Pandemic Influenza Preparedness:
Business Continuity Planning for the Pharmaceutical Industry in Ireland

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INTRODUCTION

Irish Pharmaceutical Healthcare Association (IPHA) members play an important role in maintaining and improving the health of Irish citizens through the development, manufacture and supply of medicines to the Irish market. However, like other companies, they are vulnerable to external events and crises that can interrupt their business operations and ability to serve their customers and communities.

The World Health Organisation (WHO) believes that an influenza pandemic may be imminent and that some newly emerged strain of influenza may transition to a viral form enabling widespread human to human transmission. While the severity and impact of such an influenza strain remains uncertain, this transition has the potential to create a pandemic that will massively affect society, leading to widespread illness and death and interruptions in critical business and governmental operations.

Given the increasing likelihood of a pandemic, IPHA members are encouraged (if they have not already done so) to adapt their business continuity plans to include a response to pandemics. This paper provides preliminary guidelines for such a plan. It outlines four key areas for business continuity planning and identifies critical continuity issues in each area. It proposes a process for planning and preparation aligned to the WHO stage model for pandemics. IPHA recommends that its members develop their own detailed plans that address the key issues in this paper. IPHA also recommends that members provide a summary report to the Association and consider publishing a non-confidential overview on their company websites to enhance the confidence of key stakeholders: employees, investors, customers, suppliers, distributors, healthcare professionals and the State. The availability of a plan will assure stakeholders that steps have been taken to ensure business continuity and stakeholder needs on a best effort basis when confronted with a major pandemic crisis.

Pandemics

An epidemic is the increased occurrence of an infectious illness that appears for a limited time in a limited location. In contrast, a pandemic is the widespread occurrence of an infectious disease that occurs across multiple continents for a limited time. This paper will focus on an influenza pandemic – although the business continuity planning issues suggested in this report may be applied more broadly to other pandemics or other emergency situations affecting business continuity.

Influenza pandemics which have caused unusually high levels of illness or death have previously occurred in 1918, 1957 and 1968. Influenza pandemics pose various challenges from a medical perspective. Vaccines are usually the most effective way of preventing seasonal influenza infection, but have not been widely available for previous pandemics. Vaccines against a new strain of influenza virus can take anywhere between three to six months to develop and manufacture. This response time could be too slow to protect people against the first wave of a pandemic. This situation would be further exacerbated if no prototype or pre-pandemic vaccines were available that could provide cross protection against the pandemic strain.

Prior to the availability of effective influenza pandemic vaccines, antiviral medicines would be the principle medical intervention for reducing morbidity and mortality (as stated by the WHO1). In addition to treating infected patients, front line workers required to maintain public services during the pandemic (e.g. healthcare personnel, Garda Síochána, etc) may be protected using stockpiled anti-virals or vaccines (although the latter may not be perfectly matched to the actual pandemic strain).

Given the challenges of creating and delivering effective vaccines in response to a pandemic, business personnel and leadership may have to increase social distance or be isolated from

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person-to-person contact to reduce exposure and prevent human-to-human transmission. The likely interruptions arising from increased social distancing or widespread disease make it imperative for IPHA members to establish a business continuity plan for the contingency of a pandemic. The plan would help operations to continue, to promote the safety and wellbeing of employees, and help to keep accessible and available manufacturers’ products that are vital to the public interest and health.

While the impact and magnitude of a pandemic are uncertain and will vary across companies, the impact of an influenza pandemic is expected to be significant. Based on previous pandemics, reasonable estimates for absenteeism are between 30% and 50% with overall mortality rates between one and two percent. This can be significantly disruptive to businesses and society in general.

**A FRAMEWORK FOR BUSINESS CONTINUITY PLANNING**

Most major business organisations are likely to have business continuity plans in place to address different contingencies from both man-made and natural disasters. These plans will have to be adapted to the specific contingency of a pandemic and the special role of IPHA members in society. Based on an analysis of prior business continuity models, this paper proposes that IPHA members should plan business continuity along four key dimensions in relation to a pandemic.

These include:

(a) **Leadership and Staff Continuity** – i.e. ensuring leadership decision making processes are effectively in place to handle any disruptions from a pandemic, and ensuring processes are in place to meet the wellness needs of employees, and minimise their exposure to morbidity and mortality from a pandemic.

