic, SUKL has extended the deadline for 'step 1' responses in respect of nitrosamine risk evaluation processes in accordance with the Committee for Medicinal Products for Human Use (CHMP) opinion under Article 5 (3) of Regulation (EC) No. 726/2004 on the presence of nitrosamine impurities in human medicinal products to 30 September 2020 (originally until 26 March 2020). (available here).

2. If yes, which ones and what are the requirements to fall within the scope of the emergency provisions?

Links for the respective statements are available in the text above.

3. What are the expiry dates, if any?

No guidance on expiry dates has been published.

4. Under which competent authority(s) do these emergency provisions fall in both English and the original language?

State Institute for Drug Control. In Czech "Státní úřad pro kontrolu léčiv" (SUKL).

5. Are there specific procedures to be followed and what are those procedures?

The Request for deadline extension as specified above shall be submitted 5 days prior to the deadline.

6. Do the emergency provisions outline what information (if any) must be provided to the relevant approval authority and if yes, what information?

The Request shall state the reasons for extension and proposed additional time limit.

7. Are there any additional requirements that must be met or other relevant information related to market access?

Not published.

B. Emergency legislation/guidance for marketing authorisations for COVID-19 medicinal products.

1. Did national authorities issue other guidance on "emergency authorisation" for market authorisations specifically for Covid-19 medicinal products (e.g. lower threshold for obtaining marketing authorisation, waiving quality requirements)?

The above mentioned individual guidelines for non Covid-19-specific medicinal products are also applicable to COVID-19 related medicinal products.

In addition, SUKL has announced that COVID-19 related applications will be prioritized. Especially those applications that aim at ensuring the availability of pharmaceutical products that are necessary for provision of standard medical care during COVID-19 crisis (such as applications for new registration or variations). Please note that the SUKL proclamation is rather general and each application will be considered on case-by-case basis.

2. If yes, which ones and what are the requirements to fall within the scope of the emergency authorisation?

Abovementioned in item 8 is part of the Q&A (available here in Czech).

3. What are the expiry dates, if any?

No guidance on expiry dates has been published.

4. Under which competent authority(s) do these emergency authorisations fall in both English and the original language?

State Institute for Drug Control. In Czech "*Státní úřad pro kontrolu léčiv*" (SUKL).

5. Are there specific procedures to be followed and what are those procedures?

COVID-19 related applications shall be identified in the introductory letter and marked as "COVID-19 related". In addition, connection with COVID-19 shall be described.

In addition to the standard delivery, a copy shall be sent to the email address registrace.LP@sukl.cz to ensure prompt processing.

6. Do the emergency provisions outline what information (if any) must be provided to the relevant approval authority and if yes, what information?

See above.

7. Are there any additional requirements that must be met?

No.

8. Does the emergency legislative provision for the products, or other legislation, provide "immunity" from, or any limitation on, liability and if yes, what are the provisions?

No.

SUKL informs about the potential risks of using product registered for different purposes than for COVID-19 treatment. Each individual case shall be considered, whether the non-indicated treatment outweigh the potential risks. SUKL advice all potential patients against internet purchases of non-registered products offered for COVID-19 treatment (available here).

C. Emergency legislation/guidance on GMP, GDP, QP, changes in manufacturing, packaging and supply chain (please indicate if only applicable to COVID-19)

1. Is there emergency legislation/guidance on implementing changes in manufacturing or the supply chain and what are the key points?

The governmental decree, prohibiting export of pharmaceutical products designed for the Czech market, had been effective until the cancellation of emergency state in the Czech Republic (i.e. until 18 May 2020).

In addition, Ministry of Health of the Czech Republic ("**Ministry of Health**") regularly updates a list of medicinal products with a duty of prior announcement to the SUKL in cases when distributors intend to export the products on the list abroad. The list is available here.

Ministry of Health has adopted a decree restricting prescriptions of PLAQUENIL 200MG TBL

FLM 60 as of 3 April 2020. PLAQUENIL can only be prescribed by medical specialists named in the decree for treatments not exceeding 2 months with a limitation of 2 packaging for each patient.

2. Is there emergency legislation/guidance to address difficulties in conducting on-site **GMP** inspections and what are the key points?

No guidance has been published.

3. Is there emergency legislation/guidance to address difficulties in conducting on-site **GDP** inspections and what are the key points?

No guidance has been published.

4. Is there emergency legislation/guidance on QP work and what does it entail (e.g. remote batch certification)?

No guidance has been published.

5. Is there emergency legislation/guidance on the packaging requirements, also including over-labelling?

SUKL has announced that distributors shall inform SUKL if there is a risk of shortage of certain pharmaceutical products. Subsequently, based on case-by-case basis the distribution of foreign language packaging might be approved by SUKL in order to overcome the COVID-19 crisis (available here).

On 9 April 2020, SUKL has published the guidelines for applications for distribution of foreign language packaging. Such a distribution must be justified by public health concerns. The permission can only be granted for pharmaceutical products only available on prescription and similar products with Czech packaging cannot be offered on the market.

The application must contain following:

- SUKL code, name of pharmaceutical product, form, concentration and registration number;
- Quantity of the product that need to be imported;
- Original language of the packaging;
- Batch number;
- Reasons behind the application;
- Affidavit that every packaging will contain approved documentation; and
- Specimen of original packaging.

Over-labelling is permitted only to the licenced subjects.

Additional details can be found in Czech here.

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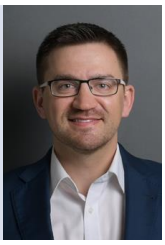

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Denmark

A. Emergency legislation for marketing authorisations non COVID-19 specific medicinal products.

1. Did national authorities issue guidance on "emergency provision" for marketing authorisations for non Covid-19 specific medicinal products (e.g. postponing of renewal applications, sunset clause applicability)?

No.

B. Emergency legislation/guidance for marketing authorisations for COVID-19 medicinal products.

1. Did national authorities issue other guidance on "emergency authorisation" for market authorisations specifically for Covid-19 medicinal products (e.g. lower threshold for obtaining marketing authorisation, waiving quality requirements)?

No. However, the Danish Medicines Agency refers to the regulatory guidance for marketing authorisation holders prepared by European Medicines Agency (EMA) and the Heads of Medicines Agency (HMA).

For further information please see here.

C. Emergency legislation/guidance on GMP, GDP, QP, changes in manufacturing, packaging and supply chain (please indicate if only applicable to COVID-19)

1. Is there emergency legislation/guidance on implementing changes in manufacturing or the supply chain and what are the key points?

Yes. As to COVID-19 notice no. 252 of March 22nd, 2020 , sections 9 – 13 and section 14 gives the Danish Medicines Agency the possibility to:

- Order pharmacies to distribute prescription drugs in volumes corresponding to the needed volume for a specified period regardless of the prescribed volume.
- Order pharmacies to only to distribute prescription drugs to specified groups of persons.
- Order pharmacies to repack larger packings into to smaller packings to support the effectuating of the abovementioned authority.
- If repacked a copy of the “patient information” notice should be inserted if possible.
- Order that repacking and manufacturing is done in a specific way.
- Order how the prices on repacked drugs are calculated.
- Oder substitution drugs to be excluded
- Order pharmacies to limit the distribution of a non-prescribed drug to the smallest packing on stock or a specific amount or number of packages.
- Order pharmacies to repack larger drug packings to smaller packings.
- Change and execute new delivery groups.
- Prohibit companies or persons with permission to distribute OTC drugs outside pharmacies to buy certain drugs and prohibit drug manufacturers and wholesalers from delivering drugs to such distributors.

2. Is there emergency legislation/guidance to address difficulties in conducting on-site **GMP** inspections and what are the key points?
Yes, the Danish Medicines Agency has stated that it will not execute the GMP inspections because of the pandemic. A GMP inspection will only be completed if there is a potential risk to patient safety. The Danish Medicines Agency is working with the European Medicines Agency to find common control methods and guidance for the industry to be used under the current COVID-19 breakout. The common agreement is to ensure that both inspections and controls can be conducted in compliance with the preventive measures to contain the spread of the virus, while safeguarding patient safety and ensuring that critical clinical trial applications are not affected. Please see here.
3. Is there emergency legislation/guidance to address difficulties in conducting on-site **GDP** inspections and what are the key points?
No.
4. Is there emergency legislation/guidance on QP work and what does it entail (e.g. remote batch certification)?
No.
5. Is there emergency legislation/guidance on the packaging requirements, also including over-labelling?
Yes. As to COVID-19 notice no. 252 of March 22nd, 2020, section 14, the Danish Medicines Agency possesses the possibility to order limited authorisation of packaging of both approved and non-approved medicines. More specifically the Danish Medicines Agency collaborates with the procurement organisation Amgros and the two pharmacy wholesalers Nomeco and TMJ to adjust their stocks with a view to supporting supplies to the Danish hospitals and pharmacies of especially critical medicines. In addition, the Minister of Health activated the drug preparedness in March 2020 to avoid shortages of medicines due to hoarding. This activation has been deactivated as per May 29, 2020.

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Finland

B. Emergency legislation for marketing authorisations non COVID-19 specific medicinal products.

1. Did national authorities issue guidance on "emergency provision" for marketing authorisations for non Covid-19 specific medicinal products (e.g. postponing of renewal applications, sunset clause applicability)?

Yes. The Finnish Medicines Agency ("**Fimea**") has given the following guidance:

- The applicant has the opportunity to request additional time to submit a renewal application. Marketing authorization holders should contact EMA (centralized products), RMS (MRP/DCP products) or national authority (national products). A request must be reasoned and submitted prior to the closing date of the renewal application. Urgent COVID-19 communications should be sent to *mrp@fimea.fi* with a clear request;
- Sunset clause exemption is regulated by the Medicines Act (395/1987). The holder of the marketing authorization or registration must submit an application to Fimea for the renewal of the marketing authorization or registration at least three months before the expiry of the three-year period;
- Fimea may grant an exemption of the language requirements for product labeling and product information if a medicinal product is critical for the Finnish pharmaceutical services and its availability would otherwise be jeopardised. The exemption is only applicable if the product has a valid marketing authorisation or registration. Otherwise, the special permit procedure must be followed.
- Further information can be found here.

Furthermore, due to the circumstances due to the COVID-19 pandemic, some medicinal products requiring special permit were granted a temporary special permit by Fimea. Such products can be found through here.

2. If yes, which ones and what are the requirements to fall within the scope of the emergency provisions?

See above.

3. What are the expiry dates, if any?

There are no specific expiry dates for the national guidelines.

4. Under which competent authority(ies) do these emergency provisions fall in both English and the original language?

Lääkealan turvallisuus- ja kehittämiskeskus (Fimea) /

The Finnish Medicines Agency (Fimea).

5. Are there specific procedures to be followed and what are those procedures?

No.

6. Do the emergency provisions outline what information (if any) must be provided to the relevant approval authority and if yes, what information?

Regarding Sunset clause exemption application, the applicant must provide all the essential information of the medicinal product, contact details and reasons for the exemption.

Concerning the exemption application of the language requirements for product labeling and product information, the applicant may submit a free-form application. However, the marketing authorization holder must usually

provide at least the following information:

- A description of the problem and the requested exemption;
- Justification for the criticality of the preparation for Finland's pharmaceutical services;
- An estimate of the duration of non-availability and the sales data of the preparation for e.g. the last 6 or 12 months;
- Information about the lot that the exemption applies to;
- If necessary, mock-ups of packages that are in a foreign language.

If all details are not known at the time of application, it can be agreed that some information will be submitted later, after the exemption has been granted.

7. Are there any additional requirements that must be met or other relevant information related to market access?

No.

B. Emergency legislation/guidance for marketing authorisations for COVID-19 medicinal products.

1. Did national authorities issue other guidance on "emergency authorisation" for market authorisations specifically for Covid-19 medicinal products (e.g. lower threshold for obtaining marketing authorisation, waiving quality requirements)?

