

COVID-19 response
for Pharma companies
Respond. Recover. Thrive.

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During these unprecedented times, pharmaceutical companies are responding to the rapid challenges arising from disruption in supply chains and the need to change business processes. If the current COVID-19 pandemic lasts for a medium/long span of time, it may impact the supply of active material and ingredients (mainly from China), as well as the import and export of pharmaceuticals. There is also the potential for negative impacts of both a medium- and longer-term nature on R&D and manufacturing activities, as well as delay on projects/programmes not related to the core supply chain/data management operations. While the full impact of the global pandemic is still unknown, pharma companies need to respond, recover and thrive.

The document contains key pointers that companies should make a note of during this crisis.

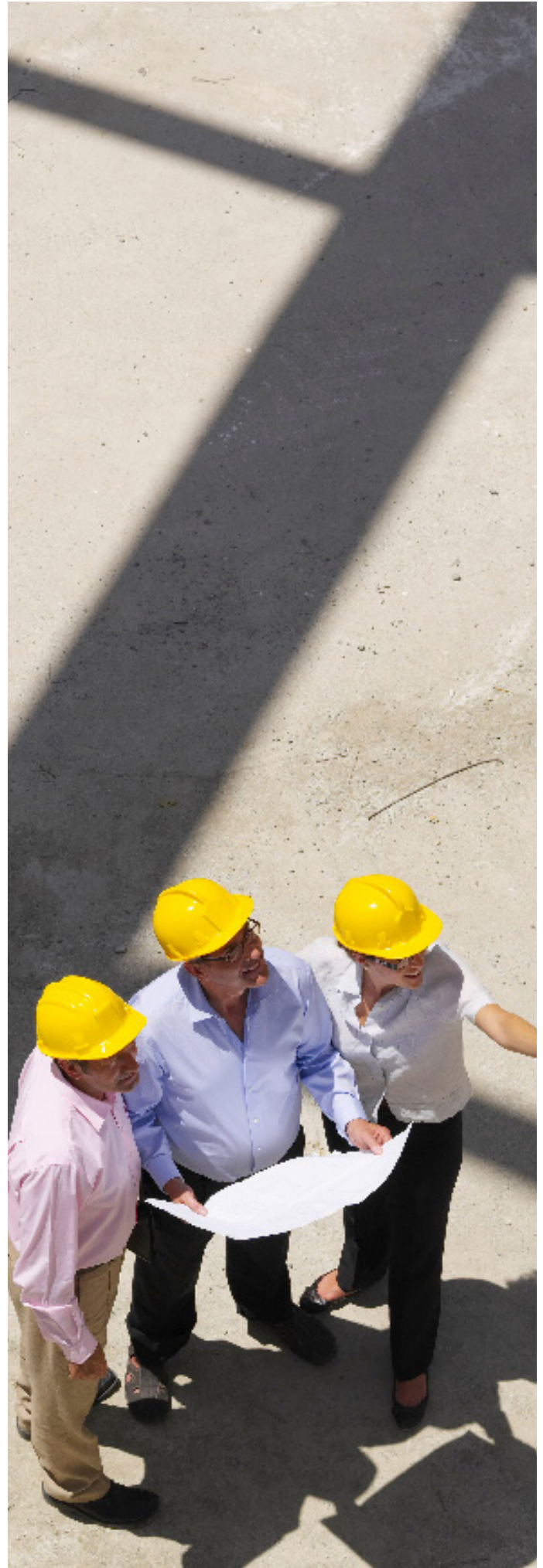
1 Crisis management team

Potential risk

Business continuity risk

Mitigation measures

- Set up a crisis management team/PMO, responsible for taking decisions during a pandemic. The crisis management team can:
 - Assign separate sub PMO leads for SCM, plant ops, people, IT, regulatory, finance, and industry.
 - Define scenario planning, triggers for action, and responsibility/time lines for action (during and after lockdown).
 - Define communication plans for employees, customers, and vendors.
- Include key members from critical functions as a part of the crisis management team.
- Schedule meetings or calls among members of the crisis management team on a periodic basis to evaluate the current situation.
- Set up business continuity and recovery plans based on various scenarios.
- Get a confirmation from the health insurance company that employee insurance includes Covid-19 cover.



