Medicines & Healthcare products Regulatory Agency

ExCo Minutes (final) ExCo/20/049

Title of meeting	Executive Committee meeting
Date	3 November 2020
Time	09.00 – 11.00
Venue	MS Teams meeting
Chair	June Raine
Attendees	ExCo
Apologies	Carly McGurry

Full meeting attendees

June Raine	Chief Executive Officer (Chair)
Jon Fundrey	Chief Operating Officer
Samantha Atkinson	Chief Quality and Access Officer
Christian Schneider	Chief Scientific Officer
John Quinn	Chief Technology Officer
[redacted]	Deputy Head of Directorate

Attendees for part of the meeting

[redacted]
Kirsty Wydenbach for item 7: Human Challenge Studies
Vanessa Birchall-Scott and Boryana Stambolova for item 8: Approval for Surge resources
[redacted] and Boryana Stambolova for item 9: Financial Reforecast

1. Apologies and Announcements

1.1 Dr Raine welcomed all attendees to the meeting. Apologies were received from Carly McGurry.

2. Draft Minutes of the 19 October 2020 ExCo meeting (ExCo/20/027)

2.1 The ExCo reviewed the draft minutes of the 19 October 2020 ExCo meeting and provided comments.

3. Final minutes of the 06 October 2020 ExCo meeting (ExCo/20/028)

3.1 The ExCo noted the final minutes of the 06 October 2020 ExCo meeting.

4. Actions Log (ExCo/20/029)

4.1 The ExCo reviewed the actions log and provided comments. The actions from previous CET minutes will be reviewed and if necessary actions added in to this actions log.

Action: Review previous CET actions log; add any continuing actions to the new actions log. (Action [redacted])

FOR DECISION – DYNAMIC ORGANISATION

[redacted]

PATIENT SAFETY/MARKET ACCESS

7. Human Challenge Studies (ExCo/20/033)

7.1 Kirsty Wydenbach presented a paper regarding human challenge studies which was written in response to multiple request regarding the use of challenge agents in Covid-19 trials. The ExCo considered how as the medicines regulator can the Agency help protect public health by supporting the development of challenge models, outside of the context of a clinical trial of a medicine.

7.2 The ExCo noted that the remit of the MHRA is in the oversight of quality and safety of infections agents used to model disease and/or examine the efficacy of a medicinal product. To regulate human challenge studies, these products would need to be classified as medicines or the MHRA's regulatory remit would need to be expanded to include 'GMP certification' and assessment/authorisation of a physiological/immunological study using these agents to determine the infection model, prior to use in a trial of a medicine.

7.3 The ExCo recommended that this should be explored with the Heath Research Authority (HRA) and with an Ethics Committee recommend by the HRA to identify where the gaps in regulation and what work will need to be done in this area. The ExCo noted that it is likely there is demand to perform these trials not just for Covid-19 treatments but for other products too; this should be explored with the research community via a survey to identify any appetite to undertake these trials and any other thoughts. It was noted that these trials are regulated in a variety of different ways throughout other countries in the EU and worldwide.

7.4 [redacted] The ExCo agreed that careful ethical consideration should be given to these trials due to the risks of infecting a healthy individual. It was agreed that it is important that this area of clinical trials is regulated by an appropriate authority. Once further research has been undertaken in this area this may be considered by the Patient & Safety Assurance Committee of the Board.

Action: Explore with HRA and Ethics Committee to identify where the gaps in regulation are. Explore with research community (potentially via a survey) what the need/appetite is and any other thoughts, to feed into a potential proposal. [redacted]

FINIANCIAL SUSTAINABILITY

8. Approval for Surge resources (ExCo/20/034)

8.1 Boryana Stambolova and Vanessa Birchall-Scott presented a paper informing the ExCo that the Agency's Covid-19 and EU Transition response has led to a requirement for additional people resources. It was noted that there appears to be a lack of a clear and consistent process to gain approval; therefore the ExCo were presented with a set of recommendations to manage the risks identified.

8.2 The ExCo reviewed the recommendations and agreed this is a problem which needs addressing; commented that it will be beneficial to establish a clear governance process for

surge resource. A review of the membership of each of the new governance committees should be undertaken to ensure adequate HR representation across the board. ExCo agreed that this should be taken forward through the Resources Committee.

Action: A clear governance process and standardised forms are required. This should be taken forward through the resources committee. HR and finance will draw up a proposal for resources committee.

9. Financial Reforecast (ExCo/20/035)

8.1 [redacted] and Boryana Stambolova presented the 2020/21 Forecast as at 30 September 2020 to the ExCo. [redacted] The ExCo agreed that these figures reinforce the need for discussion on the future Size and Shape of the Agency; and reinforced the need to take action on the back of the EY review. [redacted] ExCo agreed it is important for the Strategic Change Committee to review all inflight projects. [redacted]

Action: [redacted]

PAPERS FOR INFORMATION

10. AOB

10.1 No items of AOB were raised.