Yes. Fimea has issued guidance for situations where the product already has a marketing authorisation in another EU/EEA country, the product is critical for the treatment of COVID-19 and also necessary for a new member state. In these cases, 0-day MR/RU processes are stated to be possible to expedite the marketing authorization process.

https://www.fimea.fi/-/helpotuksia-ihmisille-tarkoitettujen-laakkeiden-viranomaismenettelyihin-koronapandemian-aikana

In addition, Section 74 of the Communicable Diseases Act (1227/2016) includes an emergency provision allowing the Ministry of Social Affairs and Health to decide, under certain circumstances (including in immediate threat of an exceptional epidemic in order to prevent or treat such disease or a secondary disease), on the use of a medicinal product without a marketing authorisation.

2. If yes, which ones and what are the requirements to fall within the scope of the emergency authorisation?

There are no additional specific requirements for the 0-day MR/RU processes.

The applicability of the emergency provision under Section 74 of the Communicable Diseases Act (1227/2016) requires a generally hazardous disease, an exceptional epidemic or other similar disruption in health care.

3. What are the expiry dates, if any?

There are no expiry dates at the moment.

4. Under which competent authority(ies) do these emergency authorisations fall in both English and the original language?

Lääkealan turvallisuus- ja kehittämiskeskus (Fimea) / The Finnish Medicines Agency (Fimea) shall decide on the 0-day MR/RU processes.

Sosiaali- ja terveysministeriö / The Ministry of Social Affairs and Health shall decide on exceptions in accordance with Section 74 of the Communicable Diseases Act (1227/2016).

5. Are there specific procedures to be followed and what are those procedures?

Under 0-day MR/RU processes and as regards Finland, it has been instructed to send an email to mrp@fimea.fi with the subject "Urgent COVID-19 request".

6. Do the emergency provisions outline what information (if any) must be provided to the relevant approval authority and if yes, what information?

See above.

7. Are there any additional requirements that must be met?

No.

8. Does the emergency legislative provision for the products, or other legislation, provide "immunity" from, or any limitation on, liability and if yes, what are the provisions?

No.

C. Emergency legislation/guidance on GMP, GDP, QP, changes in manufacturing, packaging and supply chain (please indicate if only applicable to COVID-19)

1. Is there emergency legislation/guidance on implementing changes in manufacturing or the supply chain and what are the key points?

For the essential medicinal product in the treatment of COVID-19 patients, a new manufacturing or quality control site may be established by the ECMP process without prior approval in order to prevent or alleviate non-availability of the product. The site must have a GMP certificate issued by the EU or MRA partner, subject to the provision of the EU. These urgent ECMP notices should be sent to Fimea mrp@fimea.fi with the title "COVID-19, ECMP" and with the process number included. Further information can be found here.

Finnish government has recently passed acts (which entered into force on 13 July 2020), amending the Medicines Act (395/1987), the Act on Obligatory Reserve Supplies of Medicinal Products (979/2008), and the Communicable Diseases Act (1227/2016), whereby:

- The Ministry of Social Affairs and Health may temporarily restrict or target the distribution, sale or release for consumption of a medicinal product due to a disruption in availability. Restrictions could include e.g. that a consumer may purchase only one package of self-medication at a time;
- Medicinal product reserve supplies required by law have to be physically located in Finland;
- Medicinal product wholesalers have an obligation to notify of drug supply interruptions. Such notification should include information about the interruption and an estimate of the duration of non-availability.

According to Section 87 of the Finnish Emergency Powers Act (1552/2011), the supply and sale of medicines may in exceptional circumstances be instructed to be expanded, changed or restricted by a separate decision by the Ministry of Social Affairs and Health.

2. Is there emergency legislation/guidance to address difficulties in conducting on-site **GMP** inspections and what are the key points?

Yes. Fimea has issued general guidance on special arrangements for GMP inspections. These arrangements are mainly agreed at European Union level. The key points are:

- The validity periods of GMP certificates will automatically continue until the end of 2021 without on-site inspections.
- On-site inspections continue as soon as the Covid-19 situation allows.
- Reduced and more flexible GMP inspections for medicines which are essential for the treatment of Covid-19.

3. Is there emergency legislation/guidance to address difficulties in conducting on-site **GDP** inspections and what are the key points?
Yes. Fimea has issued general guidance on special arrangements for GDP inspections. These arrangements are mainly agreed at European Union level. The key points are: • The validity periods of GDP certificates will automatically continue until the end of 2021 without on-site inspections. • On-site inspections continue as soon as the Covid-19 situation allows. • -During quarantine and travel restrictions, the responsible director has the opportunity to work outside the company's premises if certain conditions are met. • Approval of new pharmaceutical wholesale facilities and equipment based on limited preliminary examinations. • Planned deviations from normal operating procedures are possible.
4. Is there emergency legislation/guidance on QP work and what does it entail (e.g. remote batch certification)?
Yes. It is stated in the guidance issued by Fimea that when auditing a medicinal substance factory for QP-declaration, QP may rely on a written audit and also take into account possible inspections carried out by an EEA pharmaceutical authority.
5. Is there emergency legislation/guidance on the packaging requirements, also including over-labelling?
According to the Medicines Act (395/1987), Fimea may grant an exemption from the provisions on information on the labelling and package leaflet of medicinal products and the obligation to draw up the labelling and package leaflet in Finnish and Swedish. (see Section A).

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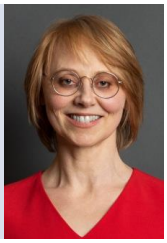

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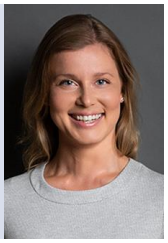

France

A. Emergency legislation for marketing authorisations non COVID-19 specific medicinal products.

1. Did national authorities issue guidance on "emergency provision" for marketing authorisations for non Covid-19 specific medicinal products (e.g. postponing of renewal applications, sunset clause applicability)?

Yes, in the form of guidelines issued by the ANSM.

2. If yes, which ones and what are the requirements to fall within the scope of the emergency provisions?

This document, in the form of FAQ, is available here.

This document provides guidance to applicants and marketing authorization holders for medicinal products for human use on regulatory expectations as well as possible adaptations during the COVID-19 pandemic, in line with those already provided at European level.

3. What are the expiry dates, if any?

There is no expiration date. This document remains valid until further notice.

4. Under which competent authority(ies) do these emergency provisions fall in both English and the original language?

French Medicines Agency (ANSM)

5. Are there specific procedures to be followed and what are those procedures?

Only electronic applications are accepted.

It is recommended to defer non-priority requests to the extent possible, i.e. those not related to COVID or

risks of essential medicines shortage.

The applicable timelines could be extended for these non-priority requests.

Concerning the dossier content, some requirements can be waived/adapted, in particular :

- In general, in place of the original signatures, only the surname, first name and function of the person who in principle signs the document can be accepted.
- In the event that certain documents are not submitted in support of the application, this should be duly justified and this will be examined by the ANSM on a case by case basis.

A commitment may be proposed to provide certain documents not available at the time of the application due to COVID (such as GMP certificates) during the procedure and in any case before the end of the 1st assessment round.

Applications for renewal:

Partial submissions are possible, provided that conditions and timelines described in the European guidelines are fulfilled (cf. European guidelines).

The COVID situation does constitute a reason for sunset clause waiver:

The COVID situation can cause a delay in the launch of certain medicines. The European recommendations remind companies of the need to apply for the sunset clause waiver as usual.

These waiver requests linked to the COVID context should be submitted to the ANSM; they will be examined as

usual. A justification should be provided in the usual form.

6. Do the emergency provisions outline what information (if any) must be provided to the relevant approval authority and if yes, what information?

N/A

7. Are there any additional requirements that must be met or other relevant information related to market access?

N/A

B. Emergency legislation/guidance for marketing authorisations for COVID-19 medicinal products.

1. Did national authorities issue other guidance on "emergency authorisation" for market authorisations specifically for Covid-19 medicinal products (e.g. lower threshold for obtaining marketing authorisation, waiving quality requirements)?

Yes, in the form of guidelines issued by the ANSM .

2. If yes, which ones and what are the requirements to fall within the scope of the emergency authorisation?

This guideline is available here. (The same guideline deals with non-Covid and Covid medicines).

Priority will be given to applications for marketing authorization and variations concerning:

- COVID related medicines,
- a risk of shortage of an essential drug involved in the care of patients with COVID-19
- a risk of shortage of other essentials drugs.

3. What are the expiry dates, if any?

There is no expiration date. This document remains valid until further notice.

4. Under which competent authority(ies) do these emergency authorisations fall in both English and the original language?

French Medicines Agency (ANSM)

5. Are there specific procedures to be followed and what are those procedures?

Only electronic applications are accepted.

The applicant shall:

- clearly identify in the comment field of the CESP repository: "COVID" or "risk of essential medicines shortage"
- clearly identify in the subject of the cover letter the priority nature of the application, specifying at the beginning of the subject "COVID" or "risk of essential medicines shortage"
- provide the reasons justifying the priority in the cover letter

The regulatory deadlines could be reduced when it comes to priority requests.

Some requirements can be waived/adapted for application:

In place of the original signatures, only the surname, first name and function of the person who in principle signs the document can be accepted.

In the event that certain documents are not submitted in support of the applications, this should be duly justified

and this will be examined by the ANSM on a case by case basis.

A commitment may be proposed to provide certain documents not available at the time of the application due to COVID (such as GMP certificates) during the procedure and in any case before the end of the 1st assessment round.

(cf. European guidance).

ASMF (Active Substance Master File):

Any information concerning an ASMF evaluation by another Member State of the EU can usefully contribute to the evaluation conducted by the ANSM and speed up processing.

It is recommended to mention it in the cover letter with the following information and to provide a copy of the approval of the corresponding competent authority in the annex to the cover letter:

- DCI / ASMF No./ version No.
- Approval date for the ASMF / Competent Authority,
- Specialty (name, dosage, pharmaceutical form) for which the ASMF has been approved by the Member State.

6. Do the emergency provisions outline what information (if any) must be provided to the relevant approval authority and if yes, what information?

N/A

7. Are there any additional requirements that must be met?

N/A

8. Does the emergency legislative provision for the products, or other legislation, provide "immunity" from, or any limitation on, liability and if yes, what are the provisions?

No.

C. Emergency legislation/guidance on GMP, GDP, QP, changes in manufacturing, packaging and supply chain (please indicate if only applicable to COVID-19)

1. Is there emergency legislation/guidance on implementing changes in manufacturing or the supply chain and what are the key points?

Where the period of validity of a renewable prescription has expired and in order to avoid any interruption of treatment prejudicial to the health of the patient, pharmacies were authorized to dispense, with the dosage initially laid down, the medicinal products necessary for the continuation of treatment until 31 May 2020. The renewable prescription covers also those drugs: hypnotic and anxiolytic benzodiazepines, cases of opiate substitution therapy, narcotics and medical devices.

The dispensing of paracetamol without a prescription was limited to two boxes per patient. (Note from the French Ministry of Health, April 24th, 2020 which apply until May, 31st 2020).

2. Is there emergency legislation/guidance to address difficulties in conducting on-site **GMP** inspections and what are the key points?

As a result of government containment and social distancing measures, the ANSM has suspended its routine on-site inspection program until further notice.

Remote assessment procedures by ANSM may be envisaged.

Therefore, the absence of certain documents not available at the time of submission due to COVID (in particular GMP certificates) in support of the applications will not prevent the ANSM from examining them, provided that this is duly justified. A commitment will be proposed to provide certain documents during the procedure and in any case

before the end of the 1st round of evaluation.
3. Is there emergency legislation/guidance to address difficulties in conducting on-site **GDP** inspections and what are the key points?
The ANSM simply specifies on its website that if an on-site inspection is required, it will be conducted in strict compliance with government hygiene regulations.
4. Is there emergency legislation/guidance on QP work and what does it entail (e.g. remote batch certification)?
No.
5. Is there emergency legislation/guidance on the packaging requirements, also including over-labelling?
No.