2 People management

Risk

Spread of infection across employees working from home and operating within plants

Mitigation measures

- Set up a covid HR team to monitor the status of every employee in the organisation on the following parameters:
 - Where they are currently situated
 - Their health status
 - Their current activity status
 - Disclosure of their family members' health issues.
- Daily monitoring (across all locations).
- Launch a digital employee health declaration system to track employee well-being and comply with administrative reporting requirements.
- Set up a panel of doctors to provide virtual guidance to employees on health issues. (COVID HR team to monitor).
- Prepare a roster of employees operating in the plant on a rotation basis, keeping in mind risk assessment, location proximity, executive health reports, and annual checkup reports.
- Develop and disseminate/communicate strict protocols for staff working at plants and from home.
- Conduct a periodic medical checkup, including a thermal checkup/scanning at entry point for all employees. In case anyone is found positive for COVID -19,
 - Ask employees to track all contact with co-workers and visitors in case they develop symptoms.



- Ask employees to report confirmed cases of themselves or family members, and stay at home for 14 days or until cleared by a doctor.
- Isolate employees diagnosed at work, and immediately disinfect anything they have come in contact with. Notify other employees and clients that may have been in contact with the individual, without releasing their name.

- Document a policy pertaining to work from home, if not available.
- Restrict non-essential travel (domestic/international) and promote flexible working arrangements.
- Communicate emergency toll-free numbers to handle any crisis that may come up.
- Educate employees on COVID-19 symptoms and prevention through video/audio conferences.
- Encourage employees to speak to a counsellor for advice on managing stress and boosting morale.
- Communicate personal hygiene good practices to employees, and educate them on social distancing measures.
- Provide masks, wipes, and other personal hygiene products to on-site employees.

Risk

Inadequate availability of laptops in the market for work-from-home concept

Mitigation measures

- Reassess the need for laptops at each level and rebadge/reassign laptops, if required, to manage critical activities from home. IT may take a call to implement security requirements on personal laptops used for official work.
- Effectively plan for acquisition of IT assets, in the event of IT equipment shortage.

- Request for special permission from the police or local government to send a desktop to an employee's home in the event of laptop shortage.
- Encourage the use of technologies including chorus calls, Zoom, MS Teams, Webex, Go to Meetings, etc. to communicate with staff effectively.

Risk

Contract employee health issues

Mitigation measures

Restrict contractor access to plant or office operations. In case contractor access is inevitable,

- Confirm from third parties/vendors that no employees are infected, and measures are being taken to detect the virus.
- Set up thermal scanning/check-up at all entry points.
- Review if the contractor has acquired health insurance for its staff.
- Declare that staff has not been forced to come to work under the current scenario.

Risk

Contamination from employees returning from a tour/restricted zone

Mitigation measures

- Enforce/implement the 14-day quarantine for employees returning from a restricted zone.
- Permit access to shop floor only after a doctors certificate, and if possible also test the employees for COVID-19 symptoms.

Risk

Inadequate availability of manpower due to absenteeism spikes

Mitigation measures

Plant operations

- Prepare a roster of employees operating in the plant on a rotation basis, keeping in mind risk assessment, location proximity, executive health reports, annual checkup reports, and production-line requirements.
- Provide a production plan based on critical products to serve the market, and focus on domestic market (as the export market may face dispatch issues).
- Obtain police passes/letters for employees who have to travel and require a transport vehicle and drivers.
- Ensure that the central PMO monitors deployment of people and staff.

Corporate operations

- Classify business activities as mission critical (critical activities that need to be completed during lockdown) and others.
- Prepare and effectively communicate a detailed work chart for 30 days of activities, roles, and responsibilities.
- Simplify processes to drive efficiencies and ensure people are redeployed. For instance, HR/admin team can be retrained to perform certain PMO tasks.
- Ensure that all payments and collection transactions are done electronically, and that bank transfer details are collected and updated for all electronic transfers.

