BAUSCH+LOMB

Via email
Therapeutic Goods Administration (TGA)
OTCBPRconsultationpaper@tga.gov.au and
Medsafe, Ministry of Health medsafeapplications@medsafe.govt.nz

6 November 2012

Re: September 2012, Version 1.0: Over-the-Counter (OTC) Medicines Business Process Reform

7 Giralda Farms, Suite 1001
Madison, NJ 07940
T 877-442-6925

Dear Sir or Madam:

On 17 September 2012, the TGA and Medsafe released a consultation paper entitled, "Over-the-counter (OTC) medicines business process reform consultation paper", Version 1.0. The purpose of the consultation paper is to seek feedback on the proposed reforms before proceeding with a detailed design of the new business processes, and development of associated documentation, such as regulatory guidelines. In support of the Business Process Reform, an information session was held on 18 October 2012.

Bausch + Lomb is one of the best-known and most respected healthcare companies in the world. Our core businesses include contact lenses and lens care products, ophthalmic surgical devices and instruments, and ophthalmic pharmaceuticals. Founded in 1853, our company is headquartered in Rochester, N.Y., and employs more than 10,000 people worldwide. Our products are available in more than 100 countries including Australia.

Bausch + Lomb supports the objectives of the OTC Medicines Business Process reforms, as well as the proposed strategies for achieving these objectives. However, additional detail and clarity are needed on the implementation of these strategies and the following comments are provided.

Comment #1- Forthcoming Guidance In Support Of Risk Categorisation

Page 10, "Risk based approach to regulating OTC medicines" incudes a general framework for rating risk and additional guidance provided in Appendix 1[1]. During the 18 October 2012 information session, it was noted that each application must include identification of the appropriate risk category. If an incorrect risk category is identified by the sponsor, the application will be rejected outright and application fees will be unrecoverable.

[1] Appendix 1: Risk categorisation framework for new medicine applications

BAUSCH+LOMB

Based on the consequences of not properly identifying the category as noted above and to further support the correct category assignment, the TGA indicated during the information session that a more detailed guidance would be issued. Bausch + Lomb looks forward to this additional guidance since there are examples not currently covered by the consultation paper that require clarification[2]. Towards that end, Bausch + Lomb requests the following:

- The anticipated guidance be published for public consultation allowing industry the opportunity to review and provide recommendations to clarify any areas of ambiguity
- The TGA include a defined approach for the sponsor to seek advice regarding the appropriate category assignment

Comment #2 – Additional Guidance Requested On Criteria for the Application Screening Phase

Bausch + Lomb agrees with the five-phase approach proposed for the OTC medicines evaluation process intended to create a harmonised approach to the regulation of OTC medicines in Australia and New Zealand. With that noted, we offer the following recommendation to enhance the overall process.

As per page 17 of the consultation paper, the screening phase will consist of two parts: first, an administrative check and second, a technical screen. Because of the importance of this screening phase[3], Bausch + Lomb requests that additional guidance be made available regarding the specific screening criteria that will be used to assess the applications. For example, a checklist that defines the minimum requirements and a description of what would be considered acceptable. Availability of these criteria will ensure a consistent approach during the screening process. This will benefit both the TGA and the applicant; by enhancing compliance and reducing administrative burden.

Comment #3 –Submission in Common Technical Document (CTD) Format

Page 16 of the consultation paper states, "The relevant supporting information will be required to be submitted electronically in CTD format." Bausch + Lomb agrees that submitting this information in CTD format enhances the clarity of data requirements for the sponsor and will enable the regulators to more easily locate specific elements in the data package. Currently, the CTD format is not required for OTC applications and because of this[4]; products are available to the Australian community that are a different classification from the country of the

[2] Specifically, products that may not unambiguously fall into one of the categories
[3] Forfeiture of the application fee by the TGA if the application is found to be deficient
[4] Differences in the components required for a CTD submission

BAUSCH+LOMB

parent company. For example, products for which the CTD format is neither mandated nor available. Significant resources will be required to convert existing data for such products to the CTD format suitable for electronic submission. This impacts both new OTC applications as well as critical major variations, especially those that have been planned to be filed around the expected TGA implementation date of the end of April 2013.

To ensure timely access to important medicines, a longer phase-in period (e.g., two years) or acceptability of a hybrid document is requested to support the transition to the CTD requirement.

For the same reasons noted above, certain companies may not have the data in NeeS format and as such, a longer phase-in period is requested (e.g. two years). It is also requested that the TGA clarify in the final guidance whether NeeS is preferred or required.

Comment #4 – Planning Letter Recommended for OTC Medicines Business Process Reform

Similar to the Prescription Medicine Business Process Reform and issuance of a planning letter[5] which includes the milestones and the dates once the application is accepted, Bausch + Lomb requests that this same type of planning letter be issued for the OTC Medicines Business Process Reform. The timelines defined in planning letter are invaluable in managing expectations by both industry and the Health Authority(ies) and would be welcomed addition to the OTC process.

Should this be implemented as recommended, we also request that any dates that cannot be met by the Agency be promptly communicated to the sponsor (refer to comment #5 below).

Comment #5 – Consequences for Not Meeting Target/Aspirational Timelines

Page 24 - 25 of the consultation paper provides target/aspirational timelines for the revised OTC medicine evaluation process to provide sponsors with predictable timelines. As noted in the consultation paper, an "initial performance indicator proposed is for completion of 80% …within the target timelines." Bausch + Lomb values having these target timelines defined; predictability enables the sponsor to plan its activities and allocate resources to support the application during the evaluation period. However, Bausch + Lomb

[5] http://www.tga.gov.au/industry/pm-ssp-qa.htm

BAUSCH+LOMB

also requests that the TGA also address consequences should the TGA not achieve its target timelines[6,7].

Page 25 of the consultation paper notes that Medsafe and TGA will publish performance at appropriate (e.g., 6 monthly) intervals. In support of this activity, Bausch + Lomb recommends there be an opportunity to provide public input on what is working well and how processes can be enhanced to ensure timelines are met and/or improved upon.

Comment #6 – Payment of Fees – Recommendation for a Phased Approach

Page 17 of the consultation paper states, "Fees will be payable upon receipt of an application. If an application is deficient it will not be accepted for evaluation and the application fee will be forfeited." In addition, page 25 of the consultation paper states that later in 2013, the TGA will release a consultation paper on the proposed revisions to the OTC fee framework. In anticipation of the future consultation paper, Bausch + Lomb recommends that the fee be invoiced in a two phases. Specifically, the first fee for the screening phase[8] and if the application is accepted, a second fee to initiate the evaluation phase. This phased approach would reduce the financial burden on the sponsor should the application be rejected during the screening phase.

Bausch + Lomb appreciates the opportunity to provide this feedback and trusts these comments will enhance the OTC Medicines Business Process Reform, when implemented.

Sincerely,

[redacted]

Kimberly Belsky [redacted]
Executive Director, Policy and Communication
Global Regulatory Affairs – Pharmaceuticals
7 Giralda Farms, Suite 1001
Madison, NJ 07940
(973)-360-6414

And locally, Pty Ltd, Level 4, 207 Pactific Hwy, St. Leonards, NSW, 2065 Australia

---

[6] Bausch + Lomb acknowledges the backlog and efforts to reduce the backlog as noted on page 25

[7] For example, a partial refund of the application fee

[8] Reference is made to Comment #2 above and the request for specific criteria for acceptance during the screening phase.