(b) **Operational Continuity** – i.e. ensuring the company facilities and operational processes can continue to produce and deliver its essential products and services to key customers.

(c) **Distributor and Customer Continuity** – i.e. ensuring vital supplies remain available and processes for delivering and serving customers remain operational during a pandemic.

(d) **Public Health Continuity** – i.e. coordination with public health providers such as the Health Service Executive and appropriate public private partnerships to ensure critical healthcare needs are being addressed. Due to the special role and capabilities of IPHA members in producing medicines, coordination with the State to minimise the disruptive primary or secondary morbidity and mortality impacts of a pandemic remains vital. Consideration should be given to measures that can reduce the impact of a pandemic on essential medicines for non-influenza conditions.

When undertaking planning along each of these four dimensions, it is important to consider not only the positive measures that must be taken to ensure continuity, but also those areas that must be scaled down in parallel. Similarly, while the plan will outline the steps required to maintain continuity, it should also consider the measures required to reverse the process once the external environment permits the Organisation to re-enter normal operations.

This paper expands on some considerations for planning around each of the dimensions. Business continuity planners may also find the Forfás Business Continuity Planning – Responding to an Influenza Pandemic Advice and Checklist2 a useful adjunct to this document.

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(a) Leadership and Staff Continuity

The leadership and personnel of the company form the foundation for creating business value. IPHA members should prepare their pandemic plans to address continuity of leadership and personnel, and their well being.

Six key contingency plans required to achieve effective leadership and staff continuity should be established and addressed:

1. Leadership and decision making
2. Human resources identifying critical workforce for continued operations
3. Remote work and social distancing
4. Employee wellness
5. Education
6. Communication

(1) Leadership and Decision Making:

A pandemic crisis will create new demands for leadership and decision-making in the company, on how to respond to the crisis. In the event of a crisis, management will be called upon to assure continuity and execute a continuity plan. To facilitate these new demands, a pandemic planning and response team should be specified. The pandemic plan should outline decision rights and delegation of spending authorities to managers under such a contingency, and will include the identification of backup individuals with appropriate decision-making rights to provide interim management in the place of colleagues who become unavailable during a crisis. Advance allocation of critical decision rights and spending authorities can help managers respond more quickly to such crises.

(2) Human Resource Planning:

Human resource (HR) planning identifies strategies for coping with staff absences during a pandemic and reviews and revises existing policies to address issues and employee concerns that may arise in a crisis. While estimates vary, 30% to 50% of staff may be absent during the height of a pandemic due to illness, the need to tend to family members and community needs, or due to a greater perception of safety at home. HR plans must consider the potential impact of schools closing, should account for large absences, and identify who are the essential employees required to be available to maintain essential operations. In addition, it should outline any incentives to be provided to essential employees and any impact on the remuneration and benefits of those requested to stay at home. The plan will identify which critical staff are required onsite and how to best make them available and minimise risk to them on and offsite, as well outlining any sites that may need to be closed and associated policies for requiring staff to work from home. It will identify work related risk groups to enable rapid diagnosis and treatment for those who become ill. Furthermore it will identify alternatives if key staff are unavailable due to illness and prepare in advance to ensure key skills and people are available to continue operations including within the HR function, which may require additional resources during a crisis that results in added demands on HR processes. The plans will establish leave of absence policies related to the crisis, and policies covering travel, medical insurance and life cover, support for ex-patriot employees and employee assistance/counselling support. In addition, plans should consider any impact on these policies if authorities were to place restrictions on travel or the crossing of borders. HR plans will also establish guidelines for company routine internal operations, meetings and events so that opportunities for person-to-person transmission of illness are minimised as a pandemic emerges.
When developing the continuity plan, HR should not be the sole source of absenteeism planning. HR should work closely with each area likely to be impacted, such as Supply Chain, Commercial, Public Affairs, Finance, Administration, Information Technology, Research and Development, Legal, Security, Facilities etc. to identify business continuity critical functions and appropriate staffing requirements, including the potential for outsourcing.