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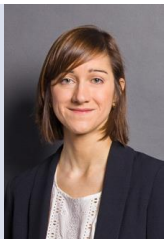

Germany

A. Emergency legislation for marketing authorisations non COVID-19 specific medicinal products.

1. Did national authorities issue guidance on "emergency provision" for marketing authorisations for non Covid-19 specific medicinal products (e.g. postponing of renewal applications, sunset clause applicability)?

Yes.

The Federal Ministry of Health issued a regulation on ensuring the public supply of medicinal products (MedBVSV). The regulation addresses certain exceptions of regulations regulated in the Medical Products Act (Arzneimittelgesetz - AMG).

The regulation notably includes:

- Relaxations regarding labelling and enclosing the patient information leaflet
- Prolonged Marketing authorisation for expired medical products if no threat is posed by those products
- Relaxation regarding marketing authorisation for medical products, which are not produced according to the GMD regulations
- Special authorisation for medicinal products (fast track procedure), if required to ensure public supply after performing well in the benefit-risk-assessment (already granted for medicinal products containing propofol in 100ml vials).

2. If yes, which ones and what are the requirements to fall within the scope of the emergency provisions?

See above.

The regulation covers medicinal products, initial materials, excipients, substances listed in annex I and II to the national Narcotics Act, medical devices, PPE and disinfectants. All the exceptions and special authorisations will apply if required to ensure the supply with medical products. The Federal Ministry of Health will be responsible of granting exceptions and special authorisations.

3. What are the expiry dates, if any?

The regulation MedBVSV will expire once the end of the epidemic on national level is ascertained but by no later than 31st of March 2021.

4. Under which competent authority(ies) do these emergency provisions fall in both English and the original language?

Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)

(Federal Institute for Drugs and Medical Devices).

5. Are there specific procedures to be followed and what are those procedures?

No.

The BfArM will decide case by case for which medicinal products exceptions and special authorisation will be granted. For further questions and information: COVID-19@bfarm.de

6. Do the emergency provisions outline what information (if any) must be provided to the relevant approval authority and if yes, what information?
See above. Authorisation will be granted case by case. It is recommended to contact the BfArM for information on the evaluation criteria in the particular case.
7. Are there any additional requirements that must be met or other relevant information related to market access?
No.

B. Emergency legislation/guidance for marketing authorisations for COVID-19 medicinal products.

1. Did national authorities issue other guidance on "emergency authorisation" for market authorisations specifically for Covid-19 medicinal products (e.g. lower threshold for obtaining marketing authorisation, waiving quality requirements)?
The national authorities did not issue guidance on market authorisations specifically for COVID-19 medical products. See above at item A1, which would also be applicable to COVID-19 related medicinal products.
2. If yes, which ones and what are the requirements to fall within the scope of the emergency authorisation?
See above at item A2.
3. What are the expiry dates, if any?
The regulation MedBVSV will expire once the end of the epidemic on national level is ascertained but by no later than 31st of March 2021.
4. Under which competent authority(ies) do these emergency authorisations fall in both English and the original language?
Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM). (Federal Institute for Drugs and Medical Devices)
5. Are there specific procedures to be followed and what are those procedures?
See above at item A5.
6. Do the emergency provisions outline what information (if any) must be provided to the relevant approval authority and if yes, what information?
See above at item A6
7. Are there any additional requirements that must be met?
No.
8. Does the emergency legislative provision for the products, or other legislation, provide "immunity" from, or any limitation on, liability and if yes, what are the provisions?
No.

C. Emergency legislation/guidance on GMP, GDP, QP, changes in manufacturing, packaging and supply chain (please indicate if only applicable to COVID-19)

1. Is there emergency legislation/guidance on implementing changes in manufacturing or the supply chain and what are the key points?

In case of imminent supply shortfall, the BfArM may insure the supply of pharmaceutics through order according to § 52b AMG on conducting measures of curtailment of supplies.

Pharmaceutical manufacturers are required to deliver products to the following extent:

- Ensuring sufficient delivery of products to pharmacies for statuary minimum of stock (one week)
- Pharmaceutical manufacturers are required to ensure the supply of pharmaceutical wholesaler for statuary minimum of stock (two weeks).

In addition, a Task force was established to ensure supply with medical products through:

- Short dated agreement on substance catalogue vital for ICU
- Development of model procedure to ensure supply of hotspots
- Specific investigation of demand and product capacity
- Measures to avoid supply shortfall in ICU

2. Is there emergency legislation/guidance to address difficulties in conducting on-site GMP inspections and what are the key points?

No.

The national regulation for GMP (AMWVH) applies.

3. Is there emergency legislation/guidance to address difficulties in conducting on-site GDP inspections and what are the key points?

No.

4. Is there emergency legislation/guidance on QP work and what does it entail (e.g. remote batch certification)?

No.

5. Is there emergency legislation/guidance on the packaging requirements, also including over-labelling?

Pharmaceuticals may be placed on the market without labelling or patient information leaflet, if permitted by the BfArM and necessary to ensure the supply of pharmaceuticals. The product information will be published by the BfArM.

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Hungary

A. Emergency legislation for marketing authorisations non COVID-19 specific medicinal products.
1. Did national authorities issue guidance on "emergency provision" for marketing authorisations for non Covid-19 specific medicinal products (e.g. postponing of renewal applications, sunset clause applicability)?
Yes, although the Hungarian regulator (National Institute of Pharmacy and Nutrition, "**NIPN**") merely referred to the "Practical guidance of the CMDh for facilitating the handling of processes during the COVID-19 crisis" prepared by Co-ordination Group for Mutual Recognition and Decentralized Procedures – Human (available here). The NIPN provided a Hungarian translation of this guidance and stated that it should be interpreted in line with and complementing "Notice to Stakeholders - Questions and Answers on Regulatory Expectations for Medicinal Products for Human Use During the Covid-19 Pandemic" (available here).
2. If yes, which ones and what are the requirements to fall within the scope of the emergency provisions?
See above.
3. What are the expiry dates, if any?
N/A
4. Under which competent authority(s) do these emergency provisions fall in both English and the original language?
National Institute of Pharmacy and Nutrition (In Hungarian: Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet).
5. Are there specific procedures to be followed and what are those procedures?
N/A
6. Do the emergency provisions outline what information (if any) must be provided to the relevant approval authority and if yes, what information?
N/A
7. Are there any additional requirements that must be met or other relevant information related to market access?
N/A
B. Emergency legislation/guidance for marketing authorisations for COVID-19 medicinal products.
1. Did national authorities issue other guidance on "emergency authorisation" for market authorisations specifically for Covid-19 medicinal products (e.g. lower threshold for obtaining marketing authorisation, waiving quality requirements)?
Yes, on one hand the Hungarian regulator (National Institute of Pharmacy and Nutrition, NIPN) referred to the

"Practical guidance of the CMDh for facilitating the handling of processes during the COVID-19 crisis" prepared by Co-ordination Group for Mutual Recognition and Decentralized Procedures – Human (available here). The NIPN provided a Hungarian translation of this guidance and stated that it should be interpreted in line with and complementing "Notice to Stakeholders - Questions and Answers on Regulatory Expectations for Medicinal Products for Human Use During the Covid-19 Pandemic" (available here).

On the other hand the Hungarian government adopted decrees, namely Governmental Decree No. 99/2020 and Governmental Decree No. 67/2020 concerning the prescription of medicinal products without marketing authorization or for unauthorized indication for facilitating COVID-19 treatment:

1 Governmental Decree No. 99/2020 facilitates the compassionate use of investigational medicinal products or medicinal products that does not have marketing authorization for COVID-19 treatment upon the ad hoc authorization by the NIPN the following way:

- it is sufficient if the medicinal product has been or is being tested in a phase I clinical trial (instead of phase II) or it is subject to ongoing marketing authorization procedure in Hungary or in another country with equivalent regulations;
- the request for the ad hoc authorization of the NIPN can be submitted by the healthcare provider (instead of the treating doctor) concerning a group of patients (not only one specific patient) who have suffered a life-threatening or debilitating medical condition;
- it is not necessary that the manufacturer of the medicinal product authorizes the use, undertakes to provide the medicinal product free of charge, and warrants the quality of the medicinal product;

provided that the patient has given their informed consent and the compassionate use of medicinal products does not manifest in unlawful commercial practices. These facilitated rules are applicable during the state of emergency.

2 Governmental Decree No. 67/2020 allows for the prescription of medicinal products for an unauthorized indication in order to treat COVD-19 if the medicinal product has marketing authorization in Hungary or in another country, without prior ad hoc authorization from the NIPN if the medicinal product contains the active substance listed on the NIPN's webpage[1], provided that other standard conditions are met. In such case the request for ad hoc authorization should be submitted within 90 days following the termination of the state of emergency by the healthcare provider.

If the active substance is not on the list of the NIPN, then prior ad hoc authorization should be requested for prescription medicinal products for unauthorized indication for treating COVID-19. This request will be handled in an urgent procedure.

2. If yes, which ones and what are the requirements to fall within the scope of the emergency authorisation?

See above, Governmental Decree No. 99/2020 and Governmental Decree No. 67/2020.

At this stage, no further specific requirements are published.

3. What are the expiry dates, if any?

For compassionate use of investigational medicinal products or medicinal products that does not have marketing authorization for COVID-19 treatment, the rules are applicable during the state of emergency.

For the prescription of medicinal products for an unauthorized indication in order to treat COVD-19, the request for ad hoc authorization should be submitted within 90 days following the termination of the state of emergency by the healthcare provider.

4. Under which competent authority(s) do these emergency authorisations fall in both English and the original language?

National Institute of Pharmacy and Nutrition (In Hungarian: Országos Gyógyszerészeti és Élelmezés-egészségügyi

[1] Hydroxychloroquine-sulfate, Chloroquine, Remdesivir, Lopinavír, Ritonavir, Ruxolitinib, Azithromycin, Oseltamivir, Tocilizumab, Favipiravir, Infliximab, Adalimumab, Baricitinib, Canakinumab, IVIG-treatment (intravenous immunglobulins), Sarilumab, Siltuximab, Sofosbuvir, Interferon-alfa.

Intézet).

5. Are there specific procedures to be followed and what are those procedures?

See above at B1.

6. Do the emergency provisions outline what information (if any) must be provided to the relevant approval authority and if yes, what information?

n/a

7. Are there any additional requirements that must be met?

n/a

8. Does the emergency legislative provision for the products, or other legislation, provide "immunity" from, or any limitation on, liability and if yes, what are the provisions?

In respect of compassionate use of investigational medicinal products or medicinal products that does not have marketing authorization for COVID-19 treatment (see above in B.8) it is not necessary that the manufacturer of the medicinal product authorizes the use, undertakes to provide the medicinal product free of charge, and warrants the quality of the medicinal product; provided that the patient has given their informed consent and the compassionate use of medicinal products does not manifest in unlawful commercial practices.

C. Emergency legislation/guidance on GMP, GDP, QP, changes in manufacturing, packaging and supply chain (please indicate if only applicable to COVID-19)

1. Is there emergency legislation/guidance on implementing changes in manufacturing or the supply chain and what are the key points?

Yes, although the Hungarian regulator (National Institute of Pharmacy and Nutrition, NIPN) merely referred to the "Practical guidance of the CMDh for facilitating the handling of processes during the COVID-19 crisis" prepared by Co-ordination Group for Mutual Recognition and Decentralized Procedures – Human (available here). The NIPN provided a Hungarian translation of this guidance and stated that it should be interpreted in line with and complementing "Notice to Stakeholders - Questions and Answers on Regulatory Expectations for Medicinal Products for Human Use During the Covid-19 Pandemic" (available here).

2. Is there emergency legislation/guidance to address difficulties in conducting on-site **GMP** inspections and what are the key points?

N/A

3. Is there emergency legislation/guidance to address difficulties in conducting on-site **GDP** inspections and what are the key points?

