SAHPRA
South African
Health Products
Regulatory Authority

CSIR Campus
Building 10F
Meiring Naudé Road
Brummeria
Pretoria

ADDENDUM 1: CONDUCTING REMOTE VIRTUAL GDP INSPECTIONS DURING EMERGENCIES/DISASTERS INCLUDING THE COVID- 19 PANDEMIC.

CHECKLIST FOR REMOTE VIRTUAL GDP INSPECTION

INFORMATION ABOUT THE REMOTE VIRTUAL GDP INSPECTION	
Company Name:	
Company Address:	
Responsible Pharmacist:	
Contact Details:	
Purpose of the inspection:	
Remote Virtual GDP Inspection Reference Number:	
Date(s) of inspection including all the inspection phases:	
Inspector(s):	

Legend: **✓- YES** **X – NO**	**NR – NOT REVIEWED** **NA – NOT APPLICABLE**

CSIR Campus
Building 10F
Meiring Naudé Road
Brummeria
Pretoria

PHASE 1: VIRTUAL GDP INSPECTION			
ITEM NO.	**REQUIREMENT**	**✓/X/NR/NA**	**COMMENTS**
1.	**COMPANY DECLARATION DOCUMENT, AND CONFIDENTIALITY AGREEMENT DOCUMENT**		
1.1	Is there a declaration by the company that all the information provided to the Regulator is accurate and authentic and that all documents supplied meet the standards of data integrity?		
1.2	Is a confidentiality agreement document between the company and the Regulator in existence and has been signed?		
2.	**COMPANY APPLICATION FORM AND SMF**		
2.1	Is the company application form available with the Regulator?		
2.2	Is the updated company SMF document available with the Regulator? If not the inspector will need to request the latest version of the document from the company.		
2.3	If available, are all the components of the SMF all included in the document as required by the guideline?		
2.4	Is the SMF an official document, version controlled, signed and dated?		
2.5	Subsequent to review of the company application form and SMF , has the inspection notification letter been sent to the company to notify them of the upcoming inspection of their site?		
3.	**NOTIFICATION LETTER AND PROPOSED INSPECTION PLAN**		
3.1	Has the inspection plan been sent in preparation for virtual meeting?		
3.2	Does the notification letter mention the suggested modes of virtual connection to be used between the company and the Regulator during the virtual interaction e.g. Microsoft Teams, Zoom, WhatsApp call?		
3.3	Does the notification letter mention the availability of access to the company electronic data systems?		
3.4	Has the company acknowledged the receipt of the notification letter and also confirm the mode of virtual connection they can engage in?		
3.5	Was the proposed inspection plan sent to the company following the notification letter?		

CSIR Campus
Building 10F
Meiring Naudé Road
Brummeria
Pretoria

4.	**COMPANY CAPA FROM LAST INSPECTION**		
4.1	Was the company informed to supply the CAPA from the previous audit and the assessment of the effectiveness of the CAPA? Has all the CAPAs been closed out as per timeline? Evidence for the implementation of the CAPA such as any electronic media and/or documents shall be requested during the audit preparation phase.		
4.2	Has a list of changes implemented since the previous audit been provided? e.g. including new products, change of process, new activities, personnel within the site, and Related change management controls?		
5.	**VIRTUAL OPENING MEETING**		
5.1	Is the virtual communication platform connected well on time? Is there adequate data to conduct the meeting?		
5.2	Has the attendance register been scanned and sent to the company before the commencement of the virtual meeting?		
5.3	Are all the relevant staff present in the meeting e.g. RP?		
5.4	Have the introductions and signing of the attendance register been completed? Has the company scanned back the attendance register after signing?		
5.5	Have the objectives and scope of the inspection been agreed upon?		
5.6	Has the brief presentation of the company background (NMT 10 minutes) been done?		
5.7	Are there any questions arising from SMF?		
6.	**DISCUSSION ABOUT DOCUMENTS LISTED ON THE INSPECTION PLAN**		
6.1	Are the documents listed on the inspection plan all forwarded to the Regulator prior the virtual meeting?		
6.2	Are there any additional documents to the inspection plan list required?		
6.3	Has the company been made aware of documents required ?		
6.4	Has the company been told that the documents list is not exhaustive?		