(3) Remote Work and Social Distancing Planning:

Remote work and social distance planning is vital as illness is usually spread through person-to-person contact. Some social distancing measures may be mandated by the State. A key corollary of the human resource plan will be to establish capabilities for as many staff as possible to contribute through remote work. This may be done through the use of computer networks such as the Internet, which enables work from home. Remote work planning must involve Information Technology departments to address capacity issues that will be faced by a significant increase in home working. Capacity issues are likely to extend beyond the direct control of the company, to networks that rely on telecommunication and internet service providers, as well as infrastructure limitations at employees’ homes. Within the work place it is also important to increase social distance and discourage large group meetings during the course of the pandemic. This again will reduce the likelihood of transmission. A pandemic plan would identify how workers can best contribute through remote work and assure the availability of infrastructure to support this. It will also provide employees with guidelines for social distancing during the course of the pandemic.

Guidelines on social distancing include:

- Avoid any non-essential travel including calls by sales representatives and clinical trials monitors. Travel will be restricted/cancelled as per the recommendations of the WHO and the relevant local and national public health authorities.
- Avoid meeting people face-to-face, use the telephone, video conferencing and the internet to conduct business as much as possible, even when participants are in the same building.
- If a face-to-face meeting with people is unavoidable, minimise the meeting time, choose a large meeting room and sit at least one meter away from each other if possible; avoid shaking hands or other greetings involving contact.
- If possible, arrange for employees to work from home or work variable hours to avoid crowding at the workplace.
- Avoid public transport: walk, cycle, drive a car or go early or late to avoid rush hour crowding on public transport.
- Bring lunch and eat at your desk or away from others (avoid the cafeteria and crowded restaurants). Introduce staggered lunchtimes so numbers of people in the lunch room are reduced.
- Do not congregate in tearooms or other areas where people socialise. Do what needs to be done and then leave the area.
- Set up systems where clients/customers can pre-order/request information via phone/email/fax and have the order/information ready for fast pick-up or delivery.
- Encourage staff to avoid recreational or other leisure classes/meetings etc. where they might come into contact with infectious people.

(4) Employee Wellness Planning:

Employee wellness planning should involve close coordination with local and national authorities to enhance the safety and health of staff in partnership with the communities in which they operate. The plans advise employees on strategies to minimise the risk of infection, including advice for those travelling in affected areas in pre-pandemic stages. Furthermore, it will review healthcare options for employees and identify how to provide appropriate critical medical care during the course of the pandemic, in co-ordination with local authorities. This may include household quarantine as appropriate and access to anti-virals for treatment and to vaccines for prophylaxis. In the context of influenza pandemics some companies may choose
to acquire a security supply of anti-virals for treatment or prophylaxis (post-exposure or during a pandemic as appropriate). The WHO proposes that strong consideration be given by all stockpile-controlling authorities to include antiviral medicines in their stockpile.

It may also include providing materials that may reduce risk of infection by the use of gloves, masks or respirators. Policies for acquiring and making these resources available need to be specified in advance, and may apply for instance to limited cases such as health centre workers. Policies for the provision of specialist equipment should also consider the practicalities of such provision. For instance, wearing masks may be uncomfortable and achieving a good fit difficult, arrangements for eating and drinking should be considered, and the disposal of clinical waste associated with used equipment should be addressed.

**Hygienic Measures**

**Personal Hygiene**

Basic personal hygiene measures should be reinforced and people should be encouraged to practice them to minimise potential influenza transmission:

- Wash hands frequently with soap and water.
- Cover your mouth and nose with a tissue when you cough or sneeze.
- Put used tissues in a wastebasket.
- Cough or sneeze into your upper sleeve if you don’t have a tissue.
- Clean your hands after coughing or sneezing. Use soap and water or an alcohol-based hand cleaner.

Ensure that adequate supplies of hand hygiene products are available. This is a high planning priority as there may be interruption to the supply or shortages of hygiene products.

**Workplace Cleaning**

Cleaning of environmental surfaces with a neutral detergent followed by a disinfectant solution is recommended to minimise the transmission of the virus through environmental sources. Surfaces that are frequently touched with hands (e.g. sinks, handles, railings, mirrors, phones, keyboards, objects and counters) should be cleaned often, preferably daily.