N/A

4. Is there emergency legislation/guidance on QP work and what does it entail (e.g. remote batch certification)?

N/A

5. Is there emergency legislation/guidance on the packaging requirements, also including over-labelling?

N/A

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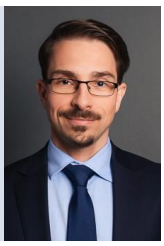

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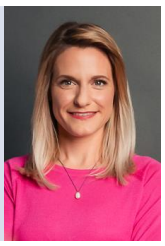

Italy

A. Emergency legislation for marketing authorisations non COVID-19 specific medicinal products.

1. Did national authorities issue guidance on "emergency provision" for marketing authorisations for non Covid-19 specific medicinal products (e.g. postponing of renewal applications, sunset clause applicability)?

Yes.

The Italian Agency for Medicinal Products ("***AIFA***"), issued a guidelines (available here) related to exemption from the normal procedure for the submission

(i) of MA variation and renewal applications/notifications through the relevant portals pending the submission of what required in the guidance dated 7th May 2019

(ii) through CESP of MA/extension applications (N,MRP,DCP) pending the submission of what required in the guidance dated 7th May 2019

(iii) of MAH Transfer applications of marketing authorization granted through national, DCP and MRP.

The mentioned applications shall be sent to protocollo@pec.aifa.gov.it; all documents that would require submission as original or legalized copies can be sent as scanned copies, including cover letter with original signature; statement that product information is in line with the latest approved one should be attached, together with details concerning parallel variations submitted on the variation portal, if any.

At the end of the restrictions related to COVID-19 emergency, in order to complete the submission and obtain the MAH transfer, the Applicant shall submit the original paper documents supporting the MAH transfer; copy of the receipt of PEC (certified email) submission shall be included together with the € 16.00 revenue stamp, if not yet already done.

(iv) the submission of ASMF and subsequent updates, shall be submitted through CESP and the submission shall be notified through mail to: asmf@aifa.gov.it

At the end of the restrictions related to COVID-19 emergency, ASMF and ASMF updates shall be sent in accordance with what established in the guidance dated 7th May 2019; copy of the CESP submission notification should be included in the package.

(v) the submission of proposed changes in accordance with artt.78 e 79 del D.Lgs. N°219/2006 (articles 61(3) and 62 of the Directive 2001/83), the applications shall be sent to protocollo@pec.aifa.gov.it and all documents that would require submission as original or legalized copies can be sent as scanned copies.

At the end of the restrictions related to COVID-19 emergency, the Applicant shall submit the original paper documents together with the copy of the receipt of the PEC submission.

The provisions given above are also applicable to responses/additional documents.

2. If yes, which ones and what are the requirements to fall within the scope of the emergency provisions?

See above at A1 (i).

3. What are the expiry dates, if any?

There is not a specific date but a generic recall to "*the end of the restrictions related to COVID-19*".

4. Under which competent author(ies) do these emergency provisions fall in both English and the original language?
Italian Medicines Agency (AIFA) Agenzia Italiana del Farmaco (AIFA)
5. Are there specific procedures to be followed and what are those procedures?
See above at A1 (i).
6. Do the emergency provisions outline what information (if any) must be provided to the relevant approval authority and if yes, what information?
See above at A1 (i).
7. Are there any additional requirements that must be met or other relevant information related to market access?
Not at this stage.

B. Emergency legislation/guidance for marketing authorisations for COVID-19 medicinal products

1. Did national authorities issue other guidance on "emergency authorisation" for market authorisations specifically for Covid-19 medicinal products (e.g. lower threshold for obtaining marketing authorisation, waiving quality requirements)?
No, not at this stage. Anyway, AIFA published the procedure that will be adopted by EMA (available here).

C. Emergency legislation/guidance on GMP, GDP, QP, changes in manufacturing, packaging and supply chain (please indicate if only applicable to COVID-19)

1. Is there emergency legislation/guidance on implementing changes in manufacturing or the supply chain and what are the key points?
AIFA, to afford the demand of medicinal products and to guarantee the supply chain, authorized the importation of foreign medicinal products (with foreign packaging) for the Hospitals supply (available here).
2. Is there emergency legislation/guidance to address difficulties in conducting on-site **GMP** inspections and what are the key points?
Yes, AIFA promoted the adoption of the following measures: • Extension until 2021 of the validity of GMP certificates, both of production and import of active substances and / or medicinal products, in deadline in 2020; • Ability to perform, where necessary, a distant assessment for extension or activation instances and the execution of related inspection activities at end of the emergency; • Possibility for QPs to carry out the remote release of the lots produced; • Ability for QPs to perform remote audits (paper based audits) of producers of active substances and starting materials; Specifically, AIFA published the following emergency measures, that will be valid until the end of the COVID-19 emergency, for manufacturers of medicines and active substances: • GMP certificates expiring by 31.12.2020 are automatically extended until 31.12.2021, without the need to update the existing certificate, unless otherwise assessed by the undersigned Office;

- in case of requests for extension for new pharmaceutical forms, active substances and / or production lines, the offices will be able to carry out a distant assessment in order to authorize the requested modification, also assessing the possibility of carrying out, if deemed necessary, a verification inspection at the end of the COVID-19 emergency;
- in case of requests for activation of new production sites, the offices will be able to carry out a distant assessment, in order to evaluate the possibility of authorizing the production site in question with the expectation of carrying out an inspection visit at the end of the COVID-19 emergency. In the event of a positive assessment, production authorization will be issued indicating that a distant assessment has been performed due to the COVID-19 emergency and that a verification inspection will be performed at the end of this emergency;
- for production sites located in third countries, the GMP certificate already issued, if expiring in 2020, is extended until the end of 2021 without the need for updating, unless otherwise assessed by the competent GMP Inspection and Authorization Offices for Medicines or Raw Materials .

The document is available here.

3. Is there emergency legislation/guidance to address difficulties in conducting on-site GDP inspections and what are the key points?

See answer C2 above.

4. Is there emergency legislation/guidance on QP work and what does it entail (e.g. remote batch certification)?

See answer C2 above.

5. Is there emergency legislation/guidance on the packaging requirements, also including over-labelling?

See answer C1 above.

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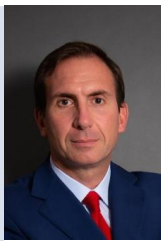

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Netherlands

A. Emergency legislation for marketing authorisations non COVID-19 specific medicinal products.

1. Did national authorities issue guidance on "emergency provision" for marketing authorisations for non Covid-19 specific medicinal products (e.g. postponing of renewal applications, sunset clause applicability)?

No.

However, a specific medicine shortage monitor has been launched, under the responsibility of the MEB. These medicines are not related to/used for the cure of COVID-19. The MEB will evaluate the current shortages and the risks that come with these shortages.

B. Emergency legislation/guidance for marketing authorisations for COVID-19 medicinal products.

1. Did national authorities issue other guidance on "emergency authorisation" for market authorisations specifically for Covid-19 medicinal products (e.g. lower threshold for obtaining marketing authorisation, waiving quality requirements)?

No. However, the Dutch Medicines Evaluation Board (CBG) has launched an initiative for research groups of small entities, hospitals and start-ups to obtain free and expedited advice from the MEB regarding their research.

C. Emergency legislation/guidance on GMP, GDP, QP, changes in manufacturing, packaging and supply chain (please indicate if only applicable to COVID-19)

1. Is there emergency legislation/guidance on implementing changes in manufacturing or the supply chain and what are the key points?

The Dutch Ministry of Health Welfare and Sports (VWS) decided that patients will receive their regular medicines in the regular quantities, however not for a longer period of time to ensure that medicines will be available for as much people as possible. Pharmacies and drugstores have been advised to only provide three packages of over-the-counter medicines per patient.

2. Is there emergency legislation/guidance to address difficulties in conducting on-site **GMP** inspections and what are the key points?

Yes, the Dutch Inspectorate for Health and Youth Care (IGJ) has stated that it will not execute the GMP inspections because of the pandemic. This only sees on the periodic routine-inspection that the Inspectorate performs at the holders of the manufacturing authorizations.

In urgent situations, for example after notification, the Inspectorate can decide to perform the inspection anyway. The Inspectorate decides for every inspection that should have been performed if a GMP-certificate with restricted validity (beperkte geldigheid). These certificates will be uploaded to the EUDRAGMDP-database.

At the end April 2020, the Inspectorate stated that all GMP certificates have been extended until at least the end of December 2021. An exception will be made for the certifications with an indicated time limit and with changes in the scope of the certificate (e.g. new premises or new medicines). In case of applications for new authorizations or changes in existing authorizations the Inspectorate will decide per situation if an inspection will be performed on site or in a different manner.

3. Is there emergency legislation/guidance to address difficulties in conducting on-site **GDP** inspections and what are the key points?
Yes, the Dutch Inspectorate for Health and Youth Care (IGJ) has stated that it will not execute the GDP inspections because of the pandemic. This only sees on the periodic routine-inspection that the Inspectorate performs at the holders of the manufacturing authorizations. In urgent situations, for example after notification, the Inspectorate can decide to perform the inspection anyway. The Inspectorate decides for every inspection that should have been performed if a GDP-certificate with restricted validity (beperkte geldigheid). These certificates will be uploaded to the EUDRAGMDP-database. At the end of April 2020, the Inspectorate stated that all GDP certificates have been extended until at least the end of December 2021. An exception will be made for the certifications with an indicated time limit and with changes in the scope of the certificate (e.g. new premises or new medicines). In case of applications for new authorizations or changes in existing authorizations the Inspectorate will decide per situation if an inspection will be performed on site or in a different manner.
4. Is there emergency legislation/guidance on QP work and what does it entail (e.g. remote batch certification)?
No.
5. Is there emergency legislation/guidance on the packaging requirements, also including over-labelling?
Yes, the Inspectorate accepted that it case of medicine shortage it is possible to provide packages of medicines of from other European countries, meaning that the packaging and the package leaflet is not in Dutch. It is deemed sufficient that the pharmacist will provide a Dutch translation. In this way, the Inspectorate aims to ensure that sufficient medicines are available for Dutch patients.

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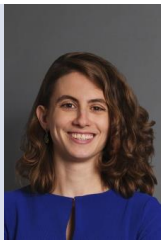

Poland

A. Emergency legislation for marketing authorisations non COVID-19 specific medicinal products.

1. Did national authorities issue guidance on "emergency provision" for marketing authorisations for non Covid-19 specific medicinal products (e.g. postponing of renewal applications, sunset clause applicability)?

No.

However, Minister of Health launched simplified **targeted import procedure and its reimbursement**. Targeted import pertains to medicinal products imported from abroad which are authorized without a necessity to obtain marketing authorization, if their use is necessary to save the patient's life or health, provided that the medicinal product is authorized in the country from which it is imported and has a valid marketing authorization.

The procedure is valid from 9 April 2020 until the date of cancellation of the state of epidemic or epidemic threat in the territory of Poland.

Apart from that, pursuant to the anti-crisis legislation in the state of epidemic emergency or the state of epidemic, announced due to Covid-19, some of the **time limits stipulated by the administrative law (substantive law) did not run**. This means that certain administrative deadlines did not start to run, and those which had already run, were suspended. This applied, among others, to the deadlines which condition the granting of legal protection before court or authority or which, if not kept, result in the expiry or change of property rights and claims and due amounts, as well as being in delay, or final deadlines which, if not kept, involve negative consequences for the party.

Most of the deadlines set in administrative proceedings concerning medicinal products (such as deadlines for filing renewal applications) were affected by this general suspension. Anti-crisis shield 2.0 amended this provision by stating that it does not apply to audits and inspections as well as administrative proceedings conducted pursuant to the provisions of the Act of 6 September 2001 - Pharmaceutical Law, if failure to carry out audit or inspection and failure to issue a decision could cause a threat to the life or health of humans or animals, or serious harm to the public interest.

The suspension of deadlines provided for in said legislation applied in the period 14 March – 24 May 2020. In this regard the President of the ORMP issued also a communications dated 3 April and 19 May 2020.