Risk

Non-availability of field force

Mitigation measures

- Partner with service providers to explore ways to introduce tele-health and tele-medicare services, and provide nodal support to hospitals and stockists.

3 Compensation to casual labour due to temporary layoffs

Risk

Non-compliance of orders from the labour commissioner

Mitigation measures

- Avail confirmation from the contracting agency that the contract worker is not working at any other organisation and is being paid in full during the COVID situation, as per the directives of the labour commissioner.



4 Remote work and cybersecurity concerns

Risk

Staying secure and productive while being connected remotely

Mitigation measures

- Allow remote access over VPN if the need arises, keeping business operations in mind.
- Formulate and implement a stringent policy for VPN access (if not already in place), by going through an in-depth security analysis of communication channels to identify the potential risks associated.
- Mitigate the risks identified, and allow for VPN connectivity.

Risk

Business continuity

Mitigation measures

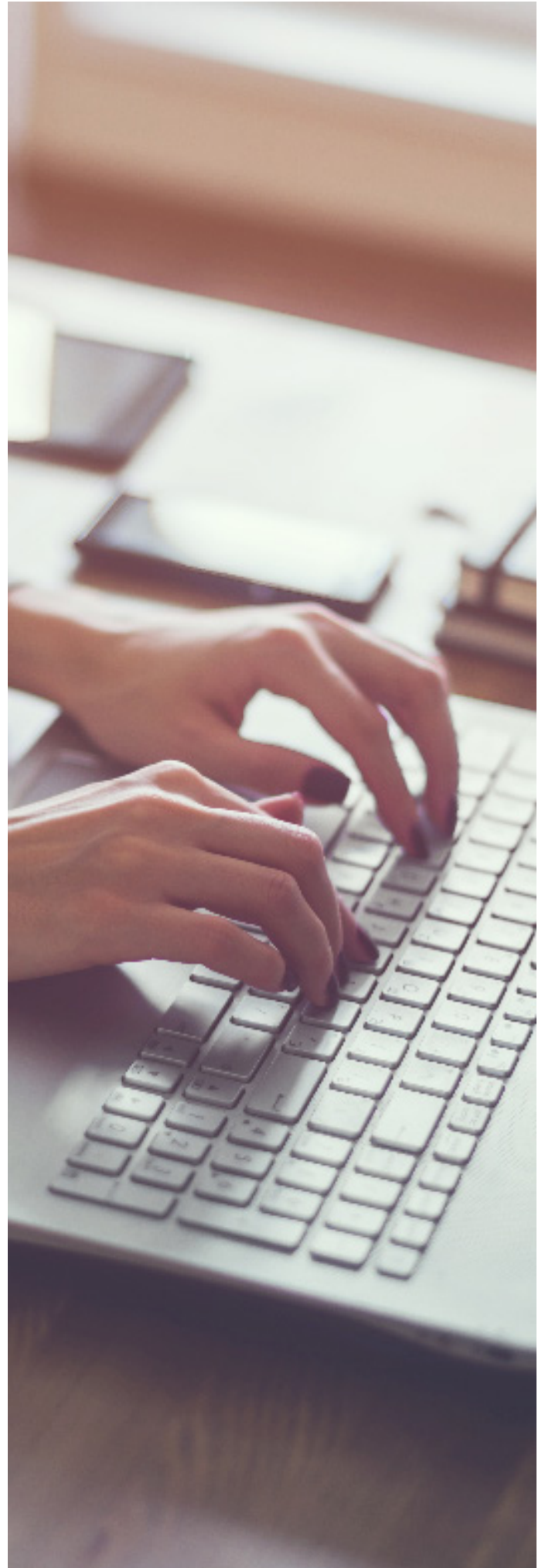
- Focus on ensuring proper arrangements for continuing business operations by instituting a Disaster Recovery (DR) centre during this crisis.
- Ensure that cyber drill activities on DR are performed on a periodic basis.

Risk

Inadequate secure access from anywhere

Mitigation measures

- Validate all ports exposed to the internet and remove unnecessary ports for employees to work remotely and access the organisation's network and servers in a secure manner.



