

# Risk management & Business Continuity Plan

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# 1. Introduction

MACOPHARMA has developed this Risk Management & Business Continuity Plan in conjunction with its already existing risk management program. The principals underlie the risk management process on which this business continuity plan is based.

The aim and subsequent risk assessments and treatments are designed to protect the staff, business and products against threats causing risk and disruption to MACOPHARMA.

## 2. Scope aim and objectives

### 2.1. Scope

This plan is intended to cover any unexpected or unplanned disruption to Macopharma operations, which threatens the delivery of key products to its customers. The plan does not deal with minor disruptions which can be managed through business-as-usual processes, nor does it cater for disruptions which are planned in advance (plant shut-downs etc).

### 2.2. Aim

The aim of this plan is to ensure that all staff who have responsibilities for managing a disruptive challenge with Macopharma have the necessary guidance and tools to enable them to manage it effectively and to a successful conclusion.

### 2.3. Objectives

This plan will:

- ➔ Detail the Macopharma strategy for managing disruptive challenges.
- ➔ List the roles and responsibilities for those staff who will manage the event.
- ➔ State the strategic objectives for Macopharma in the initial aftermath of the event.
- ➔ Detail the process for initial assessment of an event and the trigger points for activation of the plan.



# 3. Business Continuity Strategy

Macopharma provides critical lifesaving equipment and materials around the world. Whilst Macopharma values every one of its customers, the company also recognises that some of its customers have placed an enormous amount of trust in them by using them as their sole supplier of critical consumables. These are MacoPharma's priority customers. The Macopharma Business Continuity (BC) strategy then is to ensure that the effect on these priority customers is kept to a minimum and every effort will be made to ensure that there is no interruption to their supplies.

### 3.1. Strategic objectives

- To maintain so far as is reasonably practicable the uninterrupted supply of goods to Macopharma priority customers.
- To manage the event within both legal and regulatory boundaries.
- To return Macopharma to a state of Business as Usual at the earliest opportunity.
- To manage the event in such a way as to protect and if possible, enhance MacoPharma's reputation in the eyes of its stakeholders.



4. Triggers

In times of Business as usual, Macopharma is operating at Level 0 or Green.  
In the event of a disruption to activities, Macopharma will manage any event at one of three levels:

Level 1: Standard Alert (Yellow)

Any minor incident in which the impacts are potentially serious. This will usually be a disruption of the activity (non-stop) with manageable consequences for Macopharma.

Associated action: information transmitted in the EXCOM.

Examples: short-term power cut, unusual labour-union claiming, request of extraordinary meeting known a particular subject.

Level 2: High Alert (Orange)

Any incident likely to have significant impacts on the security of persons and/or on the assets or operations of Macopharma. This will usually be a complete stop on the running of an activity, but with a return to business as usual anticipated within 48 hours, and without the potential to impact on the long-term sustainability of the company.

Associated action: see above + setting in a stand-by mode of Crisis Unit, with the operational day before and the media day before.

Examples: at the beginning of fire, break of delivery, lost-time accident, blocking of wages negotiation.

Level 3: Critical Alert (Red)

Any major and serious event impacting strongly on the activity of Macopharma and being able to threaten the sustainability of the company. This will be an event likely to last more than 48 hours.

Associated action: activation of Crisis Unit

Examples: badly wounded person, contamination of products, strike, pandemic, conflict...

Initial assessment

This will be conducted by the most senior manager available at the time. The event will be assessed against the criteria shown below and an estimate made of the appropriate level of response required.



|                    | Financial impact | Impact on customer delivery                   | Client / Patient                                                       | Regulatory and legal impact                       | Brand image impact                          | Social impact                          |
|--------------------|------------------|-----------------------------------------------|------------------------------------------------------------------------|---------------------------------------------------|---------------------------------------------|----------------------------------------|
| 1<br>Insignificant | <0,250 M€        | No impact                                     | No impact                                                              | No impact                                         | Impact in internal company                  | Staff discontent                       |
| 2<br>Minor         | 0.25 to 1 M€     | Minor impact on customer deliveries (20%)     | Product usability / performance impact without patient / user trouble  | Minor offense, non-compliance with internal rules | Local media and limited social media        | Loss of internal credibility           |
| 3<br>Moderate      | 1 to 5 M€        | Moderate impact on customer deliveries (40%)  | Product usability / performance impact causing patient health troubles | Major offense, non-compliance with internal rules | National media and/or social media          | Threat of Industrial action            |
| 4<br>Major         | 5 to 20 M€       | Delivery possible for priority customers only | Impact causing the death of a patient                                  | Major offense / civil sanction                    | Specialist press and extensive social media | Localised industrial action            |
| 5<br>Catastrophic  | > 20 M€          | Customer delivery ceased                      | The death of many patients                                             | Penal / criminal sanction                         | Worldwide media                             | Widespread prolonged industrial action |

