

## SUBMISSION ON SHEEP EXTERNAL PARASITE TREATMENTS

### 1. Introduction

- 1.1 The case team has advised that it is investigating several aspects of Elanco's proposed acquisition of Bayer's Animal Health Business (the **Proposed Transaction**). In particular, the case team has identified three areas that are of particular focus:<sup>1</sup>
- (a) the constraints on the merged entity's flystrike treatment products;
  - (b) MSD's ability to expand as a supplier of external parasiticides for use in sheep; and
  - (c) generic manufacturers' ability to expand as suppliers of external parasiticides for use in sheep.
- 1.2 This document contains further submissions on the above issues, and demonstrates why none of these issues – alone or combined – give rise to competition issues in New Zealand.

### 2. Flystrike treatment products

- 2.1 The case team has identified that the Proposed Transaction will result in there being two suppliers of products indicated for the treatment of flystrike in New Zealand post-Transaction. Most flystrike treatment products are 'combination products' and are used to treat both flystrike and lice, rather than being pure flystrike treatment products.
- 2.2 We set out below why the Proposed Transaction is unlikely to give rise to competition issues in relation to combination products, in particular as the merged entity's combination products will continue to be constrained by:
- (a) BI's combination product (which has a share of ~[ ]% of the sheep external parasiticide market); and
  - (b) the pricing of other sheep external parasiticides given that, with the exception of Bayer's Maggo, all flystrike treatment products are also indicated for the *prevention* of flystrike, and thus the merged entity will be constrained by flystrike prevention products. Further, they are combination products (i.e. they are also indicated as a treatment for lice), and so are further constrained by lice treatment products.
  - (c) Maggo is also constrained indirectly by flystrike prevention products, as the combination products with which it directly competes will only move their pricing in line with the wider flystrike prevention market.
- 2.3 Given the regularity with which farmers treat their flocks to prevent flystrike and lice infestations (typically annually for both), and the relative rarity with which sheep are struck, the vast majority of the time (>95%) these combination products are purchased either for flystrike prevention or to treat lice – meaning the sales of *treatment* products are dependent on ensuring they are priced competitively compared with these numerous other sheep external parasiticide products.
- 2.4 The profitability of combination products is therefore contingent on ensuring that they continue to be sold, in substantial volumes, to farmers seeking to prevent flystrike and to treat lice. This is supported by industry evidence.

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<sup>1</sup> The Parties acknowledge that these are the views of the case team and not the Commission. The Parties further acknowledge that the case team is investigating other aspects of the Proposed Transaction.

- (a) Most farms have management programmes in place, and usually the aim is to achieve control of lice – that is, to keep lice to below detectable levels. This is often done through the use of both treatment and prevention products at different stages of the programme.
  - (b) The great majority of farmers in New Zealand also take active measures to prevent/minimise the rate of flystrike. An October 2016 survey of sheep farmers found that 94% of farmers considered it ‘important’.<sup>2</sup>
  - (c) The same survey found that for the vast majority of respondent farmers (~80-85%), less than 5% of sheep in their flocks suffered from flystrike in the previous 12 month period.
  - (d) There are significantly more flystrike prevention products on the market (including products that only have flystrike claims and do not have lice claims) than combination treatment and prevention products. This is consistent with the much higher demand for preventative products (in direct competition with combination treatment and prevention products).
  - (e) Products indicated for flystrike treatment comprise a far greater proportion of the market for the treatment of external parasites than the percentage of sheep suffering flystrike each year (5% or less of the vast majority of flocks). BI’s Cyrazin KO on its own accounts for ~[ ] of the wider market for treatment of external parasites in sheep, higher than the percentage of sheep suffering flystrike. This indicates that combination products are being used to prevent flystrike and treat lice significantly more often than they are being used to treat flystrike.
- 2.5 Given that Elanco’s and BI’s combination products predominantly compete with flystrike prevention and lice products, it is these products that provide the greatest constraint on their pricing. This will continue to be the case following the Proposed Transaction and the merged entity will not be able to increase its combination product prices without regard to flystrike prevention and lice products in the market.
- 2.6 Furthermore, Elanco’s Cyrex and BI’s Cyrazin KO both have the IGR cyromazine as an active ingredient. They therefore compete with one another, and face significant competition from the wide range of other IGR-based treatments, including Ravensdown’s Saturate Gold, PGGW’s Cyromax and Alleva’s Cyroshield.<sup>3</sup> These will continue to constrain Cyrex following the Proposed Transaction.
- 3. MSD is well-placed to expand**
- 3.1 Commission staff have indicated that it is investigating the extent to which MSD could expand in response to a post-Transaction price increase.
- 3.2 As noted in the clearance application, MSD has an estimated 12% share of the animal health industry globally. With annual revenues of USD 4.2 billion it is over twice the size of BAH and significantly larger than Elanco. It operates 16 manufacturing facilities and has a significant animal health vaccines business. In New Zealand, MSD’s business has been growing, with gross revenues up from NZD 77.4 million in FY15 to NZD 92.9 million in FY18.
- 3.3 MSD’s Magnum, Vanquish, Wipeout and Zenith offer comparable protection against flystrike and lice to products supplied by the Parties. MSD has recently been particularly aggressive in relation

