26 September 2017
EMA/635491/2017
European Medicines Agency

EMA business continuity planning and impact of staff retention scenarios from the EMA staff survey

EMA has developed a dedicated business continuity plan (BCP) prioritising the Agency's activities in order to be prepared to cope with potential significant staff loss due to the relocation of the Agency.

The plan has three priority levels for EMA's activities according to their impact on public health and the ability of the Agency to function properly. In case of a business continuity situation the Agency will first decrease the activities and therefore the FTEs spent on category 3 (lowest priority), followed by category 2 (medium priority) and lastly by category 1 (highest priority). The principles and methodology of the BCP were endorsed by the EMA Management Board in June 2017.

The number of Full Time Equivalents (FTEs) needed for the three categories is based on time recording of staff (temporary agents, contract agents and national experts) in 2016.

Priority level	**Activities**	**Full Time Equivalents (FTEs) required**
Category 1	**The highest prioritised activities are Category 1** activities which are either directly related to the assessment and safety monitoring of medicines or vital for maintaining the infrastructure of the European medicines regulatory network. These activities include for example coordination of actions to protect the safety of patients in all EU Member States.	462 FTEs
Category 2	**Medium priority, Category 2** activities are public health and strategic activities such as the contributions to fight against antimicrobial resistance, collaboration with health technology assessment bodies and initiatives in the area of availability of medicines.	140 FTEs
Category 3	**Category 3** activities are the lowest priority and cover governance and support activities such as corporate governance, audits, participation in and organisation of meetings and conferences.	110 FTEs

To prepare for a business continuity situation with potential significant loss of staff, the Agency performed in early September a staff survey using EU Survey, the European Commission's official survey management tool. The aim of the survey is to inform its recruitment strategy to compensate for such staff loss. The survey was sent to all staff members (temporary agents, contract agents and national experts). 92% of the staff completed the survey.

The Staff surveys conducted in the past have indicated that the main reason for EMA staff to relocate or not is location driven. In fact, the September survey demonstrated that for 65% of EMA staff the new EMA location will be a determining factor in their decision–making to relocate or not.

Given the high level of uncertainty reported by staff, further insight into the different staff retention scenarios was required at a more granular level. Staff were asked to indicate whether they were very likely, likely, unlikely or very unlikely to move with the Agency to each of the 19 candidate host cities, based on the official Member State offers and the extent to which they fulfil their (and their family's) needs and expectations to settle in a new location.

Prior to the survey, staff were encouraged to fully explore the candidate offers and to favourably consider their viability for their and their families' needs. All materials provided by Member States were shared with staff. The staff's assessment of whether the candidate cities fulfil their needs and expectations was a personal assessment. It was not limited to the information provided in the bids as staff were highly motivated to seek out information independently on the availability and quality of housing, the educational options and capacity, as well as job opportunities for partners in the candidate cities.

The results of the staff survey are shown in Figure 2. In line with the activity prioritisation, the candidate cities have been divided into groups depending on the staff retention rates i.e. the staff expressing that they are likely and very likely to move with the Agency:

- Group 1 (dark green) with a retention rate of 65% or above;
- Group 2 (light green) with a retention rate equal to or higher than 50% and lower than 65%;
- Group 3 (light orange) with a retention rate equal to or higher than 30% and lower than 50%;
- Group 4 (dark orange) with a retention rate below 30%.

The staff retention figures have been combined with the numbers for the business continuity categories for each of the 19 candidate host cities in Figure 1. The cut off lines for category 2 and 1 activities are shown in red.

- For the cities falling into group 1 the expressed staff retention would necessitate a reduction in category 2 activities, but not in category 1 activities. The consequences are described in Annex 1, 'Business continuity impact on staff retention scenarios'.

- The expressed staff retention in cities in group 2 will not allow the Agency to continue with its category 2 activities and there will be an impact on category 1 activities. The consequences are described in Annex 1.

- For the city in category 3 it will be necessary for the Agency to reduce category 1 activities even further. For the consequences, see Annex 1.

- For cities in group 4 the resources available would not be sufficient for the Agency to operate. There will be a public health crisis. For the consequences, see Annex 1.