- Implement and enhance access restrictions on the allowed ports to ensure there is no unauthorised access.

Risk

Data theft

Mitigation measures

Considering the activity of cyber actors on scams related to COVID-19, the management should adopt the following guidelines:

- Exercise caution in handling any email with a COVID-19-related subject line, attachment, or hyperlink.
- Use trusted sources such as legitimate government websites for up-to-date, fact-based information on COVID-19.
- Refrain from revealing any personal or financial information in an email and not responding to email solicitations for this information.

Risk

Network- and application-level security and their availability

Mitigation measures

It is always imperative to maintain the three basic pillars (confidentiality-integrity-availability) of information security. For the organisation to maintain C-I-A, they should follow the mitigation process as mentioned below:

- Perform a security analysis on your network and associated applications from all possible cyber perspectives (vulnerability assessment, penetration testing, etc.).
- Ensure all critical systems on the network are up-to-date with the latest patches.
- Maintain redundancy for all connections at the network-architecture level.
- Harden operating systems and databases associated with the organisation, as per standard organisational guidelines or CIS, DISA, etc.

Risk

Malware attacks

Mitigation measures

Malware includes viruses, spyware, ransomware, and Trojan horses and are inevitable on the internet and all connected devices. To combat these attacks, the management needs to plan and take action to,

- Implement strong access control mechanisms at the system and application level.
- Update software regularly.
- Backup important files regularly.
- Scan executable files before running them.

Risk

Phishing-vishing-smishing attacks

Mitigation measures

Criminals are banking on the panic that has been caused by COVID-19 and are using multiple ways to lure the customer into sharing confidential details. Phishing is a malicious attack over email, vishing over voice call, and smishing over text message or SMS.

In this context, every individual in the organisation should follow the steps below to avoid becoming a target of this kind of attempt:

- Be wary of fraudulent emails or phone calls requesting you to call an organisation for a particular inquiry. Look up and call the organisation's customer service number rather than the number provided in the solicitation email or phone call.
- Forward any solicitation email to the customer service or security email address of the organisation, to verify whether the email is legitimate or not.
- Do not respond to any messages or click any link mentioned in any email unless the source is a trusted or known one. Report any deviations or suspect fraudulent activities to the concerned organisation through their customer service number.

5 Plant and warehousing operations

Risk

Inadequate focus on regulatory compliance with FDA/CGMP norms, manpower resource, and schedule maintenance

Mitigation measures

- Identify and prioritise the critical products to be manufactured as per customer/government requirements.
- Plan to maximise capacities in plants located in states with fewer cases of COVID-19.
- Evaluate the allocation of available labour between production shifts to maintain the safety and well-being of workers.
- Prioritise scheduled maintenance activity such as HEPA filters.

Risk

Inadequate segregation of duty controls

Mitigation measures

- Ensure that the current governance framework is effective enough to trace transactions, and ensure that maker-checker control is active in the event of lower employee availability at sites.
- Design a temporary document for exceptional approval and allocation of additional rights.



Risk

Contamination of work place

Mitigation measures

- Frame an SOP w.r.t. COVID-19, which states the additional steps that need to be taken to ensure sanitisation. For instance, "First entry door of manufacturing area should be permanently kept open".
- Routinely clean all frequently touched surfaces in the workplace, such as workstations, keyboards, telephones, handrails, and doorknobs.
- Discourage workers from using other's phones, desks, offices, or other work tools and equipment, when possible. If necessary, clean and disinfect them before and after use.
- Provide disposable wipes so that commonly used surfaces such as doorknobs, keyboards, remote controls, desks, other work tools and equipment can be wiped down before each use.

Risk

Contamination at warehouse

Mitigation measures

- Frequently sanitise all warehouses and hubs with appropriate disinfectants.
- Check all warehouse employees for symptoms of being unwell, and thermally scan all employees at entry.
- Ensure all employees handling pharma products wear face masks and gloves.

Risk

Inadequate social distancing

Mitigation measures

To increase social distancing among employees,

- Extend lunch hours.
- Stagger lunch hours by department.