<sup>2</sup> Corner-Thomas et al, “A report on a “survey of aspects of sheep management: flystrike, lice, tailing and castration”, 2017 *Confederence Proceedings of the Society of Sheep and Beef Cattle Veterinarians and Deer Branch of the NZVA*, pp.35-36. A copy of this article is **enclosed** with this document.

<sup>3</sup> Elanco’s Extinosad is predominantly used to treat lice and is seldom used to treat flystrike (it is sometimes used as a flystrike prevention product). Similarly, Bayer’s Zapp Encore is predominantly used for the treatment of lice and is becoming less effective at treating flystrike due to increased resistance to the BPU triflumuron. [ ]

to the pricing of its Magnum product, which contains the IGR diflubenzuron and competes closely with the IGR products offered by the Parties (including Elanco's Cyrex).

- 3.4 In Australia, MSD has a share of ~15% of sheep lice treatment products, supplying several products including Vanquish (*alpha-cypermethrin*), Strike (*diflubenzuron*) and Maverick (*abamectin*). MSD's strength in Australia suggests it could easily grow its market share in New Zealand, in particular by launching Australian (or other) products such as Maverick in New Zealand.
- 3.5 MSD is also well-placed to bring brand new product technology to the sheep ectoparasiticide segment, as evidenced by its recent introduction of the Bravecto Plus Spot On product in the companion animal ectoparasiticide segment, which has captured significant market share in a short space of time. In the first year of its introduction in New Zealand, [ ] Bravecto contains the active ingredient fluralaner, which has shown potency against flies that afflict sheep.<sup>4</sup> [ ]
- 3.6 As explained in the clearance application, the ease of ACVM registration for new products in New Zealand means that barriers to entry and expansion are relatively low in all markets relevant to the Proposed Transaction, particularly where a product has been developed by a multi-national and is off-patent. [ ] all of the Parties' combination products that have any significant use as a flystrike treatment are off-patent in New Zealand.
- 3.7 In light of the above, it is clear that the threat of expansion by MSD – in addition to competition from its existing portfolio of products – will be a significant constraint on the merged entity's ability to materially increase prices to its customers. [ ]

#### 4. Multiple generic suppliers are well-placed to expand

- 4.1 The Commission has indicated that it is investigating the extent to which generics could expand in response to a post-Transaction price increase.
- 4.2 As set out in the clearance application, although the more local suppliers tend not to have individual market shares as high as the major international players based on revenues, in aggregate they account for a significant share of the market and, combined, can have a significant impact on branded products. [ ]
  - (a) Australian-based Jurox commenced supplying external parasite products for sheep in 2016. Jurox's Strikeforce contains the same active ingredient as Elanco's CLiK range, dicyclanil, and provides up to 18 weeks' flystrike protection with a withholding period of just 14 days. This makes it a very close substitute for Elanco's entire CLiK range, including products still under patent. [ ]
  - (b) PGGW has two flystrike prevention products on the market – Cyromax Liquid and Cyromax SO – which it sells in its network of almost 100 stores New Zealand-wide. These products are estimated to generate roughly [ ] as Bayer's Maggo.