*It is important to note that these are descriptors only and should not be regarded literally.*



## 5. Roles and responsibilities

### ALL MACOPHARMA STAFF:

Are responsible for:

- Being vigilant to the possibility of disruptions through untoward events
- Immediately reporting any untoward events to their line managers

### LINE / TEAM MANAGERS:

Are responsible for:

- Immediately assessing any report of an untoward event to determine the level of disruption likely, if any.
- If appropriate escalating the event to the relevant on call manager / duty senior manager.
- Managing his or her area of business through the event in line with any instructions from the Crisis Unit (CU).

### ON CALL DUTY / SENIOR MANAGERS (defined by EXCOM or plant organisation):

Are responsible for:

- Assessing the event in accordance with section 4 above
- Managing a level 1 incident in conjunction with the department manager in question.
- Advising the CU of developments
- Activating the CU if appropriate in the event of a level 2 or 3 incident.

### CHIEF EXECUTIVE OFFICER (or nominated deputy in case of crisis):

Is responsible for:

- Confirming the Macopharma strategic objectives (see section 3.1)
- Chairing and leading the CU including deciding on its composition and on its functioning (schedules, rhythm of the points of situation, taken out of crisis), coordinating the internal and external members of CU and confirming the decisions.

### DEFINE A PERSON (BY CHIEF EXECUTIVE OFFICER):

Is responsible for:

- Providing the secretariat to the CU.
- Maintaining the logbook of the incident for the Chief Executive.

### CSR / BUSINESS CONTINUITY DIRECTOR (or nominated deputy):

Is responsible for:

- Supporting the Chair of the CU.
- Managing the EHS aspects related or associated to the incident or to the event (ex: pandemic).



### COMMUNICATIONS DIRECTOR (or nominated deputy):

Is responsible for:

- Determining any communications strategy required for the incident in line with the requirements of the CU.
- Advising the CU on all aspects of communication
- Providing the lead point of contact for all media enquiries
- Leading on all stakeholder communications

### SALES/MARKETING DIRECTOR is responsible for:

- Managing relationships and communications with customers

### REGULATORY, QUALITY AND MATERIOVIGILANCE DIRECTOR is responsible for:

- Managing relationships and communications with regulatory authorities.

## 6. Crisis Management Team

### 6.1 The role of the EXCOM

Any disruption at level 2 or 3 must be managed through the EXCOM.

The EXCOM will be formed of head from all major entities, specifically:

- Manufacturing, methods and industrialization
- Regulatory, quality and materiovigilance
- Finance and legal
- Sales and marketing
- Human Resources and sustainable transformation
- Supply, purchasing, IT and strategic projects.
- Development and prospective

In addition, the following persons will systematically be integrated with members of EXCOM (in case of crisis):

- Communications Director
- CSR / Business Continuity Director

According to the extent of the disruption caused as in the case of the COVID 19 pandemic, the following roles may also join the EXCOM crisis unit on a permanent or temporary basis upon decision from the Chair of the EXCOM:

- Supply Chain Director
- Purchasing manager
- Automation Director
- ...



All EXCOM members and defined participants of the activated crisis unit are expected to provide suitable senior deputies in the event that they may not be available (see “Business Continuity replacement matrix” procedure, reference **117758**).

## 6.2. Information requirement

At an early stage of any event, the Chair of the EXCOM will be responsible for setting the EXCOM's information requirements. The information requirement will be different for any event, but will usually include amongst other issues:

- Update on outstanding actions and issues
- Current and projected stock levels for key products
- Manufacturing capacity
- Ability to be able to transport and monitor the logistics of RM, SFP and finished products.
- Status updates from all Macopharma plants
- Staffing levels both current and projected
- Media interest
- Information from our clients

In the event of a pandemic (i.e., Covid 19), the EXCOM will have to follow any information relating to the management of the pandemic given by the regulatory and health authorities from every country where Macopharma sells products or through which Macopharma products will transit. Priority shall be given to the health of our staff in order to protect them at any time.

