DISPUTE RESOLUTION PANEL OF THE PHARMACEUTICAL PRICE REGULATION SCHEME

DECISION DATED 3 JANUARY 2013

IN THE MATTER OF **PPRSDRP/JANUARY/2013/01**

SANOFI PASTEUR MSD LIMITED

-and-

THE DEPARTMENT OF HEALTH

DECISION OF THE PPRS DISPUTE RESOLUTION PANEL

1 This is a decision of the PPRS Dispute Resolution Panel appointed under the Pharmaceutical Price Regulation Scheme 2009 to consider and provide reasoned decisions in respect of disputes arising under the 2009, 2008 and 2005 Schemes. This dispute arises only under the 2009 Scheme ("the Scheme"). The Panel consists of Patrick Walker (Chairman), Sir Robert Culpin and David Hill.

2 The Panel has been assisted by the clear concise and pragmatic submissions made on behalf of Sanofi Pasteur MSD Ltd ("Sanofi") and on behalf of the Department.

THE ISSUE

3 The case is concerned primarily with the provisions of Chapter 7.51 of the Scheme construed in the context of the Scheme as a whole. Chapter 7.51 provides: *"When reporting data into primary care, companies should include sales only to wholesale and retail pharmacies, net of any volumes and values of such sales appropriate to secondary care. When reporting data into secondary care, companies should include sales to NHS hospitals and other customers, whether made directly by the scheme member or through a wholesaler, agent or distributor, at prices controlled by the scheme member."*

DH Department of Health

abpi Bringing medicines to life

4 In May 2011 the Panel made a decision in respect of the classification of bulk sales of medicines to stockpile against the contingency of a pandemic (Department of Health -v- GlaxoSmithKline UK Ltd[1]). The question arose as to whether particular stockpile drugs sold under contract with the NHS Purchasing and Supply Agency ("PASA") should be reported as appropriate to primary care or to secondary care pursuant to Chapter 7 of the Scheme. The Panel decided that such sales should be treated as sales appropriate to secondary care.

5 By letter dated the 10th August 2011, the Department of Health ("the Department") wrote to Scheme members including Sanofi stating that *"several aspects"* of the 2011 GSK Decision *"touch on the way scheme members and the Department should operate the 2009 PPRS."* The Department then set out a number of definitions *"on the basis of a reasonable interpretation of the terms as drafted."* These definitions included *"Other customers (hence secondary care): e.g. sales to homecare providers; sales to dispensing doctors; sales used to fill private prescriptions…"*

6 Sanofi does not agree with this interpretation and the issue is whether sales to dispensing doctors or 'direct to doctor' should be reported into primary or secondary care for the purposes of Chapter 7.51 of the Scheme. The parties agreed that 'direct to doctor' means *"supplies direct from a pharmaceutical company to a doctor's surgery who may or may not have a dispensary".* The parties also agreed that sales both to dispensing doctors and direct to doctor were treated by the Department as sale into primary care, prior to the 2011 GSK Decision.

7 Sanofi did not seek, the Panel did not hear significant argument upon and this decision is not directed to classification save for the two categories referred to in

[1] Published reference PPRSDRP/May/2011/02. Referred to in this decision as "the 2011 GSK Decision".

paragraph 6 above. Nor did the Panel hear from any other company or expert witness.

THE DEPARTMENT'S CASE

8 The Department describes the issue as an *"extraordinarily difficult one"*. It says that a dispensing doctor might be described as *"very like a retail pharmacist"* but 'very like' is not 'the same as'.

9 In the 2011 GSK Decision, the Panel decided that the categories of primary and secondary care within the meaning of Chapter 7, are exhaustive, and also that the phrase *"and other customers"* is a 'catchall'.

10 Neither sale directly to a doctor nor sale to a dispensing doctor, argues the Department, is sale to *"wholesale and retail pharmacies."* These are the only categories to be reported into primary care, and the remainder fall within the requirement to report *"sales to NHS hospitals and other customers…"* into secondary care.

11 The Department cautions against an interpretation based upon avoiding what might be described as an *"unbearably harsh"* financial consequence for Sanofi or a particular company, and suggests there are other companies for which classifying dispensing doctors as secondary care is *"financially advantageous."*

SANOFI'S CASE

12 Sanofi says that it *"did not approach this from the point of it being advantageous or not. We approached it from the perspective of getting the answer that was intended in the scheme to properly measure savings."*

13 Sanofi points out that the key issue in the 2011 GSK Decision concerned sales into the NHS stockpile and that the Panel was not asked to nor made any ruling in respect of dispensing doctors or direct to doctor sales.

