Medicines & Healthcare products Regulatory Agency

ExCo Minutes (final)   ExCo/20/057

Title of meeting	Executive Committee meeting
Date	17 November 2020
Time	09.00 – 11.00
Venue	MS Teams meeting
Chair	June Raine
Attendees	ExCo
Apologies	None

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
Carly McGurry	Change Strategy Lead
███████████	Deputy Head of Directorate

Attendees for part of the meeting

████████ and ████████ for item 6: 6. Device Registries, Unique Device Identifiers and Device Databases developed in the health system

████████ and Rachel Bosworth for item 7: Patient and Public Engagement and Involvement Strategy

████████, ████████████ ████████ ████████████████████████████ Rachel Bosworth for item 10: Communications around the Innovative Licensing and Access Pathway

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1. Apologies and Announcements

1.1 Dr Raine welcomed all attendees to the meeting.

2. Draft Minutes of the 3rd November 2020 ExCo meeting (ExCo/20/036)

2.1   The ExCo reviewed the draft minutes of the 3rd November 2020 ExCo meeting and provided comments.

3. Final minutes of the 19th October 2020 ExCo meeting (ExCo/20/037)

3.1   The ExCo noted the final minutes of the 19th October 2020 ExCo meeting.

4. Actions Log (ExCo/20/038)

4.1   The ExCo reviewed the actions log and provided comments. An action was taken to collate the Terms of Reference for the management committees, obtain clearance via ExCo and present to the Board.

Action: Collate the Terms of Reference for management committees; consult ExCo and the Board for sign-off.

FOR DECISION – DYNAMIC ORGANISATION

5. Digital Data and Technology strategy (ExCo/20/039)

5.1   John Quinn presented an update on the Digital, Data and Technology (DDaT) strategy. The ExCo reviewed the strategy noting it will continually develop and iterate aligning to the annual business planning cycle. The ExCo noted that delegated oversight of the DDaT strategy and its implementation will be at the Digital Data and Technology Committee. ExCo reviewed the common themes and tensions which will have an impact on the strategy, and reviewed and endorsed the proposed members of the DDaT Committee.

5.2   The ExCo agreed that full alignment to Size and Shape is the highest priority and touch points and requirements will be required. It is important to have a vision of what the system of a digitally enabled risk proportionate self-service regulator would look like; then work from this. The ExCo requested that strategic decisions for the Board should be identified ahead of the meeting on the 18th December.

Action: Present a further update to ExCo on 15th December; further discuss this at the Agency Board on 18th December. Ensure strategic decisions are identified for the Board to take.

6. Device Registries, Unique Device Identifiers and Device Databases developed in the health system (ExCo/20/040)

6.1   John Quinn, ▮▮▮▮▮▮▮ ▮▮▮▮▮▮▮▮▮ and ▮▮▮▮▮▮▮ presented an overview of how Device Registries, Unique Device Identifiers and Device Databases are being developed in the health system and the MHRA role in their development to strengthen device regulation. The ExCo agreed that this should be shared with the Board when it is developed enough; a cover sheet should be pulled together which clearly states the focus of this report. Financial sustainability must be emphasised. The ExCo agreed now is the time to take a visionary approach to this.

Action: Share with Professor Bruce Campbell, Non-Executive Director, for comments ahead of sharing wider with the rest of the Board.

PATIENT SAFETY/MARKET ACCESS

7. Patient and Public Engagement and Involvement Strategy (ExCo/20/041)

7.1   ▮▮▮▮▮▮▮ and Rachel Bosworth presented an update on the Patient and Public Engagement and Involvement (PPEI) Strategy and the proposed next steps towards publication. This will be discussed thoroughly at the December Board meeting. The ExCo agreed that evaluation measures should be emphasised in the report; these should include how swiftly are patients involved in a signal, how many patient reported outcomes are included in clinical trials, and how will the MHRA demonstrate that we have taken in to account what patients have told us about our decisions.

7.3   The ExCo agreed that once the strategy has been considered by the Board and by the Patient Safety and Assurance Committee of the Board, a formal consultation should be issued. A link into the change programme should also be included. Terminology of patients vs members of the public, and regarding internal culture should be carefully considered.

Action: Emphasise use of evaluation measures in the strategy: How swiftly are patients involved in a signal, how many patient reported outcomes are included in clinical trials, and how will the MHRA demonstrate that we have taken in to account what patients have told us about our decisions. Include a link in to the change programme.

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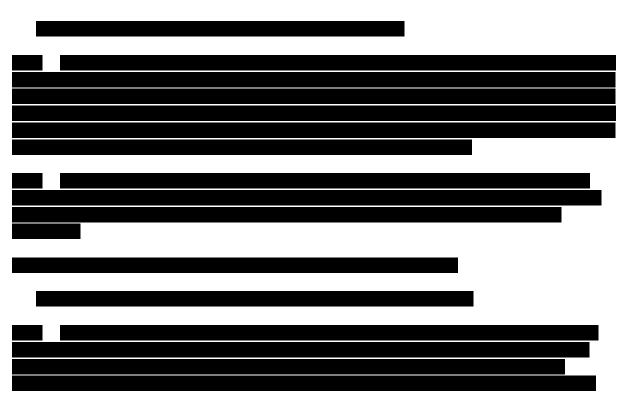███

10. Communications around the Innovative Licensing and Access Pathway (ExCo/20/046)

10.1 Samantha Atkinson and Christian Schneider presented a paper regarding communications around the Innovative Licensing and Access Pathway (ILAP); Rachel Bosworth also joined for the discussion. The ExCo reviewed the proposal and commented that it is important that further work should be done to work up the proposal fully with input from Comms, Policy and Licensing, specifically including modelling from a marketing perspective. A link into the Accelerated Access Partnership work should also be included.

10.2   The ExCo agreed that clarity must be given to the ILAP product before launch; modelling should also be undertaken with other parts of the health system including NICE. It was agreed this will be the centerpiece of the Agency's refocused operating model; this proposal should be worked up further and ExCo should be accountable. The Board will need to approve the ILAP before any communications are undertaken.

Action: Further work up this proposal with input from Policy, Comms and Licensing; include modeling from a market perspective.

FINANCIAL SUSTAINABILITY

PAPERS FOR INFORMATION

13. AOB

13.1   No items of AOB were raised.