CSIR Campus
Building 10F
Meiring Naudé Road
Brummeria
Pretoria

7.	**CLOSING OF PHASE 1 (ACKNOWLEDGEMENT LETTER)**		
7.1	Have you agreed on time taken by the virtual meeting?		
7.2	Is the process going forward explained to the client?		
7.3	Has the closing time been captured on the register?		
BILLING FOR PHASE 1: VIRTUAL GDP INSPECTION **TOTAL NUMBER OF HOURS: [Hours]** **TOTAL COST: R**			

CSIR Campus
Building 10F
Meiring Naudé Road
Brummeria
Pretoria

PHASE 2: DESKTOP INSPECTION/ REVIEW			
ITEM NO.	**REQUIREMENT**	**✓/X/NR/ NA**	**COMMENTS**
1.	**QUALITY MANAGEMENT**		
1.1	**QUALITY MANUAL**		
1.1.1	Is the Quality Manual (QM) forwarded/ available to the Regulator?		
1.1.2	Are all the relevant aspects related to quality manual included in the QM as per the guideline?		
1.1.3	Is the QM version controlled and an official document?		
1.2	**QUALITY MANAGEMENT REVIEW MEETING**		
1.2.1	Is the SOP on how to handle quality review meeting forwarded/ available to the Regulator?		
1.2.2	How is quality measured by the organisation?		
1.2.3	Are all the aspects related to quality review meeting addressed and followed?		
1.2.4	Is evidence for quality review meeting in the form of an agenda, attendance register and report presented to the Regulator?		
1.2.5	What are the details of the review in terms of makeup of review team and timing?		
1.2.6	Has the Minutes of meeting been reviewed?		
1.2.7	How is the follow up between reviews defined?		
1.2.8	Who signs off on the minutes?		
1.3	**ANNUAL QUALITY PRODUCT REVIEW (APQR)**		
1.3.1	Is the APQR SOP forwarded/ available to the Regulator?		
1.3.2	Are all the aspects related to APQR addressed and followed?		
1.3.3	Is the review period stipulated in the SOP/ APQR schedule?		
1.3.4	Has the company supplied a list of products within the APQR system and have they been informed of the product/s that will be reviewed?		
1.3.5	Is the evidence for APQR presented in the form of reports?		

CSIR Campus
Building 10F
Meiring Naudé Road
Brummeria
Pretoria

1.4	**QUALITY RISK MANAGEMENT DOCUMENTATION/ RISK REGISTER**		
1.4.1	Is the Quality Risk Management SOP forwarded/ available to the Regulator?		
1.4.2	Are all the aspects related to quality risk management addressed and followed?		
1.4.3	Is there evidence that quality risk management is implemented in the form of the risk register?		
1.5	**VENDOR AUDIT**		
1.5.1	Is the Vendor Audit handling SOP forwarded/ available to the Regulator?		
1.5.2	Does the SOP stipulate when the different vendors are due for auditing?		
1.5.3	Is there evidence for continuous vendor audits in the form of an audit schedule/ register?		
1.6	**VENDOR APPROVAL**		
1.6.1	Is the Vendor Approval handling SOP forwarded/ available to the Regulator?		
1.6.2	Does the SOP stipulate the vendors that need to be qualified and what informs their qualification?		
1.6.3	Is the approved vendor/ supplier list available? It it an official document?		
1.7	**CLIENT VALIDITY**		
1.7.1	Is the client validity SOP forwarded/ available to the Regulator as per relevant Act ?		
1.7.2	The company needs to provide list of clients and how this validity is checked?		
1.7.3	What is the frequency of these checks e.g. companies that have ceased to operate, medical professionals deregistered etc.		
1.8	**VALIDATION MASTER PLAN (VMP)**		
1.8.1	Is the Validatiom Master Plan document forwarded/ available to the Regulator?		
1.8.2	Does the VMP stipulate the validation programme for the applicant's products which is in line with the 3rd party manufacturer?		
1.8.3	Is it the VMP version controlled and official document?		
1.8.4	How does the company review the manufacture's VMP?		
1.8.5	Is the company's internal systems part of the VMP?		
1.9	**DEVIATIONS**		
1.9.1	Is the SOP for handling of deviations forwarded/ available to the Regulator?		