- To avoid possible re-aerosolisation of influenza virus, damp, rather than dry dusting or sweeping should be performed, whenever possible. Wet-dust horizontal surfaces by moistening a cloth with a small amount of disinfectant.
- During wet cleaning, cleaning solutions and equipment soon become contaminated; clean less heavily contaminated areas first and change cleaning solutions, cleaning cloths, and mop heads frequently.
- Equipment used for cleaning and disinfection must be cleaned and dried between uses.
- Mop heads should be laundered daily and dried thoroughly before storage or reuse.
- For carpeted surfaces, a vacuum cleaner with HEPA filtration\(^3\) should be used. If such a vacuum cleaner is not available, vacuuming should be avoided, or the floors should be vacuumed when no persons are present, and the cleaning staff must be equipped with an FFP3 mask\(^4\) or equivalent.
- Cleaning staff that empty wastebaskets must wear gloves and an FFP2 mask\(^5\) or equivalent. Employees should be encouraged to close waste bags into which they have placed materials with increased infectious risk such as used masks and respirators, hygiene paper towels and tissues.

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3 The High Efficiency Particulate Arrestor (HEPA) is a 99.97% effective filter that is commonly used in hospital operating rooms and other sites where particle- and bacteria-free air is mandatory.
4 An FFP3 mask offers the highest level of protection (99% particle filtration efficiency) in the European Union grading system for disposable Air Purifying Respirators in the EN149 class.
5 The FFP2 mask offers only 95% particle filtration efficiency and is the EU's close equivalent to the American NIOSH N95.
Air Conditioning

There is scientific and medical evidence that influenza can spread in inadequately ventilated internal spaces. All internal spaces should be well ventilated, preferably by fresh air via opening windows, or otherwise by properly designed and maintained air conditioning systems. In spaces without central air conditioning, consider the use of natural ventilation (open windows in isolation rooms/areas) if weather permits, keeping the door closed.

Personal Protective Equipment

Respirators (Face masks)

People in the general public might want to make a personal decision to use some form of respiratory protection to help reduce their exposure to airborne influenza virus. Therefore, plans should determine whether face masks should be offered to all employees remaining on site for self protection, in addition to special cases such as health centre workers. Measures to avoid inhalation of infectious aerosols must be seen as a continuum, with social distancing as a simple yet effective measure. The choice of the measure is driven by the degree of protection deemed necessary, and secondary factors such as the acceptance of the mask (comfort) may also play a role in the choice. Some respirators with certified protection factors are sold with or without exhalation valves. Masks with such valves are much more comfortable to wear, especially in the long run, but provide no protection of the environment from the aerosol emissions of the wearer.

If face masks are used then it is important that instructions for use are available that include information regarding the risk of re-use of masks, particularly if the employee has been in contact with infected individuals. Masks should be immediately disposed into a waste container after use and not laid on any working surface. Hands should be washed immediately after removing and disposing of the mask as the surface of a used mask can be a source of infection. It is also important that masks do not lead to a false sense of security i.e., should not replace other defined containment and distancing measures or encourage infected individuals to venture out of their contained environment.

Examples of disposable particulate respirators acceptable for high risk situations include:

U.S.: NIOSH-certified N95 (95%), N99 (99%), N100 (99.7%)
EU: FFP2, FFP3

Note: The percentage figures indicate the filtering capability in a standardised laboratory test setting for the material used to manufacture the masks. The actual protection factors for viruses have not been determined but are certainly much lower.

Personal Protective Equipment (for Healthcare Personnel)

As per the WHO, the use of Personal Protective Equipment, for instance gloves, gowns, respirators/masks, eye protectors etc, is mandatory for healthcare workers if direct close contact with the patient is anticipated and when entering the room where aerosol producing procedures in influenza-infected patients are being performed. Ensure that adequate supplies are available and refer to WHO guidelines for details. This is a high planning priority as there may be interruption to the supply or shortages of personal protective equipment.

(5) Education Planning:

Education planning develops programmes to educate employees about business continuity planning, and includes good personal hygiene and work place cleaning practices in advance, to ensure the spread of the influenza virus is minimised during the course of the pandemic.
Education can cover seasonal influenza vaccination and advice for travellers and those residents in affected areas prior to a pandemic. In addition, it can cover what employees may do from a personal hygiene perspective and in work interactions to minimise infection. Education may also cover how employees may prepare for a pandemic at home to minimise public interactions and to outline general household emergency planning. This may include information for equipment they may use, such as masks etc, which may provide a measure of protection against the pandemic. It can also cover how employees may access healthcare and other facilities, and outline care measures for employees in the event healthcare provision is overwhelmed. Education can be provided through multiple channels and formats: meetings that build awareness prior to a pandemic, through paper and/or digital format documents, online briefing kits, etc. It is important that education is delivered through credible sources such as Medical, Human Resources or Environmental Health and Safety departments, and where appropriate dovetails with the work of external experts such as WHO, the Department of Health and Children, the Health Service Executive and other local authorities.