- Increase the area required for the canteen.
- Demarcate seating/standing areas in the canteen with adequate distance.
- Provide cleaning staff with PPEs.

Risk

Contamination risk from visitors, contractors, and third-party staff

Mitigation measures

- Evaluate all options of online communication wherever possible (video conferencing, con call, email).
- In case entry is inevitable, there is a need for,
 - Sanitisation and thermal screening of all external people who enter and exit, as well as ensuring usage of masks and gloves while in the premises.
 - Provision of tissues and no-touch disposal receptacles.
 - Provision of soap and water in the workplace. If soap and water are not readily available, use alcohol-based hand sanitisers with a minimum of 60% alcohol. If hands are visibly dirty, soap and water should be chosen over hand sanitisers.
 - Placement of adequate hand sanitisers in multiple locations to encourage hand hygiene.
 - Placement of posters that encourage hand hygiene at the entrance to workplaces and in areas where they are likely to be seen.
 - Encouragement of the use of non-contact methods of greeting.

Risk

Risk of movement of infected vehicles in the plant/warehouse

Mitigation measures

- Sanitise/disinfect vehicles used inside the plant premises.

Risk

Risk of dependency on third-party service providers (especially those dealing with HVAC systems)

Mitigation measures

The following measures should be taken to prevent transmission of air-borne particles via HVAC:

- Revisit and relook at the filters in the plants.
- Increase the frequency of change in HEPA filters.
- Increase the frequency of AMC, and conduct preventive maintenance of all air conditioners.
- Introduce a UV disinfection system if not already in place.



6 Supply chain management

A. Procurement Risk

Quality checks of material received (including external material covering checks for contamination)

Mitigation measures

High imports from China

- Review the current inventory levels against the demand (both API, KSM and PM).
- Restart the supplies from China for critical API, KSMs, and excipients (no alternate source options).
- Improve reliability and visibility of supplies.
- Review the share of business from alternate suppliers.
- Increase the warehousing capacity to quarantine the consignment received for a defined time period.
- Disinfect cartons before drawing out samples, and provide evidence of the same with other inward documents.

Risk

Shortage of raw materials/API/ solvent due to dependency, inadequate materials to complete BOMS/batch size processing

Mitigation measures

- Stock critical inventory, connect with suppliers for key components.



- Evaluate alternate sourcing for all affected materials such as availability of suppliers, additional cost due to logistics, tariffs, estimated price increases, etc.
- Evaluate investment in existing plant/new plant by maximising the use of government support policies (as mentioned subsequently in shutdown of vendor and plants/ sites section).

Risk

Shutdown of vendor plants/sites

Mitigation measures

- Identify products affected by possible shutdowns at suppliers—and suppliers’ suppliers—or logistics interruptions in Asia (especially China).
- Pressure test supply chains based on various scenarios for the COVID-19 situation (such as near-term containment, continued regional expansion, and potential “second wave” infections later in 2020).
- Develop a manufacturing network strategy fit for the future considering various government schemes/proposals such as the government-approved production linked incentive (PLI) scheme for promotion of domestic manufacturing of critical (KSMs)/ (APIs).
- Avail the government’s financial incentive to those pharma companies ready to invest INR 500 crore in an existing or new plant.
- Promote bulk drug parks for financing common infrastructure facilities.

B. Planning

Risk

Potential expiry of materials – monitoring for re-assessments and quality certificates

Mitigation measures

- Understand inventory levels in the full supply chain, and adjust to new realities i.e., situation

of countries of export, and take action for stock already produced for those countries.

- Evaluate, submit studies to the FDA, and label a product with the longest possible expiration date that the FDA agrees is scientifically justified to prevent or mitigate a shortage.

Risk

Shut down of contract manufacturers

Mitigation measures

Maintain regular contact with contract manufacturers regarding their capability to deliver products during the COVID-19 crisis and their recovery plans for the company to consider alternative supply chain options in a timely manner.