In addition, [ ]

- (c) Ravensdown has five products on the market, including three with Cyromazine, the same active ingredient as Elanco's Cyrex. These products have combined revenues [ ] than Maggo, and in excess of NZD [ ] per annum. Ravensdown generates approximately NZD [ ] million per annum in sales from its own animal health products, all in sheep and cattle products, across its New Zealand-wide network of over 100 stores. Ravensdown is a cooperative that seeks to secure products for its shareholders at competitive prices. As

<sup>4</sup> Gassel et al, "The novel isoxazoline ectoparasiticide fluralaner: Selective inhibition of arthropod  $\gamma$ -aminobutyric acid- and L-glutamate-gated chloride channels and insecticidal/acaricidal activity", *Insect Biochemistry and Molecular Biology*, Volume 45, February 2014, pp.111-124. Available online at: <https://www.sciencedirect.com/science/article/pii/S0965174813002105>.

with PGGW, Ravensdown could quickly and easily expand in response to a price increase post-Transaction.

- (d) Jaychem has the registration for Venus SO and Liquid (previously sold through Animal Health Direct, another local generic company). [ ] Alleva's Cyroshield products [ ]
  - (e) [ ]
  - (f) Donaghys has two cyromazine products. Elanco understands [ ]
  - (g) Norbrook previously produced cyromazine-based products for various channels: it sold Banish via the vet channel, PGGW sold a Norbrook product as Lucify and Farmlands also sold a Norbrook-manufactured product. Norbrook subsequently sold this business to Australian-based Abbey Laboratories. Abbey could readily re-enter the market with these products in response to a post-Transaction price increase.
- 4.3 In addition to the above, low cost toll manufacturers are able to provide "own" label generic cyromazine products to generic companies based on existing registrations. For example, Nexan Corporation provides Cyromax SO and Liquid to PGGW, and Cyromazine SO and Liquid to Ravensdown. The threat of these generics is set to further increase [ ]
- 4.4 Each of the players listed above would have the ability to expand if the merged entity attempted to increase prices post-Transaction. In particular, MSD (as an established and well-resourced branded player), PGGW and Ravensdown (with existing in-market products and extensive retail networks) and Jurox (as the supplier of an alternative dicyclanil-based product) are ideally-placed. The ease of ACVM registration for new products in New Zealand means that barriers to entry and expansion are relatively low, particularly where a product has been developed by a multi-national and is off-patent.
- 4.5 In summary, there are many generic manufacturers that provide low cost alternatives to the merged entity's products, and which could easily expand in the event of a post-Transaction price increase. These products are particularly attractive to co-operatives such as Ravensdown and Farmlands whose mandate is to provide cost effective inputs to farmers.
5. **Conclusion**
- 5.1 In light of the above, the Proposed Transaction is unlikely to give rise to competition issues in relation to external parasiticides for use in sheep, in particular because:
- (a) Elanco's flystrike products are constrained by flystrike prevention and lice treatment and prevention products;
  - (b) MSD is capable of expanding and bringing new products to market in response to a post-Transaction price increase; and
  - (c) there are many generic competitors with the capability of expanding and bringing new products to market in the event of price increases post-Transaction.
- 5.2 More generally, the Parties' product portfolios for the treatment of external parasites in sheep are complementary. There is little overlap, and therefore limited competition due to the importance of rotation, between the active chemical classes used in the Parties' products. Where there is overlap, the Parties face significant competition from multiple competitors and competing products.