B. Emergency legislation/guidance for marketing authorisations for COVID-19 medicinal products.

1. Did national authorities issue other guidance on "emergency authorisation" for market authorisations specifically for Covid-19 medicinal products (e.g. lower threshold for obtaining marketing authorisation, waiving quality requirements)?

No. However, the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products ("**ORMP**") announced an informal accelerated procedure for all the applications related to combatting and preventing COVID-19, if they will be clearly marked on their front page with the text "Concerns coronavirus SARS-CoV-2" (communication of the President of the ORMP dated 17 March 2020).

The measures described above in item 1 are also applicable to Covid-19 related medicinal products.

On 15 April 2020 the President of the ORMP published information about the European Commission's "COVID-19: Guidance on more regulatory flexibility for medicines".

On 21 April 2020 the President of the ORMP published information about the publication of „Practical guidance of the CMD h for facilitating the handling of process during the Covid-19 crisis".

On 6 May 2020 the ORMP published information about the implementation by the EMA of the fact track for support and approval of R&D projects on medicinal products and vaccines in the context of COVID-19.

However, the President of the ORMP did not provide any guidance which would specifically concern national marketing authorisations.

In case of **biocidal products**, on 13 March 2020 the President of the ORMP issued a communication about the

possibility of using the derogation from the registration requirements for biocidal products intended **for disinfection**, provided for in art. 55(1) of Regulation (EU) No. 528/2012 of the European Parliament and of the Council of May 22, 2012 regarding the making available on the market and use of biocidal products (Journal of Laws of the EU. L 167 of 27.06.2012, p. 1, as amended).

Pursuant to this provision, by way of derogation from Art. 17 and 19 of the Regulation, the competent authority may issue - for a period not exceeding 180 days - authorization for making available on the market or use of a biocidal product not complying with the requirements of the Regulation concerning the issue of such authorization, for the purpose of its limited and controlled use under the supervision of the competent authority, if such measure is necessary because of a risk to public health, animal health or the environment that cannot be prevented by other means.

Special form was provided by the ORMP for applying for marketing authorisations for such biocidal products (communication of the President of the ORMP dated 23 March 2020).

2. If yes, which ones and what are the requirements to fall within the scope of the emergency authorisation?

No specific national guidelines were published in this regard.

3.What are the expiry dates, if any?

No expiry dates *per se* have been noted in the official guidance at this stage.

4. Under which competent authority(ies) do these emergency authorisations fall in both English and the original language?

Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych / Office for Registration of Medicinal Products, Medical Devices and Biocidal Products ("**ORMP**").

5. Are there specific procedures to be followed and what are those procedures?

n/a

6. Do the emergency provisions outline what information (if any) must be provided to the relevant approval authority and if yes, what information?

n/a

7. Are there any additional requirements that must be met?

n/a

8. Does the emergency legislative provision for the products, or other legislation, provide "immunity" from, or any limitation on, liability and if yes, what are the provisions?

n/a

C. Emergency legislation/guidance on GMP, GDP, QP, changes in manufacturing, packaging and supply chain (please indicate if only applicable to COVID-19)

1. Is there emergency legislation/guidance on implementing changes in manufacturing or the supply chain and what are the key points?

The Covid-19 related legislation in Poland introduced certain measures pertaining to the supply chain or distribution of the medicinal products:

1) If necessary - setting maximum prices and margins for medicinal products, medical devices, biocidal products etc. that can be used in connection with combatting or preventing COVID-19 or whose availability is at risk by virtue of the Minister of Health's announcement (does not apply to reimbursed products);
2) Additional reporting duties imposed on pharmaceutical wholesalers, pharmacies etc. in case of threat of lack of availability of a medicinal product. medical device or biocidal product on the territory of Poland or in case

of the state of epidemic threat, the state of epidemic or in the event of a danger of spreading an infection or an infectious disease that may pose a threat to public health, in particular the occurrence of a particularly dangerous or highly contagious disease – in such cases Minister of Health may also limit quantity of a product issued to a single patient;

3) Supervision of medicinal products safety monitoring systems will be conducted by means of electronic communications only until further notice (communication of the President of ORMP dated 29 May 2020);

4) Supervision of the clinical trials is suspended until further notice and the sponsors were obliged to implement safety measures and consider ceasing or suspending already ongoing clinical trials were possible and uphold filing requests for approval of new clinical trials (communications of the President of ORMP dated 19 March 2020 and 29 May 2020).

Apart from that, the President of the ORMP issued guidance concerning conducting of the clinical trials and clinical trials' inspection during the pandemic (communications dated 9 March 2020 and 19 May 2020).

2. Is there emergency legislation/guidance to address difficulties in conducting on-site GMP inspections and what are the key points?

No, no specific guidance in relation to GMP inspections was published. With regard to supervision of medicinal products safety monitoring systems will be conducted by means of electronic communications only until further notice (communication of the President of ORMP dated 29 May 2020).

3. Is there emergency legislation/guidance to address difficulties in conducting on-site GDP inspections and what are the key points?

See above.

4. Is there emergency legislation/guidance on QP work and what does it entail (e.g. remote batch certification)?

No.

5. Is there emergency legislation/guidance on the packaging requirements, also including over-labelling?

No.

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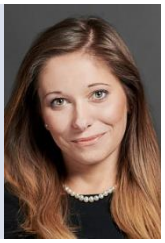

Singapore

A. Emergency legislation for marketing authorisations non COVID-19 specific medicinal products.

1. Did national authorities issue guidance on "emergency provision" for marketing authorisations for non Covid-19 specific medicinal products (e.g. postponing of renewal applications, sunset clause applicability)?

No.

B. Emergency legislation/guidance for marketing authorisations for COVID-19 medicinal products.

1. Did national authorities issue other guidance on "emergency authorisation" for market authorisations specifically for Covid-19 medicinal products (e.g. lower threshold for obtaining marketing authorisation, waiving quality requirements)?

No.

However, Remdesivir has been used in clinical trials for COVID-19 patients at the National Centre for Infectious Diseases ("**NCID**"). As of 16 May 2020, Singapore has been in talks with US manufacturer Gilead Sciences, Inc to register the drug for treatment of COVID-19 patients in Singapore. Absent any specific promulgated regulations, marketing authorisations are therefore likely to be evaluated and assessed on a case-by-case basis.

Further, a "COVID-19 Research Workgroup" comprised of the country's leading healthcare experts has been set up by the Singapore Ministry of Health, to examine how repurposed drugs may be used to treat COVID-19. These include antiviral drugs, anti-inflammatory drugs, humoral therapies (such as convalescent plasma and biologics) and vaccines.

As part of this initiative, the NCID published the *Interim Treatment Guidelines for COVID-19*. These guidelines contain an evaluation of the efficacy and recommended dosage for various drugs which were previously found to be effective against other infectious diseases.

C. Emergency legislation/guidance on GMP, GDP, QP, changes in manufacturing, packaging and supply chain (please indicate if only applicable to COVID-19)

1. Is there emergency legislation/guidance on implementing changes in manufacturing or the supply chain and what are the key points?

Public healthcare institutions have begun to offer free medication delivery for patients on prescription medication. In particular, the service is designed to facilitate treatment for patients who are stable, on regular prescriptions for chronic diseases, and who do not need to change their medication or require additional medical counselling.

This arrangement is expected to continue at least until Singapore's disease outbreak response level is downgraded from "orange".

2. Is there emergency legislation/guidance to address difficulties in conducting on-site **GMP** inspections and what are the key points?

No. The existing GMP standards and procedures continue to apply.

3. Is there emergency legislation/guidance to address difficulties in conducting on-site **GDP** inspections and what are the key points?
No. The existing GDP standards and procedures continue to apply.
4. Is there emergency legislation/guidance on QP work and what does it entail (e.g. remote batch certification)?
No. The existing QP standards and procedures continue to apply.
5. Is there emergency legislation/guidance on the packaging requirements, also including over-labelling?
The Health Sciences Authority of Singapore ("**HSA**") has advised that dealers and sellers of medicinal products are prohibited from making false and misleading claims that the products can prevent, protect against or treat diseases such as COVID-19. Any drug which purports to be effective against COVID-19 must first be evaluated by and registered with the HSA (typically as a therapeutic product). Any claims made in relation to COVID-19 must be supported by appropriate scientific evidence, such as the results of clinical trials. Failure to comply with the relevant guidelines for regulation of medicinal products in Singapore may result in criminal sanctions and a fine.

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Slovakia

A. Emergency legislation for marketing authorisations non COVID-19 specific medicinal products.

1. Did national authorities issue guidance on "emergency provision" for marketing authorisations for non Covid-19 specific medicinal products (e.g. postponing of renewal applications, sunset clause applicability)?

No.

Please note, as of 18 March 2020 the Ministry of Health of the Slovak Republic issued the measurement, by which the state of emergency *(in Slovak: "núdzový stav")* for healthcare sector was declared in Slovakia, and is in effect until further notice.

For more details about the measurement please click see:
https://www.health.gov.sk/Zdroje?/Sources/dokumenty/osobny_urad/opatrenie-mzsr-18-3-2020.pdf

Likewise, the Slovak parliament has passed a laws authorising Ministry of Health of the Slovak Republic to adopt the resolution on (i) ban of export of human drugs available without medical indication or having no categorisation, as well as of medical devices, in-vitro diagnostics and dietetics goods categorised within the dietetics goods, (ii) limit and/or regulate the dispensation of human drugs available without medical indication or having no categorisation, as well as of medical devices, in-vitro diagnostics and dietetics goods categorised within the dietetics goods, (iii) regulate the prescription of human drugs available without medical indication or having no categorisation, as well as of medical devices, in-vitro diagnostics and dietetics goods categorised within the dietetics goods. Moreover, the mentioned laws limit the distribution (sale and transfer) of personal protective device, particularly filtrating facial half mask of risk category FFP2 and FFP3 to general public.

We are also aware of the Resolution of the Ministry of Health of the Slovak Republic on ban of export and supply of (i) registered human drugs available without medical indication and containing paracetamol, ibuprophenum, acethylsalicyl acid, and (ii) unregistered drugs which therapeutic use is approved by Ministry of Health of the Slovak Republic and which contain antivirotics for systematic use from ATC J05, hydroxychlorochinon and chlorochinon.

This resolution is effective as of 7 April 2020 and is available in Slovak at:
https://www.health.gov.sk/Zdroje?/Sources/tlacove_spravy/covid-19/rozhodnutie-mzsr-zakaz-vyvozu-vybranych-liekov.pdf

We are further aware of the Measurement of the Ministry of Health of the Slovak Republic on ban on ordering and supplying the drug Plaquenil (reg. No.: 25/0505(70-C/S) under certain circumstances.

This measurement is effective as of 24 March 2020 and is available at:
https://www.health.gov.sk/Zdroje?/Sources/tlacove_spravy/covid-19/Plaquenil.pdf

B. Emergency legislation/guidance for marketing authorisations for COVID-19 medicinal products.

1. Did national authorities issue other guidance on "emergency authorisation" for market authorisations specifically for Covid-19 medicinal products (e.g. lower threshold for obtaining marketing authorisation, waiving quality requirements)?

Yes.

The State Institute for Drug Control in the Slovak Republic (SIDC) *(in Slovak: "Štátny ústav na kontrolu liečiv")* has issued a measurement on prioritised registration of human drugs to be applied for Covid-19 treatment.

The measurement of SIDC on prioritised registration of human drugs (registered and not registered within EU) to be applied for Covid-19 treatment (further as the MEASUREMENT only) is available in Slovak at https://www.sukl.sk/hlavna-stranka/slovenska-verzia/registracia-humannych-liekov/registracia-lieku/covid-19-prioritne-posudzovanie-registracii-a-klinickych-skusani?page_id=5318#_ftn1

For the sake of completeness, apart from the MEASUREMENT, please note the SIDC has also issued a guidance/navigation on prioritised approving of clinical trials for Covid-19 patients.