Risk

Quality control check at contract manufacturers or traded goods (contamination issues)

Mitigation measures

Designated quality assurance personnel at the contract manufacturer’s site should ensure the following and confirm to the CMO Head on a regular basis:

- Sanitisation and thorough quality checks of all inbound material after quarantining them for a defined period of time (24 hours).
- Adequate cleaning procedures, adequate availability of IPA at all critical locations, and adequate sanitisation of employees visiting the shop floor or warehouse.
- Sanitisation of equipment after manufacturing of all batches.
- Review of placement of CCTV cameras’ footage by QA on a regular basis.

Risk

Risk of contamination after final packing (LL/TP)

Mitigation measures

- Disinfect consignments before delivery and share pictures with a time stamp as evidence.

C. Logistics and transportation

Risk

Non-availability of local transportation for dispatch of material and finished goods

Mitigation measures

- Identify alternate logistics partner(s) for delivery.
- Review overall cost structure including logistics.
- Secure approval from the appropriate authority for movement of essential drugs in the event of a lockdown.
- Evaluate alternative outbound logistics options and secure capacity.

Risk

Contamination issues with respect to trucks and other vehicles used for dispatch

Mitigation measures

- Adequately disinfect all vehicles before the transportation of drugs.
- Plan for appropriate storage for temperature-controlled products, given the reduced frequency in outbound.
- Work with warehousing partners to plan for space to accommodate stock (in case of delays in distributors picking up stocks).

D. Exports

Risk

Contractual compliance

Mitigation measures

The individual collecting the export order should be aware of regulatory restrictions imposed by the government, for instance, molecule names.

Risk

Risk associated with contractual terms with domestic and export customers, especially contractual obligations and force majeure clauses

Mitigation measures

- Assess risk of onward supply obligations, including risks associated with breaching client supply contracts due to delay or failure of supply chain or availability of key staff. Engage with clients early to mitigate the impact of potential supply problems/penalties, and explore delivery or component solution alternatives.
- Seek advice from insurance brokers on whether protection exists for supply challenges. Fulfill contracts by supporting working capital loans, and maintain cash flow by insuring against buyer default.

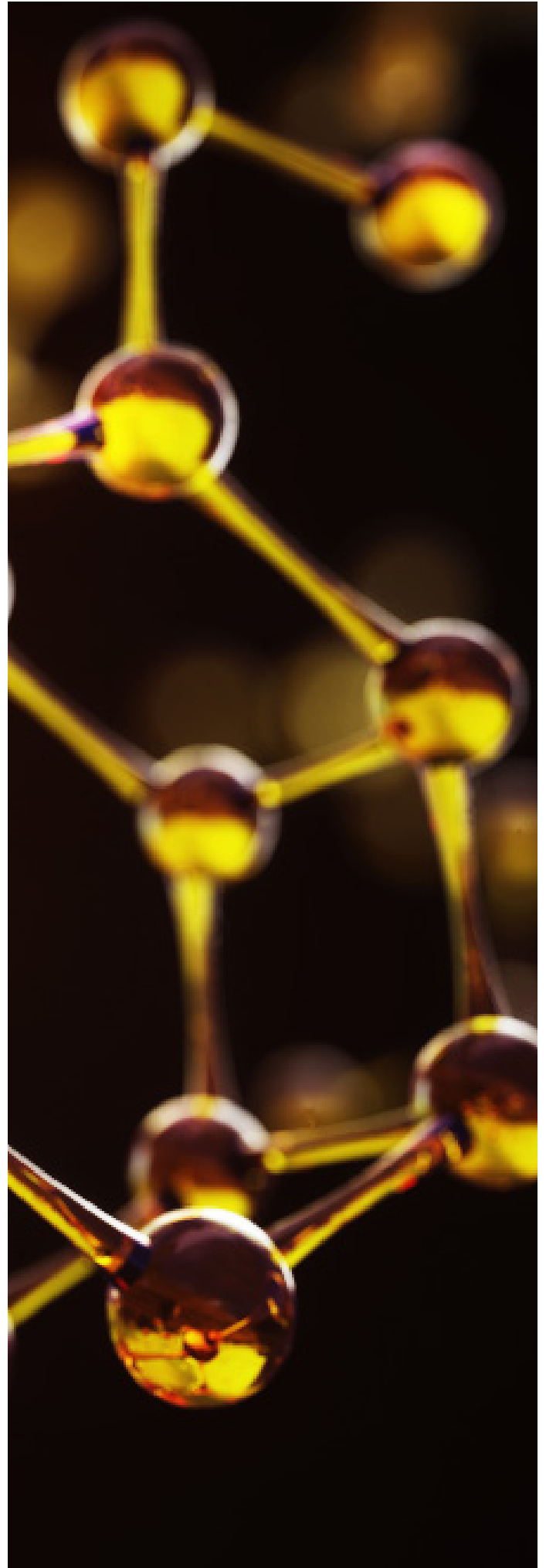
7 Research and development (R&D)

