Workshop Summary

The Product Quality Research Institute (PQRI) held a Workshop on June 13-14, 2023 to bring together material suppliers, toxicologists and safety experts, the pharmaceutical industry and regulatory experts to discuss the impact of potentially removing E171 grade of titanium dioxide (TiO_2) from pharmaceuticals would have along with the benefits and challenges of the alternatives to E171 for use in solid oral dosage forms. Many experts from around the world provided significant scientific information regarding these topics and the participants discussed their experiences in attempting to use E171 alternatives in drug product formulations.

Noted below, is a summary of some key presentations, discussions and outcomes from the Workshop:

- An overview of the current regulatory issues concerning the use of E171 in foods in Europe was discussed and how this situation could potentially lead to a ban in pharmaceuticals.
- Information was presented relating to flaws in the EFSA Opinion and the current ban of E171 in foods in Europe.
- Key expert scientific opinions on TiO_2 safety studies (in particular genotoxicity, carcinogenicity and immunotoxicity) were provided showing that TiO_2 (E171) is safe for use in foods and pharmaceuticals.
- The current views of many other global regulatory agencies regarding TiO_2 safety were shared showing that they did not have any safety concerns with TiO_2 (E171).
- Formulation experts discussed the significant limitations of all alternatives to TiO_2 and the challenges to drug development that occur when trying to work with TiO_2 (E171) alternatives.
- The potential impact a ban in pharma would have on patients, the industry and global regulators was highlighted, stressing that a TiO_2 ban WOULD lead to significant drug shortages since over 91,000 drug products on the market in the EU alone would be impacted.

In the breakout sessions, many issues were discussed, but one extremely important initiative was highlighted. This initiative entails initiating discussions with representatives of various patient-related associations that focus on pharmacists, doctors, nurses, insurance companies and other

health care related areas, to ensure they are informed of the implications for patients that would occur if there were to be a ban of TiO_2 (E171) in pharmaceutical uses. Recent studies conducted on TiO_2 continue to support the safety of the material. Given the significant issues related to drug shortages that currently exist, an unnecessary ban on TiO_2 (E171) use in pharma products would cause this drug shortage problem to be significantly increased and it will be important these organizations understand this and possibly advocate against such a ban since no real safety concerns for continued use of TiO_2 (E171) exits.

Another key outcome of the workshop, in addition to all the great presentations and information shared, is post-Workshop PQRI was invited to present a summary of what was discussed at the PQRI Workshop to IPRP Nanomedicines Working Group, a group of international regulators who focus on nanomedicines and medicines containing nanoparticles (the slides presented are available from PQRI). Further information on this WG is available here.

Next Step(s)

- PQRI will continue to advocate for the continued use of TiO_2 (E171) in pharmaceutical products based on the totality of safety data supporting its continued use and that a sufficient alternative(s) to TiO_2 have not been found to date which satisfy all of the benefits TiO_2 imparts into drug products.
- Information from the June workshop is available HERE. If you missed the Workshop and would be interested in viewing the recordings and presentations, please register HERE to obtain access for a nominal fee.
- The PQRI Workshop Planning Committee is preparing a position paper supported by the information and conclusions of the Workshop. This paper is planned for submission to interested regulatory agencies.

Questions?

For further details and information, please contact the PQRI Secretariat.