14 Sanofi takes no issue with the classification of sales of medicines to stockpile and accepts that the primary and secondary care categories are exhaustive. However, dispensing doctors and direct to doctor sales should be classified as primary care having regard to (i) the definitions in Chapter 7.51, (ii) *"the universally understood concept of primary care"* and (iii) the aim of securing *"an accurate measurement of savings delivered through modulation to the NHS drugs bill."*

15 Sanofi argued that *"if the words are either unclear or inadequate, then what you should look at is what both parties were trying to achieve and what we are achieving by putting these sales within primary care is an accurate measurement of savings to the NHS because, in that sector, the NHS price is directly linked to list price, whereas in the secondary care calculation, it's not linked to list price it's linked to average selling price…"*

16 A dispensing doctor's dispensary, it was suggested, conducts materially the same prescription medicine services as a high street pharmacy, and whilst most of the customers are likely to be the practice's own patients, there is no bar on dispensing to other people.

17 It is conceded that interpretation in respect of direct to doctor is less straightforward, but Sanofi points out that the provision (Chapter 7.51) is inadequately drafted so that, for example, there is no clear concept of 'wholesale pharmacy' and if primary care includes only retail pharmacies, *"sales to wholesalers – which account for the vast majority of medicine sales [would be] treated as secondary care. Surely an absurd result".*

PANEL'S DECISION

18 The Panel sees both practical and financial arguments for Sanofi's case. First, the Scheme is clear that sales to retail pharmacies should be reported to primary care. It does not define *"retail pharmacies"*. The phrase clearly includes pharmacies which may be next door to doctors' surgeries. The question is whether the provision excludes sales of medicines to doctors' practices which are dispensed from within the surgery. Both parties accept that sales to dispensing doctors are at the least *"very like"* sales to high street pharmacies.

19 Second, reporting to primary care may give a better approximation to the NHS costs at which the Scheme is directed, because it reflects the cost to the NHS of reimbursing doctors for the drugs they purchase, and doctors are reimbursed at a proportion of NHS list price. Reporting to secondary care may reflect the price doctors pay for drugs, but that is not the cost to the NHS. The concern of the Scheme is not with doctors' expenditure but with *"NHS expenditure on branded medicines"* (see chapters 7.3 and 7.4).

20 However, the Panel considers that whilst these arguments are persuasive, they do not entitle the parties or the Panel to ignore the wording of the provision in question (chapter 7.51) or other provisions of the Scheme which may support it. Chapter 7.51

not only provides a 'catchall' placing customers other than wholesale and retail pharmacies within secondary care, but says in terms that only sales to wholesale and retail pharmacies are to be reported into primary care.

21 Whilst not relied on by either party, chapter 9.11 of and Annex L to the Scheme make express reference to dispensing doctors. These provisions identify *"three channels - wholesalers/retail pharmacists, NHS hospitals and other (which includes dispensing doctors and General Medical Services (GMS) / Personal Medical Services (PMS) contractors)."* The Panel considers that these three categories are essentially the same as those identified in Chapter 7.51.

22 Chapter 7.51 assigns two of the categories to secondary care and in Chapter 9.11 'other' unambiguously includes dispensing doctors and general medical services. The Panel accepts that Chapter 7.51 could be better drafted but does not find sufficient ambiguity in it to accept Sanofi's interpretation. Further if there was such ambiguity Chapter 9.11 would tend to support the Department's case.

23 There was an obvious opportunity to include 'dispensing doctors' or 'doctors' as a term in Chapter 7.51 but it was not taken. The parties did not point the Panel towards and the Panel has not identified any wording which supports a wider definition of 'retail pharmacist'. The reference in Chapter 7.6(ii) to *"pharmacists and other dispensers"* illustrates the use of a wider term when considered appropriate. The reference is in the specific context of generic prescribing. It refers for that purpose to primary care, but the Panel does not find this sufficient to lead to the interpretation of Chapter 7.51 contended for by Sanofi.

24 For these reasons, the Panel finds that the Scheme assigns sales to dispensing doctors and 'direct to doctor' to secondary care for the purposes of Chapter 7.51.

CONCLUDING COMMENTS

25 The Panel is clear that this is what the Scheme provides, but is not clear that it gives the best approximation to the NHS expenditure at which the Scheme is directed, for the reason at paragraph 19 above: so far as the Panel can see, on the limited information before it, the provision under consideration appears to come closer to measuring changes in company revenues than in NHS costs. It seems to the Panel that this may be an inconsistency in the Scheme. It is beyond the Panel's remit to take this further. However, the Panel notes the provision within the Scheme for liaison between the Department and the Association of the British Pharmaceutical Industry to consider the operation of the Scheme, and where appropriate for its amendment by mutual agreement. The Panel hopes that the Department and the Association of the British Pharmaceutical Industry will consider the operation of Chapter 7.51 in the light of these comments.

26 Unless and until any amendment is agreed, the Panel considers that the Department cannot be criticised for requiring individual companies to report in accordance with what the Scheme expressly provides, rather than with what one party (or in some cases both parties) considers should have been provided.

PANEL MEMBERS

Patrick Walker (Chairman)

Sir Robert Culpin

David Hill

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