Any information regarding countries where Macopharma owns production sites shall be passed on to the Manufacturing, methods, and industrialization Director, Supply Chain Director and CSR/Business Continuity Director by the Plant Director and their CDU who will organize their own crisis unit according to the necessary topics defined by the EXCOM crisis unit.

The HR coordinator of the subsidiaries asks “area managers” for feedback on the pandemic health monitoring situation by country: number of suspected, proven, and quarantined cases for Macopharma staff. Management of the pandemic in each country. Assistance needs (health problems, administrative problems) or information from Corporate Macopharma (day to be defined according to EXCOM crisis meetings)

A summary table is sent to the HR director and the CSR/BC director in order to determine the actions to be taken.

## 6.3. Recovery

In order to recover business as usual in the shortest possible time it is essential that consideration of the recovery requirements are considered at a very early stage in any incident. It is best practice for the immediate management of the incident, and the recovery management to be separated as soon as possible and for a senior manager to be given responsibility for recovery.

The first crisis meeting of the EXCOM will take this into account and consider the need to appoint one of its members to be relieved of responsibility in relation to management of the incident and take responsibility for recovery. This person typically will have the seniority to deploy what resources are required to ensure that any business continuity plans are in place and will report back into the EXCOM on the progress of recovery to business as usual.



To assist the Crisis Management Team in recovery planning, assessments have been made of critical activities and the steps required to reinstate them following a disruption or incident. A specific table is used to analyse and define the time to complete each step to recover each activity, which is done with the people who would be involved. The objective is to have a list to manage the recovery of the activity in the event of a specific credible scenario.

# 7. Crisis Communications

Communication with key stakeholders is key during a crisis. At an early stage in the event, there will be a requirement for a communications strategy, which will need to dovetail effectively with the overall BC strategy for the event. Responsibility for the communications strategy will rest with the Communications Director but will be agreed by the Chair of the EXCOM prior to implementation (In case of simultaneous unavailability of the CEO and the Director of Communication, they will be replaced by the Head of Regulatory, quality and materiovigilance (external communication) and the Head of Human Resources/sustainable transformation (internal & social communication). Whilst it is impossible to determine a strategy in advance of every possible scenario, the following general points must be borne in mind for effective communications.

- As soon as the crisis unit is activated, it will be necessary to prepare a communication with our employees and employee representative bodies.  
This communication will be done in person in order to be able to answer questions and also reassure them (case of the Covid 19 pandemic - refer to prevention information from the country's health authorities)
- Do not delay communicating with key internal and external stakeholders (including the press). Remember; if you do not give them the facts, they can only make assumptions which does no good for them or you.
- Communication will at times be reactive: it will need to be fast but not hurried.
- Be aware of public opinion, especially if there are victims: show some empathy before explaining.
- Consider simultaneous internal and external. Always remember; the employees of the Group are our ambassadors.
- No other stakeholder will speak in place of the communication director or the Chair of the EXCOM (mastering the content of the messages).
- The Communications strategy must be agreed by the Chair of the EXCOM prior to implementation. In the case of a pandemic (eg: COVID 19), the frequency of communication with customers will be adapted and validated by the Chair of the EXCOM according to events and requests from the sales department. This communication will be general but could also be specific to a customer depending on the situation.
- Make sure your communications are clear and unambiguous. Clearly expressed; make 1-2 key messages pass according to your objectives of communication.
- Keep control of communication. If you do not act early to control communications, they will control you.
- Consider a 1st Press release within first hour of the meeting of the EXCOM; this press release can be short and will then be enriched by other Press Release
- Any request of outside information (from media as from all Stakeholders) must be transmitted to the EXCOM. Staff are not permitted to speak to the media without prior approval of the EXCOM.



## 8. Staff conditions of work

Macopharma is committed to the safety and health of its staff. In the event of disruption, the Chair of the EXCOM will allocate responsibility for staff health and safety to a member of the team. This will normally but not necessarily be the CSR/BC Director and/or Head of Human Resources/sustainable transformation. The person allocated responsibility will ensure that staff health and safety issues are included on the agenda of all future EXCOM meetings. This is important even if there is nothing to report, to ensure that the EXCOM are sighted on any potential issues.

In the event of a flu or COVID 19 pandemic, Macopharma shall ensure that all staff is properly protected. Macopharma shall supply suited protective means according to recommendations given by health authorities.

**> Collective Protective Equipment:** protective screens, adaptation of the premises to the number of people to meet safety distances, ventilation and air conditioning of the premises, hygiene and disinfection products, organisation of staff to disinfect premises and contact points, implementation of home office when possible, in order to reduce risks of exposure, only essential or even no business trips allowed...