Figure 1. Outcome of staff survey and possible impact on Agency's activities

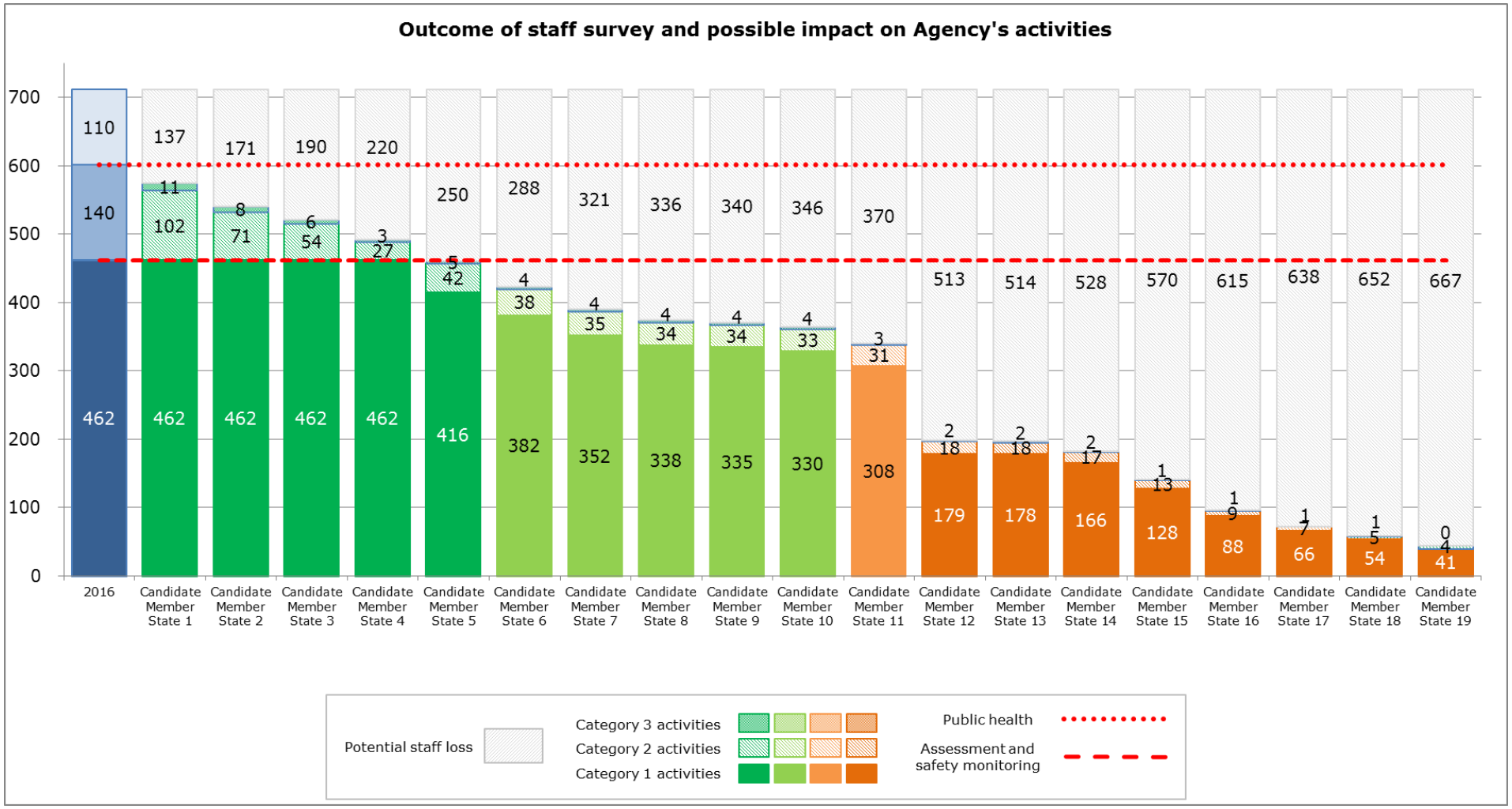
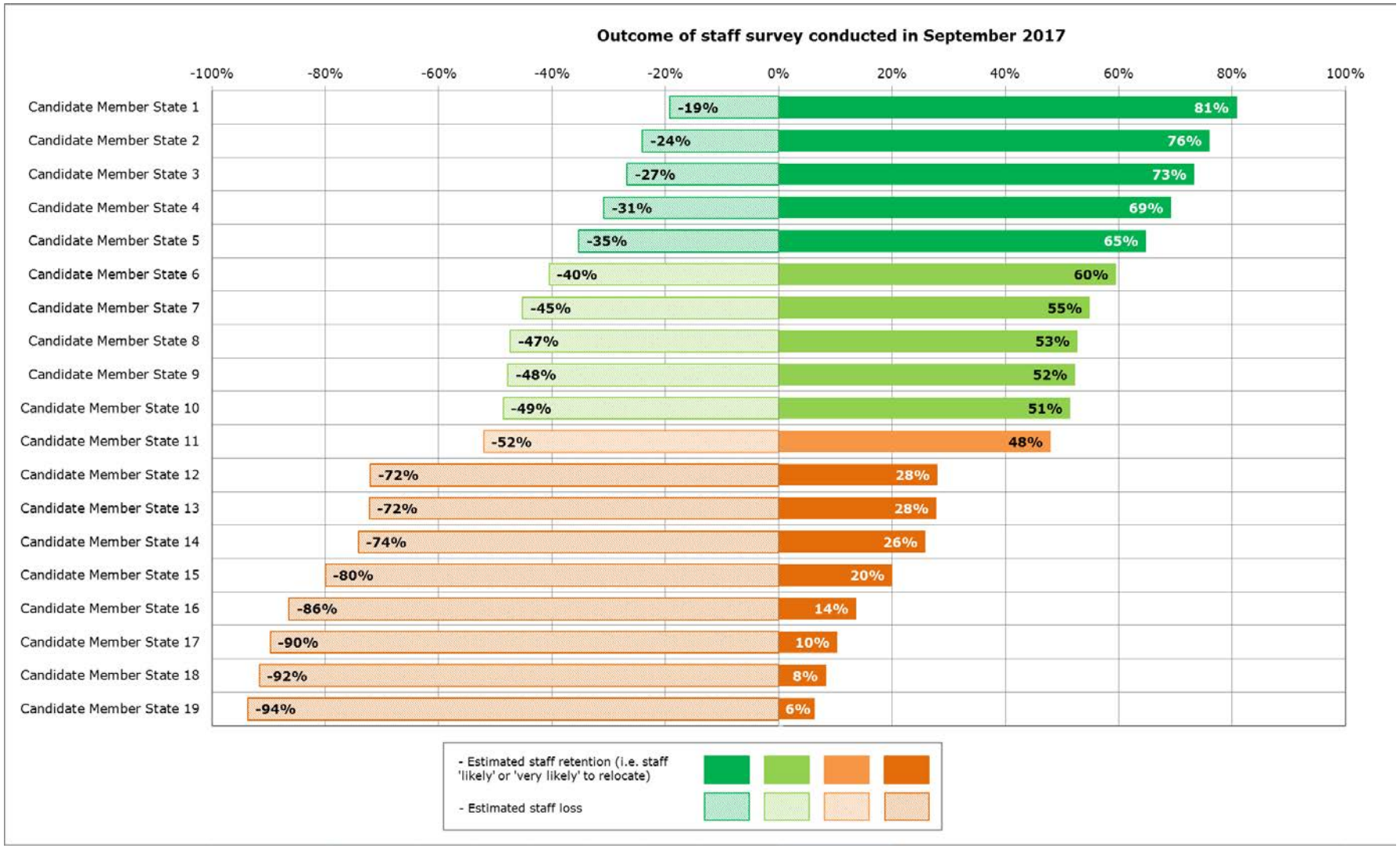