(6) Communication Planning:

Communication Planning identifies how leadership can effectively communicate with staff, partners, suppliers, distributors, customers and other stakeholders before, during, and right after a pandemic. It develops channels and assures their availability during the course of a pandemic. It ensures communication of key response plans to all relevant stakeholders, such as employees, partners, suppliers, distributors and customers, in advance of the pandemic. Again a multi-channel communication strategy should be considered.

To provide a coherent structure to Communication Planning, IPHA members may want to align their plans with the WHO Pandemic Phases as messages and themes are likely to change with the transition through the various pandemic phases and on to recovery.

(b) Operational Continuity

Operational continuity focuses on the key business processes and equipment for continuing operations and supplying of products during the course of a pandemic. Many of these categories of planning may already exist in the context of existing business continuity plans. As a complement of leadership and staff continuity plans, these plans focus on continued operations. The plan should also address areas which may impact continued operations, such as contract provisions and insurance coverage.

Five recommended areas of focus include:

1. Mapping and maintaining key business processes
2. Maintaining critical systems and infrastructure such as information technology
3. Managing physical and information security
4. Managing for compliance and medicines safety
5. Maintaining inventory

(1) Mapping and Maintaining Key Business Processes:

Successful operations are often predicated on the execution of key business processes. While these may already be documented, the processes should be tested against the hypotheses of a reduced workforce to implement the processes.

Plans should identify and prioritise key lifesaving and life sustaining products, and the entire supply chain should be mapped. At risk supplies, such as those from single sources, should be identified along with mitigation strategies (for example hedge inventories) to reduce risk of supply chain disruption.
(2) Critical Systems and Infrastructure:

Key business processes are usually supported by a series of essential system and technology infrastructures. These may be critical equipment or information systems. A key requirement for continued operation of critical equipment will be to ensure that available staff have the necessary knowledge to safely operate systems.

(3) Physical and Information Security:

While it is difficult to predict the impact of the pandemic on workforces and operations, the company’s physical location or information systems or even key employees may be targeted more actively during a pandemic. This may be the case especially if the company manufactures scarce essential products such as a vaccine or a treatment targeted to the pandemic. Security plans should be reviewed and adapted for the context of a pandemic. If necessary, physical security needs to be coordinated with An Garda Síochána or other public authorities. Consideration should also be given to security throughout the entire supply chain.

(4) Compliance and Medicines Safety:

Compliance and medicines safety is another source of business risk that must be addressed in a pandemic plan. It is important that critical safety requirements and other critical compliance requirements are met during the pandemic period. Any legal or regulatory waivers likely to be required due to reductions in the available workforce are best evaluated and applied for in advance of a pandemic.

(5) Inventory and Safety Stocks:

Pandemics can vary in duration and may consist of several waves. An influenza pandemic is therefore expected to be disruptive in any specific area ranging from a few weeks to several months. During this period it is likely that regular deliveries of essential products may be disrupted. Inventories of finished goods may also become depleted. In anticipation of these disruptions it is best where feasible that companies maintain a higher level of inventories or safety stocks in anticipation of a pandemic.

(c) Distributor and Customer Continuity

As noted above, a key to operational continuity is the availability of essential supplies and alignment of the supply chain between IPHA members and their distributors. In addition to maintaining safety stocks of critical inputs, it is important to assess the vulnerability of the distributor to a pandemic. Will the distributor be able to operate and continue past a pandemic? Assessments of distributor continuity plans can help to increase confidence in specific distributors. This can be based on the sharing of continuity plans between the distributor and the IPHA member seeking sustained supply into the marketplace.

Furthermore, payment and other systems may be compromised. IPHA members should review their capacity to distribute products, and where appropriate identify alternative distribution and logistics systems, and the capacity of key buyers to receive, store and further distribute products directly to customers.