In addition, it is possible to ask for approval of new indication of the un/registered drug either by the SIDC (in case of change of type C.I.6 according to the Classification guideline) or by the Ministry of Health of the Slovak Republic (in accordance with the Slovak Act No. 362/2011 Coll. on drugs as amended (sec. 45 par. 3 and 4). The list of approved therapeutic use of the drugs (having different indication) with regard to Covid-19 pandemic in Slovakia, as well as the official proposals for distribution of such drugs among the hospitals are available at https://www.health.gov.sk/Clanok?Hlavna-sprava-COVID-19.

2. If yes, which ones and what are the requirements to fall within the scope of the emergency authorisation?

Please see the response above.

The MEASUREMENT does not contain any specific requirements in this respect. It generally stipulates that it shall apply to the human drugs which may be applied for the Covid-19 treatment.

3. What are the expiry dates, if any?

The MEASUREMENT does not refer to any particular expiry date.

4. Under which competent authority(s) do these emergency authorisations fall in both English and the original language?

SIDC – The State Institute for Drug Control in the Slovak Republic (*(in Slovak: "Štátny ústav na kontrolu liečiv")* shall be authorised to approve registration of the human drugs to be applied for Covid-19 treatment in the Slovak Republic (either registered or not registered within EU).

Ministry of Health of the Slovak Republic *(in Slovak: "Ministerstvo zdravotníctva Slovenskej republiky")* under certain conditions – please see the response below.

5. Are there specific procedures to be followed and what are those procedures?

Yes.

In case of registration of human drugs to be applied for Covid-19 treatment which have been already registered within EU, the MRP or RUP procedure may be followed. SIDC shall approve the registration within 7 days. This procedure shall precede the confirmation of SIDC on admission of prioritised registration.

In case of registration of human drugs to be applied for Covid-19 treatment which have not been already registered within EU, the national registration procedure shall be followed. SIDC shall approve the registration within 30 days. This procedure shall precede the confirmation of SIDC on admission of prioritised registration.

In addition, please note apart from the registration with SIDC it is possible to ask for a temporary registration of the human drug by the Ministry of Health of the Slovak Republic, in case this is reasonable for the protection of public health.

6. Do the emergency provisions outline what information (if any) must be provided to the relevant approval authority and if yes, what information?

Yes.

In case of registration of human drugs to be applied for Covid-19 treatment which have been already registered within EU, the following documentation shall be submitted to SIDC: (i) application for registration itself, (ii) relevant documentation from reference state, (iii) Commercial Register excerpt, (iv) confirmation on registration fee

payment.

In case of registration of human drugs to be applied for Covid-19 treatment which have not been already registered within EU, the following documentation shall be submitted to SIDC: (i) application for registration itself, (ii) Commercial Register excerpt, (iii) confirmation on registration fee payment, (iv) relevant documentation based on the particular application.

7. Are there any additional requirements that must be met?

The MEASUREMENT does not prescribe any additional requirements.

8. Does the emergency legislative provision for the products, or other legislation, provide "immunity" from, or any limitation on, liability and if yes, what are the provisions?

The MEASUREMENT does not regulate this topic.

C. Emergency legislation/guidance on GMP, GDP, QP, changes in manufacturing, packaging and supply chain (please indicate if only applicable to COVID-19)

1. Is there emergency legislation/guidance on implementing changes in manufacturing or the supply chain and what are the key points?

Yes.

As mentioned in the response of q 1 above, there is a Resolution of the Ministry of Health of the Slovak Republic on ban of export and supply of (i) registered human drugs available without medical indication and containing paracetamol, ibuprophenum, acethylsalicyl acid, and (ii) unregistered drugs which therapeutic use is approved by Ministry of Health of the Slovak Republic and which contain antivirotics for systematic use from ATC J05, hydroxychlorochinon and chlorochinon.

The above resolution shall, in particular, prevent from the export of registered human drugs – antipyretics, available without medical indication, as well as unregistered drugs, which therapeutic use was approved by the relevant Slovak authority and which contain the medicine from therapeutic group J 05, and thus for the purposes of securing the safe supply of the drugs for the needs of the inhabitants during the state of emergency.

This resolution is effective as of 7 April 2020 and is available in Slovak at https://www.health.gov.sk/Zdroje?/Sources/tlacove_spravy/covid-19/rozhodnutie-mzsr-zakaz-vyvozu-vybranych-liekov.pdf

As also indicated in the response of q 1 above, the Measurement of the Ministry of Health of the Slovak Republic on ban on ordering and supplying the drug Plaquenil (reg. No.: 25/0505(70-C/S) under certain circumstances, has been published in Slovakia.

The above measurement shall, in particular, prevent from lack of the drug Plaquentil as well as uncontrolled prescription of this drug in the country.

This measurement is effective as of 24 March 2020 and is available at https://www.health.gov.sk/Zdroje?/Sources/tlacove_spravy/covid-19/Plaquenil.pdf

Furthermore, the SIDC has announced (on its website) that with regard to the special system of monitoring the absence of supply of drugs applied for Covid-19 treatment, every pharmaceutical company shall report the actual as well as anticipated absence of drugs applied for Covid-19 treatment to the EMA (European Medicines Agency), as well as to the national medicines agencies. In addition, the SIDC has highlighted that the obligation of the drug registration holders, to report any breakdown/cancellation/renewal of supply of drugs shall remain in effect.

2. Is there emergency legislation/guidance to address difficulties in conducting on-site **GMP** inspections and what are the key points?
We are not aware of any specific guidance adopted by the SIDC in this respect. However, the SIDC has announced (on its website) that the "commonly performed" inspections will be suspended, moreover seeing the extraordinary circumstances caused by Covid-19 pandemic, all controls and inspections will be accustomed for the purposes of elimination of any operational issues on the side of the subjects. Moreover, the SIDC has stated that it will individually assess the risk of control/inspection for the subject as well as for the inspector, and then it resolves whether the control/inspection will be performed personally, remotely or the certification validity will be administratively prolonged.
3. Is there emergency legislation/guidance to address difficulties in conducting on-site **GDP** inspections and what are the key points?
We are not aware of any specific guidance adopted by the SIDC in this respect. However, the SIDC has announced (on its website) that the "commonly performed" inspections will be suspended, moreover seeing the extraordinary circumstances caused by Covid-19 pandemic. all controls and inspections will be accustomed for the purposes of elimination of any operational issues on the side of the subjects. Moreover, the SIDC has stated that it will be individually assessing the risk of control/inspection for the subject as well as for the inspector, and then it resolves whether the control/inspection will be performed personally, remotely or the certification validity will be administratively prolonged.
4. Is there emergency legislation/guidance on QP work and what does it entail (e.g. remote batch certification)?
We are not aware of any specific guidance adopted by the SIDC in this respect.
5. Is there emergency legislation/guidance on the packaging requirements, also including over-labelling?
We are not aware of any specific guidance adopted by the SIDC in this respect.

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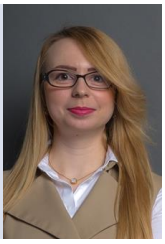

Spain

A. Emergency legislation for marketing authorisations non COVID-19 specific medicinal products.

1. Did national authorities issue guidance on "emergency provision" for marketing authorisations for non Covid-19 specific medicinal products (e.g. postponing of renewal applications, sunset clause applicability)?

No.

B. Emergency legislation/guidance for marketing authorisations for COVID-19 medicinal products.

1. Did national authorities issue other guidance on "emergency authorisation" for market authorisations specifically for Covid-19 medicinal products (e.g. lower threshold for obtaining marketing authorisation, waiving quality requirements)?

No, although especial measures have been issued to encourage research into medicinal products in connection with Covid-19.

On one hand, the Royal Decree- Law 8/2020, of 17 March, establishes measures to support COVID-19 research: (i) exceptional labour measures and (ii) economic measures such as granting subsidies.

On the other hand, the Spanish Agency for Medicinal Products and Medical Devices (AEMPS) has published a Guide to both ongoing clinical trials and potential clinical trials for medicinal products in connection with Covid-19. In accordance with the Sixth Additional Provision of Royal Decree - Law 13/2020, 7 April, no fees are required if potential clinical trials for medicinal products in connection with Covid-19 are carried out for non-commercial purposes.

C. Emergency legislation/guidance on GMP, GDP, QP, changes in manufacturing, packaging and supply chain (please indicate if only applicable to COVID-19)

1. Is there emergency legislation/guidance on implementing changes in manufacturing or the supply chain and what are the key points?

Yes.

- Article 4 of Royal Decree-Law 6/2020, of 10 March, allows the Health Authority to agree on the centralized supply of medicinal products or to set special prescription conditions for certain groups.
- Article 7 of Royal Decree-Law 7/2020, of 12 March, allows the Government to set the prices of medicinal products.
- Article 13 of Royal Decree 463/2020, of 14 March, allows the Minister of Health to issue the necessary orders to ensure the supply of medicinal products and to conduct temporary requisitions of all types of property. In these cases, the affected parties are entitled to the corresponding compensation.

Entitled by this Royal Decree, the Minister of Health has issued the Order SND 276/2020 of 23 March, establishing obligations for the supply of information, supply and manufacture of certain medicinal products and the Order SND/293/2020 of 25 March, establishing conditions for the supplying and the administration of medicinal products for hospital use:

– Order SND 276/2020 of 23 March compels manufacturers and marketing authorization holders of medicinal products included in Annex I of the Order to (i) inform the AEMPS on a daily basis of the available stock of medicinal products and the quantity supplied and (ii) establish the necessary measures to ensure the supply of

these medicinal products to health centers and services, which may be required to be supplied on a daily basis.

In addition, article 5 of the Order states that the Minister of Health may order the prioritization of the manufacture of medicinal products, and the AEMPS may request information from manufacturers on planned manufacturing operations.

The medicinal products included in Annex I of the Order include multiple presentations of about one hundred API's, including, for example, morphine, insulin, paracetamol, glucose, heparin, chloroquine and hydroxychloroquine.

- Order SND/293/2020 of 25 March establishes restrictions on the supply of medicinal products: (i) hospital pharmacy services may not supply medicinal products for more than two monthly treatments and the AEMPS may decrease this limit to one month to guarantee the availability of medicinal products (however, this restriction does not apply to medicinal products supplied in the course of clinical trials) and (ii) exceptionally, the competent health authority may establish measures for the administration of medicinal products for hospital use outside the hospital.

- To handle the rising demand for certain medicinal products due to Covid 19 the AEMPS has issued a Recommendation on the use of opiates and benzodiazepines/neuroleptics and a Recommendation on the use of midazolam, propofol and remifentanyl, dexmedetomidine, suggesting alternative medicinal products to avoid stock-outs.
- Likewise, due to the rising demand for hydroxychloroquine and chloroquine to treat Covid-19, the AEMPS has issued a Recommendation (i) prioritizing the use of these medicinal products for patients already under treatment and for those in their authorized indications and (ii) controlling the supply of hydroxychloroquine and chloroquine in hospitals.
- In addition, two Orders have been issued extending the validity of certain authorizations that may affect the manufacture of medicinal products:
  - Order APA/349/2020, of 15 April, extends the validity of authorisations for projects involving animals used in experiments for scientific purposes.
  - Order SND/325/2020, of 6 April, extends the validity of industrial safety certificates and the validity of metrology certificates.

2. Is there emergency legislation/guidance to address difficulties in conducting on-site GMP inspections and what are the key points?

Yes, the AEMPS extends the deadline for marketing authorisation holders to report the risk of nitrosamines in medicinal products until 1 October 2020.

3. Is there emergency legislation/guidance to address difficulties in conducting on-site GDP inspections and what are the key points?

No.

4. Is there emergency legislation/guidance on QP work and what does it entail (e.g. remote batch certification)?

No.

5. Is there emergency legislation/guidance on the packaging requirements, also including over-labelling?

No.

