CPD Exemplar Cycle: Industry Pharmacist

Cycle name: Management of post approval changes to registered pharmaceutical products

Scheduled

This learning activity is within my current scope of practice ✓

This learning activity is relevant to the safe and effective practice of pharmacy ✓

All criteria are essential and must be completed successfully for the cycle to meet the required standard.

Reflection

1. I identified the following specific learning need(s)... (500 word maximum)

I need to learn about the management of post approval changes to a registered pharmaceutical product.

Specifically, I need to learn the following;

- How to define post approval changes
- The regulatory requirements for post approval changes

2. I wanted to learn about this because (give context for learning activity / activities)... (500 word maximum)

I need to learn about this because I am the technical lead for an approved and registered medicine, which is on the market. Post approval changes are common for an approved medicine e.g. to the manufacturing process/analytical methods. As part of my role as technical lead, I am responsible to have oversight of these changes. Therefore, I need to learn about the definition and regulatory requirements for post approval changes to perform my role effectively.

Planning

3. I plan/planned to complete the following learning activity/activities to meet the identified learning need(s). (Please describe the learning activity/activities and the planned completion date(s)).

I plan to complete the following activities to meet my two identified learning needs.
I plan to read International Council for Harmonization (ICH) guideline Q12 “Technical and Regulatory considerations for pharmaceutical product lifecycle management” (2019) and Q12 “Annexes” to learn how to define post approval changes in November 2023. Website - https://www.ema.europa.eu/en/ich-q12-technical-and-regulatory-considerations-pharmaceutical-product-lifecycle-management-scientific-guideline

I plan to read and review the “European Medicines Agency (EMA) post-authorization procedural advice for users of the centralised procedure” to learn the regulatory requirements for post approval changes in November 2023. Website - https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation.

I plan to speak with a peer who is very experienced in the management of post approval changes in November 2023. This colleague has the role of “Pharmaceutical Expert” and is very experienced in both the defining of post approval changes and the regulatory requirements for post approval changes.

I plan to complete my learning by the end of November 2023.

Action

4. In meeting the identified learning need(s), I completed the following learning activity/activities

Activity: Private reading of “ICH Q12 Guideline” & “ICH Q12 Annexes”.

Hours: 2

Start date: 10/11/2023

End date: 10/11/2023

Evidence type: Notes/Handouts

Evidence: Self Study

Evidence upload (optional): ICH Q12 and Q12 annexes PDF's. Handwritten notes. Online PDF's found at- https://www.ema.europa.eu/en/ich-q12-technical-and-regulatory-considerations-pharmaceutical-product-lifecycle-management-scientific-guideline

Activity: Private reading of “EMA post-authorization procedural advice for users of the centralised procedure”.

Hours: 1.5

Start date: 17/11/2023

End date: 17/11/2023

Evidence type: Notes/Handouts

Evidence: Self Study

Evidence upload (optional): EMA post-authorization procedural advice for users of the centralised procedure PDF. Handwritten notes. Online PDF found at- https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation

Activity: Speaking with experienced peer via Microsoft Teams.

Hours: 1.5

Start date: 01/11/2023

End date: 30/11/2023

Evidence type: Notes/Handouts

Evidence: Self Study

Evidence upload (optional): Email confirmation of activity from peer/ colleague. Handwritten notes.

Summary of what has been learned in relation to the identified learning need(s) (500 word maximum)

Summary of what has been learned in relation to learning needs:

How to define of post approval changes. When a pharmaceutical product is approved by a health authority the key information relating to the chemistry, manufacturing, and controls (CMC) of that medicine are recorded in a dossier. When changes are introduced to the CMC information during the product's lifecycle, the health authority must be informed. A post approval change is any change to "established conditions for manufacturing and control". An "established condition" is defined as "legally binding information considered necessary to assure product quality" and is noted in the dossier. "Established conditions" for a manufacturing process may be critical process parameters which need to be controlled to ensure that a product is of the required quality e.g. temperature exposure limits, target filling ranges or mixing speed. For an analytical procedure used to test a medicine, "established conditions" are the parameters which directly impact on the performance of the method or the site where the method is conducted.

Regulatory requirements for post approval changes. Depending on the risk associated with a change, there are different requirements to inform a health authority about a post approval change. a. Prior approval of a change. This process is for the highest risk changes where there may be a significant impact to quality, safety or efficacy of the medicine. The health authority will require detailed information about the change and will approve the change prior to it being implemented. In the EU this is called a "Type II" variation (EMA) and in the US, a "prior approval supplement" (FDA). b. Notification of change. This is for moderate to low-

risk changes. Less information is required by the health authority and the changes to not require prior approval before implementation. In the EU these changes are called a Type IA or IB variation and in the US, “CBE-30” changes. c. Recording of changes with the related information. This is for the lowest risk changes and the regulatory requirements for these changes are for the company to have this information available when requested from the health authority.

Evaluation

5. Having met the specific learning need(s) identified, my practice has changed or will change as follows: (500 word maximum)

My specific learning needs have been met. I have successfully learned about 1. defining post approval changes and 2. the regulatory requirements associated with post approval changes. I have applied my learning by assessing a proposed change in December 2023. The proposed change impacted the medicine that I am technical lead for. The change related to an analytical method and a change in site where the method would be performed.

As a result of meeting my learning needs, I was able to successfully assess that this change impacted the “established condition” of the analytical method due to performance of the method potentially being impacted, as well as the site where the method is performed also changing. Therefore, I defined this change as a post approval change. After defining the change, I worked with colleagues in regulatory affairs and it was agreed that, due to the risk posed by this change, a prior approval from the health authorities was required to implement this change. Therefore, it was decided that the regulatory requirement for this change was for a detailed description of the change to be submitted to the US FDA as a “prior approval supplement”.

In summary, having met my specific learning needs my practice has changed. Now I can define post approval changes and work with colleagues to clarify the associated regulatory requirements, as demonstrated by the application of my learning in the scenario above.

6. I confirm that the identified learning need(s) has/have been fully addressed in this CPD cycle:

Your selection of “direct” or “simulated/future” evaluation (tick boxes below) must reflect the application of your learning described in (5) above.

This CPD cycle has been directly evaluated within my current practice and environment (minimum of 75% of cycles submitted) ✓

Community
Pharmacy Prescriber
Primary Care / Practice
Training
Hospital
Industry ✓
Academia
Other

I have recently returned to practice (within the last 12 months): NO

I have changed my scope of practice within the last 12 months: NO