**> Individual Protective Equipment:** suitable protective masks, hand sanitizer, safety glasses, gloves, face shields... shall be supplied and handed out by the defined departments (for example on the Tourcoing site: by the cleaning department and/or each workshop or department's supervisors).

## 9. Stand down

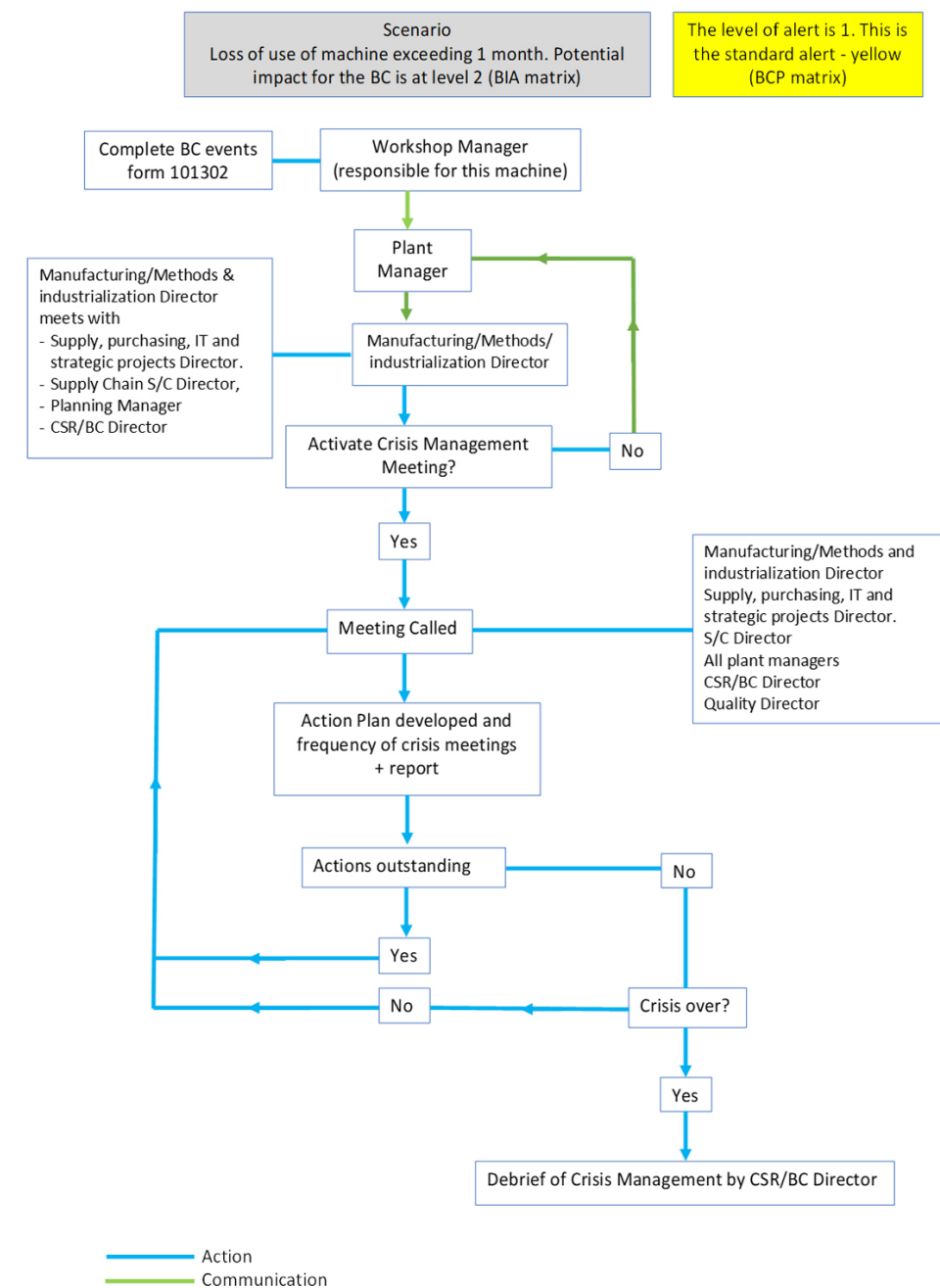
Once activated, this plan will only be stood down on the authority of the EXCOM.