Figure 2. Outcome of staff survey conducted in September 2017



Annex 1. Business continuity impact on staff retention scenarios

Business continuity category	Survey results	Impact	Likelihood of success of compensatory measures	Time needed to full recovery
Group 1 Over 65% staff retention: meets EMA requirements and ensures that EMA is operational on time.	5 candidate cities: • average of 73% • range between 65% and 81%	Depending on the extent of specific staff loss: • Approval of new medicines and safety monitoring are largely maintained, but with possibility of delays • Progress on a number of public health initiatives (e.g. support to initiatives on antimicrobial resistance and for the elderly, cooperation with health technology assessment bodies) will move at a slower pace	High	2-3 years
Group 2 50% to 64% staff retention: meets EMA requirements but raises concerns that EMA is operational on time.	5 candidate cities: • average of 54% • range between 51% and 60%	• Patients wait longer for new medicines • Safety monitoring has to be ring-fenced by rerouting resources and deprioritising other tasks • Public trust in the system starts to erode • Europe risks losing its appeal/cutting edge in scientific research • Implementation of new legislation will be significantly delayed (e.g. veterinary medicines, clinical trials, and medical devices)	Medium	3-5 years
Group 3 30% to 49% staff retention: only partially meets EMA requirements and, therefore, raises major concerns as regards EMA business continuity.	1 candidate city: • average of 48%	• Patients are at serious risk because of delays in access to medicines and poor safety monitoring • Some life-saving medicines may not be available to patients in some countries • Loss of innovation • Uncoordinated temporary solutions taken in Member States lead to inequalities between EU citizens	Low	5-10 years
Group 4 Below 30% staff retention: does not meet EMA requirements and, therefore, does not ensure EMA business continuity.	8 candidate cities: • average of 18% • range between 6% and 28%	• EMA is unable to operate - public health crisis • Unravelling of the EU single market for medicines - no centralised authorisations -medicines become unavailable - need to import from third countries • Need to rely on third countries for approval and importation (e.g. USA, Japan) • Patients exposed to side effects – deaths – litigation	Need for emergency legislative measures at EU level. Need for emergency legislative measures at national level.	Permanent damage to the system