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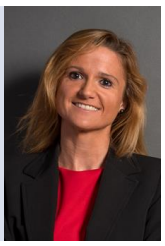

Sweden

A. Emergency legislation for marketing authorisations non COVID-19 specific medicinal products.

1. Did national authorities issue guidance on "emergency provision" for marketing authorisations for non Covid-19 specific medicinal products (e.g. postponing of renewal applications, sunset clause applicability)?

No.

But the Swedish government ordered the Swedish Medicines Agency ("MPA"), to coordinate work for the entire country **to strengthen access to important medicines** for health care in the event of any disturbances in connection with the spread of coronavirus.

Some of the key takeaways, of relevance, from the government orders for the MPA are:

- to develop the agency's information and communication about critical deficiencies to other actors, including the public and the media, if the spread of the corona virus gives rise to it;
- to obtain evidence from the healthcare providers about **possible treatment alternatives** for drugs that are deemed to be of central importance and where there is a risk that the drug in question will be shortlisted in the foreseeable future as a result of the outbreak of covid-19;
- facilitate the dialogue between the country's regions (e.g. the majority of healthcare providers) and the companies that have a marketing authorization for such drugs in order to assess what measures need to be taken to increase the likelihood that the need for these drugs can be met in the Swedish market.

2. If yes, which ones and what are the requirements to fall within the scope of the emergency provisions?

n/a

3. What are the expiry dates, if any?

n/a

4. Under which competent authority(s) do these emergency provisions fall in both English and the original language?

The Swedish government authorized – and also ordered – the Swedish Medicines Agency ("MPA"), Läkemedelsverket, to regulate and inspect the compliance to law and regulations, for majority of the emergency regulations because of the covid-19 pandemic.

5. Are there specific procedures to be followed and what are those procedures?

n/a

6. Do the emergency provisions outline what information (if any) must be provided to the relevant approval authority and if yes, what information?

n/a

7. Are there any additional requirements that must be met or other relevant information related to market access?

n/a

B. Emergency legislation/guidance for marketing authorisations for COVID-19 medicinal products.

1. Did national authorities issue other guidance on "emergency authorisation" for market authorisations specifically for Covid-19 medicinal products (e.g. lower threshold for obtaining marketing authorisation, waiving quality requirements)?

No. Nevertheless MPA collaborates with the other EU pharmaceutical authorities to support the development of drugs that can treat and prevent covid-19 in various ways, including through:

- Providing scientific and regulatory advice for all covid-19 projects;
- Establishing **regulatory fast tracks** so that different parts of the approval process should proceed as quickly as possible;
- Continuously evaluate clinical results from various drug studies to assist health care with knowledge support around various treatments.

The MPA also has set a task group to cooperate with the EMA's special working group ("COVID-ETF") to quickly coordinate resources and support various EU development projects.

C. Emergency legislation/guidance on GMP, GDP, QP, changes in manufacturing, packaging and supply chain (please indicate if only applicable to COVID-19)

1. Is there emergency legislation/guidance on implementing changes in manufacturing or the supply chain and what are the key points?

On March 12, 2020, the Swedish MPA received the government's mandate to increase coordination to secure access to medicines in Sweden as a result of the covid-19 pandemic. The assignment includes investigating what measures can be taken to minimize the risk of drug shortages linked to the outbreak of covid-19.

On March 19, the Swedish MPA therefore called on all pharmacies and retail outlets to help counteract drug hoarding. That **recommendation** remains still for all prescription drugs.

The MPA has also produced restrictions into binding acts with the regulation (Förordning 2009:659 om handel med läkemedel) that entered into force from 1 April 2020. The restrictions apply to all medicines acquired by prescription. The amount of drug that may be dispensed at one time may correspond to the estimated need for up to 90 days.

The decision also means that two-thirds of the drug must be consumed before a further withdrawal can be released. The aim is to counteract unnecessary deficiencies that could occur as a result of hoarding and to ensure an even distribution of available medicines.

The MPA's regulations are motivated by the intention to support the pharmacies in helping to counteract the hoarding of medicines.

2. Is there emergency legislation/guidance to address difficulties in conducting on-site **GMP** inspections and what are the key points?

No. Inspection of a manufacturer takes place regularly, every two to three years. The planning of inspections is risk-based, so some types of manufacturing will be inspected more often, such as sterile manufacturing.

In a new application for a manufacturing license, the Swedish Medicines Agency will always inspect the operation and the first inspection thereafter often takes place within a shorter interval than two years.

Since the guidance on monitoring clinical trials are allowed to be postponed because during the crisis, it is therefore expected that the MPA will also take in to account the same considerations regarding the GMP-inspections.

3. Is there emergency legislation/guidance to address difficulties in conducting on-site **GDP** inspections and what are the key points?
See previous answer regarding the GMP-inspections.
4. Is there emergency legislation/guidance on QP work and what does it entail (e.g. remote batch certification)?
No.
5. Is there emergency legislation/guidance on the packaging requirements, also including over-labelling?
Yes. When a shortage-situation arises or is expected to occur for a drug and there is no obvious treatment alternative, the situation can sometimes be resolved with an exemption-application for drugs that otherwise won't be able to fulfil requirements of the regulations of the MPA regarding packing and labelling (LVFS 2005:11). An exemption application must be sent to the Swedish MPA. An exemption is a temporary permit to sell a pharmaceutical packaging that does not meet the requirements of the Swedish MPA's regulations regarding labelling and package leaflets for medicines. It may, for example, apply to the supply of medicines in packaging: • which is foreign • where the 2D code differs • which has an older package leaflet than the last updated one. Exemptions are given in the event of a shortage or when it is considered a danger to public, such as the corona-pandemic. The fast track handling of covid-19 related applications is also applicable for drugs for use against the pandemic.

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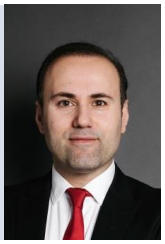

UAE

A. Emergency legislation for marketing authorisations non COVID-19 specific medicinal products.

1. Did national authorities issue guidance on "emergency provision" for marketing authorisations for non Covid-19 specific medicinal products (e.g. postponing of renewal applications, sunset clause applicability)?

No, the Ministry of Health and Prevention (the "**MoHaP**") has not issued any recent guidance/public announcements that are made available to the public in respect of marketing authorisations for medicinal products, relating to COVID-19 or otherwise.

As at the date of this legislation tracker (mid-June 2020), the overall process and requirements of obtaining a Marketing Authorization as mentioned under Federal Law No. Federal Law No.8 of 2019 on Medical Products, Profession of Pharmacy and Pharmaceutical Institutions are applicable.

In the context of COVID-19, the UAE has supplied medical supplies (including Personal Protective Equipment (PPE)) to more than 47 countries worldwide. Therefore, it may be assumed that the supply chain and distribution of medical equipment in the UAE has not been affected by the current COVID-19 outbreak.

To confirm this understanding, the MoHaP also announced on Twitter on Thursday 21 May 2020 that "*hospitals and medical centres in the country are well-equipped with necessary supplies*."

B. Emergency legislation/guidance for marketing authorisations for COVID-19 medicinal products.

1. Did national authorities issue other guidance on "emergency authorisation" for market authorisations specifically for Covid-19 medicinal products (e.g. lower threshold for obtaining marketing authorisation, waiving quality requirements)?

No, the MoHaP has not issued public guidance or specific emergency guidelines in respect of marketing authorizations for medicinal products relating to COVID-19.

As at mid-June 2020, the main test currently used to check for a COVID-19 infection in screening centres in the UAE is the Polymerase Chain Reaction (PCR) Test. In this context, the MoHaP announced that over two million PCR tests have been conducted in the UAE.

In addition to the above, we are aware that, in April 2020, the UAE government imported 5.5 million hydroxychloroquine tablets to be used for treating COVID-19 patients.

However, the MoHaP has not disclosed any information relating to marketing authorizations or any exceptions/waivers for such medicinal products, including those mentioned above. In this context, the requirements and regulations under the legislative framework (namely Federal Law No.8 of 2019 on Medical Products, Profession of Pharmacy and Pharmaceutical Institutions) continue to apply, unless exempted.

C. Emergency legislation/guidance on GMP, GDP, QP, changes in manufacturing, packaging and supply chain (please indicate if only applicable to COVID-19)

1. Is there emergency legislation/guidance on implementing changes in manufacturing or the supply chain and what are the key points?

As at mid-June 2020, the MoHaP and other local authorities have not issued any guidance/public announcements in respect of the emergency supply of medicinal products in the UAE.

The general rule is that all medicinal products which are imported or distributed in the UAE must obtain a prior marketing authorization and registration at the MoHaP.

Although, we flag that the MoHaP has great discretion in the UAE and may, on an exceptional basis, authorize the import of unregistered medical devices and equipment that are required by health institutions and in emergency situations.

2. Is there emergency legislation/guidance to address difficulties in conducting on-site GMP inspections and what are the key points?

Manufacturers in the UAE that wish to obtain a Certificate of Compliance with Good Manufacturing Practice Standards must generally submit an application to the MoHaP. MoHaP will in turn schedule an inspection.

The MoHaP has not publicly announced whether it will resume such on-site inspections and observations or otherwise in the current circumstances. As at mid-June 2020, the MoHaP has not issued any public announcements/guidelines in respect of conducting on-site inspections.

3. Is there emergency legislation/guidance to address difficulties in conducting on-site GDP inspections and what are the key points?

Please refer to our response to Question C2 above, which also applies in this context.

4. Is there emergency legislation/guidance on QP work and what does it entail (e.g. remote batch certification)?

Please refer to our response to Question C2 above, which also applies in this context.

5. Is there emergency legislation/guidance on the packaging requirements, also including over-labelling?

As at mid-June 2020, the MoHaP has not enacted/published any emergency legislation on packaging requirements of medicinal products. In this context, we flag that the requirements under the applicable laws remain in full force, including but not limited to the following:

1. The information and data inserted on the inner and outer label and the leaflet of the product must be similar to the information mentioned on the MoHaP's marketing authorization of such product.
2. The leaflet must contain information in Arabic or English, except as/when otherwise approved by the MoHaP.

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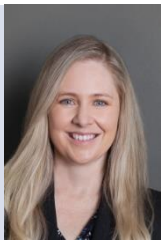

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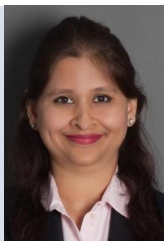

United Kingdom

A. Emergency legislation for marketing authorisations non COVID-19 specific medicinal products.

1. Did national authorities issue guidance on "emergency provision" for marketing authorisations for non Covid-19 specific medicinal products (e.g. postponing of renewal applications, sunset clause applicability)?

Yes, although in the form of guidelines.

General guidelines have been published by the UK Medicines and Healthcare products Regulatory Agency ("**MHRA**") on its website in respect of certain regulatory flexibilities occasioned by COVID-19, including in relation to *marketing authorisations* generally (available here). Such guidelines address a number of aspects, including:

- implementation of priority and expedited assessment for national variations (including batch-specific variations) and initial marketing authorisation applications that impact the medicines supply chain;
- the extension of the deadline for 'step 1' responses in respect of nitrosamine risk evaluation processes in accordance with the Committee for Medicinal Products for Human Use (CHMP) opinion under Article 5 (3) of Regulation (EC) No. 726/2004 on the presence of nitrosamine impurities in human medicinal products;
- certain relaxations to the qualified persons (QP) declaration process;
- suspension of the 30-day limit for Type 1B variation replies by the MHRA;
- the extension of the 30-day national phase for decentralised procedure concerned Member State applications. vIf requested by the company, the MHRA will hold the application with the clock off until all documentation is available;
- in certain cases, the waiver of the requirement for leaflet mock-ups to be submitted to support variations;
- considering derogations from labelling requirements and over-labelling of foreign language packs for UK market on a case-by-case basis; and
- extending the permitted implementation period for label/leaflet changes following a variation from 6 months to 9 months. This does not apply for any significant safety updates.

2. If yes, which ones and what are the requirements to fall within the scope of the emergency provisions?

See above. At this stage, no specific requirements going into granular detail have been included in the official guidelines on the MHRA website cited above regarding, amongst others, the initial application for marketing authorisations or the variations thereof.