## 10. Review of BC Plan

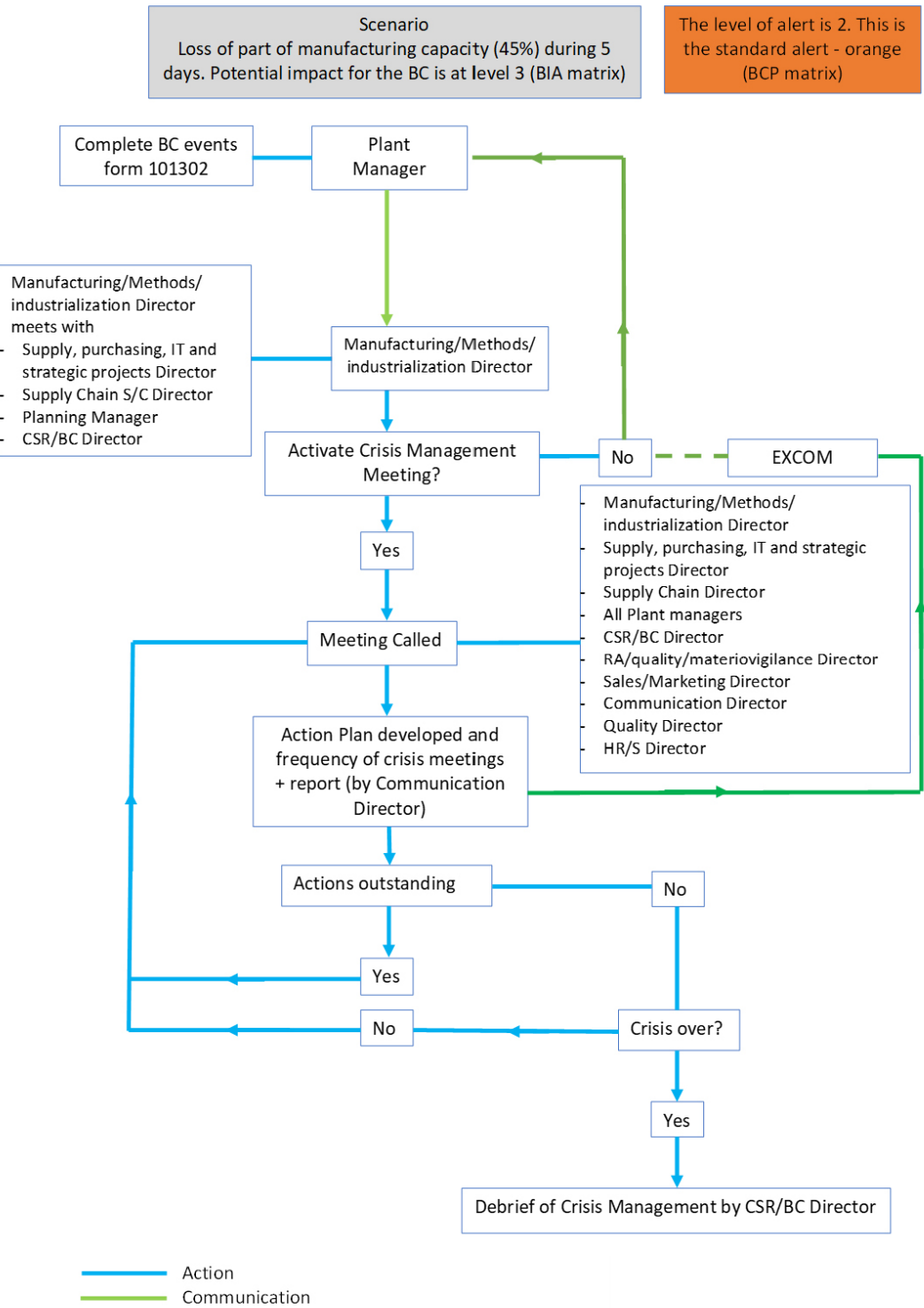
Following each activation of the BC Plan (either through incidents or exercises) the CSR/Business Continuity Director will consider whether or not the plan needs to be reviewed, to evaluate and define any improvement points. The BC plan will be formally reviewed at least annually and will also be reviewed and updated to reflect any lessons learned through incidents, exercises or internal or external audits.

## 11. Examples of organisation in case of event with BC impact

**Example of organisation in case of event with impact with level of alert 1** (This is an example – not a systematic organisation).



**Example of organisation in case of event with impact with level of alert 2** (This is an example – not a systematic organisation).



**Example of organisation in case of event with impact with level of alert 3** (This is an example – not a systematic organisation).