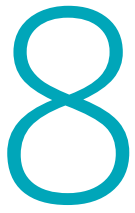
Risk

Additional stress on companies for clinical trials; on-going trials are affected

Mitigation measures

- Identify the trials that could be affected by possible shutdowns at supplier or logistic interruptions.
- Incorporate COVID-19 risk and impact tracking into trial management plans.
- Communicate with investigators to understand the specific issues COVID-19 is creating at their sites (such as local lab testing capacity, patient retention, serious adverse event risks).
- Investigate alternative timing or locations, and prioritise initiation of new investigator sites in countries with a low potential risk.
- Establish strong patient communication plans.
- Establish an internal regulatory perspective on COVID-19 to guide communications with institutional review boards and investigators.
- Understand from the regulators how to deal with enhanced event risk in currently enrolled patients.





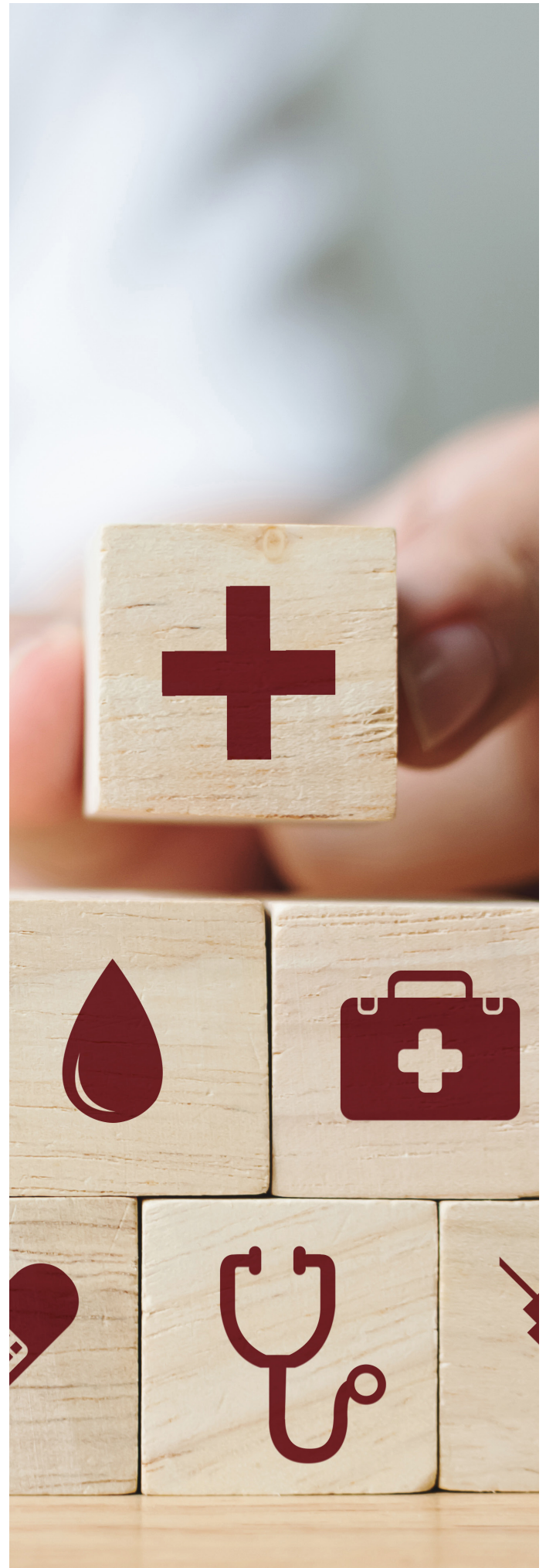
Insurance

Risk

Insurance Risks

Mitigation measures

- Revisit the coverage of existing policies.
- Obtain adequate risk covers for protection of employees, product portfolio, assets, etc. (if not availed earlier).
- Maintain proper documentation detailing the effects of an untoward event on business activities.
- Consult with insurers to understand the eligibility of claims due to the impact of COVID-19 on business activities.