(d) Public Health Continuity

An influenza pandemic will result in significantly increased demand for healthcare products directly involved in the prevention and treatment of influenza and secondary bacterial infections (notably pneumonia). These include:
- Anti-virals
- Antibiotics
- Face masks, disinfectants
- Vaccines and syringes

In addition, demand for other essential healthcare products and services will continue during the pandemic and potentially accelerate, requiring more production of essential medicines – something the manufacturers of select items should be aware of.

For public health continuity it is important to increase coordination:

- Between manufacturers and the State for the timely supply of essential medicines. Coordination between the State and industry, establishing what is required of both parties before and during a pandemic is essential.
- Among manufacturers, to identify and overcome barriers to achieving such supply, in advance of the pandemic.
PANDEMIC BUSINESS CONTINUITY MANAGEMENT PLANNING

Business Continuity Management (BCM) for pandemics anticipates how a pandemic will impact the essential functions and processes of the Organisation and provides a planned and rehearsed organisational response to the event. The purpose of BCM is the continued availability of key processes, to mitigate the negative effects of the pandemic, and to maintain business operations as efficiently as possible.

When planning, IPHA members will outline the business priorities and objectives for the pandemic period, determine the scope and magnitude of risks from a pandemic, when and how to effectively deploy different stages of the BCM plan, and who will be responsible for BCM planning and implementation.

Current estimates of the impact of an influenza pandemic vary. Reasonable planning assumptions include:

- If avian influenza adapts fully to humans, the disease will spread worldwide in a few weeks
- The pandemic will circle the globe in 2-3 waves, recurring after 4-6 months
- 25% of the population will become ill in the first wave, decreasing in subsequent waves
- Creating a peak absentee rate between 30-50% (about 20% are ill at the same time, and the remainder are absent due to care giving and other personal reasons)
- A fatality rate of 3-5% of those who are ill, resulting in about 1% mortality across the entire population
- Most commercial flights will be grounded during the first wave
- Although restricting cross-border travel (car, train, bus, air) for a period may not be particularly effective at preventing the spread of a pandemic virus it should be assumed for planning purposes that restrictions will be introduced
- Cargo transport will be restricted to land and sea, except for critical supplies (e.g. vaccines)
- Cargo transport of certain goods (e.g. food) will be restricted or forbidden
- Given the highly infectious nature of pandemic viruses, existing healthcare systems and infrastructure will be overwhelmed
- Vaccines against the exact pandemic strain will not be available until 4 – 6 months after the first wave arrives
- In the next 1 – 2 years, most governments will not have sufficient stockpiles of anti-viral agents to treat those infected.

While the timing of the influenza pandemic is hard to predict, IPHA members should assess risks and prepare along the multiple dimensions identified in this paper. This can be done through a four stage model to: plan, prepare, respond/restore, and adapt stages as illustrated in the below graph.
In the first phase managers will assess the current state of business continuity plans and undertake business impact analyses of the likely impact of a pandemic on essential business processes. These will be used to develop specific preparedness plans for leadership and staff continuity, operational, distributor and customer continuity and contributing to public health continuity. In the second phase these preparedness plans will be defined and communicated to the essential leadership and staff of the company with responsibilities for executing the plans. Specific responses and capabilities should be tested for a variety of scenarios in this phase to rehearse responses and assure management they will work. During a pandemic, and in the event of a high probability of a pandemic in the near term, the plans will be fully rolled out and executed. This will prepare most staff and focus on maintaining essential operations as a pandemic interrupts normal business operations. Once the plans are rolled out managers are likely to have to adapt the plans to unforeseen contingencies and situations.