3. What are the expiry dates, if any?

No expiry dates per se have been noted in the official guidelines at this stage.

4. Under which competent authority(s) do these emergency provisions fall in both English and the original language?

Medicines and Healthcare products Regulatory Agency (MHRA).

5. Are there specific procedures to be followed and what are those procedures?

At present, in respect of the expediting of initial marketing authorisation applications and variation applications, the official guidelines note that "*guidance is in preparation on how to highlight these at the time of submission. Please send notification of requests to expedite to MHRA in advance of submission:*

- For variations: variationqueries@mhra.gov.uk
- For marketing authorisations: RIS.NA@mhra.gov.uk

In other words, specific guidance is currently provided on a case by case basis upon contacting the abovementioned e-mail addresses.

In respect of non-COVID-19 medicinal products, applications can, for example, also be fast-tracked if there is shortage of supply of essential medicines that has been verified by the Department of Health and Social Care ("**DHSC**"). If companies wish to fast track such applications because of a shortage of supply, the MHRA recommends that this be discussed with DHSC by emailing DHSCmedicinesupplyteam@dhsc.gov.uk.

6. Do the emergency provisions outline what information (if any) must be provided to the relevant approval authority and if yes, what information?

See above.

7. Are there any additional requirements that must be met or other relevant information related to market access?

Not as this stage.

B. Emergency legislation/guidance for marketing authorisations for COVID-19 medicinal products.

1. Did national authorities issue other guidance on "emergency authorisation" for market authorisations specifically for Covid-19 medicinal products (e.g. lower threshold for obtaining marketing authorisation, waiving quality requirements)?

Yes, although in the form of guidelines.

See above in first paragraph, which would also be applicable to COVID-19 related medicinal products.

2. If yes, which ones and what are the requirements to fall within the scope of the emergency authorisation?

See above.

At this stage, no specific requirements going into granular detail have been included in the official guidelines on the MHRA website cited above regarding, amongst others, the initial application for marketing authorisations or the variations thereof.

3. What are the expiry dates, if any?

No expiry dates *per se* have been noted in the official guidance at this stage.

4. Under which competent authority(s) do these emergency authorisations fall in both English and the original language?

Medicines and Healthcare products Regulatory Agency (MHRA).

5. Are there specific procedures to be followed and what are those procedures?

See above at point 4.

In respect of COVID-19 related medicinal products, in terms of initial marketing authorisation applications, reference is made to the guidance ordinarily applicable to this application process, which is still applicable (see here).

Ordinarily (i.e. pre-COVID-19), the MHRA envisaged the fast-tracking of certain applications where there was compelling evidence to show that the product would provide a major breakthrough in the treatment of certain conditions such as, for example, the emergence of a new disease entity which has severe or life-threatening effects and for which currently available treatments are ineffective or inadequate. This would apply to COVID-19. In these circumstances, for purposes of fast-tracking the application, the applicant is required to email a letter of no more than 3 pages to RIS.NA@mhra.gov.uk, including the following information in such letter: the disease category; a brief description of the major clinical properties of the product; and evidence supporting the claimed benefits of the product for the proposed indication(s).

6. Do the emergency provisions outline what information (if any) must be provided to the relevant approval authority and if yes, what information?

See above.

7. Are there any additional requirements that must be met?

Not at this stage.

8. Does the emergency legislative provision for the products, or other legislation, provide "immunity" from, or any limitation on, liability and if yes, what are the provisions?

Not at this stage.

C. Emergency legislation/guidance on GMP, GDP, QP, changes in manufacturing, packaging and supply chain (please indicate if only applicable to COVID-19)

1. Is there emergency legislation/guidance on implementing changes in manufacturing or the supply chain and what are the key points?

Yes. The MHRA has produced guidance to introduce additional flexibilities in respect of manufacturing operations and the supply chain. In general, flexibilities can be used and notified to MHRA on a “do and tell” basis, with no prior MHRA approval required.

In respect of variations and initial applications for products required to maintain continuity of supply, the MHRA will where justified:

- Strongly encourage off-site auditing to review data/documents where possible
- Allow the re-audit window to be extended up to 4 years
- Allow the re-audit window to be extended up to 5 years where supported by an off-site audit
- Allow absence of initial onsite audit where supported by an off-site audit. If the manufacturing site has an EU GMP certificate (or appropriate certification/inspection status from a territory with which the UK/EU shares an appropriately scoped MRA or is an EU “white listed” country) then this should be stated together with any appropriate supporting data.

Guidance on exceptional GMP flexibilities for medicines manufacturers: https://www.gov.uk/guidance/exceptional-gmp-flexibilities-for-medicines-manufacturers-during-the-coronavirus-covid-19-outbreak

These flexibilities will enable manufacturers to:

- release additional quality system capacity to focus on ensuring continuity of supply using quality risk

management principles

- address specific challenges created by international travel restrictions

The areas addressed include manufacture and import, quality systems (certain activities may be put on hold) and medicines being marketed outside the UK. The QP should be involved in any decision to make use of the flexibilities and any such use should be reported.

There is a further set of guidelines on exceptional GMP flexibilities for medicines imported from third countries: https://www.gov.uk/guidance/exceptional-gmp-flexibilities-for-medicines-imported-from-third-countries-during-the-coronavirus-covid-19-outbreak

These cover issues such as unexpected deviations, relying on information from third parties, re-testing on importation and sharing information with the supply chain. Again, use of flexibilities must be notified.

See Question 19 below for detail on flexibilities regarding QP activities (provided safety and efficacy is not compromised and where the purpose of the action is to maintain supply in the interest of public health).

Specific flexibilities for manufacturers and GxP laboratories regarding maintenance and calibration of equipment have also been set out in MHRA guidance: https://www.gov.uk/guidance/guidance-for-manufacturers-and-good-practice-gxp-laboratories-on-exceptional-flexibilities-for-maintenance-and-calibration-during-the-coronavirus-co

These cover various situations regarding the availability of an engineer, off-site calibration/maintenance and substitution of lab equipment.

Approval of GxP documents when working from home has also been addressed in guidance: https://www.gov.uk/guidance/approval-of-gxp-documents-when-working-from-home-during-the-coronavirus-covid-19-outbreak

Guidance on exceptional GDP flexibilities for medicines has also been issued: https://www.gov.uk/guidance/exceptional-good-distribution-practice-gdp-flexibilities-for-medicines-during-the-coronavirus-covid-19-outbreak

These cover supply chain flexibilities, transportation/storage conditions, responsible person flexibilities, various aspects of facilities and equipment used and recording/reporting use of the flexibilities.

All these flexibilities are temporary, are being regularly reviewed and may be updated at any time.

2. Is there emergency legislation/guidance to address difficulties in conducting on-site GMP inspections and what are the key points?

The MHRA has published guidance on new arrangements for GxP inspections due to coronavirus: https://www.gov.uk/government/news/new-arrangements-for-mhra-good-practice-gxp-inspections-due-to-coronavirus-covid-19--2

The MHRA will only conduct essential on-site inspections; organisations are expected to maintain compliance. Onsite inspections are being replaced with desk-based inspections in most cases.

The MHRA will prioritise essential on-site inspections linked to the UK Government's COVID-19 response, or any other potential serious public health risk, where these sites cannot be assessed remotely.

3. Is there emergency legislation/guidance to address difficulties in conducting on-site GDP inspections and what are the key points?

See above.

4. Is there emergency legislation/guidance on QP work and what does it entail (e.g. remote batch certification)?

Please refer to general guidance mentioned in question 16 above. MHRA view is that product may be shipped from a manufacturing site under quarantine whilst quality control tests and batch certification at manufacturer are ongoing. A system should be in place to ensure that the product is not placed on the market until it has been QP certified.

MHRA notes that covid-19 is considered to be an exceptional circumstance for QP declarations, and refers to EMA guidance (EMA/196292/2014):

"Exceptional circumstances, when an on-site audit is not practical (e.g. atypical actives), are out of scope of the declaration template. An off-site, remote or "paper-based" audit may be justifiable …on a case-by-case basis.

In these cases, a suitable quality system is expected to be applied by the active substance and finished product manufacturers. As a principle, such controls must provide confidence that the active substance is fit for purpose and will not negatively affect the safety and efficacy of the medicinal product. The QP is expected to justify the controls in place on a scientific basis and record a risk assessment on a product specific basis.

Audits of each site…at regular intervals…normally within three years. Justification should be provided if the date since the last audit exceeds this"

For medicines imported from third countries, MHRA notes that Annex 16 GMP provides a mechanism to allow certain 'unexpected deviations' in analytical control methods or manufacturing processes; MHRA believes there is scope for QPs to apply the same principles to minor deviations in the finished product specifications where, in their professional judgement, safety and efficacy is not compromised. The guidance provides further details regarding relying on information from third parties, re-testing on importation and sharing information with the supply chain: https://www.gov.uk/guidance/exceptional-gmp-flexibilities-for-medicines-imported-from-third-countries-during-the-coronavirus-covid-19-outbreak

Annex 16 could provide some flexibility by not having to repeat all quality control tests on importation from a third country manufacturer. Re-testing on importation should continue whenever possible. Where the QP concludes that completion of certain re-testing prior to batch certification of imported products will itself lead to delays and supply chain shortage, flexibilities might involve, for example:

- not carrying out product re-testing on importation if the batch has been fully tested in a PIC/S country
- only performing identity and assay for products if manufactured in a non-PIC/S territory, if fully tested to equivalent standards by the third country manufacturer.

Where flexibility is used to omit re-testing on importation, a risk-based, retrospective skip lot approach for full re-testing of imported batches should be undertaken to inform QP of continued quality.

Use of flexibilities must be recorded and reported.

Regarding QP certification, MHRA will prioritise variations to add replacement QPs to MIA/MIA(IMP), including non-practising or retired QPs. QP remote working arrangements will be permitted, where procedures facilitate this approach.

5. Is there emergency legislation/guidance on the packaging requirements, also including over-labelling?

Guidance (only applicable during the covid-19 outbreak) for pharmacies wishing to 'pack down' larger packs of a medicinal product into smaller quantities for retail sale have been issued:

https://www.gov.uk/guidance/guidance-for-manufacturers-specials-licence-holders-on-packing-down-medicines-during-the-coronavirus-covid-19-outbreak

Any packs prepared under this guidance cannot be supplied under the General Sales Legislation.

Facilities with a Manufacturers Specials (MS) licence, may under normal circumstances pack down for their own use or in response to an order from a registered pharmacy, but not for retail sale. However, given the current covid-19 situation, to ensure supply at local level, MHRA does not object to MS holders packing down to allow for distribution to community (retail) pharmacies, provided that certain conditions are met e.g. this activity is to enable supply continuity during the covid-19 outbreak only and MHRA is notified, with packaging details and a clear indication of any local shortage and its cause. Labels should meet routine requirements and include the MS number of the site performing the pack-down operation. A patient information leaflet (PIL) must be included in each pack. This activity must be performed in accordance with the GMP obligations for the MS license.

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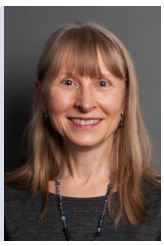

About us

Through a combination of our strong experience in the life sciences sector and our legal expertise, our mission is to develop both short and long term commercial solutions that will assist you in taking your idea from inception to market place and beyond.

Bird & Bird is a global law firm. Altogether, we have over 1,100 lawyers and legal practitioners working on our clients' issues and business goals worldwide. Our core objective is to select and develop people who possess a rare and invaluable grasp of strategic commercial issues.

By combining this talent with exceptional legal expertise and deep industry knowledge, our advice is always informed, up to date, focused and relevant.

With over 240 experts globally and a wealth of hands-on experience from working inside life sciences companies and regulatory bodies, clients choose us as their strategic partner to guide them through some of their most complex legal challenges.

Our recommendations are practical, realistic and clear.

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