9 Finance management

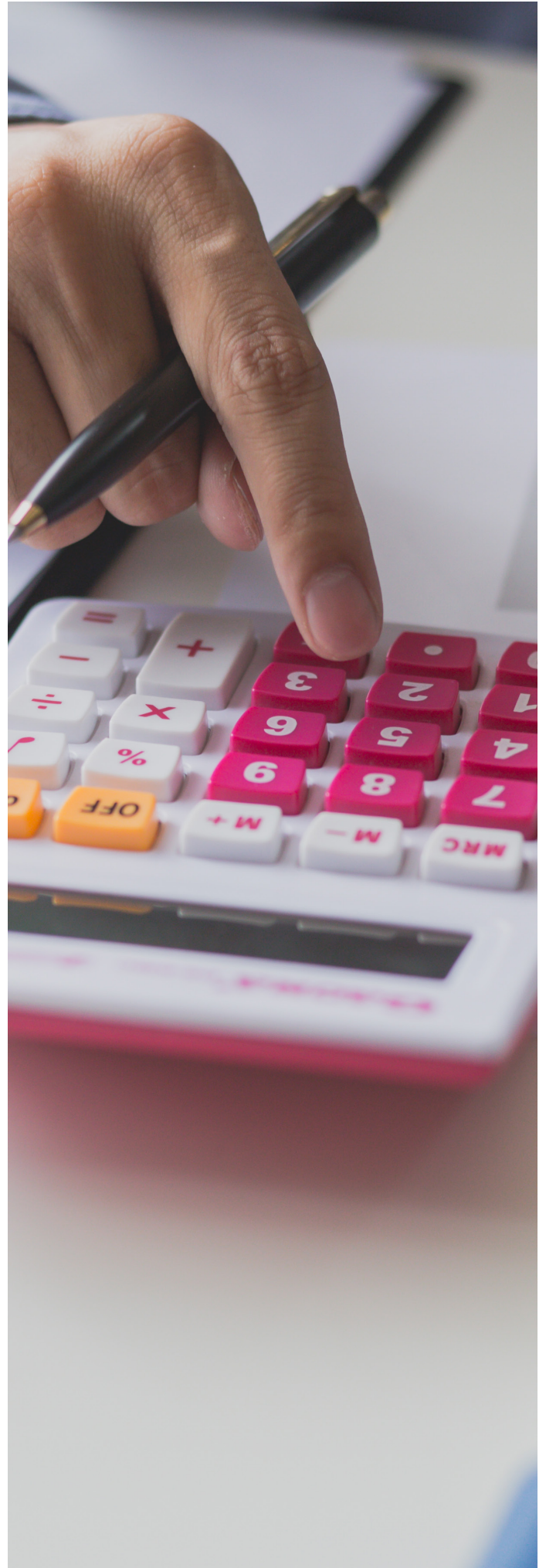
Risk

Liquidity crisis (management of effective cash flow for company survival)

Mitigation measures

Management should consider the following strategies:

- Manage payables by prioritising crucial payments such as salaries, financial obligations, etc.
- Focus on the cash-to-cash conversion cycle.
- Review debt retirement schedule and covenants.
- Manage and expedite receivables.
- Revisit variable costs.
- Revisit capital investment plans and ensure that your own financing remains viable.
- Focus on inventory management.
- Review Forex hedging exposure.
- Ensure that there is a robust review process of calculating financial loss due to supply chain risk (e.g. failure to supply penalties).
- Ensure that audit payables and receivables transactions are adhered to.



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