The World Health Organisation has created a six-phase model for the development of a pandemic. In the context of an influenza pandemic we are currently in phase 3 as illustrated below:

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<th>Phase</th>
<th>Description</th>
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<tr>
<td>1</td>
<td>Interpandemic Stage</td>
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<tr>
<td>2</td>
<td>No new influenza virus subtypes have been detected in humans. An influenza virus subtype that has caused human infection may be present in animals. If present in animals, the risk of human infection or disease is considered low.</td>
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<tr>
<td>3</td>
<td>Pandemic Alert Period</td>
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<tr>
<td>4</td>
<td>Human infection(s) with a new subtype but no human-to-human spread, or at most rare instances of spread to a close contact.</td>
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<tr>
<td>5</td>
<td>Small cluster(s) with limited human-to-human transmission but spread is highly localised, suggesting that the virus is not well adapted to humans.</td>
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<tr>
<td>6</td>
<td>Larger cluster(s) but human-to-human spread still localised, suggesting that the virus is becoming increasingly better adapted to humans but may not yet be fully transmissible (substantial pandemic risk).</td>
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<tr>
<td>7</td>
<td>Pandemic Period</td>
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<tr>
<td>8</td>
<td>Pandemic: increased and sustained transmission in general population.</td>
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Given that the timing of disease progression across phases is highly uncertain, IPHA members should aggressively plan for a pandemic as soon as possible. Preparedness plans should be developed and components tested as soon as phase four is recognised. If phase five is recognised in Ireland key components of the business continuity plan should be rolled out. If the disease transitions to a pandemic version full plans need to be rolled out and executed. While this alignment with WHO phases provides a practical reference for planners, the plans should recognise that certain actions may require more fine-tuned trigger points.

RECOMMENDATIONS AND CONCLUSIONS

This paper provides a framework that identifies essential business continuity elements to be considered in a pandemic plan. Different companies will consider these elements and choose to design and execute a plan appropriate to their context, based on their values, available resources and perceived level of risk.

IPHA recommends that all its members set up a pandemic plan that addresses most of the topics raised. IPHA also recommends that they share high level plans, planning templates and communications and recommendations to employees and the public for their safety during a pandemic. This will provide consistent approaches and reduce the costs of planning and executing business continuity plans in the event of a pandemic.
Annex 1: Coordination of Industry Manufacturing Capabilities

The pharmaceutical industry is undertaking a number of measures to increase the supply of products required to prevent or treat pandemic influenza; these include:

- Significant increases in the manufacturing capacities for the principal antiviral medicines, including sub-licensing arrangements;
- Development of pandemic vaccines; all IFPMA Influenza Vaccine Supply international task force member companies are in the process of developing prototype pandemic vaccines. Some have already filed license submissions;
- Seasonal influenza vaccine manufacturing capacity is estimated to double by 2010.

Coupled with the use of antigen sparing approaches (i.e. inclusion of novel adjuvants in the vaccine, enabling significantly lower antigen doses to be employed) and development of pandemic LAIV vaccines, the output of pandemic influenza vaccines should become several times that of seasonal vaccines.

Manufacturers are developing pre-pandemic vaccines based on current strains, with the potential to offer a level of cross protection against an actual pandemic strain. This could open up the possibility of routine vaccination of the population against potential pandemic strains before a pandemic occurs. This would overcome the delay in provision of a vaccine against the actual pandemic strain, and spread the huge workload in manufacturing and administering pandemic vaccines over several years, rather than the several months that would be required if vaccination occurred only after a pandemic struck.

Annex 2: Coordinated Funding and Regulatory Response

The pharmaceutical industry is investing heavily in the research, development and manufacturing of pandemic influenza vaccines and anti-virals – despite the fact that there is no guarantee of a significant commercial return, due to the unpredictable and sporadic timing of pandemics (once every 20 to 40 years, on average). The industry has requested governments assist with funding support for the above activities, and also the streamlining of regulatory processes to ensure that pandemic vaccines can be developed, licensed and supplied as quickly as possible come the pandemic.

The US government has been most forthcoming in funding terms, having already allocated in excess of $1 billion to pandemic vaccine development and manufacturing investments, for both egg and cell culture based vaccines. Its goal is to ensure that there is sufficient domestic production capacity to enable vaccination of the total population in the event of a pandemic.

On the regulatory front, the European Medicines Agency (EMEA) has developed a simplified regulatory process to facilitate the licensure of pandemic influenza vaccines, called the Mock-Up File process. Several companies have already made submissions under this process.

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*Sub-licenses to local manufacturers in India, China and South Africa for the production of generic oseltamivir and to local manufacturers in China for the production of generic zanamivir.*
References


“Business Continuity Planning – Responding to an Influenza Pandemic” (Forfás, 2007)

“Preparing for a Pandemic – Solvay’s plans to help protect you and your family during a flu pandemic” (Solvay, 2009)