CSIR Campus
Building 10F
Meiring Naudé Road
Brummeria
Pretoria

1.9.2	Does the SOP stipulate the different classification of deviations and time lines for their closure?		
1.9.3	Does the company have evidence of being in control of deviations in a form of deviation register or any other form?		
1.10	**CORRECTIVE ACTIONS AND PREVENTATIVE ACTIONS (CAPA'S)**		
1.10.1	Is the SOP for handling of Corrective Actions and Preventative Actions (CAPA's) forwarded/ available to the Regulator?		
1.10.2	Is there a unique sequential numbering system for CAPA's?		
1.10.3	Does the company have evidence of being in control of CAPA's in a form of CAPA's register or any other form?		
1.10.4	Has a list of CAPAs been forwarded to the Regulator?		
1.11	**CHANGE CONTROL MANAGEMENT**		
1.11.1	Is the SOP for handling of change controls forwarded/ available to the Regulator?		
1.11.2	Does the SOP clearly outline as to how the records of change controls are kept?		
1.11.3	Does the company have evidence of being in control of the change controls raised in a form of change control register or any other form?		
1.12	**STABILITY PROGRAME DETAILS**		
1.12.1	Has the Stability program and SOP been forwarded/ available to the Regulator?		
1.12.2	Has there been any stability failures?		
1.12.3	How is the stability data reviewed by the company?		
1.12.4	Who performs the stability storage and testing are there agreements in place and how is this controlled?		
1.12.5	Are the timelines defined for when products can be removed from stability ovens to completed testing to minimize products outside of defined conditions?		
1.12.6	Is there a stability back log and how is this managed?		
1.12.7	Has company been informed of which product will be assessed as part of audit for stability?		
1.12.8	Is the data in line with the dossier commitments?		
1.12.9	Which trials have been aborted and has the list with rationale been provided?		

CSIR Campus
Building 10F
Meiring Naudé Road
Brummeria
Pretoria

1.12.10	How is the stability data trended?		
1.13	**OUT OF SPECIFICATION /TREND OOS/OOT SOP AND REGISTER DETAILS**		
1.13.1	Has the OOS/OOT and document forwarded/ available to the Regulator?		
1.13.2	How does the company define OOS/OOT?		
1.13.3	How is company informed of OOS/OOT by 3rd Party manufacturer?		
1.13.4	How does the company list OOS/OOT and how is the company made aware of OOS/OOT within the market?		
1.13.5	What is the link between product OOS/OOT, complaints and recalls?		
1.13.6	What is OOS/OOT close out procedure		
1.13.7	Was the company informed of the specific OOS that will be reviewed?		
1.13.8	How is data trended?		
1.14	**BATCH RELEASE**		
1.14.1	Has the Batch Release SOP and register been forwarded/ available to the Regulator?		
1.14.2	How is the release to market effected?		
1.14.3	Has the company provided a release checklist?		
1.14.4	Who performs the release as well as back up?		
1.14.5	Are the letters of authority and delegation available?		
1.14.6	The company is required to provide the relevant job descriptions		
1.14.7	Has the company been informed by the Regulator of the review of a product document that has undergone release?		
1.14.8	What source documents are reviewed when making batch release decisions?		
1.14.9	Define the process when the product release criteria is not met?		
1.14.10	How are product release data archived and retrieved?		
1.14.11	How is this data trended?		
1.15	**ONCE OFF APPLICATIONS**		
1.15.1	Has the Once Off Application document forwarded/ available to the Regulator?		
1.15.2	What is the company's understanding of once off approvals and how is this described?		
1.15.3	List the specific batch approvals granted per product		
1.15.4	Who authorises the once off application?		

CSIR Campus
Building 10F
Meiring Naudé Road
Brummeria
Pretoria

1.15.5	What is the process defined for the once off applications?		
1.16	**POST IMPORTATION TESTING AND EXEMPTION**		
1.16.1	Has the Post Importation Testing Exemption (PITE) document forwarded/ available to the Regulator?		
1.16.2	What are the products that have been given approval?		
1.16.3	Is the approval that was provided still valid based on the reasons provided by the company?		
1.16.4	What is the quality oversight process when product is received?		
1.16.5	How do you ensure that the conditions of approval are met		
1.16.6	Are there any expired approvals and is the validity of the approvals checked?		
1.16.6	Why has the post testing exemption been extended by the company?		
1.16.7	What are the reasons why the company has applied for post importation exemption?		
1.17	**SECTION 21 PRODUCTS**		
1.17.1	Has the Section 21 process document been forwarded/ and is available to the Regulator?		
1.17.2	What are the products that have been given approval?		
1.17.3	Is the approval that was provided still valid based on the reasons provided by the company?		
1.17.4	What is the quality oversight for this process?		
1.17.5	How is transport validation handled for these products?		
1.18	**TRANSPORTATION STUDIES AND TRANSPORT VALIDATION**		
1.18.1	Has the Transport Validation for all imported products document been forwarded/ and is available to the Regulator?		
1.18.2	How is transport validation performed?		
1.18.3	How is cold chain products transport handled?		
1.18.4	How are excursions defined?		
1.18.5	How are excursions investigated?		
1.18.6	Who ensures that data loggers are present with receipt?		
1.18.7	What is the packing configuration/placement of the data loggers?		

1.18.8	How are data loggers read e.g. Is the relevant software available?		
1.18.9	How is the data archived and retrieved?		
1.18.10	How is the data trended?		
1.19	**ADVERTISING CONTROL AND ARTWORK**		
1.19.1	Has the Advertising Control and Artwork document been forwarded/ and is available to the Regulator?		
1.19.2	What is the release procedure for advertising material and artwork?		
1.19.3	Explain the quality oversight to ensure all advertising, promotional material and artwork is in compliance to the guidelines		
1.20	**PHARMACOVIGILANCE**		
1.20.1	Has the Pharmacovigilance document been forwarded/ and is available to the Regulator?		
1.20.2	How are the pharmacovigilance issues e.g. ADR reported to the Regulator		
1.20.3	How is the process defined?		
	How is Post Marketing Surveillance handled by the company		
1.20.4	Who has oversight of this program?		
1.20.5	How is the reporting done from both 3rd party suppliers and local distribution market?		
1.20.6	How is the data trended?		
2.	**PERSONNEL**		
2.1	**ORGANOGRAM**		
2.1.1	Has the company current organogram both operational and quality been forwarded/ and is available to the Regulator?		
2.1.2	Is the staff compliment relative to the scope of the work of the company?		
2.1.3	Are the reporting structures clearly defined?		
2.1.4	How is Pharmaceutical coverage provided at all times?		
2.2	**LEGAL REQUIREMENTS**		
2.2.1	Responsible Pharmacist (RP): Is the RP's SAPC Registration Certificate as a company Responsible Pharmacist, Appointment and acceptance letters for delegation for the role, SAPC Registration Certificate as a Pharmacist, SAPC Registration Certificate card, Job description been forwarded/ and is available to the Regulator?		
2.2.2	Deputy Responsible Pharmacist (DRP): Is the DRP's Appointment and acceptance letters for		

	delegation for the role, SAPC Registration Certificate as a Pharmacist, SAPC Registration Certificate card, Job description forwarded/ available to the Regulator?		
2.2.3	Is the proof of payment for SAPC annual fees available for both RP and DRP?		
2.3	**TRAINING**		
2.3.1	Is the training SOP, program and specific training records been forwarded/ and is available to the Regulator?		
2.3.2	Does the SOP address the effectiveness of the relevant training provided?		
2.3.3	Is an official training matrix available as evidence for continuous training?		
3.	**EQUIPMENT AND PREMISES**	**NA**	**NA**
4.	**DOCUMENTATION**		
4.1	**PRODUCT DOSSIER REVIEW**		
4.1.1	Is the product chosen for review listed on the company's official product list and has the list of the registered products been provided to the Regulator?		
4.1.2	Are the following parts under Module 1 forwarded/ available to the regulator i.e. 1.0; 1.2.1; 1.5.2.1; 1.5.2.2; 1.5.2.3; 1.7.1; 1.7.3; 1.7.7; 1.7.9; 1.7.13 and others?		
4.1.3	Are the following parts under Module 3 forwarded/ available to the regulator i.e. 3.2.S.2.1; 3.2.P.1; 3.2.P.3.1; 3.2.P.3.5; 3.2.P.5.2; 3.2.P.5.3; 3.2.P.7; 3.2.P.8 and others?		
4.2	**DOCUMENT CONTROL**		
4.2.1	Is the document SOP, been forwarded/ and is available to the Regulator?		
4.2.2	Does the procedure describes how documentation is managed with regards to responsibilities such as: Approval, Review, Amendments, Revision, Signing Distribution, Withdrawal, Archiving, and Retention		
4.2.3	How does the company ensure that the current version of the SOP is being used?		

4.2.4	How is the Disposal of documents handled to prevent the use of unauthorized or superseded versions and to avoid fraud?		
4.3	**MASTER DOCUMENTATION**		
4.3.1	Has the procedure for regular evaluation of master documents been forwarded and is available to the Regulator?		
4.3.2	Are all the aspects related to the following addressed: Document number, Title, Current version, Written by, Updated and reviewed, Date effective after training, Next review date		
4.3.3	Has electronic access been granted to documentation and how is this access to current versions controlled?		
4.3.4	The location and process where the document is distributed		
4.3.4	Distribution for acknowledgement of training		
4.4	**RETURNED GOODS**		
4.4.1	Has the procedure for handling of returned goods been forwarded and is available to the Regulator?		
4.4.2	Does the procedure describe a criteria used to accept returned goods?		
4.4.3	Does the procedure describe where the returned goods from the market will be stored?		
4.4.5	Does the procedure describe the involvement of the RP?		
4.4.6	Has the list of returned goods been provided to the Regulator and what is the status of these goods e.g. has any reprocessing been done? What are the controls?		
4.5	**REJECTED GOODS**		
4.5.1	Has a procedure for handling of rejected/expired/defective goods been forwarded and is available to the Regulator?		
4.5.2	How are rejected goods containing scheduled substances disposed of by the company?		
4.5.3	Does the SOP describe the destruction process of the rejected goods and who oversees this destruction to ensure no goods are returned to market? Is the destruction described in a contract?		
4.5.4	Does the procedure describe handling of rejected goods by third party distributor and is		

	there a relevant contract with respect to rejected goods?		
4.6	**COUNTERFEIT MEDICINES**		
4.6.1	Has the procedure detailing the actions to be taken for handling of counterfeit medicines been forwarded and available to the Regulator?		
4.6.2	How are investigations conducted by the RP and how are records kept?		
4.6.3	How is the Regulator informed and what are the timelines for reporting cases of counterfeit medicines		
4.7	**REPROCESSING AND REWORK**		
4.7.1	Has the SOP for handling rework and reprocessing and the Reprocessing/Rework/Redressing and List been forwarded and is available to the Regulator?		
4.7.2	Has a risk assessment been completed for the activity that was undertaken?		
4.7.3	How does the company define reworks and reprocessing, what is authorised and what is the quality oversight of this process?		
4.7.4	Is there an SOP for redressing operations in the local markets e.g. secondary packaging?		
4.8	**SAMPLING**		
4.8.1	Has the SOP for receiving and sampling of imported products at Distributors site been forwarded and is available to the Regulator?		
4.8.2	Are all aspects of sampling and dispatching of samples for post importation testing to the testing laboratory addressed in the SOP?		
4.8.3	Does the SOP stipulate the transportation of imported products, under specified storage conditions throughout the distribution?		
4.8.4	Does the procedure addresses the storage and sampling of Retention samples at the distributors' warehouse?		
4.8.5	What sampling plan is followed by the company?		
4.8.6	Has the training of sampling plan been performed?		
5.	**PRODUCTION**	**NA**	**NA**

CSIR Campus
Building 10F
Meiring Naudé Road
Brummeria
Pretoria

6.	**QUALITY CONTROL**		
6.1	Has the Post Importation Testing procedure been forwarded/ and is available to the Regulator?		
6.2	Are the method transfers been completed and available for scrutiny by the company and the Regulator?		
6.3	Are agreements in place with vendors as defined in dossier?		
6.4	Have the reference standards been defined in your agreements with the laboratory and us there evidence what standards are being purchased?		
6.5	Has the list of deviations been provided to applicants for the release/non release of products to market?		
6.6	Who signs off on these deviations		
7.	**CONTRACT MANUFACTURE AND ANALYSIS**		
7.1	**CONTRACTUAL/TECHNICAL AGREEMENTS**		
7.1.1	Has the SOP for handling of Contractual/Technical Agreements been forwarded/ and is available to the Regulator?		
7.1.2	Are contractual / technical agreements between the company and third party contractors in place? Who signs off on this contract?		
7.1.3	Are the contractual / technical agreements still valid or fall within the time period of the contract and the critical responsibilities are defined?		
8.	**COMPLAINTS AND PRODUCT RECALLS**		
8.1	Has the SOP on complaints and product recalls been forwarded/ and is available to the regulator?		
8.2	Does the artwork reflect the required aspects as per the guidelines to enable complaints to be made?		
8.3	Are all the aspects related to the SOP addressed and followed?		
8.4	What is the process for recording and closing out complaints?		
8.5	How does complaints link to product recall?		

8.6	Has the applicant informed of the complaints/recalls product/s that will be reviewed by the Regulator?		
8.7	How is the data trended?		
8.8	Was there an actual or mock recall (justification of the product chosen)? To what level and extent have you performed the mock recall?		
8.9	Is the artwork displaying the contact details of the applicant to enable a patient to institute a complaint		
8.10	How is the process of complaints linked to the pharmacovigilance or post market surveillance system?		
9.	**SELF- INSPECTION**		
9.1	Has the SOP been forwarded/ and is available to the Regulator?		
9.2	What is the makeup of the self-inspection teams and what is the qualification process of the inspections teams to be enable teams /people to perform self-inspections?		
9.3	How is the previous external audits linked to self-inspection program in terms of adapting the program to the external observations?		
9.4	Can the company to provide the gap analysis of how this difference between the external audit and the self-audit was performed and how the program was adapted?		
9.5	How is the response handled from the internal inspection to the department? When you conduct self-inspections are the previous inspections closed out?		
9.6	How are the effectiveness of the CAPA reviewed and checked?		
9.7	What are the timelines allowed for close out of self-inspection observations?		
9.8	The company to provide the self-inspection program and progress of the plan and are there any timelines missed?		
9.9	Define how the management review incorporates quality especially Self Inspection Audits?		
9.10	Has the internal audit details been shared with the Regulator?		

SAHPRA
South African
Health Products
Regulatory Authority

CSIR Campus
Building 10F
Meiring Naudé Road
Brummeria
Pretoria

BILLING FOR PHASE 2: DESKTOP INSPECTION/ REVIEW

TOTAL NUMBER OF HOURS= [Hours]

TOTAL COST: R

SAHPRA
South African
Health Products
Regulatory Authority

CSIR Campus
Building 10F
Meiring Naudé Road
Brummeria
Pretoria

PHASE 3: REMOTE VIRTUAL INSPECTION THIS PHASE REQUIRES CONNECTION WITH AUDITEE TO FUTHER EVALUATE ADDITIONAL GxP AREAS IDENTIFIED IN PHASE 2			
ITEM NO.	**REQUIREMENT**	**✓/X/NR/NA**	**COMMENTS**
1.	**VIRTUAL REMOTE INSPECTION**		
1.1	Feedback phase 2		
1.2	Clarification / Disputes		
1.3	Additional evidence		
1.4	Closing meeting		
1.5	Define the process on the way forward		
1.6	Report writing		
1.7	Response review		
1.8	Fees		
BILLING FOR PHASE 3: REMOTE VIRTUAL INSPECTION **TOTAL NUMBER OF HOURS= [Hours]** **TOTAL COST: R**			

INFORMATION ABOUT THE FOLLOW- UP PHYSICAL INSPECTION (should a need arises)	
Purpose of inspection:	
Inspection Reference Number:	
Date(s) of inspection of physical follow-up inspection